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**Impact of Cryotherapy versus Loop
Electrosurgical Excision Procedure (LEEP)
on Recurrence of Cervical Intraepithelial
Neoplasia and HIV-1 Cervical Shedding
among HIV-positive Women**

Study Protocol

Version 8.5

Michael H. Chung, MD, MPH
University of Washington
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Study Investigators

73 **Principal investigator**

74 Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University
75 of Washington

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77 Phone: (206) 543-4278

78 Dr. Chung is the PI and will directly lead the planning, implementation, and analysis of the
79 study. He will meet weekly with the study team, direct the study, and guide the study
80 coordinator. He will check progress on enrollment and follow-up with the study coordinator
81 and study doctor. In addition, Dr. Chung will serve as the point person to explain the study
82 and share data results with others and report adverse effects associated with the study. The
83 University of Washington will provide administrative, laboratory and data support to this
84 project.

85

86 **Co-investigators**

87 Nelly Mugo, MBChB, MMed, MPH, Gynaecologist, Department of Obstetrics and
88 Gynecology, Kenyatta National Hospital

89 P.O. Box 19676, University of Nairobi, Nairobi, Kenya

90 Phone: 271-4159

91 Dr. Mugo is a Co-investigator of the study and will assist Dr. Chung in the study's planning
92 and implementation. As a gynaecologist, she will ensure that the study medical staff will
93 provide excellent care and maintain high clinical standards. She will oversee the
94 gynecological care and proper medical procedures by meeting regularly with the study doctor

95 and nurses. Dr. Mugo will be involved in any gynecological complications related to the
96 study.

97

98 Samah Rafie Sakir, MBChB, Medical Director, Coptic Hospital of Kenya

99 Ngong Road, Nairobi, Kenya

100 Phone: 0733-392807

101 As Medical Director of the Coptic Hospital, Dr. Sakir will work with Drs. Chung and Mugo
102 to implement the study at the Coptic Hope Center for Infectious Diseases. He and the Coptic
103 Hospital will provide the clinical infrastructure where HIV patients will be enrolled and
104 followed in the study. Dr. Sakir will manage the health care workers at the Hope Center and
105 ensure that clinical data that is collected from the Hope Center and shared with the study is
106 accurate and timely.

107

108 Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of
109 Washington

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111 Phone: (206) 543-4278

112 Dr. John-Stewart will lend her epidemiology expertise to the analysis of the study. She has
113 significant experience in conducting and examining randomized clinical trials in Kenya. Dr.
114 John-Stewart will help analyze the data, prepare any manuscripts, and give feedback on
115 implementation of the trial.

116

117 Barbra Richardson, PhD, Research Professor, Department of Biostatistics, University of
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121 Dr. Richardson will contribute statistical support to the study and will be deeply involved in
122 statistical analysis of its findings. She will prepare the method to randomize subjects and will
123 analyze results of the study.

124

125 Dr. Hugo De Vuyst, MD, PhD, epidemiologist, Infections and Cancer Epidemiology,
126 International Agency for Research on Cancer (IARC-WHO).

127 150 cours Albert Thomas; 69372 Lyon cedex 08

128 Tel: +33 472 738521

129 Dr. De Vuyst will contribute his expertise and epidemiological skills in issues of cervical
130 cancer screening, HPV and HIV in developing countries. He will help analyze the data and
131 its association with HPV results.

132 Silvia Franceschi, MD, Epidemiologist, Head of Infections and Cancer Epidemiology Group,
133 IARC-WHO

134 150 cours Albert Thomas; 69372 Lyon cedex 08

135 Phone: +33 4728404

136 Dr. Franceschi will contribute her extensive epidemiological expertise in the field of cervical
137 cancer, HPV and HIV.

138

139 Martin Steinau, PhD, Team Lead HPV DNA, Chronic Viral Diseases Branch (CVDB),
140 Division of High-Consequence Pathogens and Pathology (DHCPP), National Center for
141 Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and
142 Prevention (CDC) 1600 Clifton Road, MS G41, Atlanta, GA 30329-4027

143 Tel: +1-404-639-0561

144 Dr. Steinau will coordinate the HPV-related study activities and data-analysis. He will
145 contribute his expertise and epidemiological skills in issues of cervical cancer screening,
146 HPV and HIV in developing countries. He will oversee the testing of HPV samples at CDC,
147 ensure quality control, and help analyze the data and its association with HPV results.

148

149 Elizabeth R. Unger, PhD, MD, Chief CVDB, DHCPP, NCEZID, CDC

150 1600 Clifton Road, MS G41, Atlanta, GA 30329-4027

151 Phone: +1-404-639-3533

152 Dr. Unger will contribute her expertise in the field of cervical cancer, HPV and HIV. She
153 will supervise and manage the laboratory where the HPV sample testing will occur and help
154 analyze the results of the study.

155

156 Nelly Yatich, DrPH, MPH, Clinical Assistant Professor, Department of Global Health,
157 University of Washington

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161 Dr. Yatich will work closely with Drs. Chung and Mugo to implement the study at the Coptic
162 Hope Center. She will provide mentorship to the research team at weekly meetings, provide
163 mentorship to the Data Manager in data analysis, and guide the study coordinator. She will
164 provide other on the ground support as needed.

165

166 Dara A. Lehman, MHS, PhD, Staff Scientist, Human Biology, Fred Hutchinson Cancer

167 Research Center Affiliate Assistant Professor, Department of Global Health, University of

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169 Fred Hutchinson Cancer Research Center

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175

176 Dr. Lehman will lead efforts to quantify the HIV-1 RNA levels of cervical and plasma

177 samples collected from subjects enrolled in the study comparing cervical cancer treatments in

178 HIV-positive women.

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Summary and Objectives

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The recent scale-up of antiretroviral treatment programs in resource-limited settings provides an unprecedented opportunity to implement a comprehensive cervical cancer screening and treatment program for women who, by virtue of having HIV, are at significant risk for cervical disease. Unfortunately, even if screening is offered free of charge to millions of women living with HIV, it is unclear which treatment modality for pre-cancerous cervical lesions will be most effective since HIV appears to affect outcomes of treatment by increasing the recurrence and severity of cervical disease. Cervical treatment may also increase shedding of HIV from the cervix which may put discordant couples at risk and possibly spread HIV more widely. This study proposes to randomize HIV-positive women with cervical intraepithelial neoplasia grade 2 and 3 (CIN 2 and 3) to cryotherapy vs. loop electrosurgical excision procedure (LEEP) and measure the recurrence of cervical disease in each group over 2-years of follow-up as well as HIV shedding from the cervix for 3 weeks after treatment.

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Our hypothesis is that compared to cryotherapy, LEEP is significantly more likely to prevent recurrence of cervical lesions over 2 years of follow-up and less likely to cause shedding of HIV-1 from the cervix over 3 weeks of follow-up.

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The objectives of this study are:

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1. To compare the rate of recurrence of cervical intraepithelial neoplasia among HIV-positive women receiving cryotherapy versus LEEP over 2 years of follow-up
2. To compare the shedding of HIV-1 from the cervix between HIV-positive women receiving cryotherapy versus LEEP over 3 weeks of follow-up

202

Background

203 The introduction of antiretroviral medications on a large-scale in resource-limited
204 settings through funding from agencies such as the President’s Emergency Plan for AIDS
205 Relief (PEPFAR) has decreased the number of HIV-positive women dying from AIDS. As a
206 result, many HIV-positive women are leading longer, healthier lives. However, despite
207 immune reconstitution many are still at risk for diseases related to their HIV infection
208 including cervical cancer.¹ Cervical cancer is the leading cause of cancer death among
209 women in resource-limited settings, and HIV-positive women are more likely to be infected
210 with human papillomavirus (HPV), the primary cause of cervical cancer, and progress to
211 invasive, life-threatening disease than those who are HIV-negative.²⁻⁶ Thus, although many
212 women may be saved by antiretroviral therapy through PEPFAR support, they may later die
213 of a disease that could have been detected and prevented at the same facilities where they
214 received their antiretroviral treatment.⁷

215 The importance of adequate cervical cancer screening among HIV-positive women is
216 being recognized by the Kenya PEPFAR program, Office of the Global AIDS Coordinator
217 (OGAC), and other clinics around the world which are treating HIV-positive women.⁸ While
218 there is a body of published knowledge on the screening and treatment of women in
219 resource-limited settings, very little has been studied on the relevance of these findings on
220 HIV-positive women.^{9, 10} For example, it has been suggested that visual inspection with
221 acetic acid (VIA) along with cryotherapy be recommended as a “screen and treat” approach
222 on the same day for women located in resource-limited settings.^{11, 12} The benefits are
223 obvious; VIA is simpler to administer than a Papanicolaou test (Pap smear), does not require
224 laboratory support, and is up to 20 times less expensive. Similarly, cryotherapy, a low
225 technology treatment option, can be offered on the same day as VIA decreasing loss-to-

226 follow-up due to referral and waiting times, and is cheaper and easier to administer than
227 LEEP. As a result, some HIV treatment programs in resource-limited settings are beginning
228 to utilize this approach for their female patients. As PEPFAR begins to consider supporting
229 cervical cancer screening among HIV-positive women enrolled in its programs, it will be
230 essential that decisions are grounded in scientific evidence since any approach may have
231 tremendous consequences on morbidity, mortality, and transmission of HIV-1.¹³

232 The issue is that there is no evidence that a “screen and treat” approach is as effective
233 among HIV-positive women as it appears to be among HIV-negative women. In fact, there
234 is data to suggest that this approach may be problematic. In HIV-negative women, VIA
235 appears to be more sensitive but less specific compared to Pap smear.^{9, 14} HIV-infected
236 women have a higher prevalence of aggressive cervical disease and are more likely to
237 experience recurrent HPV and genital infections.^{5, 15} The presence of florid disease may alter
238 the sensitivity and specificity of VIA in the presence of HIV disease, making it more
239 sensitive but less specific than Pap smear. VIA may therefore detect more cervical
240 abnormalities in HIV-infected women that are not truly cancerous. Coupled with
241 cryotherapy, this may result in many HIV-positive women receiving unnecessary treatments
242 that inflame the cervix and cause it to shed increased levels of HIV virus.¹⁶ Increasing
243 cervical shedding of HIV after cryotherapy may increase HIV transmission and infectivity in
244 a manner analogous to male circumcision which appears to increase the risk of female
245 partners acquiring the disease.¹⁷

246 The standard of care for screening and treatment in the US, according to the
247 American Society for Colposcopy and Cervical Pathology (ASCCP), is based on Pap smears
248 and excisional (cold-knife conization, loop electrosurgical excision procedures, laser
249 conization, and electrosurgical needle conization) or ablative treatments (cryotherapy, laser
250 ablation, electrofulguration, or cold coagulation).¹⁸ Women who are found to have high-

251 grade lesions on cytology may either have their lesion treated right away with LEEP or have
252 a colposcopy-directed biopsy. If the woman has a biopsy and the histology results show a
253 CIN 2 or 3 and the colposcopy is satisfactory, treatment may be undertaken with either
254 ablative or excisional therapy. If colposcopy is unsatisfactory or the CIN 2/3 is recurrent,
255 treatment should be a diagnostic excisional procedure, which is an excisional procedure
256 followed by a pathological examination of the sample tissue.

257 According to the Kenyan Ministry of Health, cervical cancer screening and treatment
258 practices include VIA and cryotherapy at the district level health centers and below, and Pap
259 smears with follow-up colposcopy with biopsy and LEEP at tertiary and provincial level
260 hospitals.¹⁹ In our study, participants will be screened using Pap smear with confirmatory
261 histology and treated with cryotherapy or LEEP. Our screening and treatment methods are
262 consistent with standards of care set at Kenyan tertiary and provincial level facilities. As
263 mentioned above, one of the reasons to study cryotherapy and LEEP is to understand how to
264 refer HIV-positive women for cervical treatment within the Kenyan government health
265 system. The reason we are utilizing cytology and histology as a screening method is the lack
266 of evidence confirming the sensitivity and specificity of VIA among HIV-positive women.
267 Given that the outcome of measurement in this study is recurrence of CIN, it is considered
268 scientifically necessary and within Kenyan standards of care to use these accurate, evidence-
269 based tests.

270 In terms of risk of serious complication, cryotherapy and LEEP are quite safe. In a
271 study from Zambia, Pfaendler, et al. found that the overall complication rate of LEEP to be
272 3.7%, all of which was managed on-site in the clinic.²⁰ Likewise, in a study of cryotherapy
273 in India, the overall complication rate was found to be 3.0%.²¹ In a large study from Peru
274 that followed 1,398 women, who underwent cryotherapy for a mean of 12 months, no serious
275 complications, including pelvic inflammatory disease, severe cramps or bleeding, or

276 anaphylactic reactions, were found.²² In a comparison study between cryotherapy and
277 LEEP, cryotherapy was found to have a 2% complication rate and LEEP, an 8%
278 complication rate, and the difference was not significant.²³

279 There has been some controversy surrounding cervical treatment and whether or not it
280 is associated with adverse pregnancy outcomes. Sadler et al. showed in their retrospective
281 analysis of 652 women that had undergone LEEP, laser ablation or laser conization that
282 LEEP did not increase the incidence of preterm delivery.²⁴ However, the authors did note a
283 significant increase in premature rupture of membranes. Acharya et al., in their matched
284 cohort of 428 women undergoing LEEP, also found no correlation between the procedure
285 and premature delivery or low birth weight, but they did find a significantly higher number of
286 women with pregnancy complications, which included premature contractions, infections and
287 cervical incompetence.²⁵

288 Finally, there is evidence that cryotherapy may be less effective compared to LEEP in
289 preventing the recurrence of cervical intraepithelial neoplasia though the literature is
290 equivocal. Overall, there have been few studies comparing the efficacy in treatment between
291 cryotherapy and LEEP, especially in HIV-infected women. Chirenje et al. found a
292 significant difference in the failure rate of cryotherapy versus LEEP, however his numbers
293 were small with only 6 high-grade recurrences in the cryotherapy arm (14.3%) and 2 in the
294 LEEP arm (4%).²⁶ Moreover, neither HIV nor HPV shedding was measured and follow-up
295 time was only one year. In another randomized study comparing cryotherapy and LEEP, this
296 time a larger study in non-HIV-infected women, no significant difference was found between
297 the two arms in terms of failure, defined as either recurrence or persistence.²³ Additionally,
298 in a 2000 Cochrane review, it was stated that “evidence suggests that there is no obviously
299 superior surgical technique for treating cervical intra-epithelial neoplasia.”²⁷

300 If cryotherapy is found to result in a greater number of failures, it may require more
301 frequent and careful follow-up screening than LEEP, and therefore may not be as cost-
302 effective or therapeutic for the patient. As a result, the individual and public health risks of a
303 “screen and treat” approach for cervical cancer screening and treatment among HIV-positive
304 women may be much greater than its benefits.

305

306

Rationale

307 The University of Washington (UW) in collaboration with the Coptic Hope Center for
308 Infectious Diseases has been providing cervical cancer screening to its female HIV positive
309 patients in Kenya since 2006. The UW/Coptic Hope Center has enrolled over 8,000 HIV-
310 positive women in its two Nairobi sites and offers a robust patient population for cervical
311 screening. The UW/Coptic Hope Center has already screened over 2,000 HIV-positive
312 women for cervical cancer using both Pap smear and VIA, and has worked in partnership
313 with Kenyatta National Hospital (KNH) to provide LEEP to those with detectable lesions.
314 Most recently, the collaboration has received a grant from the Puget Sound Partners for
315 Global Health to compare VIA versus Pap smear among women enrolled at the Hope Center
316 and to examine HIV-1 cervical shedding in a small subset who receive cryotherapy.
317 Unfortunately, funding is only available for one year and will not allow any comparison with
318 LEEP or a study of cervical disease recurrence after intervention.

319 Kenya is an appropriate site to conduct this study due to a high incidence of cervical
320 cancer and lack of cervical screening coverage. The incidence of cervical cancer in Kenya is
321 much higher compared to the West and measures between 43 and 45 cases per 100,000
322 compared to 8.4/100,000 in the USA.^{28, 29} Of 3,902 women who presented to KNH with
323 reproductive tract malignancies between 1989 and 1998, 85% had invasive cervical cancer.²⁸
324 In a sampling of 1,353 patients at the same institution in Kenya, only 22% reported having
325 received a previous Pap smear.³⁰ Although the government of Kenya has advocated the use
326 of VIA as a primary method to screen for cervical cancer, no specific recommendations are
327 made concerning HIV-positive patients. Cervical cancer screening for HIV-positive women
328 in Kenya should be a high priority since HIV-infected women in Kenya with invasive
329 cervical cancer are 10 years younger than HIV-negative women at initial presentation.^{6, 31}

330 Based on the high incidence of cervical cancer in Kenya and building upon our
331 programmatic and research work in cervical cancer screening among HIV-positive women,
332 we propose to study the effect of LEEP versus cryotherapy on the recurrence of cervical
333 intraepithelial neoplasia and the shedding of HIV-1 from the cervix. Our hypothesis is that
334 compared to cryotherapy, LEEP is significantly more likely to prevent recurrence of cervical
335 lesions over 2 years of follow-up and less likely to shed HIV-1 from the cervix over 6-weeks
336 of follow-up. This evaluation will inform PEPFAR policies on the best method to treat pre-
337 cancerous lesions in HIV-positive women and elucidate the importance of cervical treatment
338 interventions according to immune status and antiretroviral therapy. Such information is
339 directly relevant to the care of HIV-positive women in Kenya and other resource-limited
340 countries which are significantly impacted by cervical cancer.

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Timeline and Dissemination

The duration of the evaluation activity is approximately 6 years from the beginning of the funding cycle. It is estimated that it will take at least 3 years to screen at least 2,400 women and randomize approximately 400 women with high grade intraepithelial lesions to LEEP vs. cryotherapy. These randomized participants will be followed for 2 years after screening or randomization. Including preparation and analysis, it is expected that it will take approximately 6 years to complete this study.

Results of the study will be shared directly with the USG/GOK technical teams through annual reports and regular e-mail contact with designated contacts at the CDC in Atlanta and Nairobi. Reports will include analysis from regular DSMB meetings. After initiation of the study, we will confer with the CDC on whom to report to in Kenya and Atlanta. At that time, we will also determine how frequently the USG/GOK technical teams would like to be appraised of the study and its results. At a minimum, we will seek to be in phone and/or e-mail contact with USG contacts quarterly to ensure that the study and its data is relevant to USG technical working groups and policies established around cervical cancer screening in PEPFAR-supported clinics. Dissemination of study findings will also occur through public presentations and publication in internationally recognized journals. CDC and USG staff/agents will not participate in the study as co-investigators or study collaborators. They will not participate directly in the study development, analysis, or manuscript preparation.

Cervical Screening Organogram

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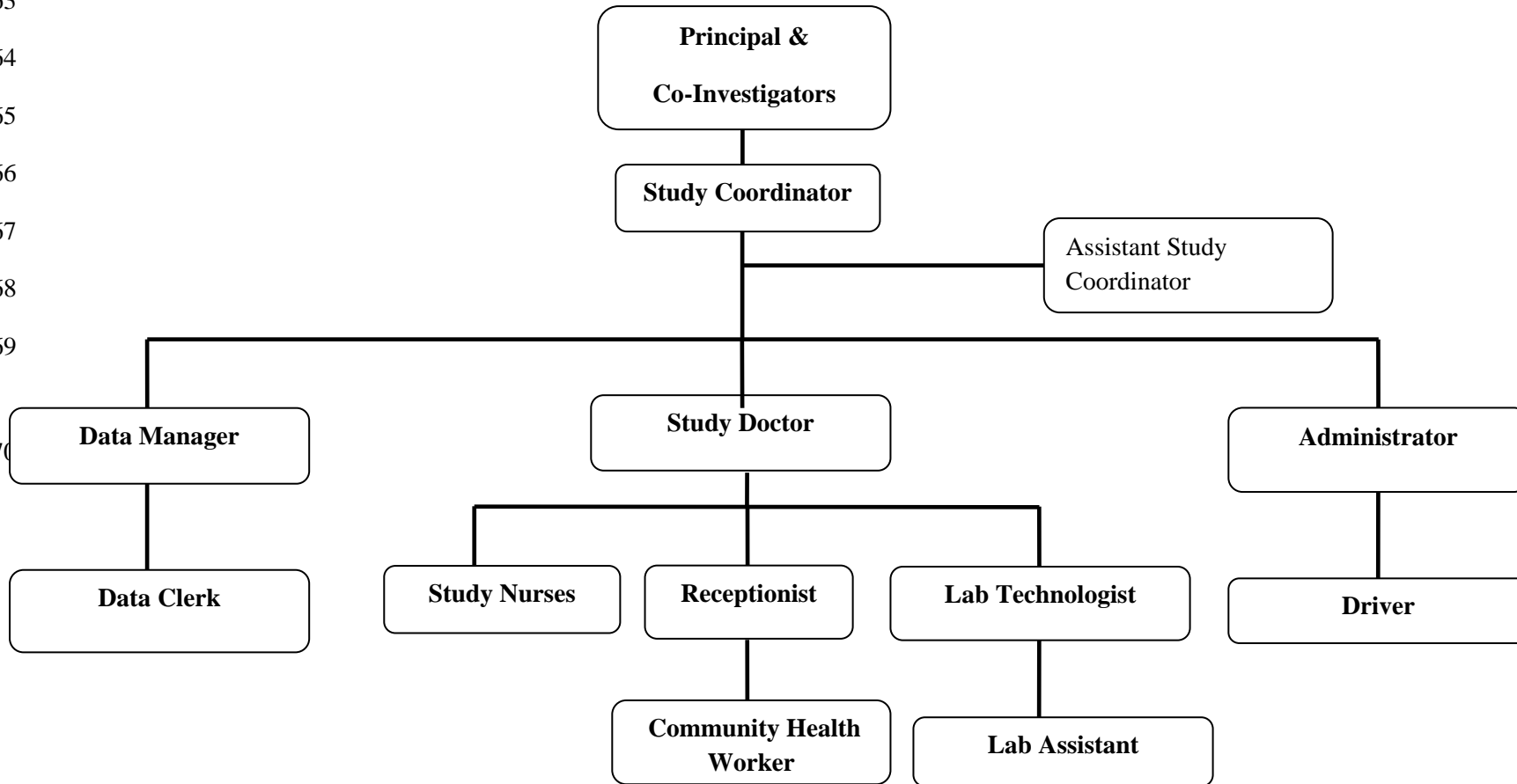
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Personnel

372 Study Coordinator

- 373 • Manage directly the Study Monitor, Data Manager, Study Doctor, Administrator, and Lab
374 technologist around aspects of the PHE cervical treatment study and R01 resistance study
- 375 • Monitor the progress of research activities and ensure the smooth and efficient day-to-day
376 operation of research and data collection activities
- 377 • Initiate and coordinate activities that improve the conduct and performance of the study
- 378 • Conduct weekly clinic meetings that are led by Study Doctor with study staff
- 379 • Conduct weekly data meetings that are led by the Data Manager to ensure data is
380 collected in a timely fashion, is cleaned, and clearly analyzed
- 381 • Conduct and lead weekly study-related administrative meetings
- 382 • Direct and be responsible for the study budget and petty cash that is managed by the
383 administrator
- 384 • Act as the primary administrative point of contact for research staff and as the principle
385 operational liaison for Coptic administration and regulatory bodies
- 386 • Analyze recruitment rates, determine if rates match expectations, and implement plans
387 that will promote recruitment
- 388 • Analyze retention rates and implement plans that will promote retention
- 389 • Supervise and coordinate the provision of support services to investigators
- 390 • Prepare periodic and ad hoc reports as required by investigators, funding agency, and/or
391 regulatory bodies

- 392 • Be responsible for renewing, updating and modifying IRB applications at UW and KNH
393 that are associated with this study
- 394 • Be responsible for generating Adverse Events, protocol violations and deviations, and
395 unanticipated problems reports
- 396 • Be responsible for liaising with the DMSB as needed
- 397 • Perform any other duties and responsibilities that may be given by the PI or co-
398 investigator

399 **Assistant Study Coordinator**

- 400 • Assist the Study Coordinator in monitoring the progress of research activities and
401 ensuring the smooth and efficient day-to-day operation of research and data collection
402 activities
- 403 • Implement and be responsible for renewing, updating, and modifying existing standard
404 operating procedures (SOPs) and develop new ones as needed
- 405 • Be responsible to ensure that all staff are following SOPs
- 406 • Implement quality control procedures throughout the conduct of the study
- 407 • Review the accuracy, completeness and timeliness of completed study related records,
408 case report forms and other documents
- 409 • Compare reported data with original source documents
- 410 • Review study related processes relative to applicable regulatory requirements, including
411 GCP and Human Subjects Protection regulations
- 412 • Verify the following items for the study: protocol compliance (i.e. subject recruitment and
413 eligibility criteria, informed consent and randomization procedures); that only designated

- 414 investigator(s) and/or appropriate research staff are performing study functions; that
415 regulatory compliance is being maintained (i.e. that investigators are providing and
416 maintaining all study related documents as required.)Be responsible for study compliance
417 with all regulations
- 418 • Communicate any serious deficiencies noted during monitoring to the Study Coordinator
 - 419 • Ensure that a record of all correspondence, monitoring reports and other written
420 documentations are maintained by the Administrator
 - 421 • Participate in all study meetings
 - 422 • Organize and coordinate all training activities
 - 423 • Respond to and be responsible for implementing all matters that may arise from CDC and
424 Study Monitor visits
 - 425 • Perform any other duties and responsibilities that may be given by the Study Coordinator
 - 426 •

427 **Study Doctor**

- 428 • Oversee and ensure that patients in the study are receiving good medical HIV care and
429 inform the study coordinator of any complications
- 430 • Identify subjects that require medical attention and refer them for care at the Hope Center
- 431 • Draw blood or obtain specimens from patients if the lab assistant or lab technologist is
432 unable or unavailable
- 433 • Oversee the cervical screening clinic and ensure it is well-stocked with necessary medical
434 supplies and equipment to perform the study

- 435 • Meet with the data clerk or data manager to correct data entry errors
- 436 • Review and confirm eligibility of each patient for study
- 437 • Administer questionnaires
- 438 • Conduct gynecological examinations, HIV and HPV swabs, colposcopy, biopsies, and
- 439 cryotherapy and LEEP
- 440 • Assist the study nurses in performing their duties if they are unable or unavailable
- 441 • Confer and communicate with Hope Center clinicians and medical staff if any questions
- 442 or problems arise concerning medically related issues
- 443 • Work closely with clinic staff at the Hope Center to ensure high recruitment for research
- 444 study
- 445 • Work with data manager and receptionist to analyze data and prepare reports
- 446 • Present weekly summaries along with the study nurse and receptionist marking progress
- 447 in enrollment and tracking of subjects in the study
- 448 • Will be responsible for reporting adverse effects to the principal investigator and co-
- 449 investigators
- 450 • Perform any other duties and responsibilities that may be given by the principal
- 451 investigator or the study coordinator

452 **Study Nurses**

- 453 • Conduct gynecological examinations, HPV swabs, and Pap smears

- 454 • Check age, previous cervical screenings and gynecological history before enrollment into
455 the program
- 456 • Provide adequate knowledge and education about the study to patients so they can sign an
457 Informed Consent
- 458 • Administer the Informed Consent and store it safely
- 459 • Administer questionnaires
- 460 • Review and confirm eligibility of each patient for research study
- 461 • Assist the study doctor in any medical procedures
- 462 • Attend weekly clinic meetings
- 463 • Maintain, and in the absence of the community health worker, clean and organize the
464 cervical screening clinic
- 465 • Transport equipment and supplies for cleaning and autoclaving
- 466 • Meet with the data clerk or data manager to correct data entry errors
- 467 • Draw blood or obtain specimens from patients if the lab assistant or lab technologist is
468 unable or unavailable
- 469 • Perform any other duties and responsibilities that may be given by the study coordinator
470 or study doctor

471 **Administrator**

- 472 • Manage petty cash and study budget
- 473 • Liaise with payroll administrators to ensure salaries are paid correctly and on time

- 474 • Make purchases, photocopy data collection tools, and keep inventories of supplies
- 475 • Maintain communication between the clinic and office
- 476 • Attend and take minutes at weekly administrative and clinic meetings and present them at
477 the next meeting
- 478 • Reconcile receipts to send to Seattle
- 479 • Communicate with Seattle when more funds are needed
- 480 • Manage the driver and arrange transportation
- 481 • Arrange for study trainings in coordination with study coordinator
- 482 • Maintain and organize files of personnel, correspondence, applications, IRB records,
483 receipts, budget, inventories, etc...
- 484 • Coordinate staff evaluation procedures
- 485 • Oversee and record the attendance of office and clinic staff in coordination with the study
486 nurse
- 487 • Make monthly reports of project expenses
- 488 • Facilitate in renewing personnel medical insurance and liaise between insurance and the
489 hospital of matters of personnel appointment
- 490 • Make weekly reports of administrative issues
- 491 • Prepare IRB and government applications for the shipment of samples
- 492 • Remind study coordinator when IRB renewals are due and work with study coordinator
493 and principal investigator to submit, modify, and renew IRB applications
- 494 • Ensure office tidiness

- 495 • Perform any other duties and responsibilities that may be given by the principal
496 investigator or study coordinator

497 **Receptionist**

- 498 • Follow subjects enrolled in the study and ensure they are retained in the study and proper
499 follow-up is done both at the research clinic and the Hope clinic

- 500 • Keep track of all the patients enrolled and determine if any patient has missed
501 appointment and take action to report and bring these patients back under care and
502 supervision

- 503 • Handle money given by the administrator and account for it by keeping the various logs
504 (i.e. calling log, transport log and client transport reimbursement forms) and meet weekly
505 with the administrator for reconciliation

- 506 • Track Excel spreadsheet of patient appointments, recruitment, and follow-up in the study
507 clinic

- 508 • Develop report of clinic flow weekly for study clinic meetings

- 509 • Present weekly summaries marking progress in enrollment and tracking of subjects in the
510 study in coordination with the study doctor

- 511 • Will work with the study doctor, lab assistant, and community health worker to follow-up
512 subjects by phone and home visits

- 513 • Perform any other duties and responsibilities that may be given by the principal
514 investigator or study coordinator

515 **Data Manager**

- 516 • Oversee the work of the data clerk as below and assume any of the duties of the clerk that
517 may be required due to his absence or inability to perform
- 518 • Manage the data clerk
- 519 • Contribute to the design and modification of protocols, which define what and when data
520 are to be collected
- 521 • Design and approve forms on which data are collected
- 522 • Be responsible for data collection forms and informed consents (both old and new) that
523 are used in the study
- 524 • Manage data information entered by the data clerk on study patients with Hope Center
- 525 • Ensure that patient study files are properly filled, documented, and stored
- 526 • Manage data backup on weekly basis
- 527 • Coordinate the transfer of data with the Coptic Hope data manager to the research
528 databases with the data clerk
- 529 • Design SPSS database and manage both the SPSS and Access databases for the study
- 530 • Ensure the databases meet requirements for the entry and reporting of clinical data
- 531 • Maintain daily, weekly, and monthly work schedules for the data office with the data
532 clerk and ensure their completion
- 533 • Check for errors in the data, correct the errors, and maintain cleanliness of the data
- 534 • Check and manage the data log book of errors produced by the data clerk
- 535 • Coordinate the data-checking process and produce a monthly report on the data quality

- 536 • Thoroughly clean the data every 3 months to ensure cleansing of errors
- 537 • Sort out any data entry or error problems weekly with the study doctor and study
538 coordinator
- 539 • Run frequencies and range checks to identify extreme values monthly
- 540 • Present weekly and monthly reports of data analysis
- 541 • Assist the study doctor and receptionist in the presentation of weekly summaries marking
542 progress in enrollment and tracking of subjects in the study
- 543 • Assist the receptionist and study doctor in the preparation of monthly summary tables on
544 number of women enrolled in each study arm and to consolidate the weekly reports
- 545 • Prepare laboratory shipping lists with the lab technologist
- 546 • Be responsible for maintaining the security of the data
- 547 • Generate study ID numbers
- 548 • Be responsible for linking and de-linking data
- 549 • Train clinical research staff to help improve the quality of the data being collected
- 550 • Assist in standardizing data management procedures such as documentation for study
551 operating procedures
552
- 553 • Develop and maintain documentation and data management guidelines
- 554 • Perform other duties that may be given by the principle investigator or study coordinator

555 **Data Clerk**

- 556 • Enter questionnaire data and laboratory testing information into a computer database

- 557 • Scan, verify, and check data in Teleform
- 558 • Prepare new patient files and ensure all files contain the required questionnaires
- 559 • Maintain Access, Excel, and SPSS computer databases for the study
- 560 • Maintain daily, weekly, and monthly work schedules and ensure their completion
- 561 • Conduct weekly data quality checks with guidance from the data manager
- 562 • Check for errors in the data, correct the errors, and maintain cleanliness of the data
- 563 • Inform the data manager and study coordinator and of any data entry problems on a
564 weekly basis
- 565 • Keep a data log book of data entry queries and inconsistencies
- 566 • Back-up all data weekly (Friday)
- 567 • Back-up all data to an off-site disk weekly (Friday)
- 568 • Coordinate the timely movement of questionnaires, data forms, and information between
569 the Hope Center, the Coptic research wing, and the KNH data office
- 570 • Ensure that the computers, printers and scanner are in good order and free from viruses
- 571 • Perform any other duties that may be given by the data manager, study coordinator, and
572 principal investigator
- 573 **Lab Technologist**
- 574 • Oversee the work of the lab assistant as below and assume any of the duties of the lab
575 assistant that may be required due to his absence or inability to perform
- 576 • Manage the lab assistant

- 577 • Ensure enrolled patients have their blood samples and/or other specimens collected at all
578 visits according the study schedule
- 579 • Ensure equipment and supplies are available, working, and well maintained
- 580 • Ensure the lab is maintaining good laboratory practices
- 581 • Maintain and manage the inventory of laboratory supplies and equipment
- 582 • Collect laboratory specimens (including blood) from study participants if the lab assistant
583 is absent or unable to perform
- 584 • Keep track of laboratory specimens by updating and maintaining the lab database
- 585 • Prepare for the shipment of lab specimens (HIV and HPV)
- 586 • Prepare media for collection of samples
- 587 • Be responsible for maintaining appropriate freezer temperature
- 588 • Monitor freezer temperature by keeping an accurate temperature chart if lab assistant is
589 unavailable
- 590 • Be responsible for and enact proper emergency procedures if the freezer is not
591 functioning
- 592 • Oversee and manage collection and storage of the following specimens: urine for
593 pregnancy, HPV swab, HIV swab/CVL, Pap smear, and biopsy specimens
- 594 • Coordinate the delivery of lab specimens (Pap smear and biopsy) and collection of results
595 with the pathologist
- 596 • Coordinate collection, delivery, and recording of CD4 counts

- 597 • Track specimens and results in lab book
- 598 • Perform other duties that may be given by the study coordinator or principal investigator

599 **Laboratory Assistant**

- 600 • Collect laboratory specimens (including urine and blood) from study participants
- 601 • Track CD4 results from the medical records office and update the CD4 results log in
602 coordination with clinic lab tech, clinic data manager, and study senior data analyst
- 603 • Ensure timely transportation of questionnaires and research files between Coptic and
604 KNH offices
- 605 • Assist the lab tech in the collection and storage of the following specimens: urine for
606 pregnancy, HPV swab, HIV swab, Pap smear, and biopsy specimens
- 607 • Assist the lab tech in the delivery of lab specimens (Pap smear and biopsy) and collection
608 of results with the pathologist
- 609 • Track specimens and results in lab book
- 610 • Assist the lab tech in the delivery of specimens and collection of results
- 611 • Assist the lab tech in the processing and freezing of samples
- 612 • Monitor freezer temperature by keeping an accurate temperature chart and inform the lab
613 technologist and study coordinator if there is a failure
- 614 • Remove frost and clean the freezer
- 615 • Record and present minutes at clinic research meetings if the administrator is not
616 available

- 617 • Clean and help organize study clinic
- 618 • Assist the receptionist in following subjects enrolled in the study and ensure they are
619 retained in the study and proper follow-up is done both at the research clinic and the Hope
620 clinic
- 621 • Assist the receptionist in keeping track of all the patients enrolled and determine if any
622 patient has missed appointment and take action to report and bring these patients back
623 under care and supervision
- 624 • Ensure completed questionnaires are delivered to the data clerk within 24 hrs
- 625 • Will perform home visits as necessary in coordination with the receptionist and study
626 doctor
- 627 • Will help phone subjects for follow-up in coordination with the receptionist and study
628 doctor
- 629 • Perform other duties that may be given by the laboratory technologist, study coordinator,
630 or principal investigator

631 **Community Health Worker**

- 632 • Accompany clients for possible enrollment from the Hope Center to the cervical
633 screening clinic or study lab for urine testing
- 634 • Accompany clients between the study lab, Coptic lab, and the cervical screening clinic
- 635 • Help clients schedule appointments at the Hope Center
- 636 • Clean and help organize study clinic

- 637 • Will perform home visits as necessary in coordination with the receptionist and study
- 638 doctor
- 639 • Will help phone subjects for follow-up in coordination with the receptionist and study
- 640 doctor
- 641 • Perform duties given by receptionist or study coordinator
- 642 **Driver**
- 643 • Transport specimens and data files
- 644 • Assist the administrator in purchase of supplies and equipment
- 645 • Maintain car and ensure it is running well and has fuel
- 646 • Perform duties given by administrator or principal investigator
- 647 • Pick supplies from the office to the clinic

648 **Study Population & Recruitment**

649 The study will be a prospective randomized clinical trial enrolling HIV-positive
650 women who receive care at the Coptic Hope Center for Infectious Diseases in Nairobi,
651 Kenya. The study clinic will screen at least 2,400 HIV-positive women from the Coptic Hope
652 Center for cervical cancer and, of whom, approximately 400 will be enrolled and randomized
653 to receive treatment.

654 It is estimated that at least 2,400 women will need to be screened in order to identify
655 400 women with high-grade intraepithelial lesions. This is based on a prospective analysis of
656 500 HIV-positive women who underwent Pap smear screening at the Hope Center between
657 July and November 2009. In this analysis, 187 (37%) women had normal cytological results,
658 292 (59%) had abnormal cytological results, and 21 (4%) had results which were
659 indeterminate due to inflammation, inadequate sample collection, or insufficient data.
660 Abnormal cytological results included 77 women (15%) with atypical squamous cells of
661 undetermined significance (ASCUS), 121 (24%) low-grade squamous intraepithelial lesions
662 (LSIL), and 92 (18%) high-grade squamous intraepithelial lesions (HSIL).

663 Adult HIV-positive women receiving care at the Coptic Hope Center who are not
664 pregnant by clinical examination or history, have an intact cervix, have not received prior
665 cervical treatment, do not have a history of a bleeding disorder, do not have any known
666 allergy to study medications OR their alternatives, have initiated sexual intercourse and are
667 above 18 years of age will be informed of the study by non-study clinicians and health care
668 workers. Subjects will be excluded by the study at initial cervical cancer screening if they are
669 HIV-negative, male, below 18 years of age, pregnant by clinical examination or history, post-
670 hysterectomy, post-cervical cancer treatment or have known allergies to study medications.

671 Potential participants will be identified by Hope Center clinical officers seeing
672 patients as part of routine HIV medical care at the Hope Center. Clinical officers will use
673 “Pre-Screening Talking Points” to inform patients about the study. If subjects are interested
674 then they will be directed to the study clinic in a physically separate room staffed by study
675 personnel. We will also use recruitment leaflets that will be distributed at the Hope Center
676 Reception. The leaflets will have the contact information of the study staff. At the study
677 clinic, a study staff member will inform potential subjects of the study using “Screening
678 Talking Points”. If subjects remain interested and are eligible then they will be enrolled (see
679 Study Flow I). An appointment calendar will be kept by the study receptionist on an MS
680 Access database to track who has attended the clinic and received screening.

681 Interested women will be referred to the study clinic (Room A) which will be staffed
682 by two study nurses trained to perform Pap smears on the same day after obtaining informed
683 consent for screening. Women who enrolled in the screening portion of the study and
684 obtained a Pap smear will be asked to return to the study clinic (Room A) for results 2 weeks
685 later. If Pap result is positive for HSIL, the subject will be referred to a separate room (Room
686 B) where a study doctor and a study nurse will obtain a biopsy to confirm CIN 2 and 3 by
687 histology. From this point, the subject will return to Room B and see the study doctor and
688 nurse for further follow-up. Four to six weeks after biopsy, the subject will return for her
689 results and to discuss treatment options. At this point, study staff will obtain informed
690 consent for randomization and follow-up, and the study doctor will randomize histology-
691 confirmed subjects (approximately 400 women) to LEEP or cryotherapy. Criteria for being
692 ineligible for cryotherapy include if a polyp or anatomic defect prevents access to the cervix
693 and/or if the lesion size is >75% of the cervix or is larger than the cryoprobe tip, or if the
694 lesion is not visible in its entire extent or extends more than 2 to 3 mm into the endocervical
695 canal. If any of these subjects are diagnosed with severe cervical disease confirmed by

696 histology at these later screening time points, they will be offered LEEP by the study or
697 referred for appropriate care.

698 Patients who require further care for cervical disease unavailable at the study clinic
699 (eg. hysterectomy) or who decline to enroll in the treatment portion of the study will be
700 referred to KNH. Through patient tracing the study doctor and staff connected to the KNH
701 gynecology department will make best efforts to assure that patients receive proper care.
702 Referral notes and copies of results for histopathology, cytopathology, CD4 count, and HIV
703 viral load will be sent with the patient during referral. All study specific documentation
704 including study numbers and title will be removed. Only the subject's name and age, as is
705 relevant to the referral, will be on the documents sent for clinical care at KNH or Coptic
706 Hospital. Subjects will receive government subsidized care at these sites but the study will
707 not pay for these interventions or treatment.

708 Study clinic visits will be conducted separately from regular medical visits a patient
709 may make at the Hope Center. Subjects will continue to follow-up with their doctors at the
710 Hope Center, schedule their visits through the Hope receptionist, and pick up their
711 medications at the clinic. However, study clinic visits will be conducted by staff employed
712 by the study in physically separate locations from routine medical visits. Study appointments
713 will not conflict with the HIV clinical care that patients receive through coordination between
714 the study receptionist and the clinic receptionist. Study doctors will not provide HIV care or
715 treatment, and subjects will remain enrolled as patients at the Hope Center and receive the
716 same care as prior to enrollment. Before lab tests for the study are performed, confirmation
717 from the subject (and if necessary, the laboratory) will be made to assure no tests, such as Pap
718 smears ordered as standard of care or blood draws, are unnecessarily repeated.

719 Medical information collected by clinic staff at the Hope Center will be made
720 available to the study team after written informed consent by the subject. This will contain
721 all information collected at the Hope Center including laboratory data. Only clinic staff will
722 collect medical information from subjects related to the management of their HIV disease.
723 Study data for the PHE will be collected on separate forms and scanned, cleaned, and
724 analyzed at a location unassociated with the clinic and its medical records. Only study staff
725 will collect study data on forms described in this protocol. If institutional IRBs approve, we
726 will make study data available to the clinic staff at the Hope Center after written informed
727 consent is signed by the subject. As soon as a participant's results become available, the
728 study staff will enter the results in a form that is stored in the participant's Hope Files as a
729 means of communicating the results to the participant's clinicians. This will be done in
730 coordination with the medical records department at the Hope Center. If clinical information
731 is discovered about a subject that needs immediate attention, clinical staff will be available on
732 site at all times to assist in care of the patient and will be informed by the study staff. In the
733 event that a participant needs emergency care, the study clinical staff will be prepared to
734 stabilize patients and emergency services are available at Coptic Hospital 24 hours a day.
735 Moreover, clinical care is available at KNH at any time if needed or preferred by the patient.
736 Participants will be given careful instruction as to which symptoms would necessitate them
737 seeking additional medical care, especially after receiving treatment. The participant will
738 receive contact information of study staff whom they should contact in case of an emergency
739 or if they need guidance as to how to manage a certain symptom or condition. Study staff
740 can share pertinent information with clinic staff in these situations by phone or in person as
741 the study clinic is located on the hospital grounds.

742 Participants will be consented for screening by study staff at their enrollment visit and
743 for randomization and follow-up at their biopsy result visit. If an

744 exited subject becomes eligible for re-enrollment due to re-reading of cytology results (See
745 QA/QC section), then re-enrollment consenting will be done at the disclosure visit for the
746 new results. All consenting study staff members will be able to describe study procedures in
747 English, Kiswahili and possibly another local language. Other nursing and study staff are
748 available and should be contacted in the case of a participant who presents for enrollment but
749 is not conversant in any of the languages the consenting staff member speaks. Consent
750 documents will be prepared in both English and Kiswahili at a basic reading level. The
751 English version will be used by study staff to produce the Kiswahili version and several
752 members of the staff will review the document to assure its accuracy and readability.

753 Participants will be encouraged to ask questions at any point during the consent
754 process and will be given a copy of the document to review on their own. If a participant has
755 a question that cannot be answered by the consenting staff member, other study staff will be
756 available for consultation. The patient may also contact other study staff at her convenience.
757 The participant may also interrupt the consent process at any time if she needs more time to
758 consider her participation.

759 Subjects with initial Pap smear results that are Normal or ASC-US will be exited from
760 the study after receiving their Pap smear results. Subjects with LSIL Pap smear results will be
761 offered Colposcopy. According to the 2012 ASCCP guidelines, participants found with LSIL
762 in the absence of HPV co-testing should be recommended colposcopic evaluation and biopsy.
763 These biopsy histology results will be treated the same as other study histology, including
764 possible treatment randomization for CIN 2/3 and CIS. This will enable researchers to
765 monitor lesions which may escalate from low-grade to high-grade in subjects who may be
766 eligible for subsequent randomization. Results from repeat Pap-smears will be treated the
767 same as results from initial Pap smears: Women with Normal/ASC-US results will be exited
768 from the study. Subjects with HSIL/ASC-H/HSIL-invasion-not-ruled-out and results

769 suggestive of cervical carcinoma (i.e. high grade intra-epithelial lesions) will undergo
770 colposcopy with biopsy, and may potentially be eligible for randomization upon confirmed
771 histology results. If a subject with high grade intraepithelial lesions detected on study-related
772 Pap smears is later found to have normal or ASCUS on a follow up Pap smear (study related
773 or not) that occurs prior to or in lieu of a colposcopic evaluation, the subject will still be
774 required to have a study related colposcopy and biopsy.

775 Subjects who have biopsy-confirmed CIN 2, 3 or CIS will be eligible for the
776 randomization and treatment portion of the study. They will be presented with the consent
777 information upon receipt of biopsy result. Subjects with biopsy results suggestive of cervical
778 carcinoma will be exited from the study and referred for further evaluation and management
779 at KNH. Subjects with CIN I biopsy results will be asked to return to the clinic for repeat
780 Pap smear in 6 months and will remain in the study. If a subject receives three consecutive
781 CIN I histology results, she will be offered LEEP treatment by the study doctor. These
782 participants will be treated and followed the same as other non-randomized LEEP
783 participants.

784

785 Of note: Women with normal or with ASCUS Pap smear results (that are exited from
786 the study) will be referred for subsequent cervical screening follow-up at the Hope Center
787 Cervical Cancer Screening Program (CCSP). This program is administered by the Coptic
788 Hospital and is supported by the Coptic Mission, PEPFAR, and other donor funding. The
789 CCSP offers free cervical cancer screening to HIV-positive women enrolled in the Coptic
790 Hope Clinic. Currently, a single visit ‘screen-and-treat’ strategy for cervical cancer
791 prevention and treatment will be used. The screen-and-treat method involves visual inspection
792 of the cervix followed by treatment of precancerous lesions by cryotherapy at the same visit.
793 Patients who cannot be treated with cryotherapy are referred to KNH for subsidized cervical

794 care and treatment. As all study subjects are drawn from the Coptic Hope HIV clinic, they
795 are all eligible to be screened, treated, and followed at the CCSP.

796 If a woman exited from her normal or ASCUS Pap smear result prefers to rescreen with
797 the study, she may be re-enrolled using the re-enrollment consent form.

798

Study Procedures

799

1. SCREENING visit (at least 2,400 patients) (see Study Flow Diagram I, Enrollment)

800

- At screening, subjects who agree to participation will:

801

- Sign a written informed consent

802

- Answer the “Enrollment” questionnaire which will ask her sociodemographic background, sexual history, and cervical cancer screening history.

803

804

- Complete “Address and Intake” questionnaire.

805

- Undergo a physical examination including a pelvic examination with a Papanicolaou smear of the cervix. The results of the physical examination will be entered in the “Pap Smear” questionnaire

806

807

808

- Women found to have evidence of an STI will undergo syndromic management according to the following algorithm:

809

810

- i. Vaginal discharge without abdominal pain

811

1. Treat for vaginitis:

812

- a. Nystatin 1 pessary everyday x 5 days and

813

- b. Metronidazole 2g x 1

814

2. If no improvement after 7 days, treat for cervicitis:

815

- a. Norfloxacin 800mg x 1 and

816

- b. Doxycycline 100mg BD x 7 days

817

- ii. Lower abdominal pain

818

1. If due to surgical or gynecological causes, refer

- 819 2. If cervical motion tenderness, treat for pelvic inflammatory
820 disease:
- 821 a. Norfloxacin 800mg x 1 and
822 b. Doxycycline 100mg BD x 7 days and
823 c. Metronidazole 400mg BD x 10 days
- 824 iii. Genital ulcer disease (GUD)
- 825 1. If multiple lesions grouped together with a history of
826 recurrence, treat for Herpes simplex genitalis:
- 827 a. symptomatic treatment
- 828 2. If other GUD, treat empirically:
- 829 a. Erythromycin 500mg three times per day x 7 days and
830 b. Benzathine penicillin 2.4 million U IM stat
- 831 2. Two-week visit for RESULTS (at least 2,400 patients)
- 832 • Patients will return to the clinic two weeks later for Pap smear results which will be
833 entered on the “Colposcopy” questionnaire. We expect that an estimated 1,700
834 women will have results (no dysplasia or ASCUS) that do not require study
835 biopsy/colpo procedures. These patients will be ineligible for randomization.
- 836 • Women with no dysplasia or ASCUS Pap smear results will be exited from the study.
837 They will be followed up at the Coptic Hope Cervical Cancer Screening Program
838 (CCSP). The Hope screening program offers free cervical screening through visual
839 inspection with acetic acid (VIA). Women who are screened and exited from this
840 study with normal Pap smear results will be followed up at CCSP one year after initial
841 screening. Women who are screened and exited from this study with ASCUS Pap
842 smear results will be followed up at CCSP 6 months after initial screening. Women
843 who have exited the study due to a cytologic diagnosis of no dysplasia or ASCUS will

844 be eligible to re-enroll in the study and obtain a study related screening pap smear,
845 approximately 12 months after their last normal/ASCUS study related pap smear.

- 846 • Women found with unsatisfactory results will have their Pap smear repeated.
- 847 • Women with LSIL will be offered Colposcopy. According to the 2012 ASCCP
848 guidelines, participants found with LSIL in the absence of HPV co-testing should be
849 recommended colposcopic evaluation and biopsy.
- 850 • Any patient who receives a cytological diagnosis of high-grade intraepithelial lesion
851 (HSIL and ASC-H, and HSIL-invasion-not-ruled-out or SCC) (~18% of the patient
852 population or approximately 400 patients), will be recommended to undergo
853 colposcopy as per 2012 ASCCP guidelines. If a subject with high grade intraepithelial
854 lesions detected on study-related Pap smears is later found to have normal or ASCUS
855 on a follow up Pap smear that occurs prior to or in lieu of a colposcopic evaluation,
856 the subject will still be required to have a study-related colposcopy and biopsy. Prior
857 to participating in any cervical procedure, including biopsy, women will undergo a
858 rapid pregnancy test. Pregnant subjects will be exited from the study and followed-up
859 in the CCSP. These women will also be referred for prevention of mother-to-child
860 transmission (PMTCT) care at Hope Center. If the pregnancy result is negative, they
861 will be referred to the study doctor for colposcopy-directed biopsy which will clarify
862 the extent and severity of disease. Results of the colposcopic examination will be
863 entered in the “Colposcopy” questionnaire (see Study Flow I). For patients who have
864 glandular epithelium abnormalities (AGC) on Pap or squamous epithelium
865 abnormalities without visible lesions on colposcopy, endocervical sampling with
866 curettage will be performed in order to identify possible abnormalities in the
867 endocervical canal.

- 868 • After undergoing abioopsy, women will be given free condoms and advised to abstain
869 from sexual activities for at least 10 days.
- 870 3. 6-8-weekvisit for RANDOMIZATION (~400 patients) (see Study Flow II)
- 871 • Subjects who have undergone biopsy will return four to six weeks later for a follow-
872 up visit to be given the results of the biopsy. Biopsy results will be entered in the
873 “Treatment” questionnaire.
- 874 • Those with biopsy results that are positive for a high grade pre-cancerous lesion (CIN
875 2/ 3 or CIS) and if the lesion is amenable to cryotherapy or LEEP as per Kenyan
876 national guidelines, will be eligible for randomization. If they are willing to undergo
877 informed consent for the treatment study, they will be randomized to receive either
878 cryotherapy or LEEP (see Study Flow II). Those who decline to participate in the
879 treatment study will be exited and referred to KNH for treatment. Randomization
880 questionnaire will also be completed during this visit.
- 881 • Those patients who do not have lesions which are amenable to cryotherapy due to size
882 or access will not be randomized but will be offered free LEEP and followed up every
883 6 months for 2 years, the same way as randomized participants. Those who
884 have lesions that are neither amenable to LEEP nor cryotherapy due to size or severity
885 of disease, or anatomy does not allow proper access to the cervix, will be referred to
886 KNH for subsidized care at this government hospital. The study will not pay for this
887 treatment. Patients will be given follow-up appointments in the study clinic after
888 referral to determine outcomes. They will have the option to continue to be followed
889 at the CCSP.

- 890 • Those with CIN 1 will not be randomized or exited but will be asked to return to the
891 study clinic after 6 months for a repeat Pap smear.
- 892 • Those who show no dysplasia on histology will be exited from the study and referred
893 to the CCSP for further follow-up.
- 894 • It is expected that approximately 400 patients will be eligible for randomization.
895 During randomization, a sealed envelope will be opened by the study doctor that will
896 reveal the randomization arm that has been assigned to the study ID number.
897 Randomization assignment will be performed on a computer by Dr. Barbra
898 Richardson, the study statistician, in Seattle, and preparation of the envelopes will be
899 performed by the study data manager in Nairobi in conjunction with Dr. Richardson.
900 This is the standard used for all randomized clinical trials conducted by the University
901 of Washington in Kenya. Study investigators and the study doctor will not have
902 access to the randomization sequence. Study investigators and staff will not be
903 blinded to randomization.
- 904 • Those eligible for randomization will have an HIV cervical viral level swab taken
905 before treatment (LEEP or cryotherapy).
- 906 • After receiving LEEP or cryotherapy, women will be given free condoms and advised
907 to abstain from sexual activities for at least 4 weeks. Women will also be offered an
908 information sheet on the treatment procedure and abstinence information to take home
909 for their spouse or partner. Information includes treatment given, recommended
910 abstinence period and reasons for abstaining from sexual intercourse. These
911 information sheets will be optional to maintain patient confidentiality and safety,
912 especially for people who have not disclosed their status.
- 913 • Patients undergoing randomization will have the following performed:

- 914 ○ Blood (10mls) will be drawn to check for HIV viral load and CD4 count
- 915 ○ Cervix will be swabbed to assess the presence of Human Papillomavirus
- 916 (HPV) prior to LEEP or cryotherapy
- 917 ○ Cervix will be swabbed for HIV viral level prior to LEEP or cryotherapy
- 918 ○ LEEP or cryotherapy performed based on randomization envelope
- 919 ○ Those undergoing LEEP will have the LEEP piece taken for histology
- 920 ○ “Randomization” questionnaire completed
- 921 ○ “Treatment” questionnaire completed
- 922 4. First, second, and third-week visits for cervical HIV-1 SHEDDING after treatment (~400
- 923 patients) (see Study Flow II)
- 924 • Patients who have been randomized and received treatment (approximately 400
- 925 patients) will be followed every 1 week for 3 weeks AFTER the treatment intervention
- 926 to assess healing and measure HIV-1 viral shedding from the cervix. These events
- 927 can be called the 7-9, 8-10, and 9-11-week visit time points and will probably
- 928 coincide with the eighth, ninth, and tenth week after enrollment. However, for
- 929 purposes of measuring HIV viral shedding, it is most important that these time points
- 930 occur 1, 2, and 3 weeks after the treatment intervention. These terms are consistent
- 931 and are used for descriptive purposes. They will return 3 times over a 3-week interval
- 932 and have the following performed:
- 933 ○ Blood (10mls) will be drawn to check for HIV viral load
- 934 ○ Cervix will be swabbed to assess the presence of HIV-1
- 935 ○ “Shedding” questionnaire completed

936 Shedding information will be considered valid if it is obtained \pm 3 days of the
937 scheduled visit. We will collect shedding information for the first three weeks after
938 treatment but if a patient misses those visits but comes back within six weeks, we will
939 still collect the samples just for comparison purposes.

940 5. Six, twelve, eighteen, and twenty-four months after randomization visits for
941 RECURRENCE (approximately 400 patients) (see Study Flow II)

942 • After the 9-11-week visit, randomized participants and those who undergo LEEP but
943 are not randomized because their lesions are not amenable to cryotherapy will return
944 at 6, 12, 18, and 24 months after treatment is administered. At the 24 month visit, the
945 subject will be exited from the study. At these 6-month interval visits, the following
946 will be performed in order:

- 947 ○ Pap smear to detect recurrence of cervical intraepithelial lesions
- 948 ○ Same Pap smear swab will be used to assess the presence of Human
949 Papillomavirus (HPV)
- 950 ○ Blood (5 mls) will be drawn to check for CD4 count
- 951 ○ “Pap Smear” questionnaire completed

952 • Pap smear results that are normal, ASCUS, will be filed in the participants file and
953 disclosed at the next scheduled follow-up visit. If pre-cancerous lesions by cytology
954 have recurred then patient will be contacted to return to the study clinic to undergo
955 colposcopic directed biopsy prior to treatment. Results of the colposcopic
956 examination will be entered in the “Colposcopy” questionnaire..

- 957 ○ If histology-confirmed lesions can be treated by LEEP, then the patient will
958 receive a free LEEP and “Treatment” questionnaire will be filled.
- 959 ○ If histology-confirmed lesions are too large or cancerous for LEEP then
960 patient will be referred to KNH for subsidized care at this government

961 hospital. The study will not pay for this treatment. Patients will be given
962 follow-up appointments in the study clinic after referral to determine
963 outcomes.

964 • Phone calls and home visits will be performed sequentially in the case of a subject
965 who has been lost to follow-up (LTFU) after screening or randomization (see LTFU
966 section). LTFU will be prepared and discussed at weekly clinic meetings. Written
967 reports will be prepared from these meetings and sent to co-investigators. Home visits
968 will be performed by community health workers trained to be discreet in their
969 approach to finding patients. They will not wear clothes that would identify them as
970 health workers and will only use public transportation or unmarked private vehicles.
971 They may ask about the participant's health or whereabouts.

972 6. Specimen transportation

973 Blood samples will be processed at the study clinic and will be sent to the US for processing
974 at a later date when enough samples have been collected, approvals have been obtained, and
975 the laboratory is ready to receive the specimens. The Pap smear and biopsy samples will be
976 transported to the pathologist on a daily basis and the results will be brought back after
977 processing. HPV collection media will be stored at room temperature at the study clinic and
978 may be transported outside of Kenya at a later date. Biopsies will be transported to the
979 pathologist and the results brought back within 2 weeks after processing. The paraffin-
980 embedded tissue blocks remaining after the histology processing will be brought back and
981 stored at the study clinic. A transport log book will be used for this purpose. A results log
982 will be kept to account for results received from the pathologist.

983 7. Infection Control

984 Hand washing with soap, disinfecting used linen and equipment, proper waste disposal,
985 single use needles and syringes, use of gloves and autoclaving of equipment at the Hope
986 Center will be adhered to.

987 8. Transport Fees

988 No money for transport will be given on enrollment for this will be treated as a scheduled
989 clinic day at the Hope Centre. All subjects screened will get Ksh 300 on return to the clinic
990 after initial enrollment and screening. If a woman would like more time to consider entry
991 into the study, she will be given money for travel at the time she returns with the intent to
992 enroll in the study. Subjects will receive travel money on presentation to the study office on
993 their scheduled visit day and a list of subjects (by study ID) who get travel money will be
994 maintained by the receptionist on daily basis. The receptionist will be getting transport
995 money from the administrator. A top up will be done whenever the amount fall below Ksh
996 3,000. Maximum amount to be collected from the administrator at any given time will be
997 Ksh 10,000.

998 9. Notification of Results

999 Cytology results: Subjects will be notified of their screening cytology results at a study visit
1000 scheduled two weeks after their screening visit. If on routine cytology QC re-readings,
1001 consensuscytology results are discordant from the initial reading and alternative management
1002 is required, subjects will be notified and called back for appropriate follow-up. Subjects with
1003 new cytology results of LSIL will be offered colposcopy and biopsy according to 2012
1004 ASCCP guidelines.If the new cytology results are HSIL, ASC-H, or HSIL cannot rule out
1005 invasion, patients will be presented with evaluation, treatment and follow-up options,which
1006 includes continuation in the study (even if previously exited). Subjects will be given consent
1007 information to re-enroll into the study. A Colposcopy form will be completed at this visit.
1008 Cytology results from bi-annual follow-up visits for randomized participants and non-

1009 randomized LEEP participants will be disclosed at the next scheduled follow-up visit if the
1010 result is Normal of ASCUS. If pre-cancerous or cancerous lesions by cytology have recurred
1011 then patient will be contacted to return to the study clinic to undergo colposcopic directed
1012 biopsy prior to treatment.

1013 Histology results: If the participant needs a biopsy (i.e., HSIL, ASC-H, HSIL cannot rule out
1014 invasion, or ICC), they will need to return 4-6 weeks later for histology results. If study staff
1015 or a participant feel that having a counselor present at any of these visits would help facilitate
1016 the conversation, this can be arranged through utilization of Hope Center counseling staff.

1017 Participants who do not come to their scheduled appointments will be called or visited at
1018 home using the contact information provided at enrollment (process described thoroughly
1019 below in the Loss to Follow-up & Mortality section).

1020 10. Exit

1021 Subjects will exit the study after an interview with the study doctor or study nurse. An “Exit”
1022 form will be completed. Participants will be notified that if they wish to know the final
1023 results of the study, they may contact the study office 6 months or a year after their
1024 participation is complete.

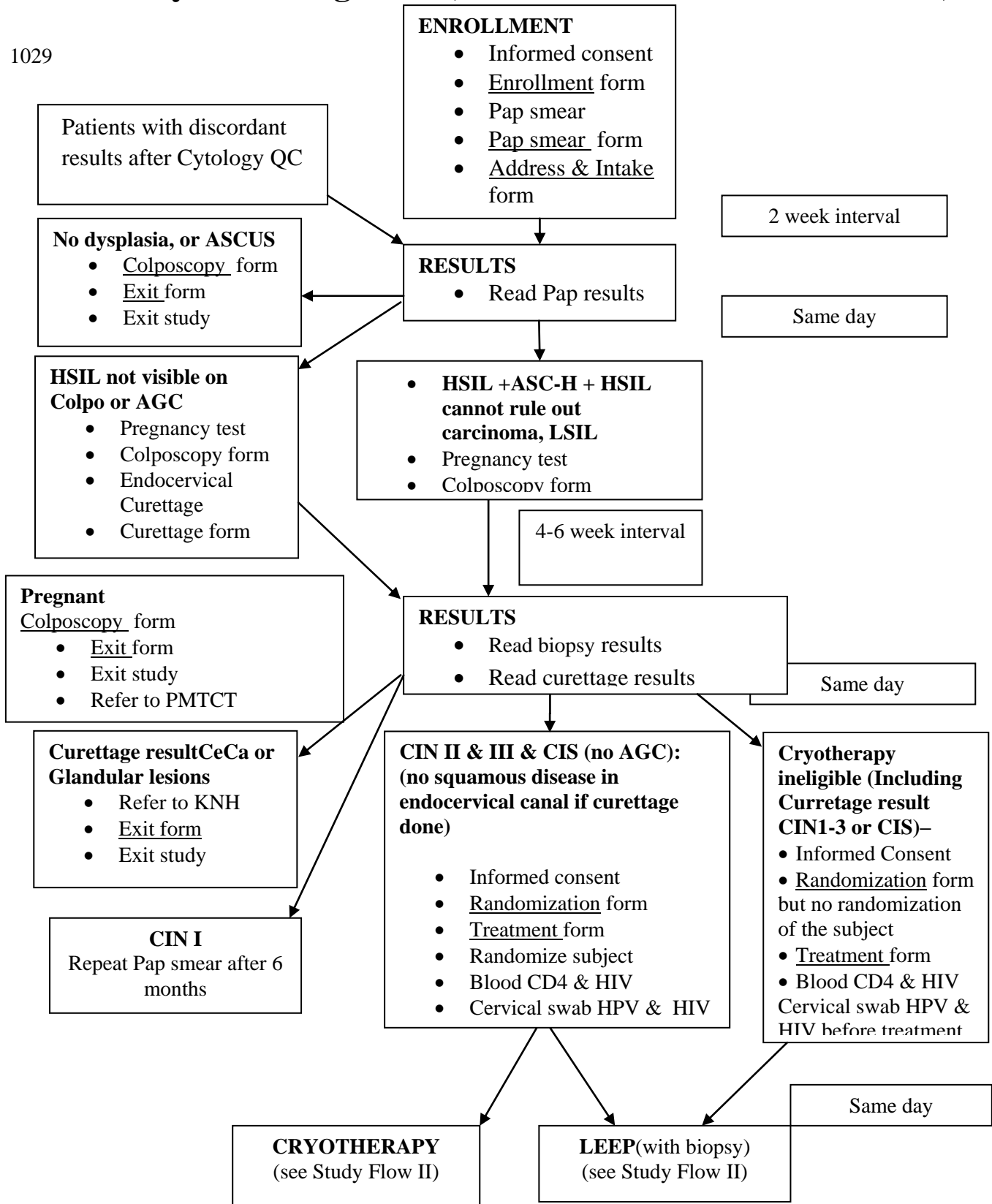
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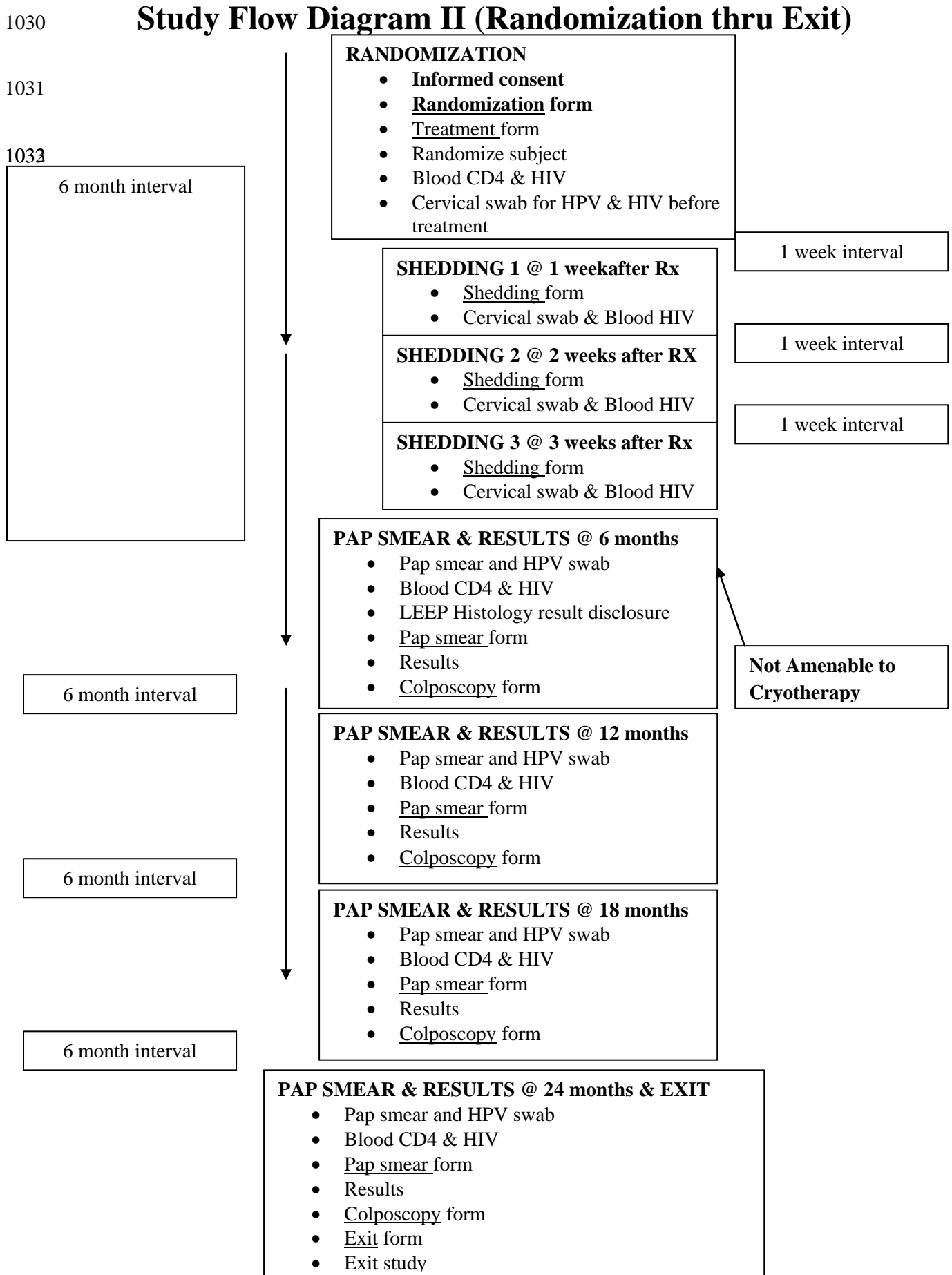
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1028 **Study Flow Diagram I (Enrollment thru Randomization)**

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Study Flow Diagram III (Study Tests)

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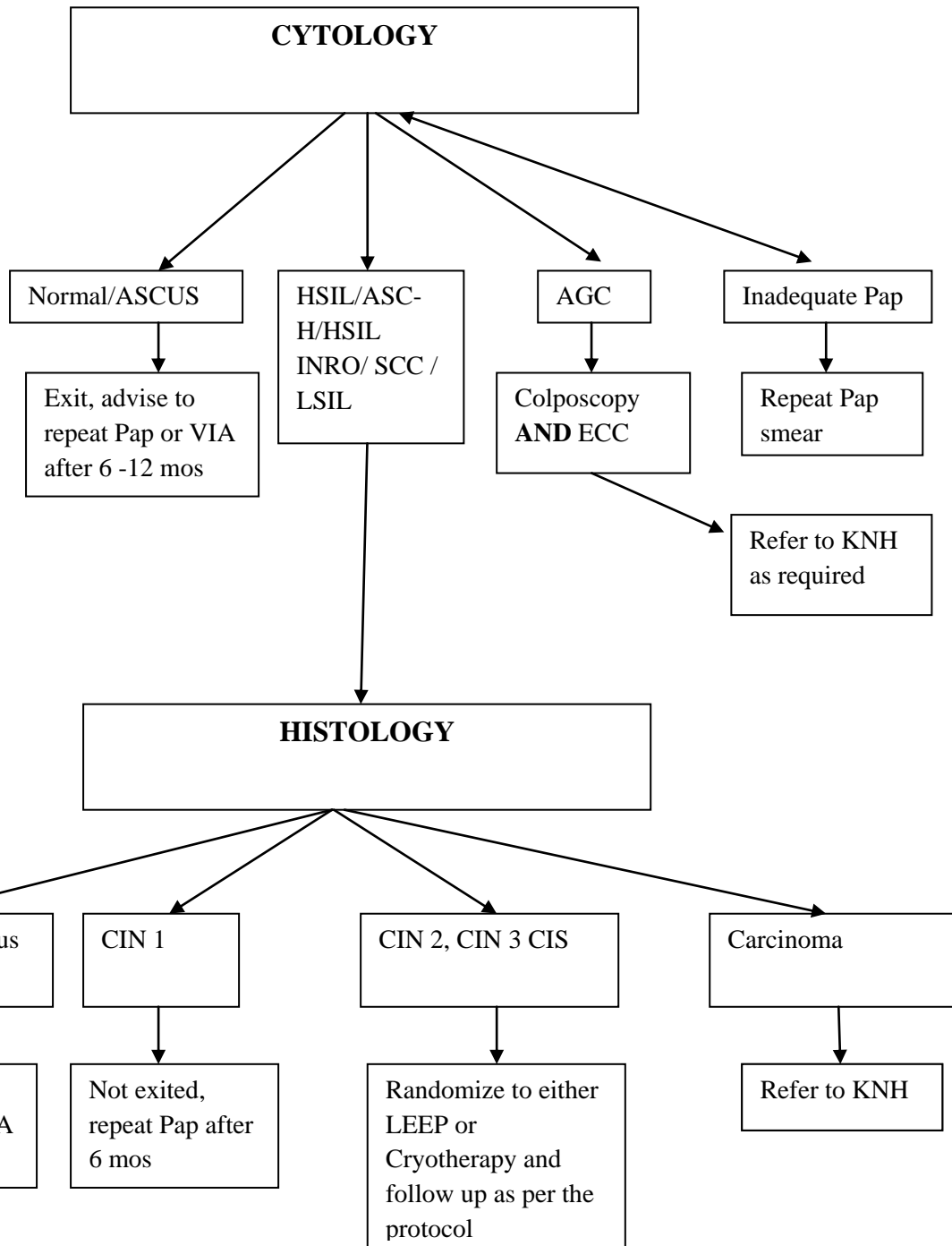
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Loss to Follow-up & Mortality

1054

1055 Tracing of randomized participants

1056 If a randomized subject fails to appear for a scheduled study clinic visit then she will
1057 be contacted by phone the next day by the receptionist. If the first phone call after a missed
1058 visit does not reach the patient or someone who is in contact with the patient, then calls will
1059 be repeated at least twice a week for two weeks. If the patient is reached by phone, another
1060 visit will be scheduled as soon as possible within one month. If the patient also fails to return
1061 for this rescheduled visit, the receptionist will call again the following day. If again the
1062 patient does not return for the next rescheduled visit (the third scheduled visit of its kind), or
1063 if at least 4 calls have been unsuccessful in reaching the subject, an attempt will be made to
1064 visit her at home by a community health worker. If a home visit is unsuccessful in reaching
1065 the subject, or if home-visit is successful but the subject fails to return to the study, then she
1066 will be considered lost to follow-up (LTFU). If a phone call or home visit reaches the
1067 subject, then an appointment will be made for the subject to return to the study clinic. (See
1068 Study Tracing Diagram for randomized patients).

1069 Tracing of non-randomized participants

1070 If a non-randomized subject fails to appear for a scheduled visit, including 6-month
1071 repeat Pap smear visit after a prior LSIL or CIN1 result she will be contacted by phone the
1072 next day by the receptionist. If the phone call does not reach the patient or someone who is in
1073 contact with the patient, then a second call will be made the following week. If both calls are
1074 unsuccessful in reaching the subject, or if the visit is rescheduled but the subject again fails to
1075 show up, then her Coptic Hope file will be flagged, and she will be considered LTFU. If a

1076 phone call or home visit reaches the subject, then an appointment will be made for the subject
1077 to return to the study clinic.

1078 Tracing of patients with new QA/QC Cytology results

1079 Both enrolled participants and patients who have been exited from the study may need
1080 to be contacted to receive new cytology results based on laboratory QA/QC. Women whose
1081 final QA/QC cytology result has been downgraded from the initial result that was disclosed to
1082 them, or women whose final results do not require treatment (Normal, ASCUS) will be
1083 followed in the same manner as non-randomized subjects: two weekly phone calls and
1084 flagged Hope file. These patients will be operationally considered lost at this same point.

1085 Women whose final results have been upgraded to ASC-H, HSIL, or SCC, and
1086 women whose final results are unsatisfactory but had at least one reading of ASC-H, HSIL,
1087 or SCC, will receive additional follow-up efforts. This includes at least 6 phone calls over 4
1088 weeks, with at least one call over the weekend. Home visits will also be conducted for these
1089 patients when possible. These subjects will be defined as LTFU on a case-by-case basis
1090 when all efforts to contact them have been completed.

1091 Tracing of patients with cancer

1092 Any woman who receives an initial or final laboratory result of SCC (cytology) or
1093 ICC (histology), whether she is randomized, non-randomized, or exited, will receive the same
1094 extensive follow-up efforts as noted above, This includes at least 6 phone calls over 4 weeks,
1095 including a phone call over the weekend, and a home visit when possible. These subjects will
1096 be defined as LTFU on a case-by-case basis when all efforts to contact them have been
1097 completed.

1098 Documentation of tracing

1099 All attempts at contacting the patient either through phone call or home visits will be
1100 documented in the participant’s chart notes. All attempts at home visit will be recorded on
1101 the “Patient Contact” form. If a subject is LTFU, this will be recorded on the “Patient
1102 Contact” form, in addition to reasons for loss. If a subject withdraws or asks to dis-enroll
1103 from the study, the “Exit” form will be completed. If a subject is determined to have died
1104 through phone call or home visit, then the “Verbal Autopsy” form will be completed.
1105 Information on loss or death will be shared with the Hope clinic team and social worker so
1106 that they may update their files.

1107 Statistical considerations for LTFU

1108 Those who are LTFU or dropout after randomization will contribute time and data to
1109 the outcomes of measurement for as long as they have remained in the study. They will
1110 continue to remain in the arm to which they have been randomized and analyses comparing
1111 interventions will include these participants. If, for example, they reach the 6 month time
1112 point but did not appear at 12 or 24 months, then data from this subject will be included until
1113 6 months after randomization in a survival analysis. The study coordinator and study doctor
1114 will oversee loss and mortality data in coordination with the receptionist.

1115

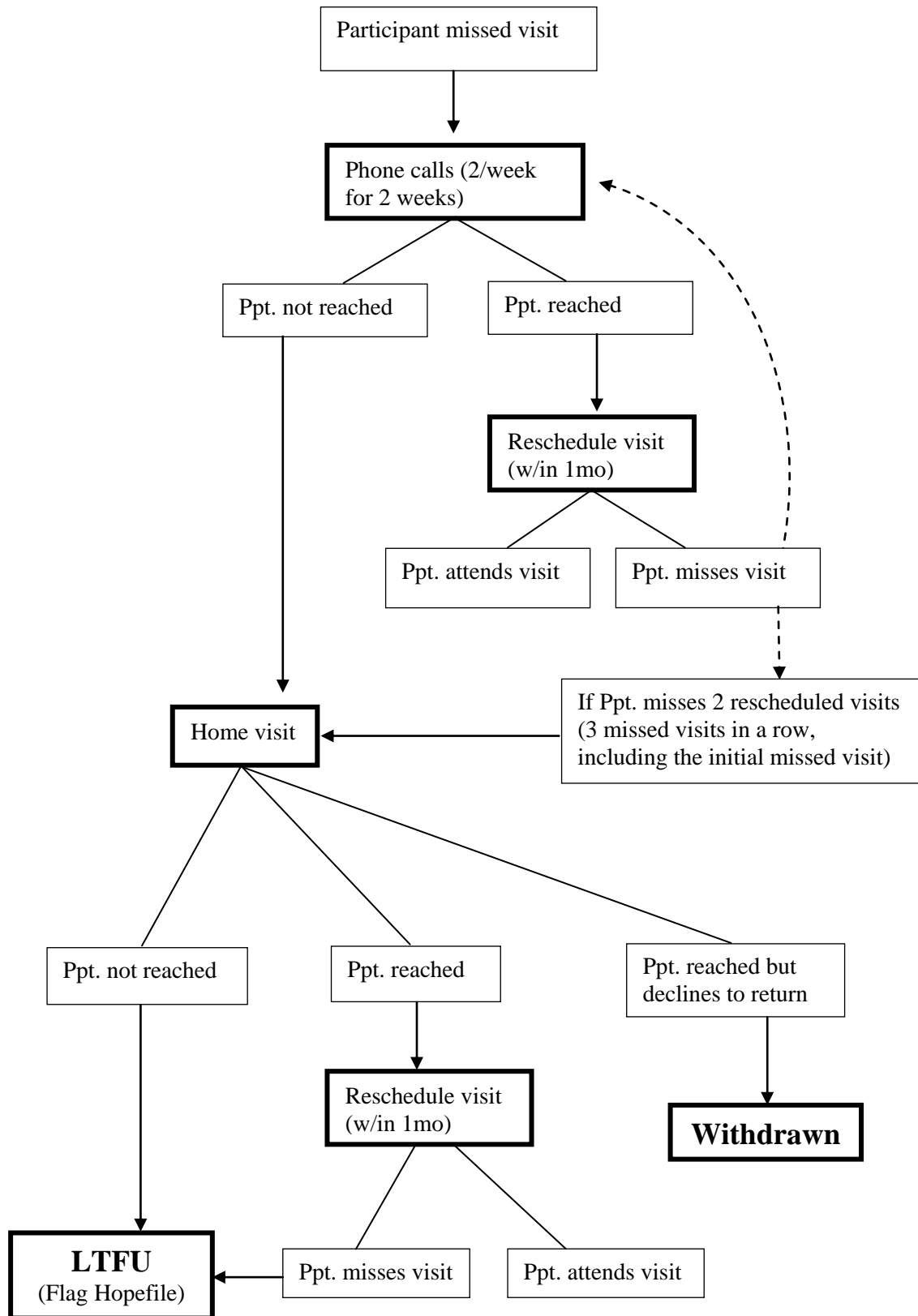
Study Tracing Diagram for Randomized Participants

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Statistical Methods

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1121 The sample size was calculated to detect a 10% difference in treatment outcomes
1122 between LEEP and cryotherapy (4% versus 14%)²⁶ with 80% power and a 0.05 significance
1123 level. Accounting for the possibility of a 20% loss-to-follow-up rate over two years, we
1124 estimated that 400 women with high grade lesions would need to be enrolled in the study
1125 with 200 women randomized to each arm. It is estimated that 200 women in each arm will
1126 allow detection of a 0.25 log₁₀ HIV virus level difference in cervical shedding between the
1127 two arms with greater than 90% power. Based on results from an ongoing cervical cancer
1128 screening study implemented at the Hope Center in 2009, our estimation of the prevalence of
1129 high-grade intraepithelial lesions is about 18%. Given this estimate and the number of
1130 women who are likely to be eligible for randomization, we calculate that we need to enroll
1131 2,400 women for initial screening.

1132 The primary analysis of the study will be to compare treatment outcomes between the
1133 LEEP and cryotherapy intervention arms in an intent-to-treat analysis. Treatment outcomes
1134 will be measured by Pap smears taken every 6 months during two-year follow-up. Pap
1135 smears demonstrating high-grade intraepithelial lesions will be considered positive and
1136 compared against negative or low-grade intraepithelial lesions. A Chi-square test will be
1137 used to compare the percentage of positive Pap smears between the intervention arms at 6,
1138 12, 18, and 24 months. Secondary analyses will compare cervical HIV-1 RNA viral shedding
1139 between the treatment arms. A comparison of the average area under the curve (AAUCMB) of
1140 long-transformed HIV-1 RNA cervical viral loads will be performed between the two arms
1141 using an analysis of covariance (ANCOVA) model.

1142 Our analysis will include contraceptive history as a potential confounder. While there
1143 has been some suggestion in the literature that HIV infectivity among women on oral

1144 contraceptives is increased,^{33, 34} a recent study from the UW did not show a significant
1145 increase in levels of HIV RNA in cervical samples obtained from women on hormonal
1146 contraception.³⁵ A more recent multicenter randomized controlled trial performed in Asia
1147 and Africa also did not find an association between hormonal contraceptive use and increased
1148 HIV transmission.³⁶ However, increased viral shedding due to hormonal contraceptive use
1149 remains an important and interesting question and one that we will examine in our study.

1150 The analysis will control for immunological status through measurement of CD4
1151 count as well as presence of and duration on antiretroviral medications. Given that the study
1152 will recruit patients from an antiretroviral treatment clinic, it is expected that the majority of
1153 subjects will be on antiretroviral medications (~75%). Type and duration of antiretroviral
1154 drugs (ARVs) will be obtained through accessing clinical medical files and CD4 count
1155 measurements will be obtained regularly during study follow-up. The impact of ARVs on
1156 recurrence of cervical intraepithelial lesions is unclear and may have minimal effect.^{37, 38}
1157 Also, despite ARV use, HIV shedding has still been detected in the genital tract.³⁹ Therefore,
1158 we are confident that the sample size will still be adequate to detect differences between
1159 treatment modalities among women on antiretroviral medications.

Data Management

1160

1161 Introduction

1162 Data will be captured on paper forms or electronically using Open Data Kit (ODK)
1163 application which has a data collection component to be used on a mobile device, and a
1164 centrally managed data store component. ODK is supported by the University of Washington
1165 (UW). Data will be cleaned, and analyzed at UW project offices located at KNH in Nairobi,
1166 Kenya. This office, which supports several UW studies, will provide administrative and
1167 database management support to this research project. Study data will be collected separately
1168 from Hope clinic data and will not be linked to the Hope dataset. The forms have been used
1169 in a recent cervical screening study and improvements have been made as a result. Analysis
1170 of the data will be conducted using SPSS version 16.0 (SPSS Inc, Chicago, Illinois, USA) by
1171 UW statisticians and epidemiologists associated with the study. Data will be managed by the
1172 Data Manager and the data clerk.

1173

1174 See Appendix B for data collection forms

1175 Facilities

1176 *Cervical Cancer Screening room at Coptic Hope Center for Infectious Diseases*

1177 The on-site facilities available for cervical cancer screening include two examination beds, one office
1178 desk, and one computer, and at least one tablet PC. Electronic and paper data collection forms and
1179 paper informed consent forms will be administered here. The address and intake form, which
1180 captures patient identifier data will be completed on paper forms only.

1181 *UW study clinic and laboratory at Coptic Hope Center for Infectious Diseases*

1182 At this site, there is one clinic room and laboratory dedicated to this study. The clinic will
1183 have one examination bed, one desk, and one computer. Data collection forms will be filled
1184 out at the study clinic and in the Cervical Cancer Screening room. Any paper data forms,
1185 including address and intake and lab request forms will be sent to the UW offices in KNH for
1186 scanning daily but returned for storage at this site, while the lab forms will be sent to the
1187 Lancet laboratory.

1188 *UW data and administrative offices at Kenyatta National Hospital*

1189 The study has an administrative and a data management office in the UNITID building at
1190 KNH. There are five computers, one laser printer, one scanner and a one copier. All
1191 computers except the data computer have internet access. All computers have antivirus
1192 software which is kept up to date by the data manager. Only non-identifiable data will be
1193 collected electronically and stored on a local ODK Aggregate (server) which is maintained by
1194 NASCOP. All data collected using the ODK will be downloaded from the nNASCOP server
1195 onto the data computer and converted in SPSS format.

1196 Databases

1197 The study data will be recorded in SPSS, MS Access, or written notebooks and include:

1198 *Data Collection Forms* – this SPSS database includes all questionnaires that are
1199 electronically and manually filled at the study.clinic In total there are 16 questionnaires to
1200 be filled

- 1201 • Enrollment
- 1202 • Pap Smear
- 1203 • Colposcopy
- 1204 • Randomization

- 1205 • Treatment
- 1206 • Address and Intake
- 1207 • Shedding
- 1208 • Patient Contact
- 1209 • Verbal Autopsy
- 1210 • Exit
- 1211 • Cytology Report
- 1212 • Colposcopic Biopsy Histology Report
- 1213 • Endocervical Curettage Histology Report
- 1214 • LEEP Biospsy Histology Report
- 1215 • CD4 Report
- 1216 • Follow-up Form
- 1217 *Cervical Cancer Screening Appointment and Tracking* – this MS Access database will track
- 1218 patients from the Hope Center who are referred to the study clinic by scheduling
- 1219 appointments and recording dates that screening tests are performed.
- 1220 *Laboratory* – this database contains an inventory of all specimens collected, stored, and
- 1221 analyzed.
- 1222 *Specimen Collection* – a written notebook provides a written record that tracks when the
- 1223 specimens have been collected and where they are going. Specimens include:
- 1224 • Blood for CD4 count
- 1225 • Blood for HIV viral level
- 1226 • Cervical swab for HIV viral level
- 1227 • Cervical swab for HPV

- 1228 • Pap smear
- 1229 • Colposcopy-directed biopsy
- 1230 • Endocervical curettage specimen
- 1231 • LEEP specimen
- 1232 *Storage* – a written notebook which tracks specimens which are stored in the freezer and
- 1233 where they are kept. Stored specimens include:
- 1234 • Cervical swab for HIV
- 1235 • Cervical swab for HPV
- 1236 • Blood plasma and cells for HIV
- 1237 *Laboratory Results* – a written notebook which tracks the results of laboratory analyses that
- 1238 are performed in Kenya. Results tracked include:
- 1239 • CD4 count
- 1240 • Pap smear result
- 1241 • Colposcopy-directed biopsy result
- 1242 • LEEP biopsy result
- 1243 • Endocervical curettage biopsy result
- 1244 Management
- 1245 *Entry*
- 1246

1247 The data collection forms will be completed either manually on paper forms or electronically
1248 on ODK. The following collection forms will be completed manually in paper forms: ,
1249 address and intake form (which captures patient identifier data), Cytology Report,
1250 Colposcopic Biopsy Histology Report, Endocervical Curettage Histology Report, LEEP
1251 Biopsy Histology Report and CD4 report, all of which serves as lab request forms.

1252 Each subject has a folder in which all paper forms and questionnaires are stored. These
1253 folders are stored in a locked cabinet at the UW study clinic at Coptic. Newly filled-out
1254 questionnaires are brought to the UW KNH data office from the study clinic daily.
1255 Questionnaires are scanned into the computer database the same afternoon, and folders are
1256 returned to the clinic the following morning. Scanned data is verified by Cardiff Teleform
1257 software and later cross-checked against the paper questionnaire on the same day by the data
1258 clerk after it is exported into SPSS.

1259 For data captured electronically, only non-identifiable data will be collected electronically
1260 and stored on a local ODK Aggregate (server) maintained by NASCOP. The Address and
1261 Intake form which collects the patients identifiable information will be completed on paper,
1262 sent to the UW office in KNH for scanning daily, and returned for storage in the Coptic study
1263 clinic where they will be kept in a locked cabinet. Once the data is collected using the
1264 encrypted electronic forms, it will be transmitted to the Nascop server through an encrypted
1265 path.. As an added layer of security, all electronic data forms (even though they contain no
1266 identifiable data) are encrypted on the data collection devices prior to transmission to the
1267 local server. The Principal Investigator, the Data Manager and the data collectors will have
1268 access to the ODK server with different rights.*Quality*

1269 The data clerk maintains a data logbook where all the data entry queries or errors encountered
1270 during data entry are recorded. Data entry queries or errors are then discussed with the study

1271 staff at least once a week. Discussions are held with both study staff and data clerk together
1272 at the study clinic and corrections are made to the database by the data clerk upon returning
1273 to the data office. The data manager ensures that all errors are attended to on a regular basis.

1274 The data manager ensures that all the data is clean at all times. Questionnaire (Address and
1275 Intake) data is checked for entry accuracy at the time of scanning. In addition, data checking
1276 is done on the databases every week and the data manager takes responsibility for organizing
1277 the data checking process. A summary report on the data quality and data entry accuracy is
1278 then produced by the data manager and distributed to the project investigators.

1279 Data checking is done using the following methods:

1280 *Ranges and Validity rules*

1281 A range of acceptable values and skip patterns (checks) has been inbuilt for all the
1282 appropriate variables during the programming of the data collection form using the xml form.
1283 Any values that fall outside this range cannot be accepted by the database. Validity rules are
1284 also set where certain variables can only be entered if they comply with a particular rule. For
1285 example, the database does not allow outside limit or blank entries for the patient
1286 identification numbers and all unreal dates are rejected. The data manager works with the
1287 data clerk to identify any inconsistent data on a weekly basis. Inconsistency checks are done
1288 when the files are in SPSS. The manager then consults with study clinicians to resolve the
1289 inconsistencies.

1290 *Line listings for data captured non-electronically*

1291 The main objectives of line listings include:

- 1292
- identifying any errors made during data entry

- 1293 • estimating the accuracy rate of the data clerk, monitor and asses his/her data entry
1294 performance

1295 The data manager produces 10% line listings of all the enrollment and follow-up files on a
1296 quarterly basis. The data team members then check the line listings against the hard copy
1297 questionnaires. Errors are highlighted on the line listings and the error rate approximated
1298 thereafter. If the error rate is higher than 0.3% then the whole database should be checked.

1299 After the checking has been completed, the data manager lists all the corrections that need to
1300 be done in the patient charts on the data entry sheet; this helps the data entry clerk easily
1301 identify the corrections that need to be done.

1302

1303 *Missing values*

1304 Restrictions have been put on all questions that are required to be answered. These checks
1305 prevent the interviewer from skipping any question that requires a response.

1306 Safety, Security, & Storage

1307 **Data security in ODK**

- 1308 All data collection devices(Tablets) will have a security code for unlocking to prevent
1309 unauthorized users
- 1310 All the electronic forms will be encrypted before loading to the ODK collect
- 1311 The data will be uploaded to Nascop server through a secured path Private key will be used
1312 to decrypt the data. ONLY the Data manager will have access to the private key
- 1313 Once the data is decrypted , it will be converted into SPSS format.
- 1314 All databases are backed up every Friday by saving the most current files on two CD
1315 disks and external harddrive and uploaded to the UW-server. All computers are
1316 password-protected, preventing access by any unauthorized persons. Data is backed

1317 up on a weekly basis by the data clerk and the data manager. Data is saved on an
1318 external hard-drive that remains in the office as well as on a CD that is kept off-site.
1319 All data on CD disks will be password protected by the data clerk. All patient
1320 records are filed according to numerical order of the patients' identification. Folders
1321 are kept in a locked storage cabinet at the study clinic for reference by research
1322 personnel. Once the subject completes the study or is lost to follow-up, her records
1323 are brought to the KNH office for storage. Participant study ID will be generated by
1324 the data manager who will be responsible for linking and de-linking data.

1325 Schedule

1326 *Daily*

1327 Electronic questionnaire entry – The nurses will complete the forms electronically and upload
1328 (send) the data to the ODK server. The data will then be downloaded from the server and
1329 saved onto the data computer in SPSS format

1330 Specimen entry – Specimens that are collected in clinic are entered into the *Clinic Specimen*
1331 *CollectionBook*. Results are entered in the *CD4 Results Book*, *Pap Smear Results Book*, and
1332 *Biopsy Results Book*.

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Laboratory Procedures

1343 Sample collection

- 1344 • Study nurse will collect Pap smear specimens and cervical swabs for HPV and HIV
- 1345 • Study doctor will collect cervical biopsy specimen under colposcopy and perform
1346 endocervical curettage when necessary
- 1347 • Study nurse or lab assistant will collect blood specimens
- 1348 • Specimens will be gathered in the laboratory before transfer
- 1349 • Lab assistant or technologist will record details in lab book. Information includes:
 - 1350 ○ Specimen Study ID
 - 1351 ○ Date
 - 1352 ○ Visit type
 - 1353 ○ Time sample was collected
- 1354 • Pap smear, cervical biopsy, and endocervical curettage specimens will be placed in a cool
1355 box and transported to the designated laboratory before 4 pm by the lab assistant or
1356 technologist. Designated laboratory will record reception of samples in a book including:
1357 specimen study ID, date, time, and number of specimens. Results will be filled in the
1358 relevant “Histology Report” and “Cytology Report”.
- 1359 • One set of blood samples will be sent to the Coptic Hospital for CD4 count. These results
1360 will be filled in the “CD4 Report”.
- 1361 • One set of blood samples will be centrifuged at the study laboratory by the lab
1362 technologist located at the Hope Center and frozen in a -80°C freezer for storage.
1363 Shipment of samples for analysis of viral levels will be performed on these samples.
- 1364 • Cervical swabs for HIV will be prepared in the study laboratory and frozen in a -80°C
1365 freezer for storage. Cervical swabs for HPV will be stored in storage medium

1366 (preservCyt) at <25° C. Shipment of samples for viral analysis will be performed on
1367 these samples.

1368 Pap smear and cervical tissue biopsy

1369 • Papanicolaou test: after the application of a speculum, a cervex brush will be inserted to
1370 its full length into the endocervical canal so that the shorter outer brush hairs are in
1371 contact with the ectocervix. The cervex brush will then be gently pushed whilst being
1372 turned 5 times in an anticlockwise direction (2.5 complete turns), in order to collect cells
1373 from both the endo- and ecto-cervix. Care will be taken not to touch the tip of the brush in
1374 order to avoid cross-contamination. Using the brush, a Pap smear will then be prepared by
1375 smearing the brush on a clean glass slide and fixing immediately with 95% isopropyl
1376 alcohol for at least 30 minutes at the study clinic. The slide will then be transported to the
1377 laboratory to be stained, and the cytology will be reported by a study pathologist from
1378 Aga Khan University Hospital using the Bethesda classification.

1379 • Samples from the colposcopy-directed biopsy of the cervix, endocervical curettage
1380 specimen and the LEEP specimen will be fixed in 10% buffered formaldehyde solution
1381 and transported for haematoxylin-eosin staining. The histopathology results will be read
1382 by a study pathologist from Aga Khan University Hospital, and the biopsy samples will
1383 subsequently be preserved and fixed in paraffin. Biopsy blocks will be collected and may
1384 be sent to the IARC for further analysis.

1385 Cervical swabs for HIV and HPV

1386 • Dacron swabs will be used to collect samples for HIV from the cervix. Endocervical
1387 secretions will be collected by rotating the swab 360 degrees in the outer part of the
1388 endocervix.

1389 • For HIV-1 DNA testing, the dry swab will be stored as such in the -80°C freezer.

- 1390 • For HIV RNA testing, the swabs will be collected in a cryovial containing 1 ml of
1391 freezing media and then stored at -80°C.
- 1392 • Cervical samples for HPV will be taken using cervex brush. The brush will be inserted to
1393 its full length into the endocervical canal so that the shorter outer brush hairs are in
1394 contact with the ectocervix. The cervex brush will then be gently pushed whilst being
1395 turned 5 times (2.5 complete turns), in order to collect cells from both the endo- and ecto-
1396 cervix. Care will be taken not to touch the tip of the brush in order to avoid cross-
1397 contamination. The brush containing cervical cellular material will be placed in a vial
1398 containing PreservCyt media (Cytoc Corporation) and labeled with the subject
1399 identification number of the participant. The brush will be fully rinsed in the media by
1400 pressing 10 times against the bottom of the vial, forcing the brush hairs to separate.
1401 Finally the brush will be vigorously shaken in the media to remove any residual cells. The
1402 brush will NOT be left in the vial, but discarded. It is very important to close the vial very
1403 tightly to avoid possible leakage during transport. Cell samples will be stored at the Hope
1404 Center at <25° C, and then later transported to the US or to IARC in Europe.

1405 Shipping

- 1406 • The UW has extensive experience measuring HIV-1 viral RNA from cervical swabs and
1407 plasma. While measuring plasma HIV-1 RNA viral levels is available in Kenya, HIV-1
1408 RNA analysis from cervical swabs has not been performed here. In order to maintain
1409 high quality standards, samples will be analyzed in Seattle. Plasma HIV-1 RNA will also
1410 be analyzed in the same laboratory so that the results, taken from two different body
1411 compartments on the same day, are comparable. The KNH IRB has approved laboratory
1412 analysis of cervical samples in Seattle for a current study on cervical cancer screening and
1413 is therefore expected to approve similar testing for this study. Analysis of samples locally

1414 is dependent on significant funding to develop a laboratory locally that could perform
1415 PCR analysis.

1416 • Samples for HPV testing will be shipped to the IARC in France and then to the
1417 Netherlands or to the US directly where the PCR testing will be conducted. The KNH
1418 IRB has also approved laboratory analysis of cervical samples in Europe for a current
1419 study (mentioned above) and is therefore expected to approve similar testing for this
1420 study.

1421

1422 Analysis for HIV-1 viral levels

1423 • HIV swabs will be stored at -80°C until shipment to Seattle. The swabs will be tested for
1424 HIV RNA using a Gen-Probe HIV-1 viral load assay (San Diego, California, USA) which
1425 has been validated for use in Kenyan HIV subtypes.⁴⁰ The assay has a lower limit of 50
1426 copies/swab in genital secretions. HIV-1 DNA will be examined in the cervical swabs by
1427 detecting proviral DNA using a nested PCR for the viral *gag* region which should detect
1428 as little as 1 copy of DNA. This technique has been validated in a number of other
1429 studies.^{39, 41}

1430 Analysis for HPV subtypes

1431 • Frozen pellets of exfoliated cervical cells collected in PreservCyt will be extracted and
1432 tested following standard operating procedures of the HPV Laboratory at CDC as
1433 implemented under the ongoing Quality Management System. The Linear Array HPV
1434 Genotyping Test (Roche Diagnostics), based on L1 consensus PCR with type-specific
1435 hybridization, will be used. The assay detects 37 HPV types: HPV6, 11, 16, 18, 26, 31,
1436 33, 35, 39, 40, 42, 45, 51, 52, 53, 54, 55, 56, 58, 59, 61, 62, 64, 66, 67, 68, 69, 70, 71, 72,
1437 73, 81, 82, 83, 84, 89, and IS39. The probe for HPV 52 (called XR) cross reacts with

1438 HPV 33, 35, and 58. If the XR band and any cross-reacting types are identified, HPV 52
1439 will be identified with a type-specific quantitative PCR assay. Samples negative for both,
1440 beta-globin and all HPV types will be reported as negative. Results will be recorded in
1441 database and securely transmitted to Dr. Chung for linking to epidemiologic and clinic
1442 data.

1443 Quality Assurance and Quality Control (QA/QC) for Cytology and Histology Specimens

1444 A Cytology and Histology QA/QC procedures document is attached to the protocol as an
1445 addendum.

- 1446 • Loss of slides or blocks: If any cytology or histology slides or blocks are misplaced
1447 during the course of QA/QC procedures, the patient will be contacted to return for repeat
1448 Pap smear or biopsy, as necessary.

1449 Quality Assurance/Quality Control of Study Procedures

- 1450 • *LEEP*: The senior gynecologist on the study will work closely with the study doctor to
1451 ensure quality procedures with a low rate of complications through regular weekly
1452 meetings and contact through cell phone and e-mail. The complication rate and type will
1453 be reviewed on a bi-monthly basis. This information will be collected by the “Adverse
1454 Event” form which has been added. All LEEP specimens will also be evaluated by
1455 histopathology with confirmatory reads as detailed above.
- 1456 • *Cryotherapy*: As with LEEP, the study doctor will be well trained and mentored by the
1457 study gynecologist to perform quality procedures with low rates of complications, and the
1458 complication rate and type will be reviewed on a bi-monthly basis. This information will
1459 be collected by the “Adverse Event” form which has been added.

- 1460 • *Colposcopy and endocervical curettage:* The study gynecologist will supervise the study
1461 doctor to conduct colposcopy with biopsy and curettage. He will receive support and in-
1462 service trainings as deemed necessary.

1463

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Ethics

1467 A. INTRODUCTION

1468 Field and laboratory procedures will be performed in
1469 Nairobi, Kenya, while data analysis will be done in both
1470 Nairobi and Seattle, Washington. The study will be reviewed
1471 by the Institutional Review Board (IRB) at the University of
1472 Washington and the Kenyatta National Hospital (KNH) Ethical
1473 Review Committee (ERC). The study will not recruit subjects
1474 prior to approval from both the University of Washington IRB
1475 and the KNH ERC. In accordance with the International
1476 Conference on Harmonisation Good Clinical Practices (ICHGCP)
1477 section 4.5.4, the investigators may deviate from protocol
1478 prior to IRB approval in order to eliminate immediate hazard
1479 to trial subjects.

1480 B. DECEPTION

1481 If any deception or withholding of complete information is required for this activity,
1482 explain why this is necessary and attach a protocol explaining if, how, when, and by
1483 whom subjects will be debriefed.

1484 No deception or withholding of complete information is
1485 required for this activity.

1486 C. SUBJECTS

1487 1. How many subjects will you need to **complete** this study?

1488 Number: approximately 400 Age range: above 18

1489 2. Explain how you will achieve equitable subject representation in the following categories.

1490 If not applicable, justify exclusions.

1491 a. Age (minors, elderly): N/A. Sexually active women are at greatest
1492 risk for cervical cancer. Adolescents will be excluded
1493 due to their high rate of regression of cervical lesions,
1494 with 90% clearing the HPV virus by 24 months. In terms of
1495 cervical dysplasia, it was been shown that in adolescents
1496 with high grade lesions, a majority will clear these
1497 lesions within 1 to 3 years. The current ASCCP guidelines
1498 state that wome with HSIL cytology should be managed with
1499 colposcopy.

1500 b. Gender: N/A. Cervical cancer affects the female reproductive
1501 system only

1502 c. Ethnic and racial minority populations: N/A. Study is performed in Kenya
1503 where the majority of the population is black

1504 3. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer
1505 for each subject group, if different.)

1506 HIV-positive, female, over the age of 18, intact cervix,
1507 initiation of sexual intercourse

1508 4. What characteristics (exclusion criteria) would exclude subjects who are otherwise
1509 eligible from this study? (Answer for each subject group, if different.)

1510 HIV-negative, male, below 18 years of age, pregnant by
1511 clinical history or physical examination, post-hysterectomy,
1512 post-cervical cancer treatment, history of a bleeding
1513 disorder, no prior initiation of sexual intercourse

1514 5. Describe the subject recruitment strategies you will use for each group of subjects.

1515 (Attach advertisements, flyers, contact letters, telephone contact protocols, Health
1516 Sciences recruitment web site template, etc.)

1517 Adult female subjects who attend the Hope Center for
1518 Infectious Diseases will be informed by a doctor at the
1519 clinic of the study and their potential eligibility using
1520 the attached form (Pre-Screening Talking Points). If the
1521 subject expresses interest, the doctor will contact the
1522 study nurse who will accompany the subject to the study
1523 clinic located less than 50 yards away. We will also use
1524 recruitment leaflets that will be distributed by the study
1525 staff at the Hope Center Reception. The leaflets will have
1526 the contact information of the study staff.

1527 6. Explain who will approach subjects to take part in the study and how this will be done to
1528 protect subjects' privacy.

1529 Doctors from the Hope Center who see the subjects at a
1530 medical follow-up or screening visit will approach subjects
1531 to take part in the study in a confidential, private room.
1532 We will also use recruitment leaflets that will be
1533 distributed by the study staff at the Hope Center Reception.
1534 The leaflets will have the contact information of the study
1535 staff.

1536 7. Explain what steps you will take during the recruitment process to minimize potential
1537 coercion or the appearance of coercion.

1538 Doctors or study staff who inform subjects of the study will
1539 follow the "Pre-Screening Talking Points" and let them know
1540 that their decision whether to participate in the study or

1541 not will not affect their clinical care at the Hope Center.
1542 In addition, women who wish to be screened but do not want
1543 to enter the study will receive free screening. The study
1544 nurse will reiterate these points during the informational
1545 interview using the "Screening Talking Points" to gauge the
1546 interest of the patient before signing an informed consent.
1547 Talking Points are enclosed in the Appendix.

1548 8. Will you give subjects gifts, payments, services without charge, or extra course credit?

1549 No Yes If yes, explain:

1550 Subjects will receive free treatment for pre-cancerous
1551 lesions amenable to cryotherapy or LEEP. Medical personnel
1552 will provide free medical services, gynecological
1553 examination, treatment, and free condoms. Randomized
1554 subjects will also receive money for transportation to
1555 return to clinic.

1556 9. Will any of the subjects or their third-party payers be charged for any study procedures?

1557 No Yes If yes, explain:

1558 10. Where will the study procedures be carried out?

1559 The study will be carried out in Nairobi, Kenya at the
1560 Coptic Hospital. IRB approval for this PHE has been granted
1561 by Kenyatta National Hospital (KNH) in Kenya and the
1562 University of Washington (UW).

1563 **D. RISKS AND BENEFITS**

1564 1. Describe nature and degree of risk of possible injury, stress, discomfort,
1565 invasionofprivacy, and other sideeffects from all study procedures, drugs and devices
1566 (standard and experimental), interviews and questionnaires. Include psycho-social risks as

1567 well as physiological risks. Include risks of withholding standard care or procedures if this
1568 is the case. Do not reference the consent form.

1569 The study may collect personal information that may be
1570 embarrassing for the subject to talk about. As part of the
1571 study, the subject may meet other patients from this clinic
1572 whom she may know from outside the clinic. We will be
1573 collecting blood samples using a needle and syringe. The
1574 puncture of the needle may be uncomfortable and leave a
1575 bruise and may cause infection or fainting. Collection of
1576 biopsy samples through the pelvic exam may cause: mild
1577 discomfort as the subject is examined, small amount of
1578 bleeding from the vagina for 1-2 days, and mild to moderate
1579 cramping for 5 minutes that is similar to mild menstrual
1580 pain. If the subject undergoes cryotherapy or LEEP, then
1581 she may experience mild abdominal cramps for less than 10
1582 minutes, discharge from the vagina for about 2 weeks, and/or
1583 bleeding for several days. Possible serious complications
1584 include excessive bleeding or infection. Additionally, some
1585 studies have shown that cervical treatment is associated
1586 with pregnancy complications including premature rupture of
1587 membranes, premature contractions, infections and cervical
1588 incompetence.

1589 If the subject undergoes a biopsy, she is requested not have
1590 sex for 10 days. The reason is that if her partner is not
1591 infected with HIV, then he may be at greater risk of
1592 becoming infected with HIV after the biopsy procedure
1593 because of a possibility of increased HIV shedding from the
1594 cervix. The participant may also be at increased risk of

1595 infection at the site of the biopsy. If the subject has
1596 received cryotherapy or LEEP, then, for the same reasons as
1597 the biopsy, we suggest that she not have sex for 4 weeks
1598 after it is performed.

1599 Subjects will be prescribed antibiotics to protect against
1600 infection after cervical treatment or as treatment for an
1601 sexually transmitted infection or other vaginal infection
1602 discovered on pelvic exam. Possible side-effects from
1603 antibiotic use include (but are not limited to) nausea or
1604 anorexia, vomiting, diarrhea, photosensitivity, rash,
1605 anaphylaxis possibly leading to death, dizziness, headache,
1606 confusion, tinnitus or hearing loss, seizures, arrhythmias,
1607 neutropenia, thrombocytopenia, hyper/hypoglycemia, tendon
1608 rupture, liver disease, kidney disease and peripheral
1609 neuropathy.

1610 2. Explain what steps you will take to minimize risks of harm and to protect subjects' rights
1611 and welfare. (If you will include protected groups of subjects (minors, fetuses in utero,
1612 prisoners, pregnant women, decisionally impaired or economically or educationally
1613 disadvantaged subjects) please identify the group(s) and answer this question for each
1614 group.)

1615 The clinical procedures of collecting blood, fluid, and
1616 tissue samples will only be performed by certified medical
1617 staff trained in these tasks. Any complications arising
1618 from these procedures will be handled by a doctor and
1619 covered by the study.

1620 Study investigators may decide to withdraw a study
1621 participant from the study if they find further enrollment

1622 may expose the participant to harm or the investigator
1623 determines the participant will not be able to abide by
1624 study safety requirements, e.g. in the case of mental health
1625 problems or drug/alcohol dependency problems.

1626 3. Is it possible that you will discover a subject's previously unknown condition (disease,
1627 suicidal intentions, genetic predisposition, etc.) as a result of study procedures?

1628 No Yes If yes, explain how you will handle this situation.

1629 The intent of this cervical cancer screening study is to
1630 detect pre-cancerous and cancerous lesions of the cervix
1631 which may not be known to the subject and then treat those
1632 lesions free of charge. If the lesions are too large or are
1633 cancerous then we will refer them to the neighboring
1634 government hospital for subsidized care.

1635 4. Describe the anticipated benefits of this research for individual subjects in each subject
1636 group. If none, state "None."

1637 The benefit of this research for the individual is that we
1638 may be able to detect and treat pre-cancerous disease of the
1639 cervix before it becomes cancerous and deadly. By
1640 participating in this study, an individual may avoid the
1641 development of a life-threatening disease.

1642 5. Describe the anticipated benefits of this research for society, and explain how the benefits
1643 outweigh the risks.

1644 The benefit of this research for society is that it may
1645 identify the most effective method to treat cervical
1646 dysplasia in HIV-positive women who are at much higher risk

1647 for cervical cancer and who number in the millions in
1648 resource-constrained settings around the world. Results of
1649 this research may impact international guidelines and the
1650 way millions of dollars of donor funding is spent on the
1651 care of HIV-positive women.

1652 As discussed above, the medical care offered through the
1653 research conforms to the standard of care established by the
1654 Kenyan MOH at tertiary care and provincial level health care
1655 facilities. Options are available to clients enrolling in
1656 the study to obtain Pap smears at these locations along with
1657 cryotherapy and LEEP treatment. At the same time, the
1658 treatment interventions that are being offered in the study
1659 do not offer unreasonable risks and provide likely clinical
1660 benefit. Both procedures are widely recommended in both
1661 developing and developed settings and one method is not
1662 known to be better than the other among HIV-positive women.
1663 As previously discussed, given the paucity of evidence-based
1664 literature there is scientific and medical equipoise in
1665 addressing this question and offering these two treatment
1666 methods.

1667 The benefits of the procedures being offered outweigh the
1668 risks. The risks of LEEP and cryotherapy are low. In the
1669 study previously mentioned from Zambia, Pfaendler, et al.
1670 found that the overall complication rate of LEEP to be 3.7%,
1671 all of which was managed on-site in the clinic.²⁰ Likewise,

1672 in a study of cryotherapy in India, the overall complication
1673 rate was found to be 3.0%.²¹ Both LEEP and cryotherapy may
1674 result in infection or bleeding, though the rates are low
1675 and the great majority can be managed in the clinic where
1676 the procedure was performed. Pfaendler et al. found
1677 bleeding as a complication in 14/697 (2.0%) and infection in
1678 12/697 (2.0%) while performing LEEP. Nene et al. in the
1679 study from India mentioned above had 9 (1.9%) cases of mild
1680 bleeding and infection in 8 (1.4%) cases. The benefits of
1681 treatment through LEEP and cryotherapy, on the other hand,
1682 are very high. It has long been known that HIV-positive
1683 women are at higher risk of cervical disease and faster
1684 progression of lesions.^{42, 43} From preliminary studies
1685 performed on our HIV-positive patient population, we have
1686 found that the prevalence of high-grade lesions is around 8%
1687 in women 30-39 years old and taking antiretroviral
1688 medications.⁴⁴ Additionally, studies have shown that either
1689 method of treatment is extremely effective in treating CIN.²⁷

1690 **E. CONFIDENTIALITY OF RESEARCH DATA**

1691 1. Will you record any direct subject identifiers (names, Social Security numbers, patient,
1692 hospital, laboratory or claim numbers, addresses, telephone numbers, locator information,
1693 etc.) No Yes If yes, explain why this is necessary and describe the coding system
1694 you will use to protect against disclosure.

1695 We will be recording names and assigning a study number that
1696 will be used on all study visits. This is to ensure

1697 accurate follow-up of study participants. This will be
1698 handled by the senior data analyst.

1699 2. Will you retain a link between study code numbers and direct identifiers after the data
1700 collection is complete? No Yes If yes, explain why this is necessary and for how
1701 long you will keep this link.

1702 The link between the study participant's name and study
1703 number is necessary to facilitate follow-up during the 1
1704 month study period. This link will no longer be needed
1705 after follow-up is completed and will be removed after 5
1706 years. This will be handled by the senior data analyst.
1707 Data and specimens will be stored for 10 years after
1708 completion of study follow-up before being destroyed.

1709 3. Describe how you will protect data against disclosure to the public or to other researchers
1710 or non-researchers. Explain who (other than members of the research team) will have
1711 access to data (e.g., sponsors, advisers, government agencies, etc.).

1712 All names and numbers will remain in confidential files that
1713 are accessible only to the investigators and study staff.
1714 Computer databases containing information about study
1715 subjects will be protected by passwords which allow access
1716 to only the investigators.

1717 Notebooks, folders and CDs will move between the study
1718 clinic site and the KNH data office in a direct manner to
1719 minimize handling of data. Information will be transported
1720 by private vehicle used by the study. There will be two CDs
1721 to back up study data, one to be kept with the administrator
1722 at an off-site location and one with the senior data
1723 analysis in a locked closet at KNH. Data files on the

1724 computer and CDs will be password protected, accessible only
1725 by data staff. Additionally, patient identifying data will
1726 be kept in a separate, locked folder from the clinical data
1727 to maximize confidentiality when reading clinical materials.
1728 All data, including physical medical files, will be
1729 physically locked when not in transport - both at the study
1730 site and at the office at KNH - to assure that only
1731 designated staff will have access to the files. The study
1732 coordinator will be responsible for ensuring patient
1733 confidentiality for both electronic data and the medical
1734 files.

1735 4. Will you place a copy of the consent form or other study information in the subject's
1736 medical or other personal record?

1737 No Yes. If yes, explain why this is necessary.

1738 5. Do you anticipate using any data (information, specimens, etc.) from this study for other
1739 studies in the future?

1740 No Yes If "Yes," explain and include this information in the consent form.

1741 Specimens may be tested for HPV at a later date. Data and
1742 specimens are requested to be stored from the participant
1743 for 10 years following enrollment for possible use in other
1744 HIV and cervical studies in the future. Approval from the
1745 UW and KNH IRBs will be obtained before any of these studies
1746 are performed.

1747 **F. ADDITIONAL INFORMATION**

1748 1. If the study will involve radiation exposure to subjects, e.g., X-rays, radioisotopes:

1749 Pending Approved NA

1750 2. Will you need access to subjects' medical, academic, or other personal records for
1751 screening purposes or during this study?

1752 No Yes. If yes, specify types of records, what information you will take from the
1753 records and how you will use them.

1754 Subjects will be enrolled at the Hope Center for their HIV
1755 care and their medical records contain information on what
1756 type of treatment they have received and the severity of
1757 their condition. We will access these records to determine
1758 what type of antiretroviral treatment they've been exposed
1759 to and their clinical status according to medical
1760 examination and laboratory values including CD4 count. This
1761 information is included in the consent form.

1762 3. Will you make audio-visual or tape recordings or photographs of subjects? No
1763 Yes. If yes, explain what type of recordings you will make, how long you will keep them,
1764 and if anyone other than the members of the research team will be able to see them.

1765 4. Will your study involve use of equipment involving energy input to the subjects (EMG,
1766 EKG, MRI, ultrasound, etc.)?

1767 No Yes. If yes, attach documentation that all equipment will be tested regularly or
1768 describe safety testing procedures you will use.

1769 **G. REPORTING OF ADVERSE EVENTS**

1770 1. Describe how unanticipated adverse events related to study participation will be reported
1771 to the local IRB/Ethics Committee.

1772 The IRBs of host institutions and the sponsor, CDC, will be
1773 notified of adverse events by the PI within 72 hours of his

1774 becoming aware if the adverse events fall into one of two
1775 categories:

1776 1. related to research procedures and unexpected and severe

1777 2. related to research procedures and expected, but more
1778 severe or occurring at a greater frequency than expected

1779 Severe adverse events related to the study include any death,
1780 any non-HIV-related hospitalization, severe infection
1781 including PID, severe bleeding or cramping and severe cervical
1782 stenosis. Any adverse events will be recorded by study staff
1783 on Adverse Events Reporting Forms at the time of the incident
1784 or at the next study visit. Documentation of severe adverse
1785 events which meet the criteria listed above will be brought to
1786 the attention of study PIs within 24 hours by the study doctor
1787 and/or study nurse via phone or email, and be assessed.

1788 Other Adverse Events that do not meet the criteria above will
1789 be reported to the IRBs as per their specific guidelines..

1790 All serious and non-serious adverse events will be reported to
1791 the DSMB during its regular meetings. All Adverse Event
1792 reports that are sent to the IRBs and DSMB will also be sent
1793 to the study sponsor.

Adverse Events

1794

1795 Specification of Safety Parameters

1796 Safety parameters for this study will include signs and symptoms of local genital
1797 irritation and of systemic effects that could be related to either Pap smear screening or study
1798 treatment procedures (LEEP or cryotherapy), side effects from any medications prescribed as
1799 part of this study, and any other health complications that subjects may experience while
1800 enrolled in this study. Methods and Timing for Assessing, Recording, and Analyzing Safety
1801 Parameters.

1802 Adverse Events (AEs)

1803 An AE is any untoward medical occurrence or unintended clinical sign, including an
1804 abnormal laboratory finding, symptom or disease, in a clinical investigation subject that
1805 occurs during the course of the study. The occurrence is considered an AE whether it is
1806 associated with the use of a medical treatment or procedure, or considered unrelated to that
1807 medical treatment or procedure. The occurrence of an AE may come to the attention of study
1808 personnel in various ways--during study visits, during interviews of a study participant
1809 presenting for medical care, or during a review by a study monitor.

1810 All AEs will be:

- 1811 • recorded on the appropriate AE CRF by the study physician and nurses
- 1812 • summarized by the data team
- 1813 • followed through resolution by a study clinician
- 1814 • reviewed and evaluated by a study clinician
- 1815 • Study-related SAEs will be immediately reported to the host IRBs and ERCs,
1816 and to the study sponsor.

1817 **In this study, the following situations will be considered AEs:**

1818 1. Occurrences related to Pap smear, LEEP or cryotherapy procedures:

1819 Symptoms such as abdominal pain that lasts longer than 2-3 days, vaginal bleeding
1820 and/or discharge, fever, or chills will be assessed at each study visit after obtaining either Pap
1821 smear or cervical biopsy.

1822 2. Occurrences related to side effects from prescribed medications related to the study:

1823 If a medication(s) are prescribed for treatment of an infection, subjects will be
1824 assessed for any potential side-effects at each visit. These symptoms may include: upset
1825 stomach, vomiting or diarrhea, sensitivity to light, rash, severe allergic reaction that could
1826 cause death, dizziness, headache, confusion, ringing in the ears or hearing loss, seizures,
1827 heart problems, blood disorders, problems with blood sugar, liver disease, kidney disease,
1828 and pain or numbness in the arms or legs.

1829 3. New medical problem(s) or worsening of an existing medical problem(s)

1830 Study staff will inquire about any new medical problem or worsening of an existing
1831 medical problem since the subject's last visit.

1832 Any medical condition that is present at the time of the Enrollment Visit should be
1833 considered as the baseline for this pre-existing condition and not reported as an adverse
1834 event. However, if there is an increase in the frequency or severity of the condition, it will be
1835 recorded as an adverse event. Anticipated day-to-day fluctuations of pre-existing conditions,
1836 which do not represent clinically significant exacerbation, will not be considered adverse
1837 events.

1838 All AEs will be graded for severity and relationship to study procedures or treatment.

1839

1840 **Classification of Severity of Adverse Event:**

1841 For adverse events that do not fall under the three categories listed above (occurrences
1842 related to study procedures, medications, or new or worsening existing medical problems),
1843 the following guidelines will be used to quantify severity:

1844 Mild: adverse events that require minimal or no treatment and do not interfere with the
1845 patient's daily activities.

1846 Moderate: adverse events that result in a low level of inconvenience for the patient's daily
1847 activities or concern with the study treatment or procedures. Moderate events may cause
1848 some interference with functioning.

1849 Severe: adverse events that interrupt a patient's usual daily activity and may require systemic
1850 drug therapy or other treatment. Severe events are usually incapacitating.

1851 Life threatening: any adverse event that places the patient or subject, in the view of the
1852 investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not
1853 include a reaction that, had it occurred in a more severe form, might have caused death.

1854 Changes in the classification of severity of an AE should be documented to allow an
1855 assessment of the duration of the event at each level of intensity. Adverse events
1856 characterized as intermittent require documentation of onset and duration of each episode.

1857 All AEs will be categorized by the study physician.

1858

1859 **Relationship of Adverse Event to Study Procedures:**

1860 All AEs must have their relationship to study procedures assessed by the study
1861 clinician.

1862 The terms used to assess the relationship of an AE to the study procedures are:

1863 1. **Related**- There is a reasonable possibility that the AE may be related to the study
1864 agent.

1865 2. **Not Related**- There is not a reasonable possibility that the AE is related to the
1866 study agent.

1867 When an AE is assessed as “not related” to study agent(s), and alternative etiology,
1868 diagnosis, or explanation for the AE should be provided.

1869

1870 **Outcome of Adverse Event:**

1871 All AEs must have their outcome assessed as either “resolved without sequelae”,
1872 “resolved with sequelae”, “ongoing”, “death”, “unknown.” The study clinician is responsible
1873 for assessing outcomes and recording them on the appropriate CRF.

1874 **Definition of Serious Adverse Event (SAE)**

1875 An SAE is defined as an AE that meets one of the following conditions:

- 1876 • Death during the period of protocol defined surveillance
- 1877 • Life-threatening event (defined as a subject at immediate risk of death at the time of
1878 the event)
- 1879 • An event requiring inpatient hospitalization or prolongation of existing hospitalization
1880 during the period of protocol defined surveillance
- 1881 • Results in congenital anomaly or birth defect
- 1882 • Results in a persistent or significant disability/incapacity
- 1883 • Any other important medical event that may not result in death, be life threatening, or
1884 require hospitalization, may be considered a serious adverse experience when, based

1885 upon appropriate medical judgment, the event may jeopardize the subject and may
1886 require medical or surgical intervention to prevent one of the outcomes listed above.

1887

1888 **Data Safety and Monitoring Plan**

1889 Introduction

1890 The data safety and monitoring board (DSMB) will act in advisory capacity to the
1891 CDC, UW, KNH, UoN, Coptic Hospital, and IARC – WHO to monitor patient safety and
1892 evaluate treatment interventions for this study. Dr. Scott McClelland (UW) will be Chairman
1893 of the DSMB.

1894 After its first meeting around study initiation, the DSMB will be responsible for
1895 reviewing interim safety and efficacy analyses at five time points during the 3 year study
1896 period. These meetings and reviews of interim analyses are expected to occur at
1897 approximately 4, 9, 15, 21, and 27 months after study initiation.

1898 1) The first meeting will take place when 100 participants have received the study
1899 intervention, and this is expected to occur around 4 months after study initiation.

1900 2) The second meeting will take place when 75 participants have received Month 6
1901 Pap smear results, and this is expected to occur around 9 months after study
1902 initiation.

1903 3) Thereafter, DSMB meetings and interim analyses will occur every 6 months after
1904 this second meeting or approximately at 15, 21, and 27 months after study
1905 initiation.

1906

1907 The DSMB will have the following responsibilities:

1908 1. Review the research protocol and plans for data safety and monitoring;

- 1909 2. Evaluate the progress of the trials, participant recruitment, accrual and retention,
1910 participant risk versus benefit, and other factors that can affect study outcome;
- 1911 3. Protect the safety of the study participants and review interim or cumulative data for
1912 evidence of adverse events;
- 1913 4. Review safety and progress report from an unblinded statistician who will use both
1914 blinded and unblinded data;
- 1915 5. Make recommendations to the institutions involved and the PIs concerning
1916 continuation, termination or other modifications of the trials based on the observed
1917 beneficial or adverse effects of the treatment under study;
- 1918 6. Review report on interim analysis of efficacy in accordance with stopping rules
1919 which are clearly defined in advance of data analysis and have the approval of the
1920 DSMB;
- 1921 7. Ensure the confidentiality of the trial’s data and the results of monitoring; and
- 1922 8. Review issues that have been identified by the study team and upon request by the
1923 study team, review problems that are identified by the monitors in relation to patient
1924 safety.

1925

1926 DSMB Recommendations

1927 The DSMB may conclude each review with recommendations to continue the trial
1928 without change, modification of the trial, or termination of the trial based on pre-defined
1929 criteria established at the beginning of the trial.

1930 Recommendations for modification of the design and conduct of the trial may
1931 include:

- 1932 1. Modifications of the study protocol based upon the review of the safety data;

- 1933 2. Suspension or early termination of the study because of serious concerns about
1934 subjects' safety, inadequate performance or rate of enrollment;
- 1935 3. Suspension or early termination of the study because study objectives have been
1936 obtained according to pre-established statistical guidelines;
- 1937 4. Optional approaches for trial design when the DSMB determines that the
1938 incidence of primary study outcomes is substantially less than expected, such as
1939 recommendations to increase the number of trial centers or extend the recruitment
1940 period/follow-up period; and,

1941 Confidentiality

1942 Confidentiality will be maintained during all phases of DSMB review and
1943 deliberations. Only voting members of the DSMB will have access to interim analyses of
1944 outcome data by treatment group. Exceptions may be made when the DSMB deems it
1945 appropriate. DSMB members must maintain strict confidentiality concerning all privileged
1946 trial results ever provided to them. The DSMB will review data only by masked study group
1947 (such as ‘Intervention 1’ versus ‘Intervention 2’ rather than cryotherapy versus LEEP) unless
1948 the DSMB determines that the identities of the groups are necessary for their decision-
1949 making. Any request to unmask data must be made in writing.

1950 Membership

1951 The DSMB will be composed of four members chosen from both the U.S. and Kenya.

1952 The members include:

- 1953 1. R. Scott McClelland, MD, MPH, Associate Professor of Medicine,
1954 Epidemiology and Global Health, UW;
- 1955 2. Elizabeth Brown, ScD, Associate Member, FHCRC, Research Associate
1956 Professor, Department of Biostatistics, UW;

- 1957 3. James Kiarie, MBChB, MMed, MPH, Professor of Obstetrics/Gynecology,
1958 KNH; and
- 1959 4. David Eschenbach, MD, Professor, Women's Health, Chairman, Department
1960 of Obstetrics and Gynecology, UW
- 1961 5. *Ad hoc* specialists may be invited to participate as non-voting members at any
1962 time if additional expertise is desired.

1963 Meetings

1964 The first meeting will take place either prior to trial initiation or early after the trial
1965 has been initiated to discuss the protocol. A designated DSMB member and the PIs will
1966 prepare the agenda to review initiation of the trial and reporting of adverse events. The
1967 DSMB will also review monitoring guidelines and approve or give recommendations..

1968 Once the trial has been initiated, the DSMB will meet, as outlined above, to examine
1969 the accumulated safety and enrollment data, review study progress and discuss other factors
1970 (internal or external to the study) that might impact continuation of the trials as designed. A
1971 DSMB meeting may be requested by DSMB members or the Principal Investigators at any
1972 time to discuss safety concerns, and includes the occurrence of any Significant Adverse
1973 Event (SAE) that is associated with the study. The study team will provide the logistical
1974 management and support of the DSMB meetings. The meetings will be convened by
1975 teleconference to decrease travel cost. An emergency meeting of the DSMB may be called at
1976 any time should questions of patient safety arise.

1977 Meeting Format

1978 The meetings will mainly be open sessions. These sessions will be attended by the
1979 Principal Investigators or designee. Other research staff may attend the open sessions but this
1980 is up to the discretion of the PI. Issues discussed at open sessions will include conduct and

1981 progress of the study, including patient accrual, compliance with protocol, and problems
1982 encountered. Patient-specific data and treatment group data will not be presented in these
1983 sessions.

1984 Closed sessions may be requested by the DSMB at any time and will be attended by
1985 voting DSMB members and the unblinded statistician. Any other trial staff may be requested
1986 to attend by the DSMB. All safety and efficacy data will be presented at this session. The
1987 discussion at the closed session is completely confidential.

1988 Should the DSMB decide to issue a termination recommendation, the full vote of the
1989 DSMB will be required. In the event of a split vote, majority vote will rule and a minority
1990 report will be appended. An appeal may be filed by study PIs if a termination decision is
1991 made.

1992 Study Stopping Criteria

1993 The DSMB may recommend stopping the study for the following reasons:

- 1994 • The data show a significantly increased risk of serious adverse effects in one of the
1995 treatment arms.
- 1996 • Interim efficacy analyses show significant treatment benefits or futility in the one
1997 treatment group. The interim efficacy analyses are based on pre-specified stopping
1998 boundaries for the primary endpoint of the study which preserve the study wide Type
1999 I error rate.
- 2000 • It becomes clear that successful completion of the study is not feasible (e.g. there is
2001 an excess of patient dropout, missing data, lack of recruitment etc).

2002 Interim Efficacy Analyses

2003 This study will employ interim analyses to assess accumulating study data for early evidence
2004 of treatment efficacy. The primary outcome, recurrence of cervical intraepithelial neoplasia
2005 grade 2 or 3, will be compared between groups at the following approximate times: months 9,
2006 15, 21 and 27, and for DSMB safety, upon cumulative enrollment and intervention of
2007 100patients. The decision criteria for stopping the study at each interim analysis are based on
2008 O'Brien-Fleming superiority boundary with Type I error controlled at alpha-level $\alpha = 0.05$. In
2009 the event that interim analyses are conducted at times other than the preplanned times (e.g.
2010 unequal information accrual) the stopping criteria will be adjusted to maintain overall type I
2011 error rate of $\alpha=0.05$. We will use Lan-DeMets alpha spending approach, to make the
2012 necessary adjustments. The decision criteria for stoppage are based on a power of 80% to
2013 detect a treatment group difference at the end of study.

2014 Report

2015 A formal report prepared by an assigned administrator will be reviewed and approved
2016 by the DSMB chair, who will prepare a summary. The minutes and summary will be sent to
2017 the full DSMB within three weeks of the meeting. Once approved by the DSMB, the chair of
2018 the DSMB will sign on behalf of the board and the report will be forwarded to the
2019 participating institutions within 4 weeks of each meeting. The PIs will submit the results of
2020 these meetings to the UW Institutional Review Board (IRB), the KNH Ethics Review
2021 Committee (ERC), and the Centers for Disease Control (CDC) which is the study sponsor.
2022 Each report will conclude with a recommendation to continue or to terminate the study. This
2023 recommendation will be made by formal majority vote. A termination recommendation may
2024 be made by the DSMB at any time by majority vote. The report will not include un-blinded
2025 data or any discussion of the un-blinded data.

2026 Any new findings discovered by the DSMB during the course of the study that may
2027 affect the willingness of subjects to remain in the study will be shared by the study doctor or
2028 nurse through direct discussions and printed pamphlets.

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Sponsor Monitoring

As the study sponsor, the Centers for Disease Control (CDC) may conduct monitoring or auditing of study activities to ensure the scientific integrity of the study and to ensure the rights and protection of study participants. Monitoring and auditing activities may be conducted by:

- CDC staff (“internal”)
- authorized representatives of CDC (e.g., a contracted party considered to be “external”)
- both internal and external parties

Monitoring or auditing may be performed by means of on-site visits to the Investigator’s facilities or through other communications such as telephone calls or written correspondence. The visits will be scheduled at mutually agreeable times, and the frequency of visits will be at the discretion of CDC. During the visit, any study-related materials may be reviewed and the Investigator along with study staff should be available for discussion of findings.

The study may also be subject to inspection by regulatory authorities (national or foreign) as well as the IECs/IRBs to review compliance and regulatory requirements.

Acronyms

2050

2051 AIDS – Acquired Immunodeficiency Syndrome

2052 CCSP – Cervical Cancer Screening Program, Coptic Hope Center for Infectious Diseases

2053 CDC – Centers for Disease Control

2054 CIN – Cervical Intraepithelial Neoplasia

2055 CIS – Carcinoma in situ

2056 CVL – Cervicovaginal Lavage

2057 HIV – Human Immunodeficiency Virus

2058 HPV – Human Papillomavirus

2059 IRB – Institutional Review Board

2060 KNH – Kenyatta National Hospital

2061 LEEP – Loop Electrosurgical Excision Procedure

2062 OGAC – Office of the Global AIDS Coordinator

2063 Pap – Papanicolaou

2064 PEPFAR – President’s Emergency Plan for AIDS Relief

2065 PHE – Public Health Evaluation

2066 RNA – Ribonucleic Acid

2067 UNITID – University of Nairobi Institute of Tropical and Infectious Diseases

- 2068 UoN – University of Nairobi
- 2069 USA – United States of America
- 2070 USG – United States Government
- 2071 UW – University of Washington
- 2072 VIA – Visual Inspection with Acetic Acid

2073

Pre-Screening Talking Points for Clinic Staff

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Dr. Michael Chung is conducting a research study at the Hope Center. This study examines what methods may best treat disease in a woman's private parts called the cervix. This disease is like a wound on the skin and can go away by itself. But in some cases, especially in women who have HIV, these wounds might become cancer. The study wants to see how treatment can prevent this problem from becoming cancer and how treatment might affect HIV. Those patients who enroll in the study will be given free screening for cervical disease that may develop into cancer and will also provide free treatment. Dr. Chung and other doctors from the University of Washington in America, the University of Nairobi, and Coptic Hospital are leading this study. You appear to be eligible to be in this study and can possibly enroll in this trial if you like. The study offers free screening for cervical disease and if treatment is received, further follow-up free testing and treatment over 2 years.

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Participation in the research study is voluntary and does not affect your medical care at the Hope Center in any way. Free screening for cervical disease is also available at the Hope Center Cervical Cancer Screening Program even if you do not participate in this study.

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The study may help you detect cervical disease that may be treated and prevent cervical cancer in the future. Are you interested in learning more about the study from the study nurse or doctor? They can explain the study in more detail if you are interested. If you are, we will send you to the study clinic right now. If not, you may go home or continue receiving care here from the pharmacy and laboratory.

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Screening Talking Points for Study Staff

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You are being invited to participate in a research study at the Hope Center.

2097

The study is being conducted by Dr. Michael Chung and other doctors from the

2098

University of Washington in America, Kenyatta National Hospital, and the Coptic

2099

Hospital. This study examines what methods may best treat disease of the female

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private parts called the cervix, and how treatment affects HIV levels. This disease is

2101

like a wound on the skin and can go away by itself. But in some cases, especially in

2102

women who have HIV, these wounds might become cancer.

2103

You do not have to join the study. Whether or not you join the study will not

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impact your care at the Hope Center in any way. If you are eligible and participate in

2105

the study, you will receive free screening and treatment that will help detect and

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remove disease from your cervix that may lead to cancer. You will be asked

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questions and undergo a pelvic examination where our doctor and nurse can examine

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you to detect any areas that look like disease. After undergoing screening, we will

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ask you to return in 2 weeks to receive the results from the test. Most likely you will

2110

not need further treatment or tests after this. If, however, we find a result that might

2111

be disease, we will conduct another test to confirm the disease and the need for

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follow-up treatment.

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If you are positive for cervical disease, you may enroll in a study to receive

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treatment. If you do, we will ask you to return every week for 3 weeks to examine you

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and test for any HIV that may be shed from your cervix after treatment. We will

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follow you for the next 2 years at 6 months intervals to test if there is any further

2117

disease. If it does, we will treat you. We will also draw blood from you in order to

2118 see how much HIV is in your blood and what is your CD4 count. All of this is free of
2119 cost.

2120 Free screening for cervical disease is also available at the Hope Center
2121 Cervical Cancer Screening Program regardless of whether you participate in this
2122 study or not. You are referred to us because the clinical officer has determined that
2123 you are a woman who may be eligible for this study.

- 2124 • Are you over 18 years of age?
- 2125 • Are you pregnant?
- 2126 • Have you had a hysterectomy?
- 2127 • Have you ever received treatment for cervical disease?
- 2128 • Have you ever had a problem with bleeding?
- 2129 • Have you initiated sexual intercourse?

2130 If you are interested in the study, I will explain more about it from the
2131 informed consent form which I will give or read to you. If you still want to be in the
2132 study after reading or being read the informed consent, you can sign the form and we
2133 can enroll you in the study

2134 Post-Medical Care Information2135 **Cervical Cancer Screening**

2136

2137

2138 Pap smear or biopsy

2139

2140 After receiving a Pap smear or biopsy, you may have any of the following symptoms which
2141 are normal:

2142

- 2143 • Slight belly discomfort (like menstrual cramps, should not last more than 1-2 days)
2144 • Slight bleeding from the vagina
2145

2146 We recommend you take paracetamol or ibuprofen for pain or cramps.

2147

2148 It is very uncommon to have severe problems but if you experience any of the following,
2149 **please notify the clinic or screening staff** (see contacts below) right away:

2150

- 2151 • Pain in the belly that lasts longer than 2-3 days
2152 • Much bleeding from the vagina
2153 • Bleeding from the vagina that is increasing in amount, or comes with belly pain
2154 • Fever, chills
2155

2156 After a biopsy, it is important to wait 10 days before having sex. This will protect you and
2157 your partner from infection. (Please discuss with the screening nurse or doctor if you cannot
2158 wait and don't forget to take condoms!)

2159

2160

2161 Treatment (cryotherapy or LEEP)

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2163 After receiving treatment, you may have any of the following symptoms which are normal:

2164

- 2165 • Belly pain like during your period (should not last longer than 1-2 days)
- 2166 • Slight bleeding from the vagina for up to 1 week
- 2167 • Clear fluid from the vagina (as long as 2 weeks)
- 2168

2169 The following symptoms are not normal and you should **contact screening staff** and **have**
 2170 **medical attention as soon as possible** if you have:

2171

- 2172 • Severe belly pain
- 2173 • Bleeding from the vagina that continues or is a large amount
- 2174 • Fever, chills
- 2175 • Cloudy (white) fluid from the vagina
- 2176

2177 After treatment, it is important to wait 4 weeks before having sex. This will protect you and
 2178 your partner from infection. (Please discuss with the screening nurse or doctor if you cannot
 2179 wait and don't forget to take condoms!)

2180 Medications

2181 You may receive medications (antibiotics) after treatment or to treat an infection found during
 2182 your exams. Please follow the directions about how to take the medications carefully. If you
 2183 have a severe problem after taking the medication or have any of the follow symptoms, please
 2184 **stop the medication and contact screening staff:**

- 2185 • upset stomach, vomiting
- 2186 • severe diarrhea or diarrhea with blood
- 2187 • sensitivity to light, rash
- 2188 • dizziness, severe headache, confusion, ringing in the ears or hearing loss
- 2189 • seizures (uncontrolled jerking of the body)
- 2190 • heart problems
- 2191
- 2192

2193 **Screening Staff Contacts:**

2194

2195 ****EMERGENCY NUMBERS (24 HOURS): 020-272-2710 or 0733-771-288**

- 2196
- 2197
- 2198
- 2199
- 2200 • Office 1: 0728-456-540
- 2201 • Office 2: 020-271-2947
- 2202 • Dr. Michael Chung: 020-271-2947
- 2203 • Dr. Nelly Mugo: 020-273-6744
- 2204 • Dr. Samir Sakr: 020-272-4737
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Information for Spouses and Partners
Cervical Cancer Screening and Treatment

2213

2214 *Treatment (cryotherapy or LEEP)*

2215 Your wife or partner has undergone the following treatment as part of a cervical cancer
2216 screening and treatment program:

2217 Cryotherapy2218 LEEP

2219

2220 After treatment, it is important to wait 4 weeks before having sex. This is because HIV
2221 shedding may increase substantially (but temporarily) at the site of cryotherapy or LEEP. This
2222 shedding may increase the risk of HIV transmission to an uninfected partner or lead to HIV
2223 re-infection. If abstinence is impossible during the healing period, it is important to use a
2224 condom every time you have sex for at least 4 weeks after treatment.

2225

2226

2227 **Screening Staff Contacts:**

2228 **If you need more information, you may call the following numbers Mon-Fri**
2229 **between 8am and 5pm: Office 1: 0728-456-540**

2230 • Office 2: 020-271-2947

2231 • Cell: 0721-289-733

2232 • Dr. Samir Sakr: 020-272-4737

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2236

Maelezo kwa mabwana na wapenzi.

2237

Ukaguza na matibabu ya saratani ya mlango wa kizazi.

2238

Matibabu ya Cryotherapy au LEEP

2239

Mke au mpenzi wako amefanyiwa matibabu yafuatayo kama mojawapo wa mpangilio wa ukaguzi na matibabu ya saratani ya mlango wa kizazi:

2241

Cryotherapy

2242

LEEP

2243

Baada ya matibabu ni muhimu usionane kimwili na mke au mpenzi wako kwa mda wa wiki nne. Hi ni kwa sababu idadi ya virusi vinanyosababisha ukimwi inaweza kuongezeka (kwa muda tu) katika sehemu iliyofanyiwa Cryotherapy au LEEP. Ongezeko la idadi ya virusi kwa mlango wa kizazi inaweza kuongezea hadhari ya kuambukiza mpenzi ambaye hajaambukizwa, au ongezeko la uambukizi mpya wa virusi vinavyosababisha ukimwi. Iwapo haiwezekani kujinyima kufanya mapenzi wakati huu ambapo mke au mpenzi wako anaendelea kupata nafuu, ni muhimu kutumia mpira wa kondomu kila wakati mnapoonana kimwili kwa mda wa wiki nne, baada ya kupokea matibabu.

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2252

2253

2254

Numbari za mawasiliano :

Iwapo ungependa kupewa maelezo zaidi, unaweza kupiga simu kwa numbari zifuatazo Jumatatu hadi ijumaa kuuanzia saa mbili asubuhi mpaka saa kumi na moja jioni.

Afisi 1: 0728-456-540

Afisi 2: 020-271-2947

- Rununu: 0721-289-733

STUDY WRITTEN CONSENT FORM

Cervical Treatment Study: Screening INITIAL CONSENT

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Full Title:

2260 Impact of Cryotherapy versus Loop Electrosurgical Excision Procedure (LEEP) on Recurrence of
2261 Cervical Intraepithelial Neoplasia and HIV-1 Cervical Shedding among HIV-positive Women

Study Investigators:

2263 Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University of
2264 Washington, 020 271-2947

2265 Nelly Mugo, MBChB, MMed, MPH, Gynecologist, Department of Obstetrics and Gynecology,
2266 Kenyatta National Hospital, 020 273-6744

2267 Samah Sakr, MBChB, Medical Director, Coptic Hospital of Kenya, 020 272-4737

2268 Hugo De Vuyst, MD, PhD, Epidemiologist, International Agency for Research on Cancer, World
2269 Health Organization, +33-472738521

2270 Silvia Franceschi, MD, Epidemiologist, International Agency for Research on Cancer, World Health
2271 Organization, +33-4728404

2272 Barbra Richardson, PhD, Research Professor, Department of Biostatistics, University of Washington,
2273 +1-206-731-2425

2274 Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of Washington, +1-
2275 206-543-4278

2276 **Emergency telephone number staffed 24 hours a day:** 020 271 2947, 0723 914 057 or 0721 289
2277 733

2278 **Ethical Review Committee Chairperson:** Professor A. N. Guantai, 020 2726300, Ext. 44102,
2279 4435544355, can be contacted for questions about research subject rights

2280

2281 Researchers' Statement

2282 We are asking you to be in a research study. The purpose of this consent form is to give you
2283 information so you can decide if you want to be in the study. Please read the form carefully. You
2284 may ask questions about the purpose of the research and what we would ask you to do for the study.
2285 You may ask about possible risks and benefits, your rights as a volunteer, and anything else about the
2286 research or this form. You may ask questions at any time (before, during, and after the study) about
2287 anything. When we have answered all your questions, you can decide if you want to be in the study
2288 or not. This process is called 'informed consent.' If you wish, we will give you a copy of this form.
2289 Please let us know if you would rather use the Kiswahili consent form.

2290 Purpose of the Study

2291 The reason we are doing this research project is to screen for disease which may lead to
2292 cervical cancer. Participation in this project lasts for up to 1 month. You were asked to participate in
2293 this project because you are:

- 2294 • HIV-positive,
- 2295 • currently receiving care at the Hope clinic,
- 2296 • not pregnant,
- 2297 • do not have a history of problems with bleeding,
- 2298 • have not had a hysterectomy (an operation to remove the uterus),
- 2299 • and have initiated sexual intercourse.

2300 Cervical cancer is the most common cancer among young and middle-aged women in Kenya. More
2301 women who have HIV get cervical cancer than those who do not have HIV. Even in HIV-infected
2302 women, cervical cancer is not common. However, in HIV-infected women, cervical disease that is
2303 not cancer is common. This disease is caused by a virus called the human papillomavirus (HPV). It is
2304 very important to find this disease and treat it before it becomes cancer. This study will screen you for
2305 cervical disease. If you screen positive for cervical disease, you may choose to enroll in a treatment
2306 study, or you will be referred elsewhere for treatment. The treatment study will be explained to you
2307 in detail before you decide. This screening study will have over 2,400 participants. By doing this
2308 study, we hope to provide free and comprehensive screening for HIV-positive women to prevent
2309 cervical cancer.

2310

2311 **Procedures (see Appendix)**

2312 All participants will be asked to come for 1 to 3 visits over 1 month. All study visits will take from
2313 20 to 40 minutes (Visit 1: consent process – 10 minutes, Pap smear – 20 minutes; Visit 2: review of
2314 Pap smear results – 10 minutes, colposcopy and biopsy – 30 minutes; Visit 3: review of biopsy
2315 results and discussion of treatment options – 30 minutes)

2316 Visit 1:

2317 If you agree, you will first undergo a pelvic exam with a Pap smear to see if you have a something
2318 like a wound (called a lesion). This lesion may possibly develop into cancer. A pelvic exam means
2319 that a doctor or nurse will examine your female parts. The Pap smear involves brushing the cervix
2320 with a small brush to collect material that can be looked at under a microscope (like a large
2321 magnifying glass).

2322 Visit 2:

2323 You will then return to this clinic 2 weeks later to find out the results of this test. Most of the time the
2324 results will show no disease or that we just have to repeat the Pap smear or visual inspection (VIA)
2325 every 6 months. If this is the case, then you will exit the study at this point and receive further
2326 follow-up at the Coptic Hope Cervical Cancer Screening Program (CCSP) or be asked to come back
2327 to the study clinic for a repeat Pap smear after 6 months. If we find lesions that need to be treated at
2328 these visits, we will discuss your treatment options with you in detail.

2329 If you are screened and we find a lesion that needs to be looked at carefully, you will first have a
2330 pregnancy test. If you are pregnant, nothing more will be done until after you deliver. We will send
2331 you for special care at the Hope center to make sure you do not pass HIV to your baby (this care is
2332 called PMTCT), and you will exit the study and receive further follow-up at the CCSP. If you are not
2333 pregnant, we will look at your cervix with a type of magnifying lens called a colposcope. We will
2334 look closely at the cervix and take a piece out, about the size of a grain of rice. This is called a
2335 biopsy. We will look at this tissue biopsy under a microscope and share the results with you 4-
2336 6weeks later. This test is very good and will help us decide whether you need to have treatment.

2337 There are some cells found in the cervix and the lining of the uterus. These are called ‘glandular
2338 cells.’ When Pap smear results show that your glandular cells are abnormal, the doctor will perform a
2339 procedure referred to as ‘Endocervical Curettage (ECC).’ This is a procedure where a spoon-shaped
2340 instrument called a ‘curette’ is used to scrape abnormal material from the passageway between the
2341 cervix and the uterus. This procedure obtains a small sample, which is then sent to the lab to be
2342 examined for abnormal cells. ECC is performed during colposcopy and takes just a few minutes to
2343 perform. You can expect to feel mild cramping, much like menstrual cramps following the
2344 procedure. If you are found to have abnormal cells but the doctor cannot see them by means of a
2345 colposcope, you will undergo ECC as described above.

2346 Visit 3: You will return to this clinic in 4-6weeks for the biopsy results. If we find cervical disease
2347 that needs treatment, we will discuss your treatment options with you. You may choose to enroll in a
2348 further treatment study, which will be explained in detail at this time. If you prefer not to enroll in
2349 another study, you will be referred for treatment at Kenyatta National Hospital (KNH) and standard
2350 care at Coptic Hope Center. Whether you choose to accept study treatment or referral, you will be
2351 exited from this screening study at your third visit.

2352 Contacting Participants

2353 We will ask you to give us contact information like a phone number so we can call you if you
2354 do not come to a scheduled visit. We may ask about your health or where you are during these calls.
2355 It is important for you to come to all of your scheduled visits. If we cannot contact you by phone, we
2356 may try to visit you at your house. If this happens, we will not wear clothes that show we are health
2357 workers. You should tell us if you do not want to be contacted in this way. If you do not return for
2358 your Pap smear or biopsy results, we will also “flag” your Coptic Hope file so that you can be
2359 notified that you have available study results at your next clinic visit.

2360 If study quality control procedures indicate that your Pap smear result is discordant from the original
2361 result you were given, we will ask you to return to the clinic to receive your new results and to
2362 discuss potential treatment options. At this point, you may be asked if you would like to re-enroll in
2363 the study.

2364

2365

2366 **Risks and discomforts of being in the study**

2367 This is an explanation of problems you may have through your participation in this study. Other
2368 problems not listed may happen as well.

2369 Screening

2370 Collection of samples through the pelvic exam may cause:

- 2371 • mild discomfort as you are examined,
- 2372 • a small amount of bleeding from the vagina for 1-2 days afterwards and
- 2373 • mild to moderate cramping for around 5 minutes that is similar to mild period pain.

2374 If you receive a biopsy, we ask that you do not have sex for 10 days. The reason is that if you are
2375 HIV-infected and your partner is not, then he may be at greater risk of becoming infected with HIV.
2376 If your partner is HIV positive, he may be at greater risk of getting re-infected with resistant HIV.
2377 Also, you need time to heal and will put yourself at higher risk of infection unless you give yourself
2378 this time. If you need help talking about these issues with your partner, a nurse, doctor or counselor
2379 can help you. We will give you free condoms to use if it is impossible for you to not have sex.

2380 Another possible discomfort you may face is the worry or anxiety that you may have disease on your
2381 cervix. You may talk about this with a study nurse or doctor or if you would like talk to a counselor,
2382 we can help to arrange this.

2383 We may find on screening that you have an infection. In this case we will give you a prescription for
2384 antibiotics. Side effects of these antibiotics may include: upset stomach, vomiting or diarrhea,
2385 sensitivity to light, rash, severe allergic reaction that could cause death, dizziness, headache,
2386 confusion, ringing in the ears or hearing loss, seizures (jerking of the body), heart problems, blood
2387 disorders, problems with blood sugar, liver disease, kidney disease and pain or numbness in your legs
2388 or arms. If you experience any of these problems, please report to study staff right away.

2389 Confidentiality

2390 The study staff will ask you for personal information that may be embarrassing to talk about like how
2391 many sexual partners you have had. You may choose not to answer any question. As part of the
2392 study, you may meet other patients from this clinic whom you know from outside the clinic. We have
2393 no plans to release your information to anyone other than the study researchers or appointed monitors.
2394 Sometimes committees that oversee research will examine study information to make sure nothing
2395 illegal or unethical is being done. Your personal information will be protected if this happens and
2396 will not be shown to anyone outside of this review. As the study sponsor, CDC may monitor or audit
2397 study activities. The reason for this would be to make sure that the study is being done the way it is
2398 supposed to be done. It would also make sure that your rights and health are protected. Your personal
2399 medical information will be kept confidential.

2400

2401 **Alternative to taking part in this study**

2402 If you choose not to take part in this study, you will continue to receive medical care at the
2403 Coptic Hope Center and free antiretroviral medications. You may also receive free cervical cancer
2404 screening at this clinic without having to enroll in this study.

2405

2406 **Benefits of the study**

2407 Your participation will help us understand more about cervical disease. By participating in
2408 this study, you receive free screening for cervical disease. If you would like to know the results of the
2409 study you can contact the study office 6 months or 1 year after you leave the study.

2410 **Compensation for injury**

2411 There is no cost to you for participating in this study other than your time. The study will pay for all
2412 screening costs for tests provided at the study clinic. If any physical injuries happen to you as a result
2413 of study participation, the study will cover the costs of care. If you think you have an injury or illness
2414 related to this study, contact the study staff (Dr. Michael Chung (020-272-2710) or Dr. Nelly Mugo
2415 (020-273-6744) or Dr. Evans Malava (0721 289 733) right away. They will treat you or refer you for
2416 treatment.

2417 **Specimen and Data Storage and Use of your Samples for Future Studies**

2418 We would like to save your medical information and Pap smear, colposcopy and endocervical
2419 curettage samples in Kenya at the Coptic Hospital and Kenyatta National Hospital for future research.
2420 This research may be done by the University of Washington or by other researchers who are working
2421 with us on this study for ten years after the end of follow-up in the study. We will use these data and
2422 samples only for research related to cervical cancer and HIV. Before your samples leave the clinic,
2423 they will be assigned a code. Your name will not be on them. Your name will be linked to the code
2424 only for five years after the study is completed. After that time, the link between your name and the
2425 code on your samples and data will be destroyed. The Institutional Review Boards are committees
2426 that watch over the safety and rights of research participants at Kenyatta National Hospital and the
2427 University of Washington. They must approve any future research studies using your samples. If
2428 you do not want to have your samples saved for future research, you can still be in this study and your
2429 samples will be destroyed once testing for the study is completed. If you agree to store your samples
2430 now, but change your mind before the end of the study, let the study staff know and we will make
2431 sure that your samples do not get stored for future research. We will not sell your samples. Tests
2432 done on your samples may lead to a new invention or discovery. We have no plans to share any
2433 money or other benefits resulting from this invention or discovery with you.

2434 **Other information**

2435 Your medical information is confidential (or kept secret) and we will keep your records in a
2436 locked office. Your medical records and information about your participation in the research will be
2437 available to you and to the study team but not to anyone outside of the study without your agreement.
2438 If you agree, we will share the information from this study with your doctors at the Hope Center.
2439 This information may help them treat your HIV and give you better care. All of your records will be
2440 kept in locked areas and all computer information will be password protected.

2441 University of Washington staff sometimes review studies such as this one to make sure they
2442 are being done safely and legally. If a review of this study takes place, your records may be
2443 examined. You may refuse to participate or may leave from the study at any time without
2444 penalty or loss of benefit or help to which you have a right to. We will tell you if there is any new
2445 information about the treatments we are studying so you can decide if you want to leave the study.
2446 Your relationship with staff and services at Coptic Hope Center for Infectious Diseases will not be
2447 affected in any way if you do or do not participate or if you enter the program and leave later. Please
2448 inform study staff if you decide you would like to leave the study. You may be asked to give some
2449 final samples but you may refuse.

2450 Study staff may decide to take you out the study if they find you may be harmed if you
2451 continue to participate. You may also be taken out of the study if the staff think you will not be able
2452 to follow study safety requirements.

2453

2454 Please contact Dr. Michael Chung (020 271-2947), Dr. Samah Sakr (020 272-4737), or Dr.
2455 Nelly Mugo (020 273-6744) for questions about the study or to report any problems.

2456

2457 Signature of study staff _____ Date _____

2458

2459 Printed name of study staff _____

2460

2461 **Subject's statement**

2462 This study has been explained to me. I volunteer to take part in this research. I give
2463 permission to the researchers to use my medical records as described in this consent form. I have had
2464 a chance to ask questions. If I have questions later about the research, I can ask one of the researchers
2465 listed above. If I have questions about my rights as a research subject, I can call the Ethical Review
2466 Committee at Kenyatta National Hospital 726-300. I will receive a copy of this consent form if I
2467 would like one.

2468 Please mark, initial and date one option:

2469 I DO agree to store my samples and data for future research

2470

2471 I DO NOT agree to store my samples and data for future research

2472

2473 Signature or thumbprint of participant _____ Date _____
2474 _____

2475

2476 Printed name of participant _____

2477 Copies to: Investigator and Subject

2478

2479

STUDY WRITTEN CONSENT FORM

Cervical Treatment Study: Screening RE-ENROLLMENT CONSENT

2480
2481
2482
2483
2484

Full Title:

2485 Impact of Cryotherapy versus Loop Electrosurgical Excision Procedure (LEEP) on Recurrence of
2486 Cervical Intraepithelial Neoplasia and HIV-1 Cervical Shedding among HIV-positive Women

Study Investigators:

2488 Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University of
2489 Washington, 020 271-2947

2490 Nelly Mugo, MBChB, MMed, MPH, Gynecologist, Department of Obstetrics and Gynecology,
2491 Kenyatta National Hospital, 020 273-6744

2492 Samah Sakr, MBChB, Medical Director, Coptic Hospital of Kenya, 020 272-4737

2493 Hugo De Vuyst, MD, PhD, Epidemiologist, International Agency for Research on Cancer, World
2494 Health Organization, +33-472738521

2495 Silvia Franceschi, MD, Epidemiologist, International Agency for Research on Cancer, World Health
2496 Organization, +33-4728404

2497 Barbra Richardson, PhD, Research Professor, Department of Biostatistics, University of Washington,
2498 +1-206-731-2425

2499 Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of Washington, +1-
2500 206-543-4278

2501 **Emergency telephone number staffed 24 hours a day:** 020 271 2947, 0723 914 057 or 0721 289
2502 733

2503 **Ethical Review Committee Chairperson:** Professor A. N. Guantai, 020 2726300, Ext. 44102,
2504 44355, can be contacted for questions about research subject rights

2505

2506 Researchers' Statement

2507 We are asking you to be in a research study. The purpose of this consent form is to give you
2508 information so you can decide if you want to be in the study. Please read the form carefully. You
2509 may ask questions about the purpose of the research and what we would ask you to do for the study.
2510 You may ask about possible risks and benefits, your rights as a volunteer, and anything else about the
2511 research or this form. You may ask questions at any time (before, during, and after the study) about
2512 anything. When we have answered all your questions, you can decide if you want to be in the study
2513 or not. This process is called 'informed consent.' If you wish, we will give you a copy of this form.
2514 Please let us know if you would rather use the Kiswahili consent form.

2515 Purpose of the Study

2516 The reason we are doing this research project is to screen for disease which may lead to
2517 cervical cancer. Participation in this project lasts for up to 1 month. You were asked to participate in
2518 this project because you are:

- 2519• HIV-positive,
- 2520• currently receiving care at the Hope clinic,
- 2521• not pregnant,
- 2522• do not have a history of problems with bleeding,
- 2523• have not had a hysterectomy (an operation to remove the uterus),
- 2524• and have initiated sexual intercourse.

2525 Cervical cancer is the most common cancer among young and middle-aged women in Kenya.
2526 More women who have HIV get cervical cancer than those who do not have HIV. Even in HIV-
2527 infected women, cervical cancer is not common. However, in HIV-infected women, cervical disease
2528 that is not cancer is common. This disease is caused by a virus called the human papillomavirus
2529 (HPV). It is very important to find this disease and treat it before it becomes cancer. This study will
2530 screen you for cervical disease. If you screen positive for cervical disease, you may choose to enroll
2531 in a treatment study, or you will be referred elsewhere for treatment. The treatment study will be
2532 explained to you in detail before you decide. This screening study will have over 2,400 participants.
2533 By doing this study, we hope to provide free and comprehensive screening for HIV-positive women
2534 to prevent cervical cancer.

2535

2536 **Procedures (see Appendix)**

2537 All participants will be asked to come for 1 to 3 visits over 1 month. All study visits will take from
2538 20 to 40 minutes (Visit 1: consent process – 10 minutes, Pap smear – 20 minutes; Visit 2: review of
2539 Pap smear results – 10 minutes, colposcopy and biopsy – 30 minutes; Visit 3: review of biopsy
2540 results and discussion of treatment options – 30 minutes)

2541 Visit 1:

2542 If you agree, you will first undergo a pelvic exam with a Pap smear to see if you have a
2543 something like a wound (called a lesion). This lesion may possibly develop into cancer. A pelvic
2544 exam means that a doctor or nurse will examine your female parts. The Pap smear involves brushing
2545 the cervix with a small brush to collect material that can be looked at under a microscope (like a large
2546 magnifying glass).

2547 Visit 2:

2548 You will then return to this clinic 2 weeks later to find out the results of this test. Most of the
2549 time the results will show no disease or that we just have to repeat the Pap smear or visual inspection
2550 (VIA) every 6 months. If this is the case, then you will exit the study at this point and receive further
2551 follow-up at the Coptic Hope Cervical Cancer Screening Program (CCSP) or be asked to come back
2552 to the study clinic for a repeat Pap smear after 6 months. If we find lesions that need to be treated at
2553 these visits, we will discuss your treatment options with you in detail.

2554 If you are screened and we find a lesion that needs to be looked at carefully, you will first
2555 have a pregnancy test. If you are pregnant, nothing more will be done until after you deliver. We will
2556 send you for special care at the Hope center to make sure you do not pass HIV to your baby (this care
2557 is called PMTCT), and you will exit the study and receive further follow-up at the CCSP. If you are
2558 not pregnant, we will look at your cervix with a type of magnifying lens called a colposcope. We will
2559 look closely at the cervix and take a piece out, about the size of a grain of rice. This is called a
2560 biopsy. We will look at this tissue biopsy under a microscope and share the results with you 4-6
2561 weeks later. This test is very good and will help us decide whether you need to have treatment.

2562 There are some cells found in the cervix and the lining of the uterus. These are called
2563 ‘glandular cells.’ When Pap smear results show that your glandular cells are abnormal, the doctor
2564 will perform a procedure referred to as ‘Endocervical Curettage (ECC).’ This is a procedure where a
2565 spoon-shaped instrument called a ‘curette’ is used to scrape abnormal material from the passageway
2566 between the cervix and the uterus. This procedure obtains a small sample, which is then sent to the
2567 lab to be examined for abnormal cells. ECC is performed during colposcopy and takes just a few
2568 minutes to perform. You can expect to feel mild cramping, much like menstrual cramps following
2569 the procedure. If you are found to have abnormal cells but the doctor cannot see them by means of a
2570 colposcope, you will undergo ECC as described above.

2571 Visit 3: You will return to this clinic in 4-6 weeks for the biopsy results. If we find cervical disease
2572 that needs treatment, we will discuss your treatment options with you. You may choose to enroll in a
2573 further treatment study, which will be explained in detail at this time. If you prefer not to enroll in
2574 another study, you will be referred for treatment at Kenyatta National Hospital (KNH) and standard
2575 care at Coptic Hope Center. Whether you choose to accept study treatment or referral, you will be
2576 exited from this screening study at your third visit.

2577 Contacting Participants

2578 We will ask you to give us contact information like a phone number so we can call you if you
2579 do not come to a scheduled visit. We may ask about your health or where you are during these calls.
2580 It is important for you to come to all of your scheduled visits. If we cannot contact you by phone, we
2581 may try to visit you at your house. If this happens, we will not wear clothes that show we are health
2582 workers. You should tell us if you do not want to be contacted in this way. If you do not return for
2583 your Pap smear or biopsy results, we will also “flag” your Coptic Hope file so that you can be
2584 notified that you have available study results at your next clinic visit.

2585 If study quality control procedures indicate that your Pap smear result is discordant from the
2586 original result you were given, we will ask you to return to the clinic to receive your new results and
2587 to discuss potential treatment options. At this point, you may be asked if you would like to re-enroll
2588 in the study.

2589

2590

2591 **Risks and discomforts of being in the study**

2592 This is an explanation of problems you may have through your participation in this study. Other
2593 problems not listed may happen as well.

2594 Screening

2595 Collection of samples through the pelvic exam may cause:

- 2596• mild discomfort as you are examined,
- 2597• a small amount of bleeding from the vagina for 1-2 days afterwards and
- 2598• mild to moderate cramping for around 5 minutes that is similar to mild period pain.

2599 If you receive a biopsy, we ask that you do not have sex for 10 days. The reason is that if you
2600 are HIV-infected and your partner is not, then he may be at greater risk of becoming infected with
2601 HIV. If your partner is HIV positive, he may be at greater risk of getting re-infected with resistant
2602 HIV. Also, you need time to heal and will put yourself at higher risk of infection unless you give
2603 yourself this time. If you need help talking about these issues with your partner, a nurse, doctor or
2604 counselor can help you. We will give you free condoms to use if it is impossible for you to not have
2605 sex.

2606 Another possible discomfort you may face is the worry or anxiety that you may have disease
2607 on your cervix. You may talk about this with a study nurse or doctor or if you would like talk to a
2608 counselor, we can help to arrange this.

2609 We may find on screening that you have an infection. In this case we will give you a
2610 prescription for antibiotics. Side effects of these antibiotics may include: upset stomach, vomiting or
2611 diarrhea, sensitivity to light, rash, severe allergic reaction that could cause death, dizziness, headache,
2612 confusion, ringing in the ears or hearing loss, seizures (jerking of the body), heart problems, blood
2613 disorders, problems with blood sugar, liver disease, kidney disease and pain or numbness in your legs
2614 or arms. If you experience any of these problems, please report to study staff right away.

2615 Confidentiality

2616 The study staff will ask you for personal information that may be embarrassing to talk about
2617 like how many sexual partners you have had. You may choose not to answer any question. As part
2618 of the study, you may meet other patients from this clinic whom you know from outside the clinic.
2619 We have no plans to release your information to anyone other than the study researchers or appointed
2620 monitors. Sometimes committees that oversee research will examine study information to make sure
2621 nothing illegal or unethical is being done. Your personal information will be protected if this happens
2622 and will not be shown to anyone outside of this review. As the study sponsor, CDC may monitor or
2623 audit study activities. The reason for this would be to make sure that the study is being done the way
2624 it is supposed to be done. It would also make sure that your rights and health are protected. Your
2625 personal medical information will be kept confidential.

2626

2627 **Alternative to taking part in this study**

2628 If you choose not to take part in this study, you will continue to receive medical care at the
2629 Coptic Hope Center and free antiretroviral medications. You may also receive free cervical cancer
2630 screening at this clinic without having to enroll in this study.

2631

2632 **Benefits of the study**

2633 Your participation will help us understand more about cervical disease. By participating in
2634 this study, you receive free screening for cervical disease. If you would like to know the results of the
2635 study you can contact the study office 6 months or 1 year after you leave the study.

2636 **Compensation for injury**

2637 There is no cost to you for participating in this study other than your time. The study will pay
2638 for all screening costs for tests provided at the study clinic. If any physical injuries happen to you as
2639 a result of study participation, the study will cover the costs of care. If you think you have an injury
2640 or illness related to this study, contact the study staff (Dr. Michael Chung (020-272-2710) or Dr.
2641 Nelly Mugo (020-273-6744) or Dr. Evans Malava (0721 289 733) right away. They will treat you or
2642 refer you for treatment.

2643 **Specimen and Data Storage and Use of your Samples for Future Studies**

2644 We would like to save your medical information and Pap smear, colposcopy and endocervical
2645 curettage samples in Kenya at the Coptic Hospital and Kenyatta National Hospital for future research.
2646 This research may be done by the University of Washington or by other researchers who are working
2647 with us on this study for ten years after the end of follow-up in the study. We will use these data and
2648 samples only for research related to cervical cancer and HIV. Before your samples leave the clinic,
2649 they will be assigned a code. Your name will not be on them. Your name will be linked to the code
2650 only for five years after the study is completed. After that time, the link between your name and the
2651 code on your samples and data will be destroyed. The Institutional Review Boards are committees
2652 that watch over the safety and rights of research participants at Kenyatta National Hospital and the
2653 University of Washington. They must approve any future research studies using your samples. If
2654 you do not want to have your samples saved for future research, you can still be in this study and your
2655 samples will be destroyed once testing for the study is completed. If you agree to store your samples
2656 now, but change your mind before the end of the study, let the study staff know and we will make
2657 sure that your samples do not get stored for future research. We will not sell your samples. Tests
2658 done on your samples may lead to a new invention or discovery. We have no plans to share any
2659 money or other benefits resulting from this invention or discovery with you.

2660 **Other information**

2661 Your medical information is confidential (or kept secret) and we will keep your records in a
2662 locked office. Your medical records and information about your participation in the research will be
2663 available to you and to the study team but not to anyone outside of the study without your agreement.
2664 If you agree, we will share the information from this study with your doctors at the Hope Center.
2665 This information may help them treat your HIV and give you better care. All of your records will be
2666 kept in locked areas and all computer information will be password protected.

2667 University of Washington staff sometimes review studies such as this one to make sure they
2668 are being done safely and legally. If a review of this study takes place, your records may be
2669 examined. You may refuse to participate or may leave from the study at any time without
2670 penalty or loss of benefit or help to which you have a right to. We will tell you if there is any new
2671 information about the treatments we are studying so you can decide if you want to leave the study.
2672 Your relationship with staff and services at Coptic Hope Center for Infectious Diseases will not be
2673 affected in any way if you do or do not participate or if you enter the program and leave later. Please
2674 inform study staff if you decide you would like to leave the study. You may be asked to give some
2675 final samples but you may refuse.

2676 Study staff may decide to take you out the study if they find you may be harmed if you
2677 continue to participate. You may also be taken out of the study if the staff think you will not be able
2678 to follow study safety requirements.

2679

2680 Please contact Dr. Michael Chung (020 271-2947), Dr. Samah Sakr (020 272-4737), or Dr.
2681 Nelly Mugo (020 273-6744) for questions about the study or to report any problems.

2682

2683 Signature of study staff _____ Date _____

2684

2685 Printed name of study staff _____

2686

2687 **Subject's statement**

2688 This study has been explained to me. I volunteer to take part in this research. I give
2689 permission to the researchers to use my medical records as described in this consent form. I have had
2690 a chance to ask questions. If I have questions later about the research, I can ask one of the researchers
2691 listed above. If I have questions about my rights as a research subject, I can call the Ethical Review
2692 Committee at Kenyatta National Hospital 726-300. I will receive a copy of this consent form if I
2693 would like one.

2694 Please mark, initial and date one option:

2695

2696

2697

2698

2699 Signature or thumbprint of participant _____ Date _____
2700 _____

2701

2702 Printed name of participant _____

2703 Copies to: Investigator and Subject

STUDY WRITTEN CONSENT FORM**Cervical Treatment Study: Cryotherapy vs. LEEP**2704
27052706 **Full Title:**2707 Impact of Cryotherapy versus Loop Electrosurgical Excision Procedure (LEEP) on Recurrence of
2708 Cervical Intraepithelial Neoplasia and HIV-1 Cervical Shedding among HIV-positive Women2709 **Study Investigators:**2710 Michael H. Chung, MD, MPH, Assistant Professor, Department of Global Health, University of
2711 Washington, 020 271-29472712 Nelly Mugo, MBChB, MMed, MPH, Gynecologist, Department of Obstetrics and Gynecology,
2713 Kenyatta National Hospital, 020 273-6744

2714 Samah Sakr, MBChB, Medical Director, Coptic Hospital of Kenya, 020 272-4737

2715 Hugo De Vuyst, MD, PhD, Epidemiologist, International Agency for Research on Cancer, World
2716 Health Organization, +33-4727385212717 Silvia Franceschi, MD, Epidemiologist, International Agency for Research on Cancer, World Health
2718 Organization, +33-47284042719 Barbra Richardson, PhD, Research Professor, Department of Biostatistics, University of Washington,
2720 +1-206-731-24252721 Grace John-Stewart, MD, PhD, Professor, Department of Medicine, University of Washington, +1-
2722 206-543-42782723 **Emergency telephone number staffed 24 hours a day:** 020 271 2947, 0723 914 057 or 0721 289
2724 7332725 **Ethical Review Committee Chairperson:** Professor A. N. Guantai, 020 2726300, Ext. 44102,
2726 4435544355, can be contacted for questions about research subject rights

2727

2728 **Researchers' Statement**2729 We are asking you to be in a research study. The purpose of this consent form is to give you
2730 information so you can decide if you want to be in the study. Please read the form carefully. You
2731 may ask questions about the purpose of the research and what we would ask you to do for the study.
2732 You may ask about possible risks and benefits, your rights as a volunteer, and anything else about the
2733 research or this form. You may ask questions at any time (before, during, and after the study) about
2734 anything. When we have answered all your questions, you can decide if you want to be in the study
2735 or not. This process is called 'informed consent.' If you wish, we will give you a copy of this form.
2736 Please let us know if you would rather use the Kiswahili consent form.2737 **Purpose of the Study**

2738 The reason we are doing this research project is to find the best treatment of disease which
2739 may lead to cervical cancer. Participation in this project lasts for 2 years. You were asked to
2740 participate in this project because you are:

2741

- 2742• HIV-positive,
- 2743• currently receiving care at the Hope clinic,
- 2744• not pregnant,
- 2745• do not have a history of problems with bleeding,
- 2746• have not had a hysterectomy (an operation to remove the uterus),
- 2747• have initiated sexual intercourse
- 2748• have not received treatment for cervical disease in the past
- 2749• and have received a positive result for cervical disease from Pap smear and biopsy screening.

2750 Cervical cancer is the most common cancer among young and middle-aged women in Kenya.
 2751 More women who have HIV get cervical cancer than those who do not have HIV. Even in HIV-
 2752 infected women, cervical cancer is not common. However, in HIV-infected women, cervical disease
 2753 that is not cancer is common. This disease is caused by a virus called the human papillomavirus
 2754 (HPV). It is very important to find this disease and treat it before it becomes cancer. This study will
 2755 compare two ways of treating cervical disease: cryotherapy and loop electrosurgical excision
 2756 procedure (LEEP). Both treatments are commonly done for women around the world and are not
 2757 new. We will explain these treatments for you. This study will have 400 participants. By doing this
 2758 study, we hope to find the best way to treat HIV-positive women to prevent cervical cancer.

2759

2760 **Procedures (see Appendix)**

2761 All participants will be asked to come for 5 to 8 visits over 2 years. All study visits will take from
 2762 15 to 40 minutes.

2763

2764 Randomization (Visit 1: review of biopsy results – 10 minutes, randomization and treatment– 30
 2765 minutes)

2766 Based on your Pap smear and biopsy results, we have found cervical disease that needs
 2767 treatment. If you decide to participate in this study, we will offer you one of two common and
 2768 effective treatment methods. One method is called cryotherapy. It is a procedure which will freeze
 2769 and remove the diseased part of your cervix. We freeze by touching your cervix with a small stick
 2770 that is very cold. For cryotherapy, you will be offered an oral painkiller. The other method is called
 2771 LEEP and uses a heated wire to do the same thing after the cervix is numbed by medication. The
 2772 heated wire will scoop out the disease from the cervix.

2773 You will be randomly assigned to one of these methods. Random assignment is like
 2774 “flipping a coin.” You have an equal chance of receiving either of these methods. We won’t know
 2775 which treatment you will receive until we open an envelope that has a sheet of paper telling us which
 2776 treatment you will get. Neither of us will choose your treatment. We are randomly assigning one of

2777 these methods because we do not know if one treatment is better than another for women who have
2778 HIV.

2779 If we see that the diseased part of your cervix or ‘lesion’ is too large and cannot be treated
 2780 well by cryotherapy, then we will not randomize you and will choose to treat you with LEEP. You
 2781 will receive LEEP treatment free of charge and we will follow you every 6 months for 2 years. If the
 2782 lesion cannot be treated well by either cryotherapy or LEEP, then we will refer you to Kenyatta
 2783 National Hospital (KNH). At KNH you can receive different types of treatments at the lower cost of
 2784 a government hospital. We will send copies of forms with you that will be important for your care.
 2785 These forms will not show that you are part of a study. We will provide follow-up for you for 2 years
 2786 after your care at KNH. If you agree to be treated by either cryotherapy or LEEP at the study clinic, 2
 2787 teaspoons (10 mls) of your blood will be taken with a needle from your arm. We will check a CD4
 2788 count and the levels of HIV in your blood. We will also brush your cervix and later test the sample
 2789 for levels of HIV and for HPV. We would like to look at your medical records at the Hope Center.
 2790 We want to gather a full picture of your prescribed medications and medical condition, the results of
 2791 your laboratory tests, and your attendance in clinic.

2792 Follow-up after Randomization (Visits 2-8: review results and cervical swab – 30 minutes)

2793 If you are randomized to cryotherapy or LEEP, we will ask you to return again at the 1, 2,
 2794 and 3-week visits after treatment. At these visits, we will draw 2 teaspoons (10mls) of blood and
 2795 again brush your cervix to see how much HIV is there. We will want to see whether the level of virus
 2796 is increased in your cervix after treatment and when it returns to usual levels.

2797 If you are randomized or offered LEEP but not randomized, we will also ask you to return at
 2798 6, 12, 18, and 24 months after treatment for repeat Pap smears. This is to make sure that the diseased
 2799 part of your cervix was completely removed and/or no new abnormal tissue has formed. We will also
 2800 brush your cervix to test for HPV at this time and take 2 teaspoons (10 mls) of blood to measure your
 2801 CD4 count and HIV viral levels. If we find more abnormal lesions at this time, we will treat you with
 2802 LEEP or refer you for further care at KNH. The study will not pay for care you receive at KNH.

2803 Contacting Participants

2804 We will ask you to give us contact information like a phone number so we can call you if you
 2805 do not come to a scheduled visit. We may ask about your health or where you are during these calls.
 2806 It is important for you to come to all of your scheduled visits. We want to follow you carefully to
 2807 find and treat any cervical disease you might have or develop later on. If we cannot contact you by
 2808 phone, we may try to visit you at your house. If this happens, we will not wear clothes that show we
 2809 are health workers. You should tell us if you do not want to be contacted in this way.

2810

2811 **Risks and discomforts of being in the study**

2812 This is an explanation of problems you may have through your participation in this study. Other
 2813 problems not listed may happen as well.

2814 Treatment

2815 There may be risks or discomforts from receiving treatment. If you have cryotherapy, then
 2816 you may have:

2817• mild abdominal (or belly) cramps (usually last less than 10 minutes),

2818• fluid from the vagina for about 2 weeks (may last longer),

2819

2820• bleeding,

2821• infection that we will need to treat here at the clinic or in rare cases, at the hospital. Infection
2822 may cause fevers, chills, night sweats, or white fluid from the vagina.

2823 If you have LEEP, you may develop:

2824• bleeding during or after the procedure (you may have to return to the clinic if the bleeding starts
2825 and continues after the procedure is done)

2826• infection.

2827 All of these complications can be treated with medications or treatments that will be provided
2828 free of charge by the clinic. Possible treatments may include:

2829• antibiotic medications to treat infection,

2830• packing the vagina with bandages to stop bleeding,

2831• putting stitches in the cervix to stop bleeding or

2832• hospitalization for severe infection or bleeding.

2833 Please tell us if you have any of these problems after treatment. If you have received cryotherapy
2834 or LEEP, then we ask that you do not have sex for 4 weeks after it is performed. The reason is the
2835 same that your partner may be at greater risk of becoming infected with HIV. Also, you may be at
2836 greater risk of getting an infection. We can help you to discuss this with your partner.

2837 All participants who have treatment (cryotherapy or LEEP) will get a prescription for
2838 antibiotics. These antibiotics include doxycycline, metronidazole or norfloxacin.

2839 Effects of these antibiotics may include upset stomach (must avoid alcohol for 2 days),
2840 vomiting or diarrhea, sensitivity to light, rash, dizziness, headache, confusion, seizures (jerking of the
2841 body), heart problems, blood disorders, problems with blood sugar, problems, liver disease and pain
2842 or numbness in your legs or arms. Any reaction to medications should be reported right away to
2843 study staff.

2844 After having the treatment, there is a small chance that you may have problems later with
2845 pregnancy. After having LEEP, some women have problems when they are pregnant including
2846 infections, early contractions or problems with the cervix. Some women develop a tightened opening
2847 of their cervix that must be stretched. Other women have had their water break early or had babies
2848 born early possibly because of the operation on their cervix.

2849 Blood draw

2850 We will be collecting blood samples, 2 teaspoons (10 mls), from you using a new needle and
2851 syringe. The puncture of the needle may be uncomfortable and leave a bruise. It may also cause
2852 infection or fainting.

2853 Confidentiality

2857 may meet other patients from this clinic whom you know from outside the clinic. We have no plans
2858 to release your information to anyone other than the study researchers or appointed monitors.
2859 Sometimes committees that oversee research will examine study information to make sure nothing
2860 illegal or unethical is being done. Your personal information will be protected if this happens and
2861 will not be shown to anyone outside of this review. As the study sponsor, CDC may monitor or audit
2862 study activities. The reason for this would be to make sure that the study is being done the way it is
2863 supposed to be done. It would also make sure that your rights and health are protected. Your personal
2864 medical information will be kept confidential.

2865

2866 **Alternative to taking part in this study**

2867 If you choose not to take part in this study, you will continue to receive medical care at the
2868 Coptic Hope Center and free antiretroviral medications. You may also receive free cervical cancer
2869 screening at this clinic without having to enroll in this study. The Coptic Hope Clinic can provide
2870 you with Cryotherapy treatment even if you do not enroll in this study. We can also refer you to
2871 Kenyatta National Hospital for different types of treatments at the lower cost of a government
2872 hospital.

2873

2874 **Benefits of the study**

2875 Your participation will help us understand more about cervical disease. This may change the
2876 way cervical disease is found and treated in developing countries like Kenya. If you would like to
2877 know the results of the study you can contact the study office 6 months or 1 year after you leave the
2878 study.

2879

2880 **Compensation for injury**

2881 There is no cost to you for participating in this study other than your time. The study will pay
2882 for all screening and treatment costs for tests and therapy provided at the study clinic. If any physical
2883 injuries happen to you as a result of study participation, the study will cover the costs of care.
2884 Treatment includes antibiotics, pain relief, and methods to stop bleeding. If you think you have an
2885 injury or illness related to this study, contact the study staff (Dr. Michael Chung (020-272-2710) or
2886 Dr. Nelly Mugo (020-273-6744) or Dr. Evans Malava (0721 289 733) right away. They will treat you
2887 or refer you for treatment.

2888

2889 **Specimen and Data Storage and Use of your Samples for Future Studies**

2890 We would like to save your medical information and samples of your blood and cervix in
2891 Kenya at the Coptic Hospital and Kenyatta National Hospital for future research. This research may
2892 be done by the University of Washington or by other researchers who are working with us on this
2893 study for ten years after the end of follow-up in the study. We will use these data and samples only
2894 for research related to cervical cancer and HIV. Before your samples leave the clinic, they will be
2895 assigned a code. Your name will not be on them. Your name will be linked to the code only for five

2896 years after the study is completed. After that time, the link between your name and the code on your
 2897 samples and data will be destroyed. The Institutional Review Boards are committees that watch over
 2898 the safety and rights of research participants at Kenyatta National Hospital and the University of
 2899 Washington. They must approve any future research studies using your samples. If you do not want
 2900 to have your samples saved for future research, you can still be in this study and your samples will be
 2901 destroyed once testing for the study is completed. If you agree to store your samples now, but change
 2902 your mind before the end of the study, let the study staff know and we will make sure that your
 2903 samples do not get stored for future research. We will not sell your samples. Tests done on your
 2904 samples may lead to a new invention or discovery. We have no plans to share any money or other
 2905 benefits resulting from this invention or discovery with you.

2906

2907 **Other information**

2908 Your medical information is confidential (or kept secret) and we will keep your records in a
 2909 locked office. Your medical records and information about your participation in the research will be
 2910 available to you and to the study team but not to anyone outside of the study without your agreement.
 2911 If you agree, we will share the information from this study with your doctors at the Hope Center.
 2912 This information may help them treat your HIV and give you better care. Some of your samples
 2913 including blood and samples from the cervix may be sent to the USA or Europe for testing. Your
 2914 information and samples will still be protected if this happens. All of your records will be kept in
 2915 locked areas and all computer information will be password protected.

2916 University of Washington staff sometimes reviews studies such as this one to make sure they
 2917 are being done safely and legally. If a review of this study takes place, your records may be
 2918 examined.

2919 You may refuse to participate or may leave from the study at any time without penalty or loss
 2920 of benefit or help to which you have a right to. We will tell you if there is any new information about
 2921 the treatments we are studying so you can decide if you want to leave the study. Your relationship
 2922 with staff and services at Coptic Hope Center for Infectious Diseases will not be affected in any way
 2923 if you do or do not participate or if you enter the program and leave later. Please inform study staff if
 2924 you decide you would like to leave the study. You may be asked to give some final samples but you
 2925 may refuse.

2926 Study staff may decide to take you out the study if they find you may be harmed if you
 2927 continue to participate. You may also be taken out of the study if the staff think you will not be able
 2928 to follow study safety requirements.

2929 Transportation costs of Ksh 300 will be given to you when you return to the clinic for a
 2930 study-related visit. You will receive transport money from the study receptionist.

2931 Please contact Dr. Michael Chung (020 271-2947), Dr. Samah Sakr (020 272-4737), or Dr.
 2932 Nelly Mugo (020 273-6744) for questions about the study or to report any problems.

2933 Signature of study staff _____ Date _____

2934

2935 Printed name of study staff _____

2944

2945

2946 Please mark, initial and date one option:

2947 I DO agree to store my samples and data for future research

2948

2949 I DO NOT agree to store my samples and data for future research

2950

2951 Signature or thumbprint of participant _____

2952 Date _____

2953

2954 Printed name of participant _____

2955

2956 Copies to: Investigator and Subject

2957

2958

2959

2960

2961

2962 **MAKUBALIANO YA PAMOJA**

2963 **KISWAHILI CONSENT FORM**

2964 **MATIBABU YA SARATANI YA MLANGO WA KIZAZI: UCHUNGUZI**

2965 **IDHINI YA AWALI**

2966 **WATAFITI**

2967 Michael H Chung, MD. MPH, Mkufunzi, Idara ya utabibu, Chuo Kikuu cha Washington 272-2710

2968 Nelly Mugo, MBChB, MMed, MPH, Gainakolojia, Mhadhiri, Idara ya Ukunga na Gainakologia,
2969 Hospitali kuu ya Kenyatta, 020-273-6744

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2978 543-4278

2979

2980 Nambari za simu ya dharura; 072-2710 au 0733-711-288

2981 Mwenyekiti wa kamati ya uchunguzi wa maadili; Proffesa A. N. Guantai, 020 2726300, Ext. 44102,
2982 44355unaweza kuwasiliana naye kwa maswala ya utafiti na maadili ya washiriki wa utafiti huu.

2983

2984 **Ujumbe wa Watafiti**

2985 Tunakuuliza kushiriki katika utafiti huu wa kitaalamu. Lengo la fomu hii ya idhini ni kukupa
2986 habari itakayokufahamisha na kukusaidia kuamua kama ungelipenda kushiriki katika utafiti huu au la.
2987 Tafathali soma maelezo haya kwa makini. Unaweza kuuliza maswali kuhusu nia/kusudi ya utafiti
2988 huu; unavyohitajika kufanya katika utafiti, uwezekano wa kuwepo na madhara au manufaa yeyote,
2989 haki yako kama aliyejitolea, na mambo mengine kuhusu utafiti huu au chochote usicho elewa kwenye
2990 fomu hii. Tukishajibu maswali yako yote, unapaswa kuamua kushiriki kwenye utafiti huu au la.
2991 Kukubali kushiriki kwenye utafiti huu kwa hiari yako kunamaanisha kuwa umeelezwa na umeelewa
2992 yote yanayohusika na kukubaliana nayo. Ukipenda, tutakupa nakala ya fomu hii kujihifadhia.
2993 Tafadhali tujulishe iwapo ungependa kutumia lugha ya Kingereza.

2994 **Lengo la Utafiti huu.**

2995 Mathumuni ya mradi huu wa utafiti ni kukupima njia yako ya uzazi kuthibitisha ikiwa una
 2996 dalili inayoashiria kuwa unaweza kupata saratani ya mlango wa uzazi (cervical cancer). Umeulizwa
 2997 kushiriki katika utafiti huu kwa sababu;

- 2998• Umeambukizwa maradhi ya UKIMWI
- 2999• Unapata matibabu katika kituo cha matibabu cha Hope
- 3000• Hauna Mimba
- 3001• Hauna historia ya shida ya kuvuja damu
- 3002• Haujapata kutolewa sehemu yako ya uzazi (uterasi)
- 3003• Umewahi fanya ngono
- 3004

3005 Saratani ya aina hii huambukiza wanawake wengi wenye umri mdogo na hata wa makamu
 3006 nchini Kenya. Wanawake walioambukizwa na virusi vinavyosababisha ukimwi (HIV) wana hatari
 3007 kubwa ya kuambukizwa saratani ya mlango wa kizazi (cervical cancer), kuliko wanawake wengine
 3008 ambao bado hawajaambukizwa na HIV. Hata hivyo, kwa wanawake walioambukizwa na virusi
 3009 vinavyosababisha ukimwi, saratani ya mlango wa kizazi si ya kawaida. Lakini katika wanawake
 3010 walioambukizwa na virusi vinavyosababisha ukimwi, maambukizo ya mlango wa kizazi usio saratani
 3011 ya mlango wa kizazi ni wa kawaida. Maambukizo haya husababishwa na virusi vya “Papiloma”
 3012 (HPV). Ni muhimu kutambua na kutibu maambukizo haya kabla hayajageuka kuwa saratani ya
 3013 mlango wa kizazi.

3014 Utafiti huu utakupima mlango wako wa uzazi. Iwapo wachunguzi wakipata chembe chembe
 3015 zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango hiki, unaweza kujiunga na utafiti wa
 3016 matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza kutumwa upate
 3017 matibabu kwingine. Tutakuelezea njia za matibabu kabla hujaamua kujiunga na utafiti huo. Katika
 3018 utafiti huu, tutakuwa na washiriki takriban 2,400. Utafiti huu utatuwezesha kupima wanawake bila
 3019 malipo ili kuwawezesha wale wanoishi na virusi vinavyosababisha ukimwi (HIV) kuishi maisha bila
 3020 saratani ya mlango wa kizazi.

3021

3022 **Hatua ya kushiriki katika utafiti**

3023 Washirika wote watahitajika kutembelea kiliniki mara 1 au 2 au 3. Kila mara, mshirika atatumia
 3024 dakika 20 hadi 40 katika kiliniki.

3025

3026 **Uteuzi:** (Kutembelea kiliniki Mara Ya 1; Makubaliano - dakika 10, Pap Smear-dakika 20; Kutembelea
 3027 kiliniki Mara Ya 2; Marejeleo ya Matokeo ya Pap Smear- dakika 10, Colposcopy na Biopsy
 3028 (ikihitajika)- dakika 30; Kutembelea kiliniki mara ya 3; Marejeleo ya matokeo ya biopsy na kujadili juu
 3029 ya njia za matibabu- dakika 30)

3030

3031 **Kutembelea kiliniki mara ya 1:**

3032 Ukikubali kushiriki katika utafiti huu, kwanza utahitajika kuchunguzwa fupanyonga (Pelvic exam)
 3033 kwa kupanguzwa sehemu yako ya siri kutumia burashi ili kuthibitisha ikiwa una dalili inayoashiria
 3034 kuwa na virusi vinavyoweza kusababisha saratani ya mlango wa uzazi (Pap Smear). Kuchunguzwa
 3035 fupanyonga, kunamaanisha kuwa muuguzi atakagua sehemu zako za siri (uke wako). Pap smear

3036 itajumuisha utumiaji wa burashi ndogo iingizwayo kwenye kizazi ili kuchukua chembe chembe
3037 zitakazochunguzwa kwa kutumia “mikroskope”. Kisha utahitajika kurudi katika kiliniki baada ya
3038 majuma mawili ili kuchukua matokeo ya uchunguzi huu.

3039 Kutembelea kiliniki mara ya 2:

3040 Utarejea kwenye kiliniki baada ya wiki mbili ili kupata matokeo ya pap smear. Mara nyingi, matokeo
3041 huwa ni sawa (hakuna kasoro) na mtu hahitaji matibabu ya ziada, ila kurudia “Pap smear” tena baada
3042 ya kila miezi sita au kufanyaukaguzi na asidi asetiki (VIA) baada ya miezi sita. Ikiwa hujambo
3043 utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika Kiliniki ya ukaguzi wa
3044 Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre, [*Coptic Hope Cervical Cancer*
3045 *Screening Program (CCSP)*] ampapo utapokea VIA, au utaulizwa kurudi katika kiliniki ya utafiti
3046 baada ya miezi sita ili kurudia “Pap smear”.

3047 Wachunguzi wakipata chembe chembe zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango
3048 hiki, watakuzelea juu ya matibabu.

3049

3050 Lakini watafiti wakigundua chembe chembe zisizo za kawaida, watachunguza sehemu yako ya siri
3051 kwa makini. Kwanza utapimwa kama wewe ni mjamzito. Kama wewe ni mjamzito, Hakuna utafiti
3052 mwingine utaendelea hadi utakapojifungua mtoto. Watafiti watakutuma kupata matibabu ya dharura
3053 katika kituo cha Hope ili kuhakikisha hauambukizi mtoto wako virusi vinavyosababisha ukimwi
3054 (PMTCT). Kisha utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika
3055 Kiliniki ya ukaguzi wa Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre, [*Coptic*
3056 *Hope Cervical Cancer Screening Program (CCSP)*].

3057 Ikiwa wewe si mjamzito, watafiti wakigundua chembe chembe zisizo za kawaida,
3058 watachunguza sehemu yako ya siri kwa makini wakitumia chombo kiitwacho “colposcope”, ili
3059 kuchukua tishu, kiwango kama kipande kimoja cha mchele, utarabu huu unajulikana kama “Biopsy”.
3060 Tishu iliyochukuliwa, itachunguzwa kwa mikroskope na utajulishwa matokeo baada ya wiki nne hadi
3061 sita. Mwenendo huu wa kupima ambao majibu yake huwa ni sahihi utatuwezesha kujua kana kwamba
3062 unahitaji matibabu.

3063 Kuna chembe chembe za ndani ya njia ya kizazi katikati ya mlango wa kizazi na kizazi na pia
3064 zinaendelea mpaka ndani ya kizazi. Hizi chembe chembe zinaitwa ‘glandular cells’. Ikiwa majibu ya
3065 pap smear itaonyesha ‘glandular’ cells si kawaida, daktari ata gwaruza kwa njia ya kizazi kutumia
3066 chombo chenye umbo cha kijiko ili sampuli ndogo ipatikane ya kukaguliwa. Utaratibu huu unaitwa
3067 ‘Endocervical curettage (ECC)’. Kukwaruza inafanywa wakati ‘colposcopy’ na inachukuwa dakika
3068 chache. Unaweza pata maumivu ya tumbo kidogo kama wakati unapo pata damu ya mwezi. Pia,
3069 kama chembe chembe za mlango wa kizazi kwa pap smear inaonyesha si kawaida na mabadiliko ya
3070 ugonjwa kwa mlango wa kizazi wakati wa colposcopy haionekani, hii kukwaruza itafanywa kama
3071 vile imeelezwa hapo mbeleni.

3072 Kutembelea kiliniki mara ya 3:

3073 Utarejea kwenye kiliniki kati ya wiki nne na wiki sitaili kupata matokeo ya biopsy. Iwapo tutagundua
3074 maambukizi yanayohitaji matibabu, tutakujulisha matibabu ambayo unaweza pata. Unaweza kujiunga
3075 na utafiti wa matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza chagua
3076 matibabu kwingine, au tunaweza kukutuma Hospitali Kuu ya Kenyatta (KNH) na uendeleo kupokea

3077 matibabu yako ya kawaida katika Coptic Hope Center.Ukichagua kuendelea na utafiti wa matibabu
3078 au la, katika kiwango hii, tutakuondoa katika utafiti wa kupimwa mlango wa kizazi.

3079 Tutatumia rekodi zako za afya ziliko HOPE Center ili kukusanya habari zote kuhusu afya
3080 yako ili kuelewa vyema dawa ambazo umekuwa ukitumia, hali ya afya yako kwa sasa na majibu ya
3081 vipimo kutoka maabara na pia jinsi umekuwa ukihudhuria kliniki.

3082

3083

3084 Kuwasiliana na Washiriki

3085 Tutakuuliza utupatie jinsi ya kuwasiliana nawe kama vile nambari yako ya simu ili tuweze
3086 kukupigia usipotembelea kiliniki kama ilivyopangwa. Tunaweza kukuuliza kuhusu afya yako au
3087 ulipokuwa katika mawasiliano haya. Ni muhimu kwako kutembelea kiliniki kama ilivyopangwa.
3088 Iwapo hatuwezi kuwasiliana nawe kwa njia ya simu, tunaweza kukutembelea kwako nyumbani.
3089 Iwapo tutakutembelea kwako nyumbani, hatutavalia mavazi yatakayoashiria kuwa sisi ni wahudumu
3090 katika hospitali. Unaweza kutuarifu iwapo hupendi njia hii ya mawasiliano.Usiporejea kupokea
3091 matokeo yako ya pap smear au biospy, tutawasiliana na wafanyi kazi wa mapokezi ya Coptic waweke
3092 mawaidha kwa faili yako ili unaporejea kwa matibabu yako ya kawaida, utakumbushwa kupitia
3093 kwenye kiliniki ya utafiti kupokea matokeo yako.

3094 Kamataratibu zakudhibiti ubora wautafitizinaonyesha
3095 kuwaPapsmearyakomatokeonitofautinamotokeoya awali uliyo pewa,tutakuuliza
3096 urudiklinikikupokeamotokeo yakompya nakujadilimatibabu inayowezekana.Katika hatua hii,unaweza
3097 kuulizwakamaungependakujiandikisha tena katikautafiti.

3098

3099 **Athari na usumbufu wa kushiriki kwenye utafiti huu.**

3100 Haya ni maelezo ya athari na usumbufu unayoweza kukumbana nayo kwa kushiriki katika utafiti huu.
3101 Athari na usumbufu mwingine ambao haujatajwa unaweza kutokea pia.

3102

3103 Kiingilio (Screening)

3104 Kuchukua sampuli kutoka kwenye fupanyonga (pelvic) kwaweza sababisha;

- 3105• kukerwa kidogo wakati ukaguzi ukiendelea,
 - 3106• kutokwa na damu kidogo kwenye uke wako baadaye kwa siku moja au mbili, na
 - 3107• kupata uchungu mdogo wa tumbo kama ule wa damu ya mwezi kwa dakika tano hivi.
- 3108

3109 Ukifanyiwa uchunguzi wa “Biopsy” kwenye fupanyonga (Pelvic), tunakusihi usishiriki ngono kwa
3110 muda wa siku kumi. Hii ni kwa sababu ikiwa una virusi vinavyosababisha ukimwi na (HIV) ili hali
3111 mpenzi hana, atakuwa katika hatari kubwa zaidi ya kuambukizwa na virusi hivi vya ukimwi. Ikiwa
3112 mpenzi wako ana virusi vinavyosababisha ukimwi, atakuwa katika hatari kubwa ya kuambukizwa
3113 tena na virusi stahimilivu vinavyosababisha ukimwi. Pia, wewe unahitaji muda wa kupona na
3114 utajiweka katika hatari ya maambukizi usipojipatia muda huu. Iwapo unahitaji msaada wowote wa

3115 kuongelea mambo haya na mpenzi wako, muuguzi, daktari au mshaurikatika hospital atakusaidia.

3116 Tutakupatia mipira ya kondomu bila malipo iwapo hutaweza kutoshiriki katika ngono.

3117 Athari nyengine unayoweza kukumbana nayo ni wasiwasiya kuwa una ugonjwa katika
3118 mlango wako wa uzazi. Unaweza kuongea kuhusu jambo hili na muuguzi wa kitafiti, daktari, au
3119 ukitaka kuongea na mshaurikatika hospitali, tutakusaidia kupanga haya.

3120 Tunaweza kugundua katika kiingilio kuwa una maambukizo. Iwapo utapatikana na
3121 maambukizo, tutakupa maagizo ya kupata dawa. Madhara ya dawa hizi yanaweza kuwa kuumwa na
3122 tumbo, kutapika na kuharisha, usikivu wa mwangaza, mwasho, mzio mkali mmenyuko unaoweza
3123 kusababisha kifo, kizunguzungu, kuumwa na kichwa, kuchanganyikiwa, kupigapiga kwenyemasikio
3124 au kupoteza usikivu, mshtuko wa mwili (jerking of the body), maumivu ya moyo, machafuko ya
3125 damu, shida ya kisukari, ugonjwa wa maini, ugonjwa wa figo na uchungu au kuganda kwenye
3126 mikono na miguu. Ikiwa utahisi mojawepo ya athari hizi, mfahamishe mkaguzi katika utafiti huu
3127 mara moja.

3128 **Uwekaji wa siri**

3129 Wahudumu katika utafiti huu, watakusanya habari ya binafsi na waweza kuona aibu kuongea
3130 kuhusu habari zako za ndani kama vile; idadi ya wapenzi ambao ushakuwa nao. Unaweza kuchagua
3131 kutojibu maswali yoyote. Pia, ukija kiliniki, waweza kukutana na wagonjwa wengine ambao
3132 umewajua mbeleni. Hatuna mpango wa kupeana habari yako ya kibinafsi kwamtu yeyote nje ya utafiti
3133 huu isipokuwa watafiti au wachunguzi walioteuliwa. Wakati mwingine kamati inayosimamia utafiti
3134 huu watachunguza habari ya utafiti huu ili kuhakikisha hakuna jambo lolote ambalo ni kinyume na
3135 sheria au kinyume na maadili litakalotendwa. Habari yako ya kibinafsi italindwa ipasavyo ikiwa
3136 hayo yatatendeka na hakuna mtu yeyote atakayeona habari hiyo nje ya uchunguzi
3137 huu. Kamamdamini watafiti, CDC wanaweza kufuatilia au kukaguashughuli zautafiti. Sababu
3138 hii itakuwahakikishakuwa utafiti unafanyika kwanji inayotakiwa, napia kuhakikishakwamba
3139 hakiyakonaafya yako inalindwa. Matibabuyakotaarifa binafsi itakuwasiri.

3140 **Mbadala wa kujiunga na utafiti huu**

3141 Ukichagua kutoshiriki kwenye utafiti huu, utaendelea kuhudumiwa kikamilifu na kupata
3142 matibabu na dawa za ART kutoka “Coptic Hope Centre” bila malipo. Unaweza pia kupata uchunguzi
3143 wa saratani ya mlango wa nyumba ya uzazi bila malipo yeyote katika kiliniki hii bila kushiriki katika
3144 utafiti huu.

3145 **Manufaa kutokana na utafiti huu**

3146 Kushiriki kwako katika utafiti huu, kutatuwezesha kuelewa zaidi kuhusu ugonjwa wa mlango wa
3147 nyumba ya uzazi. Kwa kujiunga na utafiti huu, utapata kupimwa mlango wako wa uzazi bila malipo.
3148 Kama ungependa kujua matokeo ya utafiti huu, unaweza kuwasiliana na ofisi ya utafiti huu miezi sita
3149 au mwaka mmoja baada ya kumaliza utafiti huu.

3150 **Gharama na Fidia ya Majeraha**

3151 Hakuna gharama yoyote ya kushiriki katika utafiti huu, ila muda wako pekee. Utafiti huu
3152 utalipia gharama ya uchunguzi wowote utakayopokea kwenye kiliniki ya utafiti. Ikiwa utapata
3153 majeraha kutokana na kushiriki katika utafiti huu, utafiti huu utafidia gharama yote ya malipo ya
3154 utunzaji. Ikiwa unafikiri kuwa umepata jeraha ama maumivu kutokana na utafiti huu, wasiliana na
3155 wahudumu wa utafiti huu, (Daktari Michael Chung (020-272-2710) au Daktari Nelly Mugo (020-273-

3156 6744) au Daktari Evans Malava (0721 289 733)) mara moja. Watakuhudumia kwa matibabu au
3157 kukupendekeza kwa matibabu.

3158 **Kuhifadhi kwa Sampuli na Data na Matumizi ya sampuli hizi kwa utafiti wa baadaye**

3159 Tungependa kuhifadhi habari yako ya matibabu na sampuli za pap smear na biopsy katika
3160 Hospitali ya Coptic na katika Hospitali kuu ya Kenyatta kwa madhumuni ya utafiti wa baadaye.
3161 Utafiti huu waweza kufanywa na Chuo kikuu cha Washington au na watafiti wengine wanaofanya
3162 kazi nasi katika utafiti huu kwa muda wa miaka kumi baada ya mwisho wa kufuatiliwa katika utafiti.
3163 Tutatumia data na sampuli hizi kwa minajili ya utafiti unaogemea na saratani ya mlango wa kizazi
3164 na UKIMWI. Kabla sampuli yako kutoka kwenye kiliniki, itapewa kifichomaalumu Jina lako
3165 halitakuwemo. Jina lako litahusishwa na kificho hiki kwa miaka mitano pekee yake baada ya
3166 kukamilisha utafiti huu. Baada ya muda huu, kihusishi baina ya jina lako na kificho kilichoko katika
3167 sampuli na data kitaangamizwa. Bodi za taasisi ya mapitio ni kamati zinazoagalia usalama na haki za
3168 washiriki wa utafiti katika Hospitali kuu ya Kenyatta na Chuo kikuu cha Washington. Lazima
3169 ziidhinishe utafiti wowote wa baadaye utakaotumia sampuli na data yako. Ikiwa hupendi sampuli
3170 zako zihifadhiwe kwa minajili ya utafiti wa baadaye, unaweza kushiriki katika utafiti huu na sampuli
3171 zako zitaharibiwa mara tu uchunguzi utakapokamilika. Ukikubali uhufadhi wa sampuli zako leo,
3172 kisha ubadilishe nia yako baadaye kabla ya utafiti kukamilika, wafahamisha watafiti ambao
3173 watahakikisha kuwa sampuli zako hazitahifadhiwa kwa minajili ya utafiti wa baadaye. Hatutauza
3174 sampuli zako. Uchunguzi utakao fanya kwenye sampuli zako waweza kutuelekeza katika uvumbuzi
3175 mpya. Hatuna mpango wowote wa kugawana nawe pesa zozote au faida nyinginezo zitakazotokana
3176 na uvumbuzi huu -

3177 **Maelezo ya ziada**

3178 Habari kuhusu utambuzi wa ugonjwa wako ni siri na tutaweka rekodi ya afya yako kwa afisi
3179 inayofungwa. Habari kuhusu uchunguzi na ushiriki wako kwenye utafiti huu utatolewa kwako na
3180 kikundi cha watafiti pekee wala si mtu mwingine yeyote nje ya utafiti huu bila idhini yako. Ikiwa
3181 utapeana idhini, tutawafahamisha habari yako daktari wa Coptic Hope Center. Habari hii inaweza
3182 kuwasaidia kukupa matibabu na huduma bora ya UKIMWI. Rekodi zako zote zitahifadhiwa katika
3183 sehemu zilizofungwa na kifuli na tarakilishi zote zitakuwa zina neno la siri la kuhakikisha ulinzi.

3184 Wakati mwingine, wafanyikazi wa chuo kikuu cha Washington wanakagua utafiti kama huu
3185 ili kuhakikisha unafanywa kwa njia inayofaa na iliyo halali. Ikiwa ukaguzi wa utafiti huu utafanyika,
3186 rekodi zako zaweza kuchunguzwa. Waweza kukataa kushiriki au waweza kuondoka kwenye
3187 utafiti huu wakati wowote bila kuadhibiwa au kupoteza faida iliyokuwa haki yako. Tutakueleza ikiwa
3188 kuna habari geni zinazohusu matibabu ambayo tunatafiti ili uweze kuamua iwapo utajiondoa kwenye
3189 utafiti huu. Uhusiano wako na wafanyikazi wa huduma za Coptic Hope Centre for infectious diseases,
3190 hautaadhiriwa kwa vyovyote ikiwa utakubali kushiriki kwenye utafiti huu ama ukiingia kwenye
3191 mpangilio halafu baadaye uondoke kabla ya kumaliza uchunguzi. Tafadhali wafahamisha wahudumu
3192 wa utafiti huu ikiwa utaamua kuondoka katika utafiti huu. Unaweza kuulizwa kupeana sampuli za
3193 mwisho lakini waweza kukataa.

3194 Wahudumu katika utafiti huu wanaweza kuamua kukuondoa kwenye utafiti huu wakigundua
3195 kuwa unaweza kupata madhara ukiendelea kushiriki. Unaweza kuondolewa kwenye utafiti huu ikiwa
3196 wahudumu watagundua kuwa huwezi kufuata masharti ya usalama.

3197 Maswali yeyote kuhusu utafiti huu, ama athari mbaya kutokana na uchunguzi huu yapaswa
 3198 kuelekezwa kwa mtafiti anayekuhudumia au Daktari Michael Chung (272-2710), Daktari Samah Sakr
 3199 (272-4737), au Daktari Nelly Mugo (273-6744).

3200 **Je, una maswali yeyote?**

3201 Sahihi ya mtafiti..... Tarehe.....

3202

3203 Jina la Mtafiti.....

3204 **Mhusika**

3205 Nimeelezwa juu ya utafiti huu. Najitolea kwa hiari kushiriki kwenye utafiti huu. Nimewapa
 3206 watafiti ruhusa ya kutumia rekodi zangu za utabibu kama ilivyopendekezwa kwenye fomu hii ya
 3207 makubaliano. Nimekuwa na fursa ya kuuliza maswali. Nikiwa na maswali yeyote kuhusu utafiti huu
 3208 baadaye, naweza kumuuliza mojawapo wa watafiti waliotajwa kwenye fomu hii. Nikiwa na maswali
 3209 kuhusu haki yangu kama mhusika kwenye utafiti, naweza piga simu kwa kamati ya uchunguzi wa
 3210 maadili walioko Hospitali kuu ya Kenyatta kwa kutumia nambari 020-726-300. Nikitaka, nitapewa
 3211 nakala ya fomu hii yangu binafsi.

3212 Tafadhali tia alama, ufupi wa jina na anwani katika chaguo moja:

3213 _____Nimekubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

3214

3215 _____Sijakubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

3216

3217 Sahihi au alama ya kidole cha gumba cha mshiriki _____

3218

3219 Tarehe_____

3220

3221 Jina la Mshiriki lililochapishwa_____

3222

3223 Nakala kwa Mtafiti na Mshiriki

- 3224 **MAKUBALIANO YA PAMOJA**
- 3225 **KISWAHILI CONSENT FORM**
- 3226 **MATIBABU YA SARATANI YA MLANGO WA KIZAZI: UCHUNGUZI**
- 3227 **UANDIKISHAJI UPYA**
- 3228 **WATAFITI**
- 3229 Michael H Chung, MD. MPH, Mkufunzi, Idara ya utabibu, Chuo Kikuu cha Washington 272-2710
- 3230 Nelly Mugo, MBChB, MMed, MPH, Gainakolojia, Mhadhiri, Idara ya Ukunga na Gainakologia,
3231 Hospitali kuu ya Kenyatta, 020-273-6744
- 3232 Sarah Sakr, MBChB, Msimamizi wa afya, Hospitali ya Coptic, Kenya 020-272-4737
- 3233 Hugo De Vuyst, MD, PhD, Epidemiologisti, Idara ya Kimataifa ya Utafiti wa Saratani, Shirika la
3234 Afya la Dunia (WHO), +33-472738521
- 3235 Silvia Franceschi, MD, Epidemiologisti, Idara ya Kimataifa ya Utafiti wa Saratani, Shirika la Afya la
3236 Dunia (WHO), +33-4728404
- 3237 Barbara Richardson, PhD, Profesa Msaidizi katika Utafiti, Idara ya Biostatistiki, Chuo Kikuu cha
3238 Washington, +1-206-731-2425
- 3239 Grace John Stewart, MD, PhD, Profesa, Kitivo Cha Utabibu, Chuo Kikuu Cha Washington, +1-206-
3240 543-4278
- 3241
- 3242 Nambari za simu ya dharura; 072-2710 au 0733-711-288
- 3243 Mwenyekiti wa kamati ya uchunguzi wa maadili; Proffesa A. N. Guantai, 020 2726300, Ext. 44102,
3244 44355unaweza kuwasiliana naye kwa maswala ya utafiti na maadili ya washiriki wa utafiti huu.
- 3245
- 3246 **Ujumbe wa Watafiti**
- 3247 Tunakuuliza kushiriki katika utafiti huu wa kitaalamu. Lengo la fomu hii ya idhini ni kukupa
3248 habari itakayokufahamisha na kukusaidia kuamua kama ungelipenda kushiriki katika utafiti huu au la.
3249 Tafathali soma maelezo haya kwa makini. Unaweza kuuliza maswali kuhusu nia/kusudi ya utafiti
3250 huu; unavyohitajika kufanya katika utafiti, uwezekano wa kuwepo na madhara au manufaa yeyote,
3251 haki yako kama aliyejitolea, na mambo mengine kuhusu utafiti huu au chochote usicho elewa kwenye
3252 fomu hii. Tukishajibu maswali yako yote, unapaswa kuamua kushiriki kwenye utafiti huu au la.
3253 Kukubali kushiriki kwenye utafiti huu kwa hiari yako kunamaanisha kuwa umeelezwa na umeelewa
3254 yote yanayohusika na kukubaliana nayo. Ukipenda, tutakupa nakala ya fomu hii kujihifadhia.
3255 Tafadhali tujulishe iwapo ungependa kutumia lugha ya Kingereza.
- 3256 **Lengo la Utafiti huu.**

3257 Mathumuni ya mradi huu wa utafiti ni kukupima njia yako ya uzazi kuthibitisha ikiwa una
 3258 dalili inayoashiria kuwa unaweza kupata saratani ya mlango wa uzazi (cervical cancer). Umeulizwa
 3259 kushiriki katika utafiti huu kwa sababu;

- 3260• Umeambukizwa maradhi ya UKIMWI
- 3261• Unapata matibabu katika kituo cha matibabu cha Hope
- 3262• Hauna Mimba
- 3263• Hauna historia ya shida ya kuvuja damu
- 3264• Haujapata kutolewa sehemu yako ya uzazi (uterasi)
- 3265• Umewahi fanya ngono
- 3266

3267 Saratani ya aina hii huambukiza wanawake wengi wenye umri mdogo na hata wa makamu
 3268 nchini Kenya. Wanawake walioambukizwa na virusi vinavyosababisha ukimwi (HIV) wana hatari
 3269 kubwa ya kuambukizwa saratani ya mlango wa kizazi (cervical cancer), kuliko wanawake wengine
 3270 ambao bado hawajaambukizwa na HIV. Hata hivyo, kwa wanawake walioambukizwa na virusi
 3271 vinavyosababisha ukimwi, saratani ya mlango wa kizazi si ya kawaida. Lakini katika wanawake
 3272 walioambukizwa na virusi vinavyosababisha ukimwi, maambukizo ya mlango wa kizazi usio saratani
 3273 ya mlango wa kizazi ni wa kawaida. Maambukizo haya husababishwa na virusi vya “Papiloma”
 3274 (HPV). Ni muhimu kutambua na kutibu maambukizo haya kabla hayajageuka kuwa saratani ya
 3275 mlango wa kizazi.

3276 Utafiti huu utakupima mlango wako wa uzazi. Iwapo wachunguzi wakipata chembe chembe
 3277 zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango hiki, unaweza kujiunga na utafiti wa
 3278 matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza kutumwa upate
 3279 matibabu kwingine. Tutakuelezea njia za matibabu kabla hujaamua kujiunga na utafiti huo. Katika
 3280 utafiti huu, tutakuwa na washiriki takriban 2,400. Utafiti huu utatuwezesha kupima wanawake bila
 3281 malipo ili kuwawezesha wale wanoishi na virusi vinavyosababisha ukimwi (HIV) kuishi maisha bila
 3282 saratani ya mlango wa kizazi.

3283

3284 **Hatua ya kushiriki katika utafiti**

3285 Washirika wote watahitajika kutembelea kiliniki mara 1 au 2 au 3. Kila mara, mshirika atatumia
 3286 dakika 20 hadi 40 katika kiliniki.

3287

3288 **Uteuzi:** (Kutembelea kiliniki Mara Ya 1; Makubaliano - dakika 10, Pap Smear-dakika 20; Kutembelea
 3289 kiliniki Mara Ya 2; Marejeleo ya Matokeo ya Pap Smear- dakika 10, Colposcopy na Biopsy
 3290 (ikihitajika)- dakika 30; Kutembelea kiliniki mara ya 3; Marejeleo ya matokeo ya biopsy na kujadili juu
 3291 ya njia za matibabu- dakika 30)

3292

3293 **Kutembelea kiliniki mara ya 1:**

3294 Ukikubali kushiriki katika utafiti huu, kwanza utahitajika kuchunguzwa fupanyonga (Pelvic exam)
 3295 kwa kupanguzwa sehemu yako ya siri kutumia burashi ili kuthibitisha ikiwa una dalili inayoashiria
 3296 kuwa na virusi vinavyoweza kusababisha saratani ya mlango wa uzazi (Pap Smear). Kuchunguzwa
 3297 fupanyonga, kunamaanisha kuwa muuguzi atakagua sehemu zako za siri (uke wako). Pap smear

3298 itajumuisha utumiaji wa burashi ndogo iingizwayo kwenye kizazi ili kuchukua chembe chembe
3299 zitakazochunguzwa kwa kutumia “mikroskope”. Kisha utahitajika kurudi katika kiliniki baada ya
3300 majuma mawili ili kuchukua matokeo ya uchunguzi huu.

3301 Kutembelea kiliniki mara ya 2:

3302 Utarejea kwenye kiliniki baada ya wiki mbili ili kupata matokeo ya pap smear. Mara nyingi, matokeo
3303 huwa ni sawa (hakuna kasoro) na mtu hahitaji matibabu ya ziada, ila kurudia “Pap smear” tena baada
3304 ya kila miezi sita au kufanyaukaguzi na asidi asetiki (VIA) baada ya miezi sita. Ikiwa hujambo
3305 utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika Kiliniki ya ukaguzi wa
3306 Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre, [*Coptic Hope Cervical Cancer*
3307 *Screening Program (CCSP)*] ampapo utapokea VIA, au utaulizwa kurudi katika kiliniki ya utafiti
3308 baada ya miezi sita ili kurudia “Pap smear”.

3309 Wachunguzi wakipata chembe chembe zisizo za kawaida ambazo zinahitaji kutibiwa katika kiwango
3310 hiki, watakuelezea juu ya matibabu.

3311

3312 Lakini watafiti wakigundua chembe chembe zisizo za kawaida, watachunguza sehemu yako ya siri
3313 kwa makini. Kwanza utapimwa kama wewe ni mjamzito. Kama wewe ni mjamzito, Hakuna utafiti
3314 mwingine utaendelea hadi utakapojifungua mtoto. Watafiti watakutuma kupata matibabu ya dharura
3315 katika kituo cha Hope ili kuhakikisha hauambukizi mtoto wako virusi vinavyosababisha ukimwi
3316 (PMTCT). Kisha utaondoka utafitini katika kiwango hiki na kupokea matibabu mengine katika
3317 Kiliniki ya ukaguzi wa Ugonjwa wa saratani ya mlango wa kizazi ya Coptic Hope Centre, [*Coptic*
3318 *Hope Cervical Cancer Screening Program (CCSP)*].

3319 Ikiwa wewe si mjamzito, watafiti wakigundua chembe chembe zisizo za kawaida,
3320 watachunguza sehemu yako ya siri kwa makini wakitumia chombo kiitwacho “colposcope”, ili
3321 kuchukua tishu, kiwango kama kipande kimoja cha mchele, utarabu huu unajulikana kama “Biopsy”.
3322 Tishu iliyochukuliwa, itachunguzwa kwa mikroskope na utajulishwa matokeo baada ya wiki nne hadi
3323 sita. Mwenendo huu wa kupima ambao majibu yake huwa ni sahihi utatuwezesha kujua kana kwamba
3324 unahitaji matibabu.

3325 Kuna chembe chembe za ndani ya njia ya kizazi katikati ya mlango wa kizazi na kizazi na pia
3326 zinaendelea mpaka ndani ya kizazi. Hizi chembe chembe zinaitwa ‘glandular cells’. Ikiwa majibu ya
3327 pap smear itaonyesha ‘glandular’ cells si kawaida, daktari ata gwaruza kwa njia ya kizazi kutumia
3328 chombo chenye umbo cha kijiko ili sampuli ndogo ipatikane ya kukaguliwa. Utaratibu huu unaitwa
3329 ‘Endocervical curettage (ECC)’. Kukwaruza inafanywa wakati ‘colposcopy’ na inachukuwa dakika
3330 chache. Unaweza pata maumivu ya tumbo kidogo kama wakati unapo pata damu ya mwezi. Pia,
3331 kama chembe chembe za mlango wa kizazi kwa pap smear inaonyesha si kawaida na mabadiliko ya
3332 ugonjwa kwa mlango wa kizazi wakati wa colposcopy haionekani, hii kukwaruza itafanywa kama
3333 vile imeelezwa hapo mbeleni.

3334 Kutembelea kiliniki mara ya 3:

3335 Utarejea kwenye kiliniki kati ya wiki nne na wiki sitaili kupata matokeo ya biopsy. Iwapo tutagundua
3336 maambukizi yanayohitaji matibabu, tutakujulisha matibabu ambayo unaweza pata. Unaweza kujiunga
3337 na utafiti wa matibabu ya ugonjwa unaosababisha saratani ya mlango wa uzazi, ama unaweza chagua
3338 matibabu kwingine, au tunaweza kukutuma Hospitali Kuu ya Kenyatta (KNH) na uendeleo kupokea

3339 matibabu yako ya kawaida katika Coptic Hope Center.Ukichagua kuendelea na utafiti wa matibabu
3340 au la, katika kiwango hii, tutakuondoa katika utafiti wa kupimwa mlango wa kizazi.

3341 Tutatumia rekodi zako za afya ziliko HOPE Center ili kukusanya habari zote kuhusu afya
3342 yako ili kuelewa vyema dawa ambazo umekuwa ukitumia, hali ya afya yako kwa sasa na majibu ya
3343 vipimo kutoka maabara na pia jinsi umekuwa ukihudhuria kliniki.

3344

3345

3346 Kuwasiliana na Washiriki

3347 Tutakuuliza utupatie jinsi ya kuwasiliana nawe kama vile nambari yako ya simu ili tuweze
3348 kukupigia usipotembelea kiliniki kama ilivyopangwa. Tunaweza kukuuliza kuhusu afya yako au
3349 ulipokuwa katika mawasiliano haya. Ni muhimu kwako kutembelea kiliniki kama ilivyopangwa.
3350 Iwapo hatuwezi kuwasiliana nawe kwa njia ya simu, tunaweza kukutembelea kwako nyumbani.
3351 Iwapo tutakutembelea kwako nyumbani, hatutavalia mavazi yatakayoashiria kuwa sisi ni wahudumu
3352 katika hospitali. Unaweza kutuarifu iwapo hupendi njia hii ya mawasiliano.Usiporejea kupokea
3353 matokeo yako ya pap smear au biospy, tutawasiliana na wafanyi kazi wa mapokezi ya Coptic waweke
3354 mawaidha kwa faili yako ili unaporejea kwa matibabu yako ya kawaidia, utakumbushwa kupitia
3355 kwenye kiliniki ya utafiti kupokea matokeo yako.

3356 Kamataratibu zakudhibiti ubora wautafitizinaonyesha
3357 kuwaPapsmearyakomatokeonitofautinamotokeoya awali uliyo pewa,tutakuuliza
3358 urudiklinikikupokeamotokeo yakompya nakujadilimatibabu inayowezezana.Katika hatua hii,unaweza
3359 kuulizwakamaungependakujiandikisha tena katikautafiti.

3360

3361

3362 **Athari na usumbufu wa kushiriki kwenye utafiti huu.**

3363 Haya ni maelezo ya athari na usumbufu unayoweza kukumbana nayo kwa kushiriki katika utafiti huu.
3364 Athari na usumbufu mwingine ambao haujatajwa unaweza kutokea pia.

3365

3366 Kiingilio (Screening)

3367 Kuchukua sampuli kutoka kwenye fupanyonga (pelvic) kwaweza sababisha;

- 3368• kukerwa kidogo wakati ukaguzi ukiendelea,
 - 3369• kutokwa na damu kidogo kwenye uke wako baadaye kwa siku moja au mbili, na
 - 3370• kupata uchungu mdogo wa tumbo kama ule wa damu ya mwezi kwa dakika tano hivi.
- 3371

3372 Ukifanyiwa uchunguzi wa “Biopsy” kwenye fupanyonga (Pelvic), tunakusihi usishiriki ngono kwa
3373 muda wa siku kumi. Hii ni kwa sababu ikiwa una virusi vinavyosababisha ukimwi na (HIV) ili hali
3374 mpenzi hana, atakuwa katika hatari kubwa zaidi ya kuambukizwa na virusi hivi vya ukimwi. Ikiwa
3375 mpenzi wako ana virusi vinavyosababisha ukimwi, atakuwa katika hatari kubwa ya kuambukizwa
3376 tena na virusi stahimilivu vinavyosababisha ukimwi. Pia, wewe unahitaji muda wa kupona na

3377 utajiweka katika hatari ya maambukizi usipojipatia muda huu. Iwapo unahitaji msaada wowote wa
 3378 kuongelea mambo haya na mpenzi wako, muuguzi, daktari au mshaurikatika hospital atakusaidia.
 3379 Tutakupatia mipira ya kondomu bila malipo iwapo hutaweza kutoshiriki katika ngono.

3380 Athari nyengine unayoweza kukumbana nayo ni wasiwasiya kuwa una ugonjwa katika
 3381 mlango wako wa uzazi. Unaweza kuongea kuhusu jambo hili na muuguzi wa kitafiti, daktari, au
 3382 ukitaka kuongea na mshaurikatika hospitali, tutakusaidia kupanga haya.

3383 Tunaweza kugundua katika kiingilio kuwa una maambukizo. Iwapo utapatikana na
 3384 maambukizo, tutakupa maagizo ya kupata dawa. Madhara ya dawa hizi yanaweza kuwa kuumwa na
 3385 tumbo, kutapika na kuharisha, usikivu wa mwangaza, mwasho, mzio mkali mmenyuko unaoweza
 3386 kusababisha kifo, kizunguzungu, kuumwa na kichwa, kuchanganyikiwa, kupigapiga kwenyemasikio
 3387 au kupoteza usikivu, mshtuko wa mwili (jerking of the body), maumivu ya moyo, machafuko ya
 3388 damu, shida ya kisukari, ugonjwa wa maini, ugonjwa wa figo na uchungu au kuganda kwenye
 3389 mikono na miguu. Ikiwa utahisi mojawepo ya athari hizi, mfahamishe mkaguzi katika utafiti huu
 3390 mara moja.

3391 **Uwekaji wa siri**

3392 Wahudumu katika utafiti huu, watakusanya habari ya binafsi na waweza kuona aibu kuongea
 3393 kuhusu habari zako za ndani kama vile; idadi ya wapenzi ambao ushakuwa nao. Unaweza kuchagua
 3394 kutojibu maswali yoyote. Pia, ukija kiliniki, waweza kukutana na wagonjwa wengine ambao
 3395 umewajua mbeleni. Hatuna mpango wa kupeana habari yako ya kibinafsi kwamtu yeyote nje ya utafiti
 3396 huu isipokuwa watafiti au wachunguzi walioteuliwa. Wakati mwingine kamati inayosimamia utafiti
 3397 huu watachunguza habari ya utafiti huu ili kuhakikisha hakuna jambo lolote ambalo ni kinyume na
 3398 sheria au kinyume na maadili litakalotendwa. Habari yako ya kibinafsi italindwa ipasavyo ikiwa
 3399 hayo yatatendeka na hakuna mtu yeyote atakayeona habari hiyo nje ya uchunguzi
 3400 huu. Kamamdamini watafiti, CDC wanaweza kufuatilia ukukaguashughuli zautafiti. Sababu
 3401 hii itakuwahakikishakuwa utafiti unafanyika kwanji inayotakiwa, napia kuhakikishakwamba
 3402 hakiyakona afya yako inalindwa. Matibabu yako tarifa binafsi itakuwasiri.

3403 **Mbadala wa kujiunga na utafiti huu**

3404 Ukichagua kutoshiriki kwenye utafiti huu, utaendelea kuhudumiwa kikamilifu na kupata
 3405 matibabu na dawa za ART kutoka “Coptic Hope Centre” bila malipo. Unaweza pia kupata uchunguzi
 3406 wa saratani ya mlango wa nyumba ya uzazi bila malipo yeyote katika kiliniki hii bila kushiriki katika
 3407 utafiti huu.

3408 **Manufaa kutokana na utafiti huu**

3409 Kushiriki kwako katika utafiti huu, kutatuwezesha kuelewa zaidi kuhusu ugonjwa wa mlango wa
 3410 nyumba ya uzazi. Kwa kujiunga na utafiti huu, utapata kupimwa mlango wako wa uzazi bila malipo.
 3411 Kama ungependa kujua matokeo ya utafiti huu, unaweza kuwasiliana na ofisi ya utafiti huu miezi sita
 3412 au mwaka mmoja baada ya kumaliza utafiti huu.

3413 **Gharama na Fidia ya Majeraha**

3414 Hakuna gharama yoyote ya kushiriki katika utafiti huu, ila muda wako pekee. Utafiti huu
 3415 utalipia gharama ya uchunguzi wowote utakayopokea kwenye kiliniki ya utafiti. Ikiwa utapata
 3416 majeraha kutokana na kushiriki katika utafiti huu, utafiti huu utafidia gharama yote ya malipo ya
 3417 utunzaji. Ikiwa unafikiri kuwa umepata jeraha ama maumivu kutokana na utafiti huu, wasiliana na

3418 wahudumu wa utafiti huu, (Daktari Michael Chung (020-272-2710) au Daktari Nelly Mugo (020-273-
3419 6744) au Daktari Evans Malava (0721 289 733)) mara moja. Watakuhudumia kwa matibabu au
3420 kukupendekeza kwa matibabu.

3421 **Kuhifadhi kwa Sampuli na Data na Matumizi ya sampuli hizi kwa utafiti wa baadaye**

3422 Tungependa kuhifadhi habari yako ya matibabu na sampuli za pap smear na biopsy katika
3423 Hospitali ya Coptic na katika Hospitali kuu ya Kenyatta kwa madhumuni ya utafiti wa baadaye.
3424 Utafiti huu waweza kufanywa na Chuo kikuu cha Washington au na watafiti wengine wanaofanya
3425 kazi nasi katika utafiti huu kwa muda wa miaka kumi baada ya mwisho wa kufuatiliwa katika utafiti.
3426 Tutatumia data na sampuli hizi kwa minajili ya utafiti unaoegemea na saratani ya mlango wa kizazi
3427 na UKIMWI. Kabla sampuli yako kutoka kwenye kiliniki, itapewa kifichomaalumu Jina lako
3428 halitakuwemo. Jina lako litahusishwa na kificho hiki kwa miaka mitano pekee yake baada ya
3429 kukamilisha utafiti huu. Baada ya muda huu, kihusishi baina ya jina lako na kificho kilichoko katika
3430 sampuli na data kitaangamizwa. Bodi za taasisi ya mapitio ni kamati zinazoagalia usalama na haki za
3431 washiriki wa utafiti katika Hospitali kuu ya Kenyatta na Chuo kikuu cha Washington. Lazima
3432 ziidhinishe utafiti wowote wa baadaye utakaotumia sampuli na data yako. Ikiwa hupendi sampuli
3433 zako zihifadhiwe kwa minajili ya utafiti wa baadaye, unaweza kushiriki katika utafiti huu na sampuli
3434 zako zitaharibiwa mara tu uchunguzi utakapokamilika. Ukikubali uhufadhi wa sampuli zako leo,
3435 kisha ubadilishe nia yako baadaye kabla ya utafiti kukamilika, wafahamishe watafiti ambao
3436 watahakikisha kuwa sampuli zako hazitahifadhiwa kwa minajili ya utafiti wa baadaye. Hatutauza
3437 sampuli zako. Uchunguzi utakao fanya kwenye sampuli zako waweza kutuelekeza katika uvumbuzi
3438 mpya. Hatuna mpango wowote wa kugawana nawe pesa zozote au faida nyinginezo zitakazotokana
3439 na uvumbuzi huu ..

3440 **Maelezo ya ziada**

3441 Habari kuhusu utambuzi wa ugonjwa wako ni siri na tutaweka rekodi ya afya yako kwa afisi
3442 inayofungwa. Habari kuhusu uchunguzi na ushiriki wako kwenye utafiti huu utatolewa kwako na
3443 kikundi cha watafiti pekee wala si mtu mwengine yeyote nje ya utafiti huu bila idhini yako. Ikiwa
3444 utapeana idhini, tutawafahamisha habari yako daktari wa Coptic Hope Center. Habari hii inaweza
3445 kuwasaidia kukupa matibabu na huduma bora ya UKIMWI. Rekodi zako zote zitahifadhiwa katika
3446 sehemu zilizofungwa na kifuli na tarakilishi zote zitakuwa zina neno la siri la kuhakikisha ulinzi.

3447 Wakati mwengine, wafanyikazi wa chuo kikuu cha Washington wanakagua utafiti kama huu
3448 ili kuhakikisha unafanywa kwa njia inayofaa na iliyo halali. Ikiwa ukaguzi wa utafiti huu utafanyika,
3449 rekodi zako zaweza kuchunguzwa. Waweza kukataa kushiriki au waweza kuondoka kwenye
3450 utafiti huu wakati wowote bila kuadhibiwa au kupoteza faida iliyokuwa haki yako. Tutakueleza ikiwa
3451 kuna habari geni zinazohusu matibabu ambayo tunatafiti ili uweze kuamua iwapo utajiondoa kwenye
3452 utafiti huu. Uhusiano wako na wafanyikazi wa huduma za Coptic Hope Centre for infectious
3453 diseases, hautaadhiriwa kwa vyovyote ikiwa utakubali kushiriki kwenye utafiti huu ama ukiingia
3454 kwenye mpangilio halafu baadaye uondoke kabla ya kumaliza uchunguzi. Tafadhali wafahamishe
3455 wahudumu wa utafiti huu ikiwa utaamua kuondoka katika utafiti huu. Unaweza kuulizwa kupeana
3456 sampuli za mwisho lakini waweza kukataa.

3457 Wahudumu katika utafiti huu wanaweza kuamua kukuondoa kwenye utafiti huu wakigundua
3458 kuwa unaweza kupata madhara ukiendelea kushiriki. Unaweza kuondolewa kwenye utafiti huu ikiwa
3459 wahudumu watagundua kuwa huwezi kufuata masharti ya usalama.

3460 Maswali yeyote kuhusu utafiti huu, ama athari mbaya kutokana na uchunguzi huu yapaswa
 3461 kuelekezwa kwa mtafiti anayekuhudumia au Daktari Michael Chung (272-2710), Daktari Samah Sakr
 3462 (272-4737), au Daktari Nelly Mugo (273-6744).

3463 **Je, una maswali yeyote?**

3464 Sahihi ya mtafiti..... Tarehe.....

3465

3466 Jina la Mtafiti.....

3467 **Muhusika**

3468 Nimeelezwa juu ya utafiti huu. Najitolea kwa hiari kushiriki kwenye utafiti huu. Nimewapa
 3469 watafiti ruhusa ya kutumia rekodi zangu za utabibu kama ilivyopendekezwa kwenye fomu hii ya
 3470 makubaliano. Nimekuwa na fursa ya kuuliza maswali. Nikiwa na maswali yeyote kuhusu utafiti huu
 3471 baadaye, naweza kumuuliza mojawapo wa watafiti waliotajwa kwenye fomu hii. Nikiwa na maswali
 3472 kuhusu haki yangu kama mhusika kwenye utafiti , naweza piga simu kwa kamati ya uchunguzi wa
 3473 maadili walioko Hospitali kuu ya Kenyatta kwa kutumia nambari 020-726-300. Nikitaka, nitapewa
 3474 nakala ya fomu hii yangu binafsi.

3475 Tafadhali tia alama , ufupi wa jina na anwani katika chaguo moja:

3476 _____Nimekubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

3477

3478 _____Sijakubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

3479

3480 Sahihi au alama ya kidole cha gumba cha mshiriki _____

3481

3482 Tarehe_____

3483

3484 Jina la Mshiriki lililochapishwa_____

3485

3486 Nakala kwa Mtafiti na Mshiriki

3487 **MAKUBALIANO YA PAMOJA**

3488 **KISWAHILI CONSENT FORM**

3489 **MATIBABU YA SARATANI YA MLANGO WA KIZAZI; CRYOTHERAPY AU LEEP**

3490 **WATAFITI**

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3502 543-4278

3503

3504 Nambari za simu ya dharura; 072-2710 au 0733-711-288

3505 Mwenyekiti wa kamati ya uchunguzi wa maadili; Proffesa A. N. Guantai, 020 2726300, Ext. 44102,
3506 44355 unaweza kuwasiliana naye kwa maswala ya utafiti na maadili ya washiriki wa utafiti huu.

3507

3508 **Ujumbe wa Watafiti**

3509 Tunakuuliza kushiriki katika utafiti huu wa kitaalam. Lengo la fomu hii ya idhini ni kukupa
3510 habari itakayokufahamisha na kukusaidia kuamua kama ungelipenda kushiriki katika utafiti huu au la.
3511 Tafathali soma maelekezo haya kwa makini. Unaweza kuuliza maswali kuhusu nia/kusudi ya utafiti
3512 huu; unavyohitajika kufanya katika utafiti, uwezekano wa kuwepo na madhara au manufaa yeyote,
3513 haki yako kama aliyejitolea, na mambo mengine kuhusu utafiti huu au chochote usichoelewa kwenye
3514 fomu hii. Tukishajibu maswali yako yote, unapaswakuamua kushiriki kwenye utafiti huu au la.
3515 Kukubali kushiriki kwenye utafiti huu kwa hiari yako kunamaanisha kuwa umeelezwa na umeelewa
3516 yote yanayohusika na kukubaliana nayo. Ukipenda, tutakupa nakala ya fomu hii kujihifadha.
3517 Tafadhali tujulishe iwapo ungependa kutumia lugha ya Kingereza.

3518 **Lengo la Utafiti huu.**

3519 Mathumuni ya mradi huu wa utafiti, ni kutafuta njia iliyo bora ya kutibu ugonjwa
 3520 unaosababisha saratani ya mlango wa kizazi (cervical cancer). Umeulizwa kushiriki katika utafiti huu
 3521 kwa sababu;

- 3522• Umeambukizwa maradhi ya UKIMWI
- 3523• Unapata matibabu katika kituo cha matibabu cha Hope
- 3524• Hauna Mimba
- 3525• Hauna historia ya shida ya kuvuja damu
- 3526• Haujapata kutolewa sehemu yako ya uzazi (uterasi)
- 3527• Umewahi fanya ngono
- 3528• Haujawahi kupata matibabu yoyote ya mlango wa kizazi hapo mbeleni
- 3529• Umepatikana kuwa na chembe chembe zisizo za kawaida kwa mlango wa uzazi kwenye pap smear ua
- 3530 biopsy.
- 3531

3532 Saratani ya aina hii huambukiza wanawake wengi wenye umri mdogo na hata wa makamo
 3533 nchini Kenya. Wanawake walioambukizwa na virusi vinavyosababisha ukimwi (HIV) wana hatari
 3534 kubwa ya kuambukizwa saratani ya mlango wa kizazi (cervical cancer), kuliko wanawake wengine
 3535 ambao bado hawajaambukizwa na HIV. Hata hivyo, kwa wanawake walioambukizwa na virusi
 3536 vinavyosababisha ukimwi, saratani ya mlango wa kizazi si ya kawaida. Lakini katika wanawake
 3537 walioambukizwa na virusi vinavyosababisha ukimwi, maambukizo ya mlango wa kizazi usio saratani
 3538 ya mlango wa kizazi ni wa kawaida. Maambukizo haya husababishwa na virusi vya “Papiloma”
 3539 (HPV). Ni muhimu kutambua na kutibu maambukizo haya kabla hayajageuka kuwa saratani ya
 3540 mlango wa kizazi.

3541 Utafiti huu utalinganisha namna mbili za ukaguzi wa mlango wa kizazi; Cryotherapy na
 3542 LEEP (loop electrosurgical excision procedure). Njia hizi mbili hutumika sana kwa wanawake wengi
 3543 duniani na sio geni. Tutakuelezea njia hizi mbili za utabibu. Katika utafiti huu, tutakuwa na washiriki
 3544 400. Utafiti huu utatuwezesha kutambua matibabu bora itakayowawezesha wanawake wanaoishi na
 3545 virusi vinavyosababisha ukimwi (HIV) kuishi maisha bila saratani ya mlango wa kizazi.

3546

3547 **Hatua ya kushiriki katika utafiti**

3548 Washirika wote watahitajika kutembelea kliniki mara 5 au 8 kwa muda usiozidi miaka 2. Kila mara,
 3549 mushirika atatumia dakika 15 hadi 40 katika kiliniki.

3550

3551

3552

3553 **Utaratibu wa kupeana matibabu bila mapendeleo (Randomization)**

3554 (Marejeleo ya Matokeo ya Biopsy – dakika 10, Utaratibu wa kupeana matibabu bila mapendeleo
 3555 (ikihitajika) – dakika 30)

3556

3557 Matokeo ya pap smear na biopsy yameonyesha ya kuwa uko na maambukizo yanayohitaji
 3558 matibabu. ukiamua kujiunga na utafiti huu, tutatumia mojawapo ya njia mbili ambazo ni za
 3559 kutumainika. Njia moja inaitwa “Cryotherapy”. Njia hii inatia barafu sana (freeze) kwenye sehemu
 3560 yako ya uzazi iliyoambukizwa na ugonjwa. Unaweza pewa dawa ya kumeza kupunguza maumivu
 3561 baada ya Cryotherapy. Njia ya pili inajulikana kama, “LEEP”. Njia hii inatumia chuma kidogo
 3562 kilichopashwajoto ili kutoa sehemu iliyoambukizwa baada ya kugandishwa kwa dawa. Utahudumiwa
 3563 kwa njia mojawapo ya hizi bila mapendeleo ili kudhibitisha ni njia ipi iliyo bora kuliko nyengine.

3564 Njia ya kuchagua matibabu bila mapendeleo ni kama “kuzungusha peni”, kila upande wa
 3565 peni una uwezo uliyo sawa, kama ilivyo njia hizi mbili za matibabu. Hatujui kwa hakika ni njia gani
 3566 ya matibabu utakayopata hadi tutakapofungua bahasha iliyo na kijikaratasi kitakachotujulisha ni njia
 3567 gani ya matibabu utakayopata. Sio sisi wala wewe utakayechagua njia ya matibabu, bali ni bahasha
 3568 iliyo na vijikaratasi vitakavyo tuelekeza ni njia ipi itakayotumika baada ya kufungua ile bahasha.
 3569 Tutakuashiria kutumia mojawapo ya njia hizi mbili bila mapendeleo (kuegemea njia moja) kwa
 3570 sababu hatujui ni njia ipi iliyo bora kutumiwa na wanawake walioambukizwa na virusi
 3571 vinavyosababisha ukimwi (HIV).

3572 Tukigundua kuwa sehemu ya kizazi iliyoambukizwa ni kubwa mno, na haiwezi kutibika sawa
 3573 sawa kwa “Cryotherapy”, tutakutibu tukitumia njia ya “LEEP”. Utapata matibabu ya LEEP bila
 3574 malipo yoyote.

3575 Ikiwa sehemu iliyoambukizwa haiwezi kutibika vizuri kwa “Cryotherapy” au “LEEP”,
 3576 utaondoka kwenye utafiti huu na kuelekezwa kwenye hospitali kuu ya Kenyatta (KNH) utakapopata
 3577 matibabu ya aina nyengine ya matibabu kwa bei nafuu katika hospitali ya serikali. Watafiti
 3578 watakupatia fomu zako za matibabu ambazo ni muhimu kwa matibabu yako. Hizi fomu
 3579 hazitaonyesha kuwa wewe ni mshirika wa utafiti huu. Baada ya matibabu utakayopokea kutoka KNH,
 3580 tutakufuatilia kwa miaka 2 na kukupa matibabu.

3581 Tukikupa njia mojawapo ya matibabu yaliyotajwa (Cryotherapy au LEEP), vijiko viwili vya
 3582 chai (tea spoons [10mls]) vya damu vitatolewa ili kuhesabu chembe chembe za CD4 na kuthibitisha
 3583 kiwango cha virusi vinavyosababisha ukimwi (HIV) katika damu yako kwa wakati huu. Kisha
 3584 tutapanguza kwa burashi sehemu yako ya kizazi na kukagua kiwango cha virusi vinavyosababisha
 3585 ukimwi. Mwisho, tutapangusa sehemu yako ya kizazi ili kukagua kiwango cha virusi vya “Papiloma”
 3586 (HPV) ambavyo ni viini vinavyoambukiza sehemu ya kizazi na kusababisha saratani ya uzazi
 3587 (Cervical cancer).

3588 Tutatumia rekodi zako za afya ziliko HOPE Center ili kukusanya habari zote kuhusu afya
 3589 yako ili kuelewa vyema dawa ambazo umekuwa ukitumia, hali ya afya yako kwa sasa na majibu ya
 3590 vipimo kutoka maabara na pia jinsi umekuwa ukihudhuria kiliniki.

3591

3592 **Mpangilio baada ya kupata matibabu bila mapendeleo**

3593 (Kutembelea kiliniki Mara Ya 2-8; Marejeleo ya Matokeo na usufi wa mlango wa kizazi- dakika30)

3594 Ukipata mojawapo ya matibabu (Cryotherapy au LEEP) bila mapendeleo, watafiti
3595 watakuuliza urudi kwenye kiliniki tena wiki ya kwanza (1), pili (2) na tatu (3) baada ya matibabu.

3596 Kila mara utakaporudi kiliniki, vijiko viwili vidogo vya damu vitatolewa na kisha kupanguza
3597 sehemu yako ya kizazi ili kuthibitisha kiwango cha virusi vinavyosababisha ukimwi (HIV).
3598 Tungependa kujua kama kiwango hiki kimeongezeka baada ya matibabu na kitarudi katika hali yake
3599 ya kawaida lini?

3600 Ukipata mojawapo ya matibabu (Cryotherapy au LEEP), tutakuuliza kurudi kiliniki ya utafiti
3601 mwezi wa sita (6), kumi na mbili (12), kumi na nane (18) na pia mwezi wa ishirini na nne (24) baada
3602 ya matibabu yako ya kwanza ili kurejelea “Pap smear” kudhibitisha Ikiwa sehemu yako ya kizazi
3603 iliyoambukizwa imeondolewa kabisa na hakuna tishu iliyojitenga au isiyo ya kawaida iliyojitengeza.
3604 Tutapanguza sehemu yako ya kizazi (cervix), ili kukagua virusi vya “Papiloma” (HPV) kwa wakati
3605 huu na kutoa vijiko viwilividogo vya damu ili kuhesabu chembe chembe za CD4 na kudhibitisha
3606 viwango vya virusi vinavyosababisha ukimwi (HIV). Tukigundua hali isiyo ya kawaida, tutakutibu
3607 kwa kutumia LEEP, kisha tutakuelekeza katika hospitali kuu ya Kenyatta (KNH) kwa matibabu ya
3608 ziada yaliyo nafuu.

3609

3610 Kuwasiliana na Washiriki

3611 Tutakuuliza utupatie jinsi ya kuwasiliana nawe kama vile nambari yako ya simu ili tuweze
3612 kukupigia usipotembelea kiliniki kama ilivyopangwa. Tunaweza kukuuliza kuhusu afya yako au
3613 ulipokuwa katika mawasiliano haya. Ni muhimu kwako kutembelea kiliniki kama ilivyopangwa.
3614 Tunataka kukufuatilia vyema na kwa makini ili kutibu ugonjwa wowote katika mlango wa kizazi ulio
3615 nao sasa au utakaupata baadaye. Iwapo hatuwezi kuwasiliana nawe kwa njia ya simu, tunaweza
3616 kukutembelea kwako nyumbani. Iwapo tutakutembelea kwako nyumbani, hatutavalia mavazi
3617 yatakayoashiria kuwa sisi ni wahudumu katika hospitali. Unaweza kutuarifu iwapo hupendi njia hii
3618 ya mawasiliano.

3619

3620 **Athari na usumbufu wa kushiriki kwenye utafiti huu.**

3621 Haya ni maelezo ya athari na usumbufu unayoweza kukumbana nayo kwa kushiriki katika utafiti huu.
3622 Athari na usumbufu mwingine ambao haujatajwa unaweza kutokea pia.

3623

3624 **Matibabu**

3625 Kuna uwezekano wa madhara au maumivu ukipata matibabu haya. Ukishiriki katikautibabu
3626 wa “Cryotherapy”, waweza kuhisi;

- 3627• maumivu madogo ya tumbo kwa muda unaopungua dakika kumi,
- 3628• kutokwa na majimaji kwenye uke wako kwa muda wa wiki mbili (au zaidi).
- 3629• Kuvuja damu
- 3630• Maambukizo ambayo tunaweza kutibu hapa katika kiliniki au katika hospitali kwa nadra sana.
- 3631 Maambukizo haya yanaweza kusababisha homa, baridi, kutokwa na jasho usiku, au majimaji meupe
- 3632 kutoka kwenye uke wako.

3633
3634

3635 Ukitibiwa kwa LEEP, unaweza;

3636• kuvuja damu baada au wakati matibabu haya yanapoendelea. (Unashauriwa kurudi kiliniki Ikiwa
3637 uvujaji huu wa damu utaanza, kisha kuendelea baada ya matibabu kwa ukaguzi wa ziada.)

3638• Kuna uwezekano wa kuambukizwa kwenye eneo la matibabu.

3639 Madhara haya yote yanaweza kutibiwa bila malipo yeyote katika kiliniki hii. Matibabu haya
3640 yanaweza kuwa;

3641• kupewa dawa ya kuuguza maambukizi.

3642• Kuingiza pamba kwenye uke wako kuzuia kuvuja damu,

3643• Kushona kwenye mlango wako wa uzazi ili kuzuia kuvuja kwa damu au

3644• Kulazwa hospitalini kwa makali ya maambukizo au uvujaji wa damu.

3645 Tafadhali tufahamishe ikiwa una madhara haya baada ya matibabu.

3646 Baada ya kupokea matibabu ya “Cryotherapy”, au LEEP tunakusihia usishiriki katika kitendo
3647 cha gono kwa muda wa juma nne, sababu ni kuwa waweza kumwambukiza mwenzio kwa urahisi. Pia
3648 kuna uwezekano wa wewe kupata maambukizo. Tunaweza kukusaidia kuongelea jambo hili na
3649 mpenzi wako.

3650 Washiriki wote watakaopata matibabu ya “Cryotherapy” au “LEEP” watapata maagizo ya
3651 dawa ya “antibiotiki”. Dawa hii ya antibiotiki itashirikisha doxyclyne, metronidazole or norfloxacin.

3652 Madhara ya dawa hizi yanaweza kuwa usumbufu wa tumbo (Lazima usikunywewe
3653 tembo/pombe kwa siku 2) kutapika na kuharisha usikivu wa mwangaza, mwasho, mzio mkali
3654 mmenyuko unaoweza kusababisha kifo, kizunguzungu, kuumwa na kichwa, kuchanganyikiwa,
3655 kupigapiga kwenyemasikio au kupoteza usikivu, mshutuko wa mwili (jerking of the body), maumivu
3656 ya moyo, machafuko ya damu, shida ya kisukari, ugonjwa wa maini, ugonjwa wa figo na uchungu au
3657 kuganda kwenye mikono na miguu. Ikiwa utahisi mojawepo ya athari hizi, mfahamishe mkaguzi
3658 katika utafiti huu mara moja.

3659 Baada ya kupata matibabu haya, kuna uwezekano wa kupata matatizo utakapobeba mimba
3660 baadaye. Baada ya kupata matibabu ya “LEEP”, wanawake wengine wamepata matatizo wanapobeba
3661 mimba kama vile;maumivu ya mapema wakati wa kujifunguaau shida katika mlango wa mfuko wa
3662 uzazi.Katika Wanawake wachache, mlango wa mfuko wa uzazi huziba na inabidi ulegezwe.
3663 Wanawake wengine huvuja majimaji ya uzazi kabla ya muda ufaao wa kuzaa mtoto pengine kutokana
3664 na operesheni ya mlango wa mfuko wa uzazi (cervix).

3665 **Utoaji wa damu**

3666 Tutakusanya sampuli za damu, vijiko 2 (10 mls), kutoka kwako kwa kutumia shindano na
3667 “sirinji”. Kudungwa shindano kwaweza kuwa chungu na yaweza kuacha alama kidogo kwa muda
3668 mfupi. Yaweza kusababisha maambukizo au kuzirai.

3669 **Uwekaji wa siri**

3670 Wahudumu katika utafiti huu, watakusanya habari ya binafsi na waweza kuona aibu kuongea
 3671 kuhusu habari zako za ndani kama vile; idadi ya wapenzi ambao ushakuwa nao. Unaweza kuchagua
 3672 kutojibu maswali yoyote. Pia, ukija kiliniki, waweza kukutana na wagonjwa wengine ambao
 3673 umewajua mbeleni. Hatuna mpango wa kupeana habari yako ya kibinafsi kwantu yeyote nje ya utafiti
 3674 huu isipokuwa watafiti au wachunguzi walioteuliwa. Wakati mwingine kamati inayosimamia utafiti
 3675 huu watachunguza habari ya utafiti huu ili kuhakikisha hakuna jambo lolote ambalo ni kinyume na
 3676 sheria au kinyume na maadili litakalotendwa. Habari yako ya kibinafsi italindwa ipasavyo ikiwa
 3677 hayo yatatendeka na hakuna mtu yeyote atakayeona habari hiyo nje ya uchunguzi
 3678 huu. Kamamdhmini watafiti, CDC wanaweza kufuatilia aukukaguashughuli zautafiti. Sababu
 3679 hii itakuwahakikishakuwa utafiti unafanyika kwanji inayotakiwa, napia kuhakikishakwamba
 3680 hakiyakonaafya yako inalindwa. Matibabuyakotaarifa binafsi itakuwasiri.

3681 **Mbadala wa kujiunga na utafiti huu**

3682 Ukichagua kutoshiriki kwenye utafiti huu, utaendelea kuhudumiwa kikamilifu na kupata matibabu na
 3683 dawa za ART kutoka “Coptic Hope Centre” bila malipo. Unaweza pia kupata uchunguzi wa saratani
 3684 ya mlango wa nyumba ya uzazi bila malipo yeyote katika kiliniki hii bila kushiriki katika utafiti huu.
 3685 Unaweza kutibiwa na Cryotherapy katika Hospitali ya kiliniki ya Hope hata ukichagua kutojiunga na
 3686 utafiti huu. Pia, tunaweza kukutuma kupewa huduma katika hospitali kuu ya Kenyatta, ambapo
 3687 malipo ni kama ya hospitali za serikali.

3688

3689 **Manufaa kutokana na utafiti huu**

3690 Kushiriki kwako katika utafiti huu, kutatuwezesha kuelewa zaidi kuhusu ugonjwa wa mlango wa
 3691 nyumba ya uzazi. Pia, kushiriki kwako katika utafiti huu kutachangia katika elimu ya nyanja hii
 3692 ambayo yaweza kutoa mabadiliko katika jinsi ya ugonjwa wa saratani ya mlango wa uzazi
 3693 unavyogunduliwa na kutibiwa. Kwenye nchi inayoendelea kama Kenya. Kama ungependa kujua
 3694 matokeo ya utafiti huu, unaweza kuwasiliana na ofisi ya utafiti huu miezi sita au mwaka mmoja baada
 3695 ya kumalizika utafiti huu.

3696 **Gharama na Fidia ya Majeraha**

3697 Hakuna gharama yeyote ya kushiriki katika utafiti huu, ila muda wako pekee. Utafiti huu
 3698 utalipia gharama ya uchaguzi na matibabu yoyote utakayopokea kwenye kiliniki ya utafiti. Ikiwa
 3699 Utapata majeraha kutokana na kushiriki katika utafiti huu, utafiti huu utafidia gharama yote ya malipo
 3700 ya utunzaji. Matibabu yatahusisha dawa zinazopambana na vidudu vilivyo hai (antibiotics), dawa
 3701 zinazopunguza maumivu na njia zinazoachisha kuvuja damu. Ikiwa unafikiri kuwa umepata jeraha
 3702 ama maumivu kutokana na utafiti huu, wasiliana na wahudumu wa utafiti huu, (Daktari Michael
 3703 Chung (020-272-2710) au Daktari Nelly Mugo (020-273-6744) au Daktari Evans Malava (0721 289
 3704 733)) mara moja. Watakuhudumia kwa matibabu au kukupendekeza kwa matibabu.

3705 **Kuhifadhi kwa Sampuli na Data na Matumizi ya sampuli hizi kwa utafiti wa baadaye**

3706 Tungependa kuhifadhi habari yako ya matibabu na sampuli za damu yako na mlango mfuko
 3707 wa uzazi, Kenya katika Hospitali ya Coptic na katika Hospitali kuu ya Kenyatta kwa madhumuni ya
 3708 utafiti wa baadaye. Utafiti huu waweza kufanywa na Chuo kikuu cha Washington au na watafiti
 3709 wengine wanaofanya kazi nasi katika utafiti huu kwa muda wa miaka kumi baada ya mwisho wa
 3710 kufuatiliwa katika utafiti. Tutatumia data na sampuli hizi kwa minajili ya utafiti unaogemea na

3711 saratani ya mlango wa kizazi na UKIMWI. Kabla sampuli yako kutoka kwenye kiliniki, itapewa
 3712 kifichomaalumu Jina lako halitakuwemo. Jina lako litahusishwa na kificho hiki kwa miaka mitano
 3713 pekee yake baada ya kukamilisha utafiti huu. Baada ya muda huu, kihusishi baina ya jina lako na
 3714 kificho kilichoko katika sampuli na data kitaangamizawa. Bodi za taasisi ya mapitio ni kamati
 3715 zinazoangalia usalama na haki za washiriki wa utafiti katika Hospitali kuu ya Kenyatta na Chuo kikuu
 3716 cha Washington. Lazima ziidhinisha utafiti wowote wa baadaye utakaotumia sampuli na data yako.
 3717 Ikiwa hupendi sampuli zako zihifadhiwe kwa minajili ya utafiti wa baadaye, unaweza kushiriki katika
 3718 utafiti huu na sampuli zako zitaharibiwa mara tu uchunguzi utakapokamilika. Ukikubali uhifadhi na
 3719 sampuli zako leo, kisha ubadilishe nia yako baadaye kabla ya utafiti kukamilika, wafahamishe
 3720 watafiti ambao watahakikisha kuwa sampuli zako hazitahifadhiwa kwa minajili ya utafiti wa baadaye.
 3721 Hatutauza sampuli zako. Uchunguzi utakao fanya kwenye sampuli zako waweza kutuelekeza katika
 3722 uvumbuzi mpya. Hatuna mpango wowote wa kugawana nawe pesa zozote au faida nyinginezo
 3723 zitakazotokana na uvumbuzi huu ..

3724 **Maelezo ya ziada**

3725 Habari kuhusu utambuzi wa ugonjwa wako ni siri na tutaweka rekodi ya afya yako kwa afisi
 3726 inayofungwa. Habari kuhusu uchunguzi na ushiriki wako kwenye utafiti huu utatolewa kwako na
 3727 kikundi cha watafiti pekee wala si mtu mwingine yeyote nje ya utafiti huu bila idhini yako. Ikiwa
 3728 utapeana idhini, tutawafahamisha habari yako daktari wa Coptic Hope Center. Habari hii inaweza
 3729 kuwasaidia kukupa matibabu na huduma bora ya UKIMWI. Baadhi ya sampuli zako ikiwa ni pamoja
 3730 na sampuli za damu na sampuli kutoka kwenye mlango wa mfuko wa uzazi zaweza kutumwa USA au
 3731 Uropa kwa uchunguzi. Habari yako na sampuli zako zitalindwa ikiwa haya yatatendeka. Rekodi zako
 3732 zote zitahifadhiwa katika sehemu zilizofungwa na kifuli na tarakilishi zote zitakuwa zina neno la siri
 3733 la kuhakikisha ulinzi.

3734 Wakati mwingine, wafanyikazi wa chuo kikuu cha Washington wanakagua utafiti kama huu
 3735 ili kuhakikisha unafanywa kwa njia inayofaa na iliyo halali. Ikiwa ukaguzi wa utafiti huu utafanyika,
 3736 rekodi zako zaweza kuchunguzwa. Waweza kukataa kushiriki au waweza kuondoka kwenye
 3737 utafiti huu wakati wowote bila kuadhibiwa au kupoteza faida iliyokuwa haki yako. Tutakueleza ikiwa
 3738 kuna habari geni zinazohusu matibabu ambayo tunatafiti ili uweze kuamua iwapo utajiondoa kwenye
 3739 utafiti huu. Uhusiano wako na wafanyikazi wa huduma za Coptic Hope Centre for infectious diseases,
 3740 hautaadhiriwa kwa vyovyote ikiwa utakubali kushiriki kwenye utafiti huu ama ukiingia kwenye
 3741 programu halafu baadaye uondoke kabla ya kumaliza uchunguzi. Tafadhali wafahamishe wahudumu
 3742 wa utafiti huu ikiwa utaamua kuondoka katika utafiti huu. Unaweza kuulizwa kupeana sampuli za
 3743 mwisho lakini waweza kukataa.

3744 Wahudumu katika utafiti huu wanaweza kuamua kukuondoa kwenye utafiti huu wakigundua
 3745 kuwa unaweza kupata madhara ukiendelea kushiriki. Unaweza kuondolewa kwenye utafiti huu ikiwa
 3746 wahudumu watagundua kuwa huwezi kufuata masharti ya usalama.

3747 Utarejeshewa gharama ya usafiri ya Ksh 300 mara utakaporudi katika kiliniki kwa sababu
 3748 zinazohusiana na utafiti huu. Utapata pesa za usafiri kutoka kwa mhudumu wa mapokezi.

3749 Maswali yeyote kuhusu utafiti huu, ama athari mbaya kutokana na uchunguzi huu yapaswa
 3750 kuelekezwa kwa mtafiti anayekuhudumia au Daktari Michael Chung (272-2710), Daktari Samah Sakr
 3751 (272-4737), au Daktari Nelly Mugo (273-6744).

3752 **Je, una maswali yeyote?**

3753 Sahihi ya mtafiti..... Tarehe.....

3754

3755 Jina la Mtafiti.....

3756 **Mhusika**

3757 Nimeelezwa juu ya utafiti huu. Najitolea kwa hiari kushiriki kwenye utafiti huu. Nimewapa
 3758 watafiti ruhusa ya kutumia rekodi zangu za utabibu kama ilivyopendekezwa kwenye fomu hii ya
 3759 makubaliano. Nimekuwa na fursa ya kuuliza maswali. Nikiwa na maswali yeyote kuhusu utafiti huu
 3760 baadaye, naweza kumuuliza mojawapo wa watafiti waliotajwa kwenye fomu hii. Nikiwa na maswali
 3761 kuhusu haki yangu kama mhusika kwenye utafiti , naweza piga simu kwa kamati ya uchunguzi wa
 3762 maadili walioko Hospitali kuu ya Kenyatta kwa kutumia nambari 020-726-300. Nikitaka, nitapewa
 3763 nakala ya fomu hii yangu binafsi. Tafadhali tia alama , ufupi wa jina na anwani katika chaguo moja:

3764 _____Nimekubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

3765

3766 _____Sijakubali kuweka sampuli na data kwa minajili ya utafiti wa baadaye

3767

3768 Sahihi au alama ya kidole cha gumba cha mshiriki _____

3769

3770 Tarehe_____

3771

3772 Jina la Mshiriki lililochapishwa_____

3773

3774 Nakala kwa Mtafiti na Mshiriki

3775

3776

3777

3778

3779

3780

3781

3782

3783

ENROLLMENT

3784

3785 **Study ID Number** ___ ___ **Hope ID Number** ___ ___ **Interviewer Number** _

3786

3787 **Date of interview (day/month/year)** ___ ___/___ ___/___ ___ ___

3788 Agreed to store samples: Yes No Don't know Other, specify

3789

3790 **A: SOCIODEMOGRAPHIC**

3791 1. Date of birth (day/month/year) ___ ___/___ ___/___ ___ ___

3792 2. Age _____ years

3793 3. How many years of education did you complete? _____ years

3794 4. What is highest education level you have completed? None

3795 Primary

3796 Secondary

3797 Higher education/ University

3798 Don't know

3799 Refused

3800 Other, specify

3801

3802 5. Marital status (tick one): Married (monogamous)

3803 Married (polygamous)

3804 Single

3805 Divorced/Separated

3806 Widowed

3807 Refused

3808 Cohabiting

3809 Other, specify

3810

3811 6. Employment (tick one): Salaried job

3812 Self-employed

- 3813 Housewife
- 3814 Unemployed
- 3815 Casual laborer
- 3816 Refused
- 3817 Other, specify
- 3818 7. Household income per month (tick one): None
- 3819 < 5000 Ksh
- 3820 5001 – 10000 Ksh
- 3821 10001 – 15,000 Ksh
- 3822 >15,000 Ksh
- 3823 Don't know
- 3824 Refused

3825

3826 **B: SEXUAL HISTORY**

- 3827 8. How old were you when you first had vaginal intercourse? ___ ___ Don't know
- 3828 refused never Other, specify
- 3829 9. How many sex partners have you ever had? ___ ___ Don't know refused
- 3830 Other, specify _____
- 3831
- 3832 10. How many different sex partners did you have in the last year? ___ ___
- 3833 Don't know refused Other, specify
- 3834
- 3835
- 3836 11. Have you had sex in the last month? (If no, don't know, refused, skip to 14)
- 3837 Yes No Don't know Refused Other, specify
- 3838
- 3839 12. How often have you used condoms during sex in the last month?
- 3840 Always (100%) Most of the time (75-99%)
- 3841 Half of the time (50%-74%) Sometimes (25-49%)
- 3842
- 3843 Rarely (1-25%) Never (0%)
- 3844 Refused
- 3845 Don't know Other, specify
- 3846
- 3847 13. Do you think you may be currently pregnant? Yes No Don't
- 3848 know Refused Other, specify

3849
3850

3851 **C: CERVICAL CANCER SCREENING HISTORY**

3852 14. Have you been previously screened for cervical cancer? Yes No
3853 Don't know Refused Other, specify
3854 If no, don't know or refused skip to 20.

3855 15. What cervical cancer screening test did you undergo most recently (tick one)?

3856 Pap smear

3857 Visual inspection with Acetic acid

3858 HPV

3859 Other, specify: _____

3860 Don't know

3861

3862 Refused

3863 16. Where was the most recent test performed?

3864 Coptic

3865 KNH

3866 Refused

3867 Don't know

3868 Other, specify

3869 17. When was the test performed?

3870 Don't know

3871

3872 18. What were the results?

3873 Normal

3874 Abnormal, specify _____

3875 Don't know

3876 Refused

3877 19. Did you receive any cervical treatment or surgery as a result of this test?

3878 Yes No Don't know Refused Other, specify _____

3879 If yes, specify _____

3880

3881 20. Was Pap Smear performed today? Yes No

3882 If no, explain Refused Don't know

3883 21. Comments.

3884

PAP SMEAR

3885

3886 **Study ID Number** ___ ___ ___**Interviewer Number** ___ ___

3887

3888 **Date of interview (day/month/year)** ___ ___/___ ___/___ ___ ___ ___

3889

3890 **Visit (tick one)** **Initial Visit** **Repeat** **Month 6 FU** **Month 12 FU** **Month 18**3891 **FU** **Month 24** **Other, specify** _____

3892

3893 **A: PHYSICAL EXAMINATION**

3894 1. Temperature ___ ___ °C

3895 2. Is there inguinal node enlargement Yes No 3896 3. Is there abdominal tenderness Yes No 3897 4. Are there any abdominal masses Yes No 3898 5. Were there any other abnormalities found on general physical exam Yes No

3899 If yes, specify

3900 **B: PELVIC EXAMINATION**

3901 6. What was found on the external genital exam (tick all that apply)?

3902 Abnormal visible discharge at introitus Ulcers3903 Excoriations Vesicles3904 Oedema Papules3905 Sores Normal3906 Other (Specify) _____3907 7. Were there any perineal warts on external genital exam? Yes No

3908 If yes, specify

3909 a. Size ___ ___ mm

3910 b. Number of warts ___ ___

3911 c. Location of warts _____

3912 8. Did the cervix appear abnormal on gross pelvic exam? Yes No

3913 If yes, tick all that apply

3914 Abnormal discharge Warts3915 Bleeds easily on touch Cervicitis3916 Visible lesion Condylomata

- 3917 Bloody discharge Ulcers
- 3918 Fungating mass
- 3919 Leukoplakia Cervical polyp
- 3920 Bartholian cysts Blisters
- 3921 Overt cervical cancer Other abnormality, specify
- 3922 9. Did you palpate the uterus? Yes No
- 3923 If yes, then specify
- 3924 a. Estimated uterine size ___ . ___ cm
- 3925 b. Was the uterus tender? Yes No
- 3926 c. Were there possible fibroids? Yes No
- 3927 10. Was there any adnexal tenderness? Yes No
- 3928 If yes, specify location Right Left Both

3929 **C: Pap**

- 3930 11. Were you able to take an adequate Pap smear? Yes No
- 3931 a. If no, specify why
- 3932 Patient discomfort
- 3933 Excessive bleeding
- 3934 Excessive discharge or inflammation
- 3935 Other, specify

3936 **D: DIAGNOSIS**

- 3937 12. Normal exam Yes No
- 3938 13. Candidiasis Yes No
- 3939 14. Cervicitis Yes No
- 3940 15. Pelvic inflammatory disease Yes No
- 3941 16. Vulval warts Yes No
- 3942 17. Vaginal warts Yes No
- 3943 18. Genital ulcerations Yes No
- 3944 19. Lower genital tract infection Yes No
- 3945 20. Other Yes No
- 3946 If others, specify

3947 **E: OTHER**

- 3948 21. Did you give any treatment to the participant? Yes No
- 3949 If yes, specify (treatment)
- 3950 22. Did you give referral to the participant? Yes No
- 3951 If yes, specify (diagnosis and referral institution)
- 3952 23. Comment.

3953

COLPOSCOPY

3954

3955 **Study ID Number** ___ ___**Interviewer Number** ___ ___

3956

3957 **Date of interview (day/month/year)** ___ ___/___ ___/___ ___ ___

3958

3959 **Visit (tick one)** **Initial Visit** **Month 6 FU** **Month 12 FU** **Month 18 FU**3960 **Month 24 FU** **LSIL FU** **CIN 1 FU** **Other, specify** _____3961 **A: PAP SMEAR DIAGNOSIS**

3962 1. What date was the Pap smear performed?

3963 2. What was the Pap smear diagnosis (tick all that apply)?

3964 No dysplasia (NIL)3965 ASCUS3966 LSIL (CIN 1)3967 HSIL (CIN 2 & 3)3968 ASC-H3969 Invasive carcinoma3970 ACG (Atypical Glandular Cells)3971 Cervicitis3972 Yeast infection3973 Indeterminate/insufficient sample3974 Other, specify3975 Unknown, specify reason

3976 3. Is cervical biopsy with colposcopy indicated based on Pap smear cytology?

3977

3978 Yes No

3979 If no, skip to Q24 and fill exit form where necessary

3980 If yes, and colposcopy had been done previously, skip to Q24.

3981 If yes and colposcopy had not been done previously, do a pregnancy test

3982 4. Result of pregnancy test: Pregnant Not Pregnant

3983 (If pregnant fill exit form, If not pregnant refer for colposcopy)

3984 Not pregnant

3985 **B: PHYSICAL EXAMINATION**

3986 5. Temperature ___ ___ °C

3987 6. Is there inguinal node enlargement Yes No

3988 7. Is there abdominal tenderness Yes No

3989 8. Are there any abdominal masses Yes No

3990

3991 9. Were there any other abnormalities found on general physical exam Yes No

3992 If yes, specify

3993

3994 **C: PELVIC EXAMINATION**

3995 10. What was found on the external genital exam (tick all that apply)?

3996 Abnormal visible discharge at introitus Ulcers

3997 Excoriations Vesicles

3998 Oedema Papules

3999 Sores Normal

4000 11. Were there any perennial warts on external genital exam? Yes No

4001 If yes, specify

4002 d. Size ___ . ___ ___ mm

4003 e. Number of warts ___ ___

4004 f. Location of warts _____

4005 12. Did the cervix appear abnormal on gross pelvic exam? Yes No

4006 If yes, tick all that apply

4007 Abnormal discharge Warts

4008 Bleeds easily on touch Cervicitis

4009 Visible lesion Condylomata

4010 Bloody discharge Ulcers

4011 Fungating mass

4012 Leukoplakia Cervical polyp

4013 Blisters

4014 Overt cervical cancer

4015 13. Did you palpate the uterus? Yes No
4016 If yes, the specify

4017 a. Estimated uterine size ___ . ___ cm

4018 b. Was the uterus tender? Yes No

4019 c. Were there possible fibroids? Yes No

4020 d. Was there any adnexal tenderness? Yes No

4021 d(i) If yes, specify location Right Left Both

4022

4023 **D: COLPOSCOPIC BIOPSY**

4024 15. Did you see the entire squamocolumnar junction (SCJ)? Yes No

4025 16. Was it a satisfactory colposcopy? Yes No

4026 If no, specify

4027 17. Were there colposcopic findings within the transformation zone? Yes No

4028 If yes, specify (tick all that apply)

4029 Flat acetowhite epithelium

4030 Micropapillary or microconvoluted acetowhite epithelium

4031 Leukoplakia

4032 Punctuation

4033 Mosaic

4034 Atypical vessels

4035 Iodine-negative epithelium

4036 Lesion extended into endocervix

4037 18. Draw SCJ (acetowhite, punctuation, mosaics, atypical vessels, and other lesions):

4038 19. Were there any other colposcopic findings? Yes No

4039 If yes, specify (tick all that apply)

4040 Mucosal bleeding easily induced

4041 Purulent cervicitis

4042 Opaque discharge

4043 Yellow discharge

4044 Other, specify:

4045 20. Were there colposcopic findings consistent with invasive carcinoma?

4046 Yes No

4047

4048 **E: COLPOSCOPY DIAGNOSIS**

4049 21. Is patient eligible for cryotherapy if necessary? Yes No
 4050 If no, indicate reason (tick all that apply)

4051 Lesion >75% of cervix4052 Lesion is larger than cryoprobe tip4053 Lesion suspicious for cancer4054 Polyp or anatomic defect preventing access to cervix4055 Previous treatment with cryotherapy in this study4056 Other, specify

4057 22. What was your diagnosis based on colposcopy examination (tick all that apply)?

4058 Normal colposcopic findings4059 Unsatisfactory, specify:4060 Inflammation/infection, specify4061 Leukoplakia4062 Condyloma4063 LSIL (CIN 1)4064 HSIL (CIN 2 & 3)4065 Invasive cancer4066 Other, specify:

4067

4068 **D: SPECIMEN COLLECTION**4069 23. Was a biopsy taken? Yes No

4070 a. If yes, how many biopsies were taken ___ ___

4071 b. Draw: (mark site(s) with an 'X' on colposcopy drawing)

4072 c. If no, specify why biopsy was not taken

4073

4074 E: Treatment

4075 24. Was any treatment given to the patient? Yes No

4076 If yes, specify treatment

4077 25. Was a referral given to the patient? Yes No

4078 If yes, specify diagnosis, and the referral institution

4079

4080 26.Comments:

4081

4082

RANDOMIZATION

4083

4084 **Study ID Number** ___ ___ **Hope ID Number** ___ ___ ___4085 **Randomization Number** ___ **Interviewer Number** ___4086 **Date of interview (day/month/year)** ___ ___ / ___ ___ / ___ ___ ___

4087

4088 **A: CURRENT MEDICAL HISTORY**4089 1. Do you have pain when passing urine? Yes No Other,
4090 specify Refused Don't know4091 2. Do you have any lower abdominal pain? Yes No Other, specify
4092 Refused Don't know4093 3. Do you have any abnormal vaginal discharge? Yes No Other,
4094 specify Refused Don't know4095 4. Have you noticed any growths around your vagina? Yes No 4096 Don't know Other, specify Refused Don't know

4097

4098 **B: REPRODUCTIVE HEALTH**4099 5. How old were you when you had your first menstrual period? ___ ___ Don't know
4100 refused Other, specify4101 6. Date of last menstrual period (day/month/year) ___ ___ / ___ ___ / ___ ___ ___
4102 Don't know refused Other, specify4103 7. Do you have history of abnormal vaginal bleeding Yes No
4104 Don't know 4105 Refused

4106 Other, specify

4107 If yes specify the type of bleeding

4108 Irregular4109 Heavy4110 Menorrhagia Other, specify4111 Don't know4112 Refused

4113

- 4114 8. Have you ever used any form of family planning method? Yes No
 4115 Don't know
 4116 Refused
 4117 Other, specify _____
 4118 If yes, specify (tick all that apply)
- 4119 Injectable IUCD Natural
 4120 Condoms OCP Norplant/ Implant
 4121 BTL others, specify _____
- 4122 9. Are you using any form of family planning method now?
 4123 Yes No Don't know Refused
 4124 Other, specify _____
 4125
 4126 If yes, specify (tick all that apply)
- 4127 Injectable IUCD Natural
 4128 Condoms OCP Norplant/ Implant
 4129
 4130 BTL others, specify _____
 4131
- 4132 10. How many times have you been pregnant? __ __ Refused Don't know
 4133 Other
 4134 11. How many times have you had live births? __ __ Refused Don't know
 4135 Other
 4136 12. How many abortions, miscarriages, and/or stillbirths have you had? __ __
 4137 Refused Don't know Other
 4138 13. Have you ever been admitted to the hospital with a gynecological problem?
 4139 Yes No Don't know Refused Other, specify
- 4140 14. Have you ever had abdominal surgery? Yes No Refused
 4141 Don't know Other, specify
 4142 15. Have you ever had vaginal surgery? Yes No
 4143 Refused Don't know Other, specify
 4144 16. Do you currently smoke cigarettes Yes No
 4145 Refused Don't know Other, specify
 4146

4147 **C: HIV HISTORY**

- 4148 17. When were you diagnosed as having HIV? (day/month/year) ____ ____/____
 4149 ____/____ ____ ____
 4150 18.1. How was HIV detected? (tick only one)

- 4151 - At the occasion of a VCT: Yes
- 4152 - During pre-natal check-up: Yes
- 4153 - Because of a sickness, specify: _____ Yes
- 4154 - Other, specify: _____
- 4155 - Don't know:
- 4156 - Refused:
- 4157
- 4158 19. Are you currently on antiretroviral medications? Yes No
- 4159 Don't know
- 4160 Refused
- 4161 Other, specify _____
- 4162 If yes,
- 4163 a) specify current medications: _____
- 4164 b) original start date: ____ / ____ / ____ Don't know
- 4165 c) Do you know why you were started on antiretroviral medication?
- 4166 - because of sickness, specify: _____ Yes
- 4167 - because of low CD4 count: Yes
- 4168 - because of high viral load: Yes
- 4169 - Other, specify: _____
- 4170 - Don't know:
- 4171 - Refused:
- 4172
- 4173 20. Comment

- 4202 4. Is patient indicated for LEEP or cryotherapy treatment based on histopathology?
 4203 Yes No
 4204 If no, continue to 14
- 4205 5. Is patient's lesion amenable to cryotherapy? Yes No (If yes, go to
 4206 question 6)
 4207 5(i) If no, indicate reason (tick all that apply)
- 4208 Lesion >75% of cervix
 4209 Lesion is larger than cryoprobe tip
 4210 Invasive cervical cancer on histology
 4211 Lesion suspicious for cancer
 4212 Polyp or anatomic defect preventing access to cervix
 4213 Patient declines procedure
 4214 Other, specify
- 4215 5(ii) If no, is patient's lesions amenable to LEEP? Yes No
 4216 If yes, skip to 7
 4217 If no, skip to 14
- 4218 6. Was patient randomized to LEEP or cryotherapy today? Yes No
 4219 If yes, to which treatment? LEEP Cryotherapy
 4220 If no, why?
- 4221 Patient refuses
 4222 Patient not eligible for treatment, specify reason
 4223 Other, specify
 4224
- 4225 **C: TREATMENT**
- 4226 7. Did you perform LEEP or cryotherapy today? (tick one)
 4227 LEEP Cryotherapy Neither, explain
 4228 (If neither, explain, skip to Q14)
- 4229 8. Did you visualize the full extent of lesion? Yes No
 4230 9. Was the squamocolumnar junction fully visualized? Yes No
 4231 10. Draw position of lesion and treatment performed:
 4232 11. Did the patient experience any pain during the procedure? Yes No
 4233 12. Was analgesia provided? Yes No
 4234 13. Were there any complications? Yes No

- 4235 If yes, specify
- 4236 14. Was any antibiotics given? Yes No
- 4237 If yes, specify
- 4238
- 4239
- 4240
- 4241
- 4242 **D: OTHER**
- 4243 15. Was the patient referred for further treatment at another institution? Yes
- 4244 No
- 4245 If yes, specify institution and reason
- 4246 16. Was treatment or a referral given for something other than cervical disease? Yes No
- 4247 If yes, specify (give diagnosis and treatment)
- 4248 17. Comments

4249

ADDRESS AND INTAKE

4250

4251 **Study ID number** _ _ _ _**Interviewer number** _ _ _ _

4252

4253 **Date of interview (day/month/year)** _ _ _ / _ _ _ / _ _ _ _ _ _

4254

4255 **Format(tick one)** **New** **Update (fill only updated info)**

4256

4257 **A. PERSONAL INFORMATION**

4258 1. What is your name?

4259 a. First name

4260 b. Middle name

4261 c. Last name

4262 2. How are you called in your home area?

4263 3. What is the current physical location where you live?

4264 a. District

4265 b. City

4266 c. Village

4267 d. Estate

4268 e. Plot number

4269 f. Door number

4270 g. Road name

4271

4272 4. Public Transportation to the house:

4273 4a. Type: F Bus F Boda boda F Matatu F Taxi F Other (specify)

4274 4b. Route number:

4275 4c. Stage Name

4276 4d. General Name of the Area

4277 5. Walking directions to house from the stage?

4278 6. Landmarks that aide in locating the household: (Names of schools, churches,
4279 businesses etc.)4280 7. Can you be reached by phone? Yes No

4281 If yes,

4282 7 (i)What is the phone number 1?

4283 7 (ii)What is the phone number 2?

4284

4285 7iii. Who carries the phone (tick one) self other, specify

4286

4287 **B. SIGNIFICANT CONTACT**

4288 8. Is there another person who is ware of your HIV status that we can contact through phone
 4289 if we are unable to reach you directly?
 4290 If no, skip to 9.

4291 9. What is the name of this contact person?

4292 a. First name

4293 b. Middle name

4294 c. Last name

4295 10. What is the relationship of this person to you?

4296 11. (a)What is the phone number 1?

4297 (b) What is the phone number 2?
 4298

4299 **C. UPCOUNTRY INFORMATION**

4300 12. Do you have an upcountry home? Yes No
 4301 If no, skip to 19

4302 13. What is the physical location of your upcountry home?

4303 a. District

4304 b. City

4305 c. Village

4306 d. Estate

4307 e. Plot number

4308 f. Door number

4309 14. Specific directions to residence

4310 15. Is there person located in your upcountry home whom we can contact if we are unable to
 4311 reach you directly? Yes No
 4312 If no, skip to 19

4313 16. What is the name of this contact person?

4314 a. First name

4315 b. Middle name

4316 c. Last name

4317 17. What is the relationship of this person to you?

4318 18. Does this contact have a phone number? Yes No

4319 If yes, specify: phone number 1, phone number 2
 4320

4321 **D. OTHER**

4322 Comment:

4323

SHEDDING

4324

4325 **Study ID Number** ___ ___ ___**Interviewer Number** ___ ___

4326

4327 **Date of interview (day/month/year)** ___ ___/___ ___/___ ___ ___ ___

4328

4329 **Visit (tick one)** **Week 1 FU** **Week 2 FU** **Week 3 FU** **Other, specify** _____

4330

4331 **A: MEDICAL HISTORY**

4332 1. Has the patient experienced any lower abdominal pain since the last visit?

4333 Yes No

4334 If yes, indicate:

4335 a. Duration ___ ___ days

4336 b. Severity (scale from 1 to 5; 5 being most severe) ___ ___

4337

4338 2. Has the patient experienced any vaginal bleeding since the last visit?

4339 Yes No

4340 If yes, indicate:

4341 a. Duration ___ ___ days

4342 b. Volume

4343 Stain pants4344 Requires sanitary pad4345 Other, specify

4346 3. Has the patient experienced any vaginal discharge since the last visit?

4347 Yes No

4348 If yes, indicate:

4349 c. Duration ___ ___ days

4350 d. Color

4351 Yellow4352 Brown4353 White4354 Clear

- 4355 Other, specify
- 4356 e. Smell
- 4357 Malodorous
- 4358 No odor
- 4359 Other, specify
- 4360 f. Volume
- 4361 Stain pants
- 4362 Requires sanitary pad
- 4363 Other, specify
- 4364 4. Has the patient experienced any fever after the last visit?
- 4365 Yes No
- 4366 If yes, specify duration ___ ___ days
- 4367 5. Did the patient seek medical care for these or other complaints?
- 4368 Yes No
- 4369 If yes, specify what complaint prompted the participant to seek care:
- 4370 Abdominal pain
- 4371 Fever
- 4372 Vaginal Bleeding
- 4373 Vaginal discharge
- 4374 a. Other, specify
- 4375 If yes, specify where the participant sought care:
- 4376 Study clinic
- 4377 Hope Center
- 4378 Coptic Hospital
- 4379 KNH
- 4380 b. Other, specify
- 4381 6. Was the participant's condition possibly due to a study procedure? (Ask if any of
- 4382 questions 1-4 is yes)
- 4383 Yes No

4384 If any question 1-4 is Yes and the condition is not expected as per study protocol, or is
4385 more severe than expected, fill an AE form.

4386

4387

4388 7. Date of last menstrual cycle (dd/mm/yyyy)

4389 8. Have you ever had vaginal sex since treatment? Yes No Refused

4390 Other (specify) _____

4391

4392 8 (a). If yes, how many times? __

4393

4394 8(b) If you have had vaginal sex since treatment, how often did you use condoms during
4395 sex?

4396 Always (100%) Most of the time (75-99%)

4397 Half of the time (50%-74%) Sometimes (25-49%)

4398 Rarely (1-25%) Never (0%)

4399 Refused Don't know Other, specify _____

4400

4401 9. Do you think you may be currently pregnant? Yes No

4402 10. Are you currently on antiretroviral medications?

4403 Yes Refused Other, specify

4404 No Don't know

4405 If No, Refused, or Don't Know, skip to Q14

4406 If yes, specify current medications and original start date.

4407 d4t, 3tc, nvp

4408 d4t, 3tc, efv

4409 azt, 3tc, nvp

4410 azt, 3tc, efv

4411 Other specify

4412 Original ARV start date (dd/mm/yyyy)

4413 11. During the last 7 days, how many antiretroviral pills did the patient MISS taking?

4414 12. During the last 30 days, how many antiretroviral pills did the patient MISS taking?

4415 **(If Q11 and Q12 patient did not MISS taking any pills skip to Q14)**

4416 13. If the patient missed any doses, please specify reasons (check all that apply)

- 4417 Toxicity/ side effect
- 4418 Share with others
- 4419 Forgot
- 4420 c. Felt better
- 4421 Too ill
- 4422 Stigma, disclosure or privacy issues
- 4423 Drug out of stock
- 4424 Patient lost or ran out of pills
- 4425 Delivery /travel problem
- 4426 Inability to pay
- 4427 Alcohol
- 4428 Depression
- 4429 d. Other specify

4430

4431

4432 **B: DIAGNOSIS**

4433 14. Is there any new infection that was related to the procedure since the last visit?

4434 Yes No

4435 If yes, specify and fill an Adverse Event questionnaire:

4436 15. Were there any new complications diagnosed today related to the treatment?

4437 Yes No

4438 If yes, specify and fill an Adverse Event questionnaire:

4439

4440 **C: TREATMENT**

4441 16. Was any treatment provided today? Yes No

4442 If yes, specify

4443 17. Was the patient referred for further cervical treatment at another institution?

4444 Yes No

4445 17 (i) If yes, specify institution

4446 17(ii) If yes, specify reason for referral

4447

4448

4449 **D: SPECIMEN COLLECTION**

4450 18. Did you collect cervical HIV swab? Yes No

4451 If no, specify reason:

4452 19. Did you collect blood? Yes No

4453 If no, specify reason:

4454

4455 **E: ACCEPTABILITY OF TREATMENT**

4456 **20. Please complete the items listed below by placing a checkmark on the box next to**
 4457 **each question that best indicates how the client feels about the treatment she received.**

4458

	Strongly Disagree	Disagree,	Neutral,	Agree	strongly agree
(i) I find this treatment an acceptable way of dealing with cervical lesions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(ii) I would be willing to use this procedure if I were to develop more lesions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(iii) I would recommend this procedure to someone with cervical lesions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(iv) overall, I have a positive reaction to this treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4459

4460 **F: OTHER**

4461 22.

4462 —

4463

4464 23.

4465 24. Comments:

4466

4495 6. Reasons for missed study appointment (tick all that apply)

4496 N/A, did not reach patient or patient contact Unable attend because health problem4497 No longer willing to be in study Family problems4498 Wait time too long in clinic Client will go to faith healer

4499

4500 Conflict with work Unwilling to disclose4501 Financial problems No longer willing attend Hope Clinic4502 Client moved or relocated Other (specify)

4503

4504 7. If talked to patient, did the patient wish to remain in the study?

4505 Yes (*Go to 7a*)4506 No (*Go to 8 and complete Exit Form*)4507 N/A, did not talk to patient (*Go to 9*)

4508

4509 7a. Did the patient schedule a study appointment? Yes No (*If Yes go to 7b, If No go to 7c*)

4510

4511 7b. If yes, date of scheduled appointment (DD/MM/YYYY) HH/FF/HHH

4512

4513

4514 7c. If no, why did the patient not schedule an appointment (tick all that apply)

4515 Unable to attend because of health problems4516 Family problems4517 Conflict with work4518 Financial problems4519 Client moved or relocated4520 Client lives too far away 4521 Other (specify)

4522

4523 8. If the patient does not wish to return to the study, specify why (tick all that apply)

- 4524 F Not willing to attend Hope Clinic
- 4525 F Not willing to be in study
- 4526 F Attend clinic closer to home
- 4527 F Wait time too long
- 4528 F Conflict with work
- 4529 F Financial problems
- 4530 F Unwilling to attend because of health problems
- 4531 F Family problems
- 4532 F Client will go to a faith healer
- 4533 F Not willing to disclose HIV status
- 4534 F Referred else where

4535 F Other (specify)

4536 F Unknown

4537

4538

4539 9. Comments

4540

4541

4542

4543

4574 6. Respondent's detailed account of the illness of the deceased:

4575

4576 7. Did a health care worker tell you the cause of death? Yes No Unknown

4577 *If yes go to 7a, if no*

4578 *go to 8*

4579

4580 7a. What did the health care worker say was the cause of
4581 death? _____

4582

4583 8. Did s/he have any operation for the illness? Yes No Unknown

4584 *If yes go to 8a, if no go to 9*

4585

4586 8a. How long before the death was the operation? _____ days

4587

4588 8b. On what part of the body was the operation?

4589 Abdomen Chest Head Other(Specify _____)

4590

4591 9. Has spouse or other sexual partner(s) of the deceased died in the past 5 years?

4592 Yes No Unknown

4593 *go to 10* *If yes go to 9a, if no*

4594

4595 9a. If yes, what is the believed cause(s) of death of the partner(s)

4596 9a1. Partner 1: _____

4597 9a2. Partner 2: _____

4598

4599 **Injury/accident/suicide**

4600

4601 10. Did s/he suffer from any injury or accident that led to her death? Yes No
4602 Unknown

4603 *If yes go to 10a, if no go to 11*

4604 10a. What kind of injury or accident did the deceased suffer?

4605 Road traffic accident Fall Drowning Poisoning

4606 Burns Violence/assault

4607 Other: _____

4608 Unknown

4609

4610 10b. Was the injury or accident intentionally inflicted by someone else? Yes

4611 No Unknown

4612

4613 10c. Do you think that s/he committed suicide? Yes No Unknown

4614 *Skip to Q.12*

4615

4616 11. Did s/he suffer from any animal/insect bite that led to her/his death? Yes

4617 No Unknown

4618

4619 11a. If yes, what type of animal/insect? _____

4620

4621 **History of previously known medical conditions**

4622

4623 12. Did the deceased suffer from any of the following conditions?

4624

4625 a. High blood pressure Yes No Unknown

4626 b. Diabetes Yes No Unknown

4627 c. Asthma Yes No Unknown

4628 d. Epilepsy Yes No Unknown

4629 e. Malnutrition Yes No Unknown

4630 f. Cancer Yes No Unknown

4631 f1. If yes, specify type of cancer or site: _____

4632 g. Tuberculosis Yes No Unknown

4633 h. Any other medically diagnosed illness? Yes No Unknown

4634 h1. If yes, specify: _____

4635

4636 **13. Signs, symptoms, and their severity during the last illness:**

Symptom/ Signs	Symptom present?	If present, duration of symptom
a. Fever	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
b. Loss of weight	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
c. Diarrhea	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
d. Vomiting/associated abdominal pain	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
e. Constipation/associated abdominal pain	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
f. Cough	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
g. Cough followed by vomiting	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
h. Breathing trouble (chest indrawing/difficult/rapid/wheezing)	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
i. Neck stiffness	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
j. Unconscious episodes	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
k. Fits	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
l. Jerking of individual limbs	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
m. History of epileptic illness in earlier years	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
n. Paralysis of limbs	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
o. Rigid body stiffness, unable to open mouth	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
p. Red and sore eyes	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
q. Skin rash and itching	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
r. Herpes Zoster (at any time in life)	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
s. Abscesses/body sores	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
t. White patches on the inside of mouth and tongue	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
u. Oedema	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
v. Hair changes	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
w. Yellowing of eyes or passing of brown urine	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
x. Chest pain	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
y. Other (Specify:)	F No F Yes	F ≤2 weeks F >2 weeks F Unknown

4637

Unexpected vaginal bleeding or discharge	F No F Yes	F ≤2 weeks F >2 weeks F Unknown
Pelvic or vaginal pain	F No F Yes	F ≤2 weeks F >2 weeks F Unknown

4638

- 4639 14. Records available in home, e.g., death certificate (extract findings):
- 4640 15. Comment

EXIT

4641

4642

4643 **Study ID Number:** ____ ____ ____**Interviewer Number:** ____

4644 ____

4645

4646 **Date of visit (day/month/year)** ____ ____ / ____ ____ / ____ ____ ____ ____

4647

4648 1. Is the patient exiting the study because she has completed the study protocol and qualifies
 4649 as per study guidelines to exit the study at this time? Yes No *(If Yes, go to*
 4650 *9, If No go to 2)*

4651 2. Date of last study visit (DD/MM/YYYY) HH/HH/HHH4652 3. Date last seen by study staff (DD/MM/YYYY) HH/HH/HHH4653 4. Has the patient accessed care at the Hope Clinic in the past year? Yes No

4654

4655 5. Did you talk to the patient? Yes No *(If Yes go to 6, If No go to 5a)*

4656

4657 5a. If no, who was the source of information (tick one)

4658 Clinician / clinic staff Employer Treatment supporter

4659

4660 Spouse or Partner Friend Other (specify)4661 Family member / Relative Neighbor4662 Mother or Father Caregiver

4663 6. Has the patient transferred HIV care to another program? Yes No *(If Yes go to 6a,*
 4664 *If No go to 7)*

4665

4666 6a. If yes, where is the patient transferring care to (tick one)

4667 Transferred to another non-Hope clinic, specify4668 Transferred to Industrial area clinic4669 Transferred to Maseno clinic

4670 7. Has Hope Clinic asked the patient to Exit or leave the program? Yes No (*If Yes go*
4671 *to 7a, If No go to 8)*

4672 7a. Reasons for being Exited from the program (tick all that apply)

4673 Client has not returned to clinic for 1 year

4674 Poor Adherence

4675 Poor Clinic Attendance

4676 Not willing to disclose HIV status

4677 Referred else where

4678 Tested Negative

4679 Other (specify)

4680 Unknown

4681 8. Has the patient asked to be Unenrolled from the study? Yes No (*If Yes go to 8a, If*
4682 *No go to 9)*

4683 8a. Reasons patient is asking to Unenroll from the study (tick all that apply)

4684 Not willing to attend

4685 Waiting time too long

4686 Conflict with work

4687 Financial problems

4688 Unwilling to attend because of health problems

4689 Family Problems

4690 Client will go to a faith healer

4691 Not willing to disclose HIV status

4692 Referred else where

4693 Other (specify)

4694 Unknown

4695 9. At what point was the patient exited? After Pap smear After Biopsy Mortality
4696 Withdrawn from study Other (If other specify)

4697 10. Comment

4730

4731 9. Any microbiological findings? Yes No
 4732 If “Yes”, specify findings:

- 4733 Lactobacilli
- 4734 Mixed flora
- 4735 Bacterial vaginosis
- 4736 Candida
- 4737 Trichomonas vaginalis
- 4738 Actinomyces
- 4739 Schistosoma
- 4740 Herpes simplex
- 4741 Other, specify.....

4742

4743 10. Any reactive changes observed? Yes No
 4744 If “Yes”, specify findings

- 4745 Metaplasia
- 4746 Inflammatory changes
- 4747 Follicular cervicitis
- 4748 Parakeratosis
- 4749 Atrophy
- 4750 Other reactive changes
- 4751 If “Yes”, specify.....

4752

4753 11. Squamous epithelium: Normal Abnormal
 4754 If “Yes”, specify findings

- 4755 ASC-US Yes No
- 4756 ASC-H Yes No
- 4757 Low grade SIL Yes No
- 4758 - With koilocytosis Yes No

4759 High grade SIL Yes No

4760 HSIL invasion not ruled out Yes No

4761 Squamous cell carcinoma Yes No

4762 Others, specify _____

4763

4764 12. Glandular epithelium: Normal

4765 abnormal

4766 If “Yes”, specify findings

4767 Abnormal presence of endometrial cells Yes No

4768 Atypical glandular cells, pref. neoplastic Yes No

4769 Adenocarcinoma in situ Yes No

4770 Adenocarcinoma Yes No

4771 - Endometrial Yes No

4772 - Endocervical Yes No

4773 Others, specify _____

4774 13. Other

4775 remarks.....

4776 Interviewer number of pathologist

4777 Date: _____

4778

4779

4780 **COLPOSCOPIC BIOPSY HISTOLOGY REPORT**

4781 First read Re-read 1 Consensus readingTie-break

4782 **Study ID Number**__ __ __ **Hope ID Number** __ __ __ __

4783 Test/ Visit code_____

4784 **Visit (tick one)** **Initial Visit** **Month 6 FU** **Month 12 FU** **Month 18 FU**

4785 **Month 24 FU** **Other, specify**

4786 Interviewer number --- ----**Patient Age** _____

4787 1. Date sample was collected in clinic (day/month/year) ____/____/____

4788 _____

4789 2. Time sample was collected in clinic

4790 3. Date sample was received in laboratory (day/month/year) ____/____/____

4791 _____

4792 4. Time sample was received in laboratory

4793 5. When was the biopsy processed? (day/month/year) ____/____/____

4794 6. When was the biopsy reported? (day/month/year) ____/____/____

4795 7. Was the amount of sample adequate for reading? F Yes F No Other, specify

4796 8. What was the histology result of the cervical biopsy (tick one)?

4797 No dysplasia (NIL)

4798 CIN 1

4799 CIN 2

4800 CIN 3

4801 Invasive carcinoma

4802 Indeterminate/

4803 CIS

4804 Other, specify

4805 9. Was there evidence of cervicitis? F Yes F No Other, specify

4806 10. Who read the biopsy and gave this histology result?

4807 Pathologist Interviewer number ____

4808 11. Comments:

4809

--

4810 **ENDOCERVICAL CURETTAGE HISTOLOGY REPORT**

4811 First read Re-read 1 Consensus reading Tie-break

4812 **Study ID Number** _____ **Hope ID Number** _____

4813 Test/ Visit code _____

4814 **Visit (tick one)** **Initial Visit** **Month 6 FU** **Month 12 FU** **Month 18 FU**

4815 **Month 24 FU** **Other, specify**

4816 Interviewer number --- --- **Patient Age** _____

4817 1. Date sample was collected in clinic (day/month/year) ____/____/____
4818 _____

4819 2. Time sample was collected in clinic

4820 3. Date sample was received in laboratory (day/month/year) ____/____/____
4821 _____

4822 4. Time sample was received in laboratory

4823 5. When was the biopsy processed? (day/month/year) ____/____/____

4824 6. When was the biopsy reported? (day/month/year) ____/____/____

4825 7. Was the amount of sample adequate for reading? F Yes F No Other, specify

4826 8. What was the histology result of the Endocervical Curettage biopsy (tick one)?

4827 No dysplasia (NIL)

4828 CIN 1

4829 CIN 2

4830 CIN 3

4831 Invasive carcinoma

4832 Indeterminate/

4833 CIS

4834 Other, specify

4835 9. Was there evidence of cervicitis? F Yes F No Other, specify

4836 10. Who read the biopsy and gave this histology result?

4837 Pathologist Interviewer number _____

4838 11. Comments:

4839

LEEP BIOPSY HISTOLOGY REPORT

4840

First read Re-read 1 Consensus reading Tie-break

4841

Study ID Number _____

Hope ID Number _____

4842

Test/ Visit code _____

4843

4844

Visit (tick one) Initial Visit Month 6 FU Month 12 FU Month 18 FU

4845

Month 24 FU Other, specify

4846

Patient Age _____ Interviewer number --- ----

4847

1. Date sample was collected in clinic (day/month/year) ____/____/____

4848

4849

2. Time sample was collected in clinic

4850

3. Notes:

4851

4852

4853

4. Date sample was received in laboratory (day/month/year) ____/____/____

4854

4855

5. Time sample was received in laboratory

4856

6. When was the LEEP specimen processed? (day/month/year) ____/____/____

4857

7. When was the LEEP specimen reported? (day/month/year) ____/____/____

4858

8. Was the amount of sample adequate for reading? F Yes F No Other, specify

4859

9. What was the histology result of the LEEP cervical biopsy (tick one)?

4860

No dysplasia (NIL)

4861

CIN 1

4862

CIN 2

4863

CIN 3

4864

Invasive carcinoma

4865

Indeterminate/

4866

CIS

4867

Other, specify

4868

10. Was there evidence of cervicitis? F Yes F No Other, specify

4869

11. Who read the biopsy and gave this histology result?

4870 Pathologist Interviewer number ____

4871 12. Comments:

4872

CD4 REPORT

4873

4874 Study ID Number__ __ __

Hope ID Number __ __ __ __

4875

4876

4877 Visit (tick one) Randomization/LEEP Visit Month 6FU Month 12FU Month 18
4878 FU Month 24 FU Other, specify

4879

4880

4881 Patient Age

Interviewer number

4882

4883 1. Date sample was collected in clinic (day/month/year) ___ ___/___ ___/___ ___ ___
4884 ___

4885 2. Time sample was collected in clinic

4886 3. Date sample was received in laboratory (day/month/year) ___ ___/___ ___/___
4887 ___ ___ ___

4888 4. Time sample was received in laboratory

4889 5. When was the CD4 count run? (day/month/year) ___ ___/___ ___/___ ___ ___ ___

4890 6. What was the result of the CD4 count? ___ ___ ___ ___

4891 7. Who ran the CD4 count and gave this CD4 result? Coptic lab F Other, specify
4892

4893 8. Comments:

4894

4895

4896

4897

4898

4899

FOLLOW-UP FORM

4900

4901

4902 **Study ID Number** _____ **Hope ID Number** _____ **Interviewer Number** _____

4903

4904 **Date of interview (day/month/year)** _____/_____/_____

4905 **Visit (tick one)** **Month 6 FU** **Month 12 FU** **Month 18 FU**

4906 **Month 24 FU** **Other, specify**

4907 **A: MEDICAL HISTORY**

4908 1. Did you consult a doctor or clinical officer between today and your previous study visit?

4909 Yes

4910 No (go to question 2)

4911 Don't know (go to question 2)

4912 Refused (go to question 2)

4913

4914 If yes:

4915 1.1. How many consultations?

4916 _____

4917 Don't know (go to question 2)

4918 Refused (go to question 2)

4919

4920 1.2. Why did you consult?

4921 1.2.1. Visit 1:

Reason for consultation	
Routine check-up visit not study related	<input type="checkbox"/> yes
Sickness.....	<input type="checkbox"/> yes
Other, specify	<input type="checkbox"/> yes
Do not recall the reason	<input type="checkbox"/> yes
Refused	<input type="checkbox"/> yes

4922

4923 1.2.2. Visit 2:

Reason for consultation	
Routine check-up visit not study related	<input type="checkbox"/> yes
Sickness.....	<input type="checkbox"/> yes
Other, specify	<input type="checkbox"/> yes
Do not recall the reason	<input type="checkbox"/> yes
Refused	<input type="checkbox"/> yes

4924

4925 1.2.3. Visit 3:

Reason for consultation	
Routine check-up visit not study related	<input type="checkbox"/> yes
Sickness.....	<input type="checkbox"/> yes
Other, specify	<input type="checkbox"/> yes
Do not recall the reason	<input type="checkbox"/> yes
Refused	<input type="checkbox"/> yes

4926
4927

1.2.4 Visit 4

Reason for consultation		
Routine check-up visit not study related	<input type="checkbox"/>	yes
Sickness.....	<input type="checkbox"/>	yes
Other, specify	<input type="checkbox"/>	yes
Do not recall the reason	<input type="checkbox"/>	yes
Refused	<input type="checkbox"/>	yes

4928
4929

1.2.5 Visit 5

Reason for consultation		
Routine check-up visit not study related	<input type="checkbox"/>	yes
Sickness.....	<input type="checkbox"/>	yes
Other, specify	<input type="checkbox"/>	yes
Do not recall the reason	<input type="checkbox"/>	yes
Refused	<input type="checkbox"/>	yes

4930
4931

1.2.6 Visit 6

Reason for consultation		
Routine check-up visit not study related	<input type="checkbox"/>	yes
Sickness.....	<input type="checkbox"/>	yes
Other, specify	<input type="checkbox"/>	yes
Do not recall the reason	<input type="checkbox"/>	yes
Refused	<input type="checkbox"/>	yes

4932
4933
4934

(For those previously not on ARVs- please refer to enrollment form)

4935
4936
4937
4938
4939
4940

2. Have you initiated anti-retroviral medication since the last visit?
- Yes
 - No
 - Don't know
 - Refused

4941
4942

If yes:

4943
4944
4945
4946

- 2.1. Which date did you initiate ARV's --/ --/ ----
- 2.2. Specify current regimen

4947
4948
4949
4950
4951

3. Are you still on ARVs? (For those previously on ARVs-please refer to enrollment form)
- Yes
 - No
 - NA
- (If NA go to Q4)

4952
4953
4954
4955
4956
4957
4958
4959

- 3.1 If no, reasons for not being on ARVs
- Poor adherence
 - Side effect
 - Stigma
 - Concurrent illness
 - Other (specify)

4960
4961

- 3.2 If yes, has your anti-retroviral medication changed since last cervical treatment visit?

- 4962 Yes
- 4963 No (go to question 4)
- 4964 Don't know (go to question 4)
- 4965 Refused (go to question 4)
- 4966

4967 If yes:

- 4968 3.2.1. On which date was it changed: ____/____/____
- 4969 3.2.2. What was the reason for changing your antiretroviral medication? (Check all
4970 that apply)
- 4971 a) Because of low CD4 counts: Yes
- 4972 b) Because of high viral load: Yes
- 4973 c) Because of clinical symptoms: Yes
- 4974 f) Other, specify: _____ Yes
- 4975 e) Don't know: Yes
- 4976 d) Refused: Yes
- 4977
- 4978 3.2.3 Specify current medications: _____
- 4979

4980 4. Did you receive any cervical treatment other than what we offered?

- 4981 Yes
- 4982 No (go to part B)
- 4983 Don't know (go to part B)
- 4984 Refused (go to part B)
- 4985

4986 If yes:

- 4987 4.1. On which date was this: ____/____/____
- 4988 4.2. Which treatment did you receive?
- 4989 a) Cryotherapy: Yes
- 4990 b) LEEP: Yes
- 4991 c) Cold knife exconisation: Yes
- 4992 d) Hysterectomy: Yes
- 4993 f) Other, specify: _____ Yes
- 4994 e) Don't know: Yes
- 4995 d) Refused: Yes
- 4996

4997 **B. SEXUAL HISTORY**

4998 5. Have you had sex in the last 6 months?

- 4999 Yes
- 5000 No (go to Q6)
- 5001 Don't know (go to Q6)
- 5002 Refused (go to Q6)
- 5003

5004 If yes:

- 5005 5.1. With your regular partner? Yes
- 5006 No (go to Q5.2)
- 5007 If yes,
- 5008 5.1.1. How often have you used condoms during sex with your regular
5009 partner in the last 6 months?
- 5010 Always (100%)
- 5011 Most of the time (75-99%)

- 5012 Half of the time (50%-74%)
- 5013 Sometimes (25-49%)
- 5014 Rarely (1-25%)
- 5015 Never (0%)
- 5016 Don't know
- 5017 Refused to answer

5018
5019

5020 5.1.2. Do you suspect that your partner has had other sexual partners during
5021 the last 6 months?

- 5022 Yes
- 5023 No
- 5024 Don't know
- 5025 Refused

5026
5027

5028 5.2. Did you have sex with any other partner(s) than your regular partner during the
5029 last 6 months?

- 5030 Yes
- 5031 No (Go to Q6)
- 5032 Don't know (Go to Q6)
- 5033 Refused (Go to Q6)

5034
5035

If yes:

5036 5.2.1. How many other different sexual partners besides your regular partner did
5037 you have in the last 6 months? _____

- 5038 Don't know
- 5039 Refused

5040
5041

5042 5.2.2. How often have you used condoms during sex with these other partner(s)
5043 in the last 6 months?

- 5044 Always (100%)
- 5045 Most of the time (75-99%)
- 5046 Half of the time (50%-74%)
- 5047 Sometimes (25-49%)
- 5048 Rarely (1-25%)
- 5049 Never (0%)
- 5050 Don't know

5051 6. Refused to answer

5052 7. Comment

5053

5054

5055

ADVERSE EVENTS

5056 **Study ID Number** ___ ___ ___

Interviewer Number ___ ___

5057 **Date of visit (day/month/year)** ___ ___ / ___ ___ / ___ ___

5058 **Visit (tick one)** **Shedding1** **Shedding2** **Shedding3**

5059 **Month 6 FU** **Month 12 FU** **Month 18 FU** **Month 24 FU**

5060 **Other, specify** _____

	Adverse Event	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Severity 1= Mild 2= Moderate 3= Severe 4= Life Threatening	Relationship to Study procedures 1= Related 2= Notrelated	Outcome 1= Resolved without sequelae 2= Resolved with sequelae 3= Ongoing 4= Death 5= Unknown	Serious 0= No 1= Yes**
1							
2							
3							
4							

5061

5062 Comments: _____
5063 _____

5064 ** If Serious Adverse Event, contact a PI immediately after filling this form.**

5065 **PI Contacts: Dr. Michael Chung – 020-271-2947, 0722-579-963, Dr. Nelly Mugo – 020-273-6744**

5066

5067

5068

5069

5070

UANDIKISHAJI

5071

5072 **Study ID Number** ___ ___ **Hope ID Number** ___ ___ **Interviewer Number** ___

5073

5074 **Date of interview (day/month/year)** ___ ___/___ ___/___ ___ ___

5075

5076 Ulikubali kuhifadhi sampuli : Ndio La Sijui Nyingine, eleza

5077

5078 **A: SOCIODEMOGRAPHICS**

5079 1. Tarehe ya kuzaliwa (siku/mwezi/mwaka) ___ ___/___ ___/___ ___

5080 ___ ___

5081 2. Miaka _____ years

5082 3. Ulikamilisha miaka ngapi ya elimu? _____ years

5083 4. Elimu ya juu zaidi uliyokamilisha? Hakuna 5084 Msingi 5085 Sekondari 5086 Elimu ya juu/ Chuo Kikuu 5087 Sijui 5088 Amekataa

5089 Nyingine, eleza

5090

5091 5. Hali ya ndoa (jibu moja) Ndoa (mke mmoja) 5092 Ndoa (wake wengi) 5093 Pekee 5094 Talaka/Tenganishwa 5095 Mjane 5096 Amekataa 5097 Kuishi pamoja 5098 Nyingine eleza

5099

5100 6. Ajira (jibu moga): Kazi inayokupa mshahara 5101 Kujiajiri

- 5102 Mama wa nyumbani
- 5103 Hujaajiriwa
- 5104 Mfanyikazi wa kawaida
- 5105 Amekataa
- 5106 Nyingine, eleza
- 5107
- 5108 7. Kipato cha kaya kwa mwezi (jibu moja): Hakuna
- 5109 < 5000 Ksh
- 5110 5001 – 10000 Ksh
- 5111 10001 – 15,000 Ksh
- 5112 >15,000 Ksh
- 5113 Sijui
- 5114 Amekataa

5115

5116 **B: HISTORIA YA KUFANYA MAPENZI**

- 5117 8. Ulikuwa na miaka mingapi ulipofanya ngono ya uke mara ya kwanza? __ __
- 5118 Sijui Amekataa Hujawahi Nyingine, eleza
- 5119
- 5120 9. Umewahi kuwa na wapenzi wangapi wa ngono? __ __ Sijui Amekataa
- 5121 Nyingine, eleza _____
- 5122
- 5123 10. Umekuwa na wapenzi wangapi tofauti wa ngono mwaka wa mwisho? __ __
- 5124 __ Sijui Amekataa Nyingine, eleza
- 5125
- 5126 11. Umefanya ngono katika mwezi wa mwisho? (If no, don't know, refused, skip to
- 5127 14) Ndio La Sijui Amekataa Nyingine, eleza
- 5128
- 5129 12. Ni mara ngapi umetumia mpira wakati wa ngono katika mwezi uliopita?
- 5130 Kila wakati (100%) Wengi wa wakati huo (75-99%)
- 5131 Nusu ya mudu (50%-74%) Wakati mwingine (25-49%)
- 5132 Mara chache (1-25%) Kamwe (0%)
- 5133 Amekataa Sijui
- 5134 Nyingine, eleza
- 5135
- 5136 13. Je, unafikiri unaweza kuwa ma mimba sasa? Ndio La Sijui
- 5137 Amekataa Nyingine, eleza
- 5138
- 5139

5140 **C: SARATANI YA UZAZI HISTORIA YA UCHUNGUZI**5141 14. Hapo awali, umewahi kupimwa saratani ya uzazi? Ndio La 5142 Sijui Alikataa Nyingine, eleza

5143

5144 If no, don't know or refused skip to 20.

5145 15. Uchunguzi gani wa saratani ya uzazi uliofanyiwa hivi karibuni? (jibu moja)

5146 Pap smear5147 Ukaguzi na asetiki aside5148 HPV5149 Nyingine, eleza : _____5150 Sijui5151 Amekataa

5152 16. Uchunguzi huu wa hivi karibuni ulifanyiwa wapi?

5153

5154 Coptic5155 KNH5156 Amekataa Sijui5157 Nyingine, eleza

5158 17. Uchunguzi huu ulifanyiwa wapi?

5159 sijui

5160

5161 18. Majibu yalikuwa nini?

5162 Kawaida5163 Usiokuwa ya kawaida, eleza _____5164 Sijui5165 Amekataa5166 19. Ulipokea matibabu yoyote ya kizazi au upasuaji kwasababu ya majibu ya hii
5167 uchunguzi?5168 Ndio La Sijui Amekataa Nyingine, eleza _____

5169 Kama ni ndio, eleza _____

5170

5171 20. Pap Smear ilifanywa leo? Ndio La Amekataa Sijui

5172 Kama ni la, fafana

5173 21. Maoni

5174

UBAHATISHAJI

5175

5176 **Study ID Number** ___ ___ **Hope ID Number** ___ ___ ___

5177

5178 **Randomization Number** ___ **Interviewer Number** ___

5179

5180 **Date of interview (day/month/year)** ___ ___/___ ___/___ ___ ___

5181

5182

5183 **A: HISTORIA YA SASA YA MATIBABU**

5184 1. Je, unauchungu unapopitisha mkojo? Ndio La Nyingine, eleza

5185 Amekataa Sijui

5186

5187 2. Je, una uchungu sehemu ya chini ya tumbo? Ndio La

5188 Nyingine, eleza Amekataa Sijui

5189

5190 3. Je, unatokwa na uchafu yasiyo ya kawaida katika uzazi wako wa kike? Ndio

5191 La Nyingine, eleza Amekataa Sijui

5192

5193 4. Je, umeona uvimbe yoyote katika uzazi wako wa kike? Ndio La

5194 Nyingine, eleza Amekataa Sijui

5195

5196 **B: AFYA YA UZAZI**

5197 5. Ulikuwa na miaka mingapi ulipopata damu ya mwezi? ___ Amekataa Sijui

5198 Nyingine, eleza

5199

5200 6. Tarehe ya mwisho ya kupata damu yako ya mwezi ? (dd/mm/yy) ___ ___/___

5201 ___/___ ___ ___ Sijui Amekataa Nyingine eleza

5202

5203 7. Je, una historia ya kutokwa na damu isiyo ya kawaida sehemu ya uke? Ndio

5204 La Sijui Amekataa Nyingine, eleza

5205

5206 Kama ndio, eleza aina ya damu

5207 Isiyo mara kwa mara

5208 Nzito

5209 Kutokwa na damu nzito sana wakati wako wa mwezi

5210 Nyingine, eleza

5211 Sijui

- 5212 Amekataa
- 5213
- 5214 8. Je, umewahi kutumia njia yoyote ya kupanga uzazi? Ndio La
- 5215 Sijui
- 5216 Amekataa
- 5217 Nyingine, eleza _____
- 5218 Kama ndio, eleza (chagua yote yanayotumuka)
- 5219 Sindano IUCD Asili
- 5220 Mpira Tembe Norplant/Implant
- 5221 BTL Nyingine, eleza _____
- 5222 9. Je, sasa hivi unatumia njia yoyote ya kupanga uzazi?
- 5223 ndio la Sijui Amekataa
- 5224 Nyingine, eleza _____
- 5225
- 5226 Kama ndio, eleza (chagua yote yanayotumika)
- 5227 Sindano IUCD Asili
- 5228 Mpira Tembe Norplant/Implant
- 5229 BTL Nyingine, eleza _____
- 5230
- 5231 10. Je, umekuwa na mimba mara ngapi? ___ Amekataa Sijui Nyingine
- 5232
- 5233 11. Je, umekuwa na watoto walioishi mara ngapi? ___ Amekataa Sijui
- 5234 Nyingine
- 5235
- 5236 12. Je, umetoa mimba ngapi au kupoteza mimba au mtoto kufia kabla kuzaliwa ?
- 5237 ___ Amekataa Sijui Nyingine
- 5238
- 5239 13. Je, umewahi kulazwa hospitalini na tatizo yoyote ya gynecologia?
- 5240 Ndio La Sijui Amekataa Nyingine, eleza
- 5241 14. Je, umewahi kupasuliwa tumbo? Ndio La Amekataa
- 5242 Sijui Nyingine, eleza
- 5243
- 5244 15. Je, umewahi kupasuliwa uke? Ndio La Amekataa
- 5245 Sijui Nyingine, eleza
- 5246
- 5247 16. Sasa hivi, unavuta sigara? Ndio La
- 5248 Amekataa Sijui Nyingine, eleza

5249

5250 **C: HISTORIA YA HIV**

5251 17. Uljulikana uko na HIV lini? (dd/mm/yyyy) ____ ____/____ ____/____ ____ ____

5252

5253 18.1. HIV ilitambuliwa aje? (jibu moja pekee)

5254 - Ulipotembelea kituo cha VCT: Ndio

5255 - Kwa kliniki ya wajawazito : Ndio

5256 - Kwasababu ya ugonjwa , eleza: _____ Ndio

5257 - Nyingine, eleza: _____

5258 - Sijui:

5259 - Amekataa:

5260

5261 19. Je, sasa hivi unatumia madawa ya kurefusha maisha? Ndio La

5262 Sijui

5263 Amekataa

5264 Nyingine, elezaKama

5265 ndio,

5266 a) Eleza madawa unayotumia sasa : _____

5267 b) tarehe ya awali uliyoanza ____ ____/____ ____/____ ____ ____ sijui

5268 c) Je, unajua sababu ulioanzishwa madawa ya kurefusha maisha?

5269 - Kwasababu ya ugonjwa, eleza: _____ Ndio

5270 - Kwasababu ya CD4 kuwa chini : Ndio

5271 - Kwasababu ya viwango vya virusi kuwa juu: Ndio

5272 - Nyingine, eleza: _____

5273 - Sijui:

5274 - Amekataa

5275

5276 20. Maoni

5277

ANUANI NA ULAJI

5278

5279 **Study ID number** _ _ _ _ _ **Interviewer number** _ _ _ _ _

5280

5281 **Date of interview (day/month/year)** _ _ _ / _ _ _ / _ _ _ _ _

5282

5283 **Format(tick one)** **New** **Update (fill only updated info)**

5284 **A. YA KIBINAFSI**

5285 19. Jina Lako Nani?

5286 a. Jina la kwanza

5287 b. Jina la katikati

5288 c. Jina la mwisho

5289

5290 20. Wajulikana kwa jina lipi eneo unako ishi?

5291 21. Jina kamili ya eneo unako ishi.

5292 a. Wilaya

5293 b. Mji

5294 c. Kijiji

5295 d. Mtaa

5296 e. Nambari ya ploti

5297 f. Nambari ya mlango

5298 g. Jina la barabara

5299

5300 22. Usafiri wa umma hadi kwako nyumbani:

5301 4a. Aina: F Bus F Boda boda F Matatu F Taxi F Mengine(Fafanua)

5302 4b. Numbari ya gari iendako eneo unakoishi:

5303 4c. Jina la kituo cha kuabiria magari?

5304 4d. Jina inalojulikana eneo unakoishi.

5305 23. Maelezo ya njia kutoka kwako hadi kituo cha kuabiria magari?

5306 24. Alama ya kuwa msaidizi katika kuuweka kaya: (Majina ya shule, makanisa,
5307 biashara nk)

5308 25. Je, unaweza kufikiwa kwa njia ya simu? Ndiyo La

5309 Kama ndiyo,

5310 (i) Nambari ya simu yako 1?

5311 (ii) Nambari ya simu yako 2?

5312

5313 iii. Nani anaye beba simu hiyo (Weka alama kwa moja) Mimi Mwingine,
5314 fafanua

5315

5316 **B. MAWASILIANO MUHIMU**

5317 26. Je, kuna mtu mwingine ambaye anjua hali yako ya HIV ambaye tunaweza kuwasiliana
5318 kwa njia ya simu kama hatuwezi kufikia wewe moja kwa moja? If no skip to 9.

- 5319 27. Jina lake ni nani?
5320 a. Jina la kwanza
5321 b. Jina la katikati
5322 c. Jina la mwisho
5323 28. Uhusiano gani upo kati yako na mtu huyu ?
5324 29. (a)Nambari yake ya simu1?
5325 (b) Nambari yake ya simu2?
5326

5327 **C. MAWASILIANO KUHUSU KWAKO MASHAMBANI**

- 5328 30. Je, una nyumbani bara? Ndiyo La
5329 If no, skip to 19
- 5330 31. Ni wapi kwako Bara?
5331 a. Wilaya
5332 b. Mji
5333 c. Kijiji
5334 d. Mtaa
5335 e. Nambari ya ploti
5336 f. Nambari ya mlango
5337 32. Maelekezo maalum kwa makazi
5338 33. Je, kuna mtu u ko bara ambaye tunaweza kuwasiliana kama hatuwezi kufikia wewe
5339 moja kwa moja? Ndiyo La
5340 If no, skip to 19
- 5341 34. Jina lake huyu mtu ni nani?
5342 a. Jina la kwanza
5343 b. Jina la katikati
5344 c. Jina la mwisho
5345 35. Uhusiano gani upo kati yako na mtu huyu ?
5346 36. Je huyu mtu ako na simu? Ndiyo La
5347 Iwapo ndiyo , fafanua
- 5348 (a)Nambari yake ya simu1?
5349 (b) Nambari yake ya simu2?
5350

5351 **D. ANDRA**

5352 Maoni

5353

5354

SHEDDING

5355

5356 **Study ID Number** ___ ___ ___**Interviewer Number** ___ ___

5357

5358 **Date of interview (day/month/year)** ___ ___/___ ___/___ ___ ___ ___

5359

5360 **Visit (tick one)** **Week 1 FU** **Week 2 FU** **Week 3 FU** **Other, specify** _____

5361

5362 **A: MEDICAL HISTORY**

5363

5364 1. Unasikia maumivu ya tumbo ya chini?

5365

5366 ndio la

5367 (Ndio,fafanua)

5368 a. muda wa ___ ___ (siku)

5369 b. Ukali(kidogo 1-5, 5 kuwakali zaidi)

5370

5371 9. Umekuwa na historia ya kutokwa na damu ambaye si yakawaida? Fafanua

5372

5373 Ndio La

5374 (Ndio,fafanua)

5375

5376 g. muda wa ___ ___ siku

5377 h. kiasi

5378 doasuruali)5379 Inahitajipediya usafi5380 Mwingine,eleza

5381 Unatokwa na majimaji ya uke yasiyo ya kawaida?

5382 10.

5383 Ndio la

5384 (Ndio,fafanua)

5385

5386 i. muda wa ___ ___ siku)

5387 j. rangi ya

5388 Majano5389 hudurungi5390 nyeupe5391 wazi5392 Nyingine ,fafanua

5393 k. harufu

5394 Harufu mbaya5395 Hakunaharufu5396 Mengine,eleza

5397 l. kiasi

5398 inadoasuruali5399 Inahitajipediya usafi5400 Mengine,eleza

5401 11. Mgonjwa amekuwa nahoma yoyotebaada ya ziara yamwisho?

5402 Ndio la

5403 kama ndio, fafanua muda....siku

5404 12. Je,mgonjwaametafutahuduma zamatibabu kwa ajili yahaya aumalalamiko mengine?

5405 Ndio La

5406 If yes, specify what complaint prompted the participant to seek care:

5407 Uchungu wa tumbo ya chini5408 Homa5409 Damu kutoka uzazi wa kike5410 Uchafu unaotoka katika uzazi wa kike

5411 e. Mengine, fafanua

5412 If yes, specify where the participant sought care:

5413 Study clinic5414 Hope Center

5415 Coptic Hospital

5416 KNH

5417 f. Other, specify

5418 13. Was the participant's condition possibly due to a study procedure? (Ask if any of
5419 questions 1-4 is yes)

5420 Yes No

5421 If yes, fill out a Complications questionnaire.

5422

5423

5424

5425 14. Damu yako ya mwezi ya mwisho ilikuwa lini? (dd/mm/yyyy)

5426

5427 15. Umewahi fanya ngono uke tangu utibiwe? Ndio la Kataa

5428 Nyingine fafania _____

5429

5430 8 (a). Ndio, mara ngapi?__

5431

5432 8(b) Kamawamefanya mapenziuketangumatibabu,je,ni mara ngapikutumia
5433 kondomuwakati wa ngono?

5434

5435 Kila wakati (100%) Wengi wa wakati huo (75-99%)

5436 Nusu ya mudu (50%-74%) Wakati mwingine (25-49%)

5437 Mara chache (1-25%) Kamwe (0%)

5438 Amekataa Sijui

5439 Nyingine, eleza

5440

5441

5442 9. Unafikiri unaweza kuwa mjamzito

5443 Ndio la

5444 10. Kwa sasa unatumia madawa ya kupungua makali ya virusi

5445

5446 Ndio Kataa Nyingine,fafania

5447 La Sijui

5448 Ndio, fafania madawa unayo tumia sasa na tarehe uliyo yaanza

- 5449 d4t, 3tc, nvp
- 5450 d4t, 3tc, efv
- 5451 azt, 3tc, nvp
- 5452 azt, 3tc, efv
- 5453 zingine, fafanua
- 5454 Tarehe ya kuanza ARV awali (dd/mm/yyyy)
- 5455 11 Katika siku 7 ya mwisho, mgonjwa alikosa kumeza tembe ngapi za dawaza kurefusha
5456 maisha?
- 5457 12 Katika siku 30 ya mwisho, mgonjwa alikosa kumeza tembe ngapi za dawaza kurefusha
5458 maisha?
- 5459 **(If Q11 and Q12 patient did not MISS taking any pills skip to Q14)**
- 5460 13. If the patient missed any doses, please specify reasons (check all that apply)
- 5461 Toxicity/ side effect
- 5462 Share with others
- 5463 Forgot
- 5464 g. Felt better
- 5465 Too ill
- 5466 Stigma, disclosure or privacy issues
- 5467 Drug out of stock
- 5468 Patient lost or ran out of pills
- 5469 Delivery /travel problem
- 5470 Inability to pay
- 5471 Alcohol
- 5472 Depression
- 5473 h. Other specify
- 5474
- 5475
- 5476 **B: DIAGNOSIS**
- 5477 14. Is there any new infection that was related to the procedure since the last visit?

5478 Yes No

5479 If yes, specify and fill a Complications and/or Adverse Event questionnaire:

5480 15. Were there any new complications diagnosed today related to the treatment?

5481 Yes No

5482 If yes, specify and fill a Complications and/or Adverse Event questionnaire:

5483

5484 **C: TREATMENT**

5485 16. Was any treatment provided today? Yes No

5486 If yes, specify

5487 17. Was the patient referred for further cervical treatment at another institution?

5488 Yes No

5489 17 (i) If yes, specify institution

5490 17(ii) If yes, specify reason for referral

5491

5492

5493 **D: SPECIMEN COLLECTION**

5494 18. Did you collect cervical HIV swab? Yes No

5495 If no, specify reason:

5496 19. Did you collect blood? Yes No

5497 If no, specify reason:

5498

5499

5500

5501

5502

5503

5504

5505 **E: ACCEPTABILITY OF TREATMENT**

5506 **20. Please complete the items listed below by placing a checkmark on the box next to**
 5507 **each question that best indicates how the client feels about the treatment she received.**

5508

	SIKUBALI KAMWE	haukubaliani	kadri,	kukubaliana	sanakukubaliana
(i) Naona hii njia ni mwafaka kwa kukabiliana na magonjwa ya njia ya uzazi)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(ii) Naweza tumia haya ya matibabu nikipatamagonjwa kama haya siku ya mbeli	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(iii) ningependekeza haya matibabu kwa mtu mwingine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(iv) kwa jumla nakubaliana na haya matibabu)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5509

5510 **F: OTHER**

5511

5512

5513

5514

5515 24. Comments:

5516

- 5546 7. Je, mfanyakazi wahuduma za afya alikuambiasababu ya kifo? Ndio/ La
5547 siji/ *If yes go to 7a, if no go to 8*
- 5548 7a. Ninimfanyakazi wahuduma za afyawanasemakilichosababisha kifo?
- 5549 8. Alifanyiwa upasuaji wowote kwa sababu ya ugonjwa? Ndio/ La/ siji/
- 5550 *If yes go to 8a, if no go to 9*
- 5551 8a. Upasuaji ulikuwa muda ganikabla ya kifo? _____ siku
- 5552 8b. Sehemu gani ya mwili alifanyiwa upasuahi?
- 5553 / tumbo / Kifua / Kichwa) / Mengine (fafanua) _____)
- 5554 9. Mpenzi (wapeenzi) wa marehemu wowote wamekufakatika kipindi cha miaka 5 iliyopita?
- 5555 Ndio/ La / Haijulikani / *If yes go to 9a, if no go to 10*
- 5556
- 5557 9a. Kama ndiyo, ni nini waliamini kilichosababisha kifo cha mpenzi(s)
- 5558
- 5559
- 5560 9a1. Partner 1: _____
- 5561 9a2. Partner 2: _____
- 5562
- 5563 **Injury/accident/suicide**
- 5564
- 5565 10. Je alikabiliwa namajeraha yoyote au ajali ambayo imesababisha kifo chake? Ndio/ La/
- 5566 siji/
- 5567 *If yes go to 10a, if no go to 11*
- 5568 10a. Ni aina gani ya majeraha au ajali marehemu aliteseka nayo?
- 5569 / Barabara ya ajalizi barabarani / / kuanguka / / kuzama
- 5570 / sumu
- 5571 / kuangua / / magombano / / Mengine / / Haijulikani
- 5572 10b. Majeruhi au ajali ilikuwa ya makusudi au ilifanywa na mtu mwingine) ndio/ La/
- 5573 siji/
- 5574
- 5575

5576 10c. Je, unafikirikwambayeye alijiua?) ndio La sijui

5577 11. Je, yeye aliumwa na mnyama/mdudu yeyote iliyosababishakifo chake? Ndio

5578 La Sijui

5579

5580 11a. Kama ndiyo, niaina yamnyama/mdudu?

5581

5582 **History of previously known medical conditions**

5583

5584 12. Did the deceased suffer from any of the following conditions?

5585

5586 a. High blood pressure Yes No Unknown

5587 b. Diabetes Yes No Unknown

5588 c. Asthma Yes No Unknown

5589 d. Epilepsy Yes No Unknown

5590 e. Malnutrition Yes No Unknown

5591 f. Cancer Yes No Unknown

5592 f1. If yes, specify type of cancer or site: _____

5593 g. Tuberculosis Yes No Unknown

5594 h. Any other medically diagnosed illness? Yes No Unknown

5595 h1. If yes, specify: _____

5596

5597 **13. Signs, symptoms, and their severity during the last illness:**

Symptom/ Signs	Symptom present?	If present, duration of symptom
a. Fever	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> ≤2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
b. Loss of weight	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> ≤2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
c. Diarrhea	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> ≤2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
d. Vomiting/associated abdominal pain	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> ≤2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
e. Constipation/associated abdominal pain	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> ≤2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
f. Cough	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> ≤2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown

g. Cough followed by vomiting	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
h. Breathing trouble (chest indrawing/difficult/rapid/wheezing)	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
i. Neck stiffness	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
j. Unconscious episodes	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
k. Fits	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
l. Jerking of individual limbs	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
m. History of epileptic illness in earlier years	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
n. Paralysis of limbs	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
o. Rigid body stiffness, unable to open mouth	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
p. Red and sore eyes	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
q. Skin rash and itching	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
r. Herpes Zoster (at any time in life)	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
s. Abscesses/body sores	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
t. White patches on the inside of mouth and tongue	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
u. Oedema	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
v. Hair changes	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
w. Yellowing of eyes or passing of brown urine	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
x. Chest pain	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
y. Other (Specify:)	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown

5598

Unexpected vaginal bleeding or discharge	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown
Pelvic or vaginal pain	FNo F Yes	F ≤2 weeks F >2 weeks F Unknown

5599

5600 14. Records available in home, e.g., death certificate (extract findings):

5601 15. Comment

5602

5603

5604

EXIT

5605

5606 **Study ID Number:** ____ ____ ____**Interviewer Number:** ____

5607 ____

5608

5609 **Date of visit (day/month/year)** ____ ____ / ____ ____ / ____ ____ ____ ____

5610

5611 1. Is the patient exiting the study because she has completed the study protocol and qualifies
 5612 as per study guidelines to exit the study at this time? Yes No (*If Yes, go to*
 5613 *9, If No go to 2)*

5614 2. Date of last study visit (DD/MM/YYYY) 5615 3. Date last seen by study staff (DD/MM/YYYY) 5616 4. Has the patient accessed care at the Hope Clinic in the past year? Yes No

5617

5618 5. Did you talk to the patient? Yes No (*If Yes go to 6, If No go to 5a)*

5619

5620 5a. If no, who was the source of information (tick one)

5621 Clinician / clinic staff Employer Treatment supporter

5622

5623 Spouse or Partner Friend Other (specify)5624 Family member / Relative Neighbor5625 Mother or Father Caregiver

5626 6. Je, mgonjwa anahamisha huduma ya HIV kwa mpangilio mwingine? Ndiyo La
 5627 (*If Yes go to 6a, If No go to 7)*

5628

5629 6a. If yes, where is the patient transferring care to (tick one)

5630 Kuhamishiwa kliniki ingine ambayo siya HOPE, elezea5631 Kuhamishiwa kliniki ya Industrial area5632 Kuhamishiwa kliniki ya Maseno

5633 7. Has Hope Clinic asked the patient to Exit or leave the program? Yes No (*If Yes go*
5634 *to 7a, If No go to 8)*

5635 7a. Reasons for being Exited from the program (tick all that apply)

5636 Client has not returned to clinic for 1 year

5637 Poor Adherence

5638 Poor Clinic Attendance

5639 Not willing to disclose HIV status

5640 Referred else where

5641 Tested Negative

5642 Other (specify)

5643 Unknown

5644 8. Has the patient asked to be Unenrolled from the study? Yes No (*If Yes go to 8a, If*
5645 *No go to 9)*

5646 8a. Reasons patient is asking to Unenroll from the study (tick all that apply)

5647 Kutokuwa na nia ya kuhudhuria

5648 Muda wa kusubiri kuwa mrefu sana

5649 Kutoambana na kazi

5650 Matatizo ya fedha

5651 Kukosa nia ya kuhudhuria kwa sababu ya matatizo ya kiafya

5652 Matatizo ya familia

5653 Mteja kwenda kwa mganga waimani

5654 Kutokuwa tayari kusema hali yake ya Ukimwi

5655 Kutumwa kwingine

5656 Nyingine (taja)

5657 Haijulikani

5658 9. At what point was the patient exited? After Pap smear After Biopsy

5659 Mortality Withdrawn from study Other (If other specify)

5660 10. Comment

5661

5662

5663

CERVICAL TREATMENT STUDY

5664

5665

What is a Pap smear?

5666

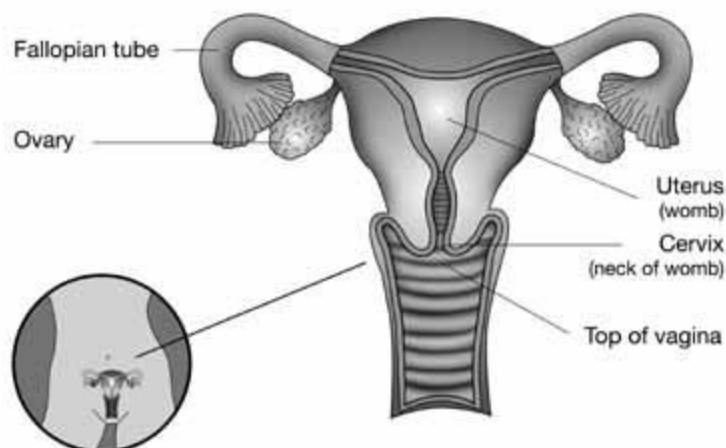
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5670

A Pap smear is a simple test to check your cervix to make sure it is healthy. Your cervix is the opening of the uterus, and is at the top of your vagina (see the diagram below). A Pap smear takes only a few minutes and is not painful. Having a Pap smear every two years is the best way to prevent cancer of the cervix.



5671

5672

5673

Why have a Pap smear?

5674

5675

5676

5677

A Pap smear can show the early warning signs of cancer of the cervix. Sometimes the cells of the cervix change from healthy to unhealthy (abnormal). A Pap smear can find abnormal cells before cancer develops.

5678

What causes cervical cancer?

5679

5680

5681

5682

5683

An infection with a virus called HPV (human Papillomavirus) is the cause of almost all cervical cancers. There are over 100 different types of HPV. Two of these types are known to cause most of the cervical cancer cases. HPV is very common. Most people (four out of five) will have HPV at some time in their lives. Anyone who has ever had sex can have HPV.

5684

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In most cases, HPV clears up by itself in a few years. Sometimes the virus can stay in your body longer, and can lead to cervical cancer. This usually takes a long time – about 10 years. A Pap smear every two years can find cell changes caused by HPV before they turn into cancer. Your doctor, nurse or health worker can then make sure your health is monitored and that you get treatment if you need it, so you can stay healthy.

5690

How is a Pap smear done?

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First the doctor or nurse asks you to undress from the waist down and to lie on your back for the examination. You can ask for a female doctor or nurse. Next the doctor or nurse will use a speculum (medical instrument) to open your vagina so your cervix can be seen more clearly. Some cells are gently wiped from your cervix with a small brush or spatula (a small plastic or wooden stick). The cells are placed on a glass slide and sent to a laboratory where they are looked at under a microscope.

5699

What does it feel like?

5700

5701

Sometimes having a Pap smear can be a little embarrassing. Remember, for the person doing the smear, this is just part of their everyday work and they are not embarrassed. The

5702 procedure might be a bit uncomfortable, but it shouldn't hurt. If it hurts, tell your doctor,
5703 nurse or health worker straight away.

5704

5705 **What if my results are not normal?**

5706 If your results are not normal this does not mean you have cancer. Very often it will be that
5707 you have something simple like an infection that will clear up naturally. Sometimes a woman
5708 may need to have a Pap smear more often. Some types of abnormal cells may need to be
5709 treated by a specialist. Make sure you talk to your doctor, nurse or health worker about what
5710 is best for you.

5711

5712 **HIV and cervical cancer**

5713 HIV-positive women are more likely to be infected with human Papillomavirus (HPV), the
5714 primary cause of cervical cancer, and progress to invasive, life-threatening disease than those
5715 who are HIV-negative.

5716 **Note: Being on HIV medication does NOT reduce your risk of cervical cancer.**

5717

5718 **Cervical Treatment Study**

5719 Researchers from the University of Washington in the USA, Kenyatta National Hospital,
5720 WHO and Coptic Hospital are conducting a study to see how treatment can prevent abnormal
5721 cells from becoming cancer, and how treatment might affect HIV. Those patients who enroll
5722 in the study will be given free screening for cervical disease that may develop into cancer and
5723 will also receive free treatment if they are found to have abnormal cells.

5724

5725 **For more information about the study, contact:**

- 5726 1. Peter Juma: 0721-898-785
5727 2. Elizabeth Makena: 0728-456-540
5728 3. Dr. Evans Malava: 0721-289-733

5729

CERVICAL TREATMENT STUDY

5730

5731

Je Pap Smear ni nini?

5732

Pap Smear ni kupimwa njia yako ya uzazi kwa njia rahisi kuhakikisha ni salama. Njia ya uzazi ni mlango wa nyumba ya mtoto tumboni na iko kwa ndani juu ya sehemu yako ya siri (angalia mchoro hapo chini). Kupimwa njia ya uzazi huchukuwa dakika chache tu na si uchungu.

5735

5736

Kupimwa njia ya uzazi kila baada ya miaka miwili ndio njia bora zaidi ya kuzuia saratani ya njia ya uzazi.

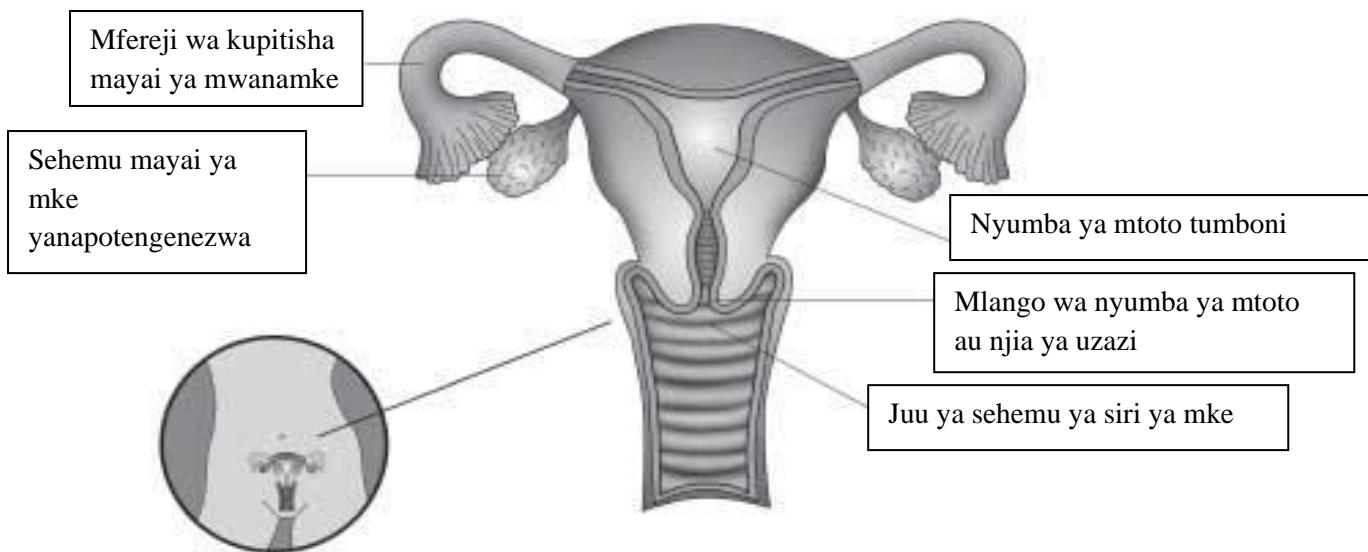
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5757

Kwa nini upimwe njia ya uzazi?

5758

Kupimwa njia ya uzazi kunaweza kuonyesha dalili za saratani ya njia ya uzazi. Wakati mwingine hali ya njia ya uzazi hubadilika, na kuwa na hitilafu. Ukipimwa njia ya uzazi inaweza kujulikana kama ina hitilafu kabla haijabadilika kuwa saratani.

5760

5761

5762

Nini kinachosababisha Saratani wa njia ya uzazi?

5763

Kuambukizwa kwa virusi vinavyoitwa HPV (humanpapillomavirus) kunasababisha karibu saratani zote za njia ya uzazi. Kuna zaidi ya aina 100 tofauti za HPV. Aina mbili za HPV zinajulikana kusababisha saratani kwa karibu wote wanaouguu njia za uzazi. Virus vya HPV vinapatikana kwa wingi. Watu wengi (wanne kwa watano) watakuwa na HPV wakati mmoja maishani mwao. Yeyote ambaye ashawahi kufanya ngono anaweza kuwa na HPV.

5767

5768

5769

Mara nyingi, virusi vya HPV hutoweka vyenyewe baada ya miaka michache. Mara nyingine hivi virusi vinaweza vikakaa mwilini na vinaweza kusababisha saratani ya njia ya uzazi. Hii huchukuwa mda mrefu – kama miaka 10. Kupimwa njia ya uzazi kila baada ya miaka miwili kunaweza kufanya mabadiliko ya njia ya uzazi yajulikane kabla hayajasababisha saratani. Daktari wako, muuguzi au mfanya kazi kutoka kituo cha afya anaweza kuhakikisha kuwa afya yako inafuatiliwa na unapata matibabu kama unayahitaji ili uwe na afya bora.

5774

5775

5776

Je mtu hupimwaje njia ya uzazi?

5777

Kwanza daktari au muuguzi anakuuliza uvue nguo kutoka kiunoni kwenda chini na ulale chali ili akupime. Unaweza kuuliza upimwe na daktari au muuguzi wa kike. Halafu daktari au

5778

5779 muuguzi atatumia chombo cha kupimia kufungua sehemu yako ya siri ili njia ya uzazi
 5780 ionekane vyema zaidi. Atapangusa ukuta katika njia yako ya uzazi na brashi ndogo au
 5781 chombo cha kupima (kijiti kidogo ama kipande cha mpira kidogo). Kilichopanguswa kutoka
 5782 njia ya uzazi, wataweka kwenye kioo kidogo na kupelekwa maabara (lebu) watakakotazama
 5783 wakitumia darubini.

5784

5785 **Je mtu husikiaje?**

5786 Wakati mwingine kupimwa njia ya uzazi ni jambo la kutahayari au kuonea aibu. Kumbuka,
 5787 kuwa

5788 anayekupima njia ya uzazi, hii ni kazi yake ya kawaida na hatahayari au kuona aibu.

5789 Unapopimwa, unaweza kusikia ovyo, lakini haina uchungu. Ukisikia uchungu, mwambie

5790 daktari wako, muuguzi au mfanyakazi kwenye kituo cha afya hapohapo.

5791

5792 **Je kama majibu yangu sio sawa au salama?**

5793 Kama majibu yako sio sawa, haimaanishi uko na saratani. Mara nyingi itakuwa una jambo

5794 dogo kama kuambukizwa ambako huisha kwenyewe bila kutibiwa. Mara nyingine

5795 mwanamke anahitaji kupimwa njia ya uzazi mara kwa mara. Hali nyingine zisizo za kawaida

5796 zahitaji matibabu maalum. Hakikisha umeshauriana na daktari wako, muuguzi au mfanya kazi

5797 wa kituo cha afya ili akufahamishe kilicho bora kwako.

5798

5799 **Uhusiano wa UKIMWI na saratani ya njia ya uzazi**

5800 Wanawake wanaouguwa ugonjwa wa UKIMWI wanauwezekano mkubwa kuliko wale ambao

5801 hawana UKIMWI kuambukizwa virusi vya human Papillomavirus (HPV), vinavyosababisha

5802 saratani ya njia ya uzazi, na iendelee hadi ivaamie mwili na iwe, kitisho kwa maisha.

5803 **Kumbuka: Kutumia dawa ya UKIMWI haiwezi kupunguza hatari ya saratani ya njia**

5804 **ya kizazi.**

5805

5806 **Utafiti wa matibabu ya njia ya kizazi (Cervical Treatment Study)**

5807 Watafiti kutoka Chuo Kikuu cha Washington huko Marekani, Hospitali Kuu ya Kenyatta,

5808 Shirika la Afya Duniani na Hospitali ya Coptic wanafanya utafiti kuona jinsi gani

5809 tiba inaweza kuzuia chembe chembe zisizo za kawaida isiwe saratani ya njia ya kizazi, na

5810 jinsi tiba inaweza kuathiri ugonjwa wa UKIWMI. Wagonjwa ambao watahusika katika utafiti

5811 huu watapewa uchunguzi (Pap smear) wa bure na pia watapata matibabu ya bure

5812 wakipatikana na chembe chembe zisizo za kawaida.

5813

5814 **Kwa habari zaidi kuhusu utafiti huu, wasiliana na:**

5815 1. Peter Juma: 0721-898-785

5816 2. Elizabeth Makena: 0728-456-540

5817 3. Dr. Evans Malava: 0721-289-733

5818

COPTIC HOPE MEDICAL RECORD FORMS

HOPE CLINIC ADDRESS AND INTAKE

Page 1

HOPE ID Number

Site Code

Today's Date (DD.MM.YYYY)

Interviewer number

Name (First, Middle,Last)

1. Gender Male Female

2. Age (Years) Month 3. Date Of Birth (DD/MM/YYYY) / /

4. In which region does the client reside(stay)?

- Nairobi province (see 4a) Rift Valley Province
 Nyanza Province (see 4b) North Eastern Province
 Western Province (see 4b) Eastern Province
 Central Province Coast Province
 Other country (specify)

4a. If Nairobi province, specify area: (tick one)

- Langata/Kibera Westlands
 Starehe Kasarani
 Dagoretti Kamukunji
 Makadara Eastland/ Industrial Area
 Embakasi Other (specify)

4b. If western or Nyanza, specify area: (tick one)

- Kisumu Rural Maseno
 Siaya Chulaimbo
 Vihiga Lela
 Kakamega Other (Specify)
 Luanda

5. Email

6. Physical Address

5819

5820

5821

HOPE CLINIC ADDRESS AND INTAKE

7. How long has the client stayed at this residence?

- Less than a year Greater than a year

8. How long does the client plan to stay at this residence?

- Less than a year Greater than a year

9. Phone number (Cell)

9a. Relationship to phone owner (tick one)

- Self Employer

- Relative Other (specify)

- Friend

10. Phone number (Landline)

10a. Relationship to phone owner (tick one)

- Self Employer

- Relative Other (specify)

- Friend

Emergency contact (in case we cannot reach the patient)

11. Name (Last, First, Middle)

11a. Relationship to client (tick one)

- Self Employer

- Relative Other (specify)

- Friend

- Husband/Wife

11b. Phone No.

Clients transferring from Pediatric Clinic

12. Pediatric Hopeid

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Scanned Date ___/___/_____ Name of data person

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HOPE CLINIC COUNSELING ADHERENCE #1

HOPE ID Number

Site Code

Today's date (DD.MM.YYYY)

 /
 /

Interviewer number

Checklist	Tick
Explain about HIV and how it affects the body	<input type="radio"/>
Explain about CD4 cells and why it is necessary to measure the CD4 count	<input type="radio"/>
Explain the difference between HIV and AIDS.	<input type="radio"/>
Explain about ARV.	<input type="radio"/>
Explain ARV is not a cure.	<input type="radio"/>
Explain the cause of resistance.	<input type="radio"/>
Explain treatment failure	<input type="radio"/>
Explain importance of adherence.	<input type="radio"/>
Explain problem of side effects.	<input type="radio"/>
Have patient think about life long commitment of therapy.	<input type="radio"/>
Have patient think about ability to follow up care	<input type="radio"/>
Explore patient support system	<input type="radio"/>
Discuss adherence promotion strategies e.g. treatment buddy, pill diary e.t.c	<input type="radio"/>

2. Identify barriers to adherence (tick all that apply)

- | | |
|---|--|
| <input type="radio"/> Poor Communication | <input type="radio"/> Lack of social support |
| <input type="radio"/> Inadequate understanding about HIV/AIDS | <input type="radio"/> Alcohol/ Drug use |
| <input type="radio"/> Failure to disclose status | <input type="radio"/> None |
| <input type="radio"/> Mental State | <input type="radio"/> Others (specify) |
| <input type="radio"/> Stigma | <div style="border: 1px solid black; width: 150px; height: 20px;"></div> |
| <input type="radio"/> Low literacy | |

3. Does the patient need to move forward with the protocol or to repeat counselling adherence #1 ?

- Move forward Repeat Counselling Adherence # 1

Notes/Remarks

For the data use only (tick after scanning the form)

Scanned Date ___ / ___ / _____ Name of data person

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HOPE CLINIC

COUNSELING ADHERENCE #2

HOPE ID Number

Site Code

Today's date (DD.MM.YYYY)

//

Interviewer number

Score scale: 1-Poor 2-Fair 3-Good

Section A: Knowledge Assessment

Question	Rationale	Score
1. What do you know about ARVs?	Assess whether information given in Counseling Adherence#1 has been understood.	<input type="checkbox"/>
2. What are the names of any ARVs?	Assess the client knows that AZT, NVP, etc. are ARVs, but septrin is not	<input type="checkbox"/>
3. How do ARVs work?	Assess the client's knowledge of basic ARV action (especially that ARV is not a cure for HIV infection.)	<input type="checkbox"/>
4. What side effects are associated with ARVs? What do you know about them?	Assess client's knowledge of side effects related to his/her ARV regimen and the appropriate response to deal with side effects.	<input type="checkbox"/>
5. How long should you normally take ARVs?	Assess whether client knows ARV is life long treatment.	<input type="checkbox"/>
6. What happens if you dont take ARVs consistently?	Assess whether client understands the problem of resistance given ARV interruptions.	<input type="checkbox"/>
7. What is the purpose of CD4 counts?	Assess whether client knows that CD4 count is a laboratory indicator for monitoring the effect of ARV	<input type="checkbox"/>
8. What are your expectations from ARVs?	Assess whether client has realistic expectations, e.g., prolonging life, keeping them well enough from their family, e.t.c. Assess for false expectations, e.g., a cure for HIV, e.t.c	<input type="checkbox"/>
9. Can someone still transmit HIV while taking ARVs?	Assess/review need for continued prevention e.g. condom use.	<input type="checkbox"/>
If total score is less than 18, patient has failed section A If total score is 18 or above, the patient passes section A		Total Score: <input style="width: 20px; height: 20px;" type="text"/>

Section B: Counselor Assessment

Question	Rationale	Score
10. Assess for barriers that help determine capability for followup	Assess whether client can attend HIV clinic for follow up medical and counselling care	<input type="checkbox"/>
11. Ask the client whether s/he has a relative/friend whom s/he can rely on to support her/him taking ARV	Assess availability of support from home	<input type="checkbox"/>
12. On a scale of 1 to 5 (5 being most ready, 1 being least), please rate the client's ability to adhere to medications	Score 1: Patient will adhere to the ARVs very poorly (Misses more than half the doses) Score 2: Patient will likely miss doses of ARVs on a regular basis (misses up to 50% of doses) Score 3: Patient will only miss some doses of ARVs (1 dose a month at most) Score 4: Patient will rarely miss a dose of ARVs (1 dose every 6 months at most) Score 5: Patient will almost never miss any doses (1 dose every year at most)	<input type="checkbox"/>
If total score is 2 or below on question 12, patient fails section B If total score is 3 or above question 12, patient passes section B		

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Coptic Hope Clinic

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HOPE CLINIC COUNSELING ADHERENCE #2

Section C: Participant Assessment

Question	Rationale	Score
13. Ask the client if s/he can come to HIV clinic for regular follow-up?	YES or NO answer	<input type="checkbox"/> Yes <input type="checkbox"/> No
14. Do you want to start ARV treatment now?	YES or NO answer	<input type="checkbox"/> Yes <input type="checkbox"/> No
If any answers in this section are "NO" then patient fails Section C		

Section D: Final Assessment

15. a) Did the patient pass section A, B and C?

Yes (Patient moves forward) No

b) If NO, is the patient scheduled to repeat counseling?

Yes No

Notes/Remarks

For the data use only (tick after scanning the form)

Scanned Date ___/___/_____ Name of data person

HOPE CLINIC COUNSELING ADHERENCE #3

To be performed 1 month after starting ARVs

HOPE ID Number

Site Code

Today's date (DD.MM.YYYY)

Interviewer number

Score scale: 1- poor 2-Fair 3-Good

Section A: Knowledge Assessment

Question	Rationale	Score
1. What do you know about ARVs?	Assess whether information given in Counseling Adherence#1 has been understood.	<input type="checkbox"/>
2. What are the names of your medications and dosage?	Assess whether the client knows his/her medication and dosage.	<input type="checkbox"/>
3. How do ARVs work?	Assess the client's knowledge of basic ARV action (especially that ARV is not a cure for HIV infection.)	<input type="checkbox"/>
4. What side effects are associated with ARVs and what do you do if you have side effects?	Assess client's knowledge of side effects related to his/her ARV regimen and the appropriate response to deal with side effects.	<input type="checkbox"/>
5. How long should you normally take ARVs?	Assess whether client knows ARV is life long treatment.	<input type="checkbox"/>
6. What happens if you don't take your ARVs consistently?	Assess whether client understands the problem of resistance given ARV interruptions.	<input type="checkbox"/>
7. What is the purpose of CD4 counts?	Assess whether client knows that CD4 count is a laboratory indicator for monitoring the effect of ARV	<input type="checkbox"/>
8. What are your expectations from ARVs?	Assess whether client has realistic expectations, e.g. prolonged life, keeping them well enough from thier family, etc. Assess for false expectations, e.g., a cure for HIV, etc.	<input type="checkbox"/>
9. How can someone still transmit HIV while taking ARVs?	Assess review need for continued prevention e.g. condom use	<input type="checkbox"/>
Total Score		<input style="width: 40px;" type="text"/>

Section B: Counselor Assessment

Question	Rationale	Score
10. During the last 7 days how many pills did the patient MISS taking?	Get exact number of pills missed	<input type="checkbox"/>
11. On a scale of 1 to 5 (5 being most ready, 1 being least), please rate the client's ability to adhere to medications?	Score 1: Patient will adhere to the ARVs very poorly (Misses more than half the doses) Score 2: Patient will likely miss doses of ARVs on a regular basis (Misses up to 50% of doses) Score 3: Patient will only miss some doses of ARVs (1 dose a month at most) Score 4: Patient will rarely miss a dose of ARV (1 dose every 6 months at most) Score 5: Patient will almost never miss any doses (1 dose every year at most)	<input type="checkbox"/>

Notes/Remarks

For the data use only (tick after scanning the form)

Scanned Date ___/___/_____ Name of data person

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Hope Clinic

Version 5.0

HOPE CLINIC PHONE NUMBER AND ADDRESS UPDATE FORM

HOPE ID Number

Site Code	Today's Date (DD.MM.YYYY)	Interviewer number
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

Name (First, Middle,last)

1. Has the client's phone number changed? Yes No *(If Yes go to 2, If No go to 4)*

2. Phone number (Cell)

2a. Relationship to phone owner (tick one)

- | | |
|--|---|
| <input type="checkbox"/> Self | <input type="checkbox"/> Friend |
| <input type="checkbox"/> Husband or wife | <input type="checkbox"/> Employer |
| <input type="checkbox"/> Relative | <input type="checkbox"/> Other (specify) <input style="width: 150px;" type="text"/> |

3. Phone number (Landline)

3a. Relationship to phone owner (tick one)

- | | |
|--|---|
| <input type="checkbox"/> Self | <input type="checkbox"/> Friend |
| <input type="checkbox"/> Husband or wife | <input type="checkbox"/> Employer |
| <input type="checkbox"/> Relative | <input type="checkbox"/> Other (specify) <input style="width: 150px;" type="text"/> |

4. Has the client moved? Yes No *(If Yes go to 5, If No go to 7)*

5. Physical Address

6. In which region does the client now reside (stay) *(For Maseno, check 2nd, 3rd and where applicable 4th column)*

- | | | |
|--|---|---|
| <input type="checkbox"/> Nairobi province (See 6a) | <input type="checkbox"/> Central province | <input type="checkbox"/> Eastern province |
| <input type="checkbox"/> Nyanza province (See 6b) | <input type="checkbox"/> Rift Valley province | <input type="checkbox"/> Coast province |
| <input type="checkbox"/> Western province (See 6b) | <input type="checkbox"/> North Eastern province | |

6a. If Nairobi province, specify area: (tick one)

- | | |
|---|--|
| <input type="checkbox"/> Langata/Kibera | <input type="checkbox"/> Westlands |
| <input type="checkbox"/> Starehe | <input type="checkbox"/> Kasarani |
| <input type="checkbox"/> Dagoretti | <input type="checkbox"/> Kamukunji |
| <input type="checkbox"/> Makadara | <input type="checkbox"/> Eastlands/Industrial Area |
| <input type="checkbox"/> Embakasi | <input type="checkbox"/> Other(Specify) <input style="width: 150px;" type="text"/> |

6b. If western or Nyanza, specify area: (tick one)

- | | |
|---------------------------------------|--|
| <input type="checkbox"/> Kisumu Rural | <input type="checkbox"/> Maseno |
| <input type="checkbox"/> Siaya | <input type="checkbox"/> Chulaimbo |
| <input type="checkbox"/> Vihiga | <input type="checkbox"/> Lela |
| <input type="checkbox"/> Kakamega | <input type="checkbox"/> Other(specify) <input style="width: 150px;" type="text"/> |
| <input type="checkbox"/> Luanda | |

HOPE CLINIC

PHONE NUMBER AND ADDRESS UPDATE FORM

7. Has the client's email changed? Yes No *(If Yes go to 8, If No go to 9)*

8. Email

Emergency contact (in case we cannot reach the patient)

9. Has the client's emergency contact changed? Yes No *(If Yes go to 10)*

10. Name (Last, First, Middle)

10a. Relationship to client (tick one)

Self Employer

Relative Other (specify)

Friend

Husband/Wife

10b. Phone No.

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Scanned Date ___/___/_____ Name of data person

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HOPE CLINIC

PATIENT PHONE CONTACT FORM

HOPE ID Number

Site Code	Today's Date (DD.MM.YYYY)	Interviewer number
□□	□□ / □□ / □□□□	□□□

1. Date of phone contact (DD/MM/YYYY) □□ / □□ / □□□□
2. Did you talk to the patient or patient's contact?
 - Yes, talked to patient *(Go to 4)*
 - Yes, talked to patient's contact *(Go to 3)*
 - No *(Go to 4)*
3. If talked to patient's contact, who was the source of information *(tick one)*

<input type="checkbox"/> Clinician/clinic staff	<input type="checkbox"/> Employer	<input type="checkbox"/> Caregiver
<input type="checkbox"/> Spouse or partner	<input type="checkbox"/> Friend	<input type="checkbox"/> Treatment supporter
<input type="checkbox"/> Family member/Relative	<input type="checkbox"/> Neighbour	<input type="checkbox"/> Other (specify)
<input type="checkbox"/> Mother/Father		
- 3a. Did the source of information have credible knowledge for whether the patient was alive or dead?
 - Yes, credible and patient confirmed alive *(Go to 4)*
 - Yes, credible and patient confirmed dead *(Go to 9 and complete Mortality form)*
 - Source did not know whether patient was dead or alive *(Go to 4)*
4. What was the reason for calling or contacting the patient or patient's contact?
 - Patient missed clinic appointment *(Go to 5)*
 - Patient missed pharmacy pickup *(Go to 6)*
 - Other (specify) *(Go to 7)*
5. Reasons for missed clinic appointment *(tick all that apply)*

<input type="checkbox"/> N/A, did not reach patient or patient's contact	<input type="checkbox"/> Unable to attend because of health problems
<input type="checkbox"/> No longer willing to attend	<input type="checkbox"/> Family problems
<input type="checkbox"/> Wait time too long	<input type="checkbox"/> Client will go to faith healer
<input type="checkbox"/> Conflict with work	<input type="checkbox"/> Unwilling to disclose
<input type="checkbox"/> Financial problems	<input type="checkbox"/> Other (specify)
<input type="checkbox"/> Client moved or relocated	
6. Reasons for missed pharmacy pickup *(tick all that apply)*

<input type="checkbox"/> Unable to attend because of health problems	<input type="checkbox"/> Got medication somewhere else
<input type="checkbox"/> Family problems	<input type="checkbox"/> Client will go to faith healer
<input type="checkbox"/> Conflict with work	<input type="checkbox"/> Unwilling to disclose
<input type="checkbox"/> Financial problems	<input type="checkbox"/> N/A, did not reach patient
<input type="checkbox"/> Client moved or relocated	<input type="checkbox"/> Other (specify)

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7. If talked to patient, did the patient wish to remain in the clinic?

- Yes (Go to 7a)
- No (Go to 8 and complete Exit form)
- N/A, did not talk to patient (Go to 9)

7a. Did the patient schedule a clinic appointment? Yes No (If YES go to 7b, If NO go to 7d)

7b. If YES, date of scheduled appointment (DD/MM/YYYY) / /

7d. If NO, why did the patient not schedule an appointment (tick all that apply)

- Unable to attend because of health problems
- Family problems
- Conflict with work
- Financial problems
- Client moved or relocated
- Client lives too far away
- Other (specify)

8. If the patient does not wish to return to the clinic, specify why (tick all that apply)

- Not willing to attend
- Attend clinic closer to home
- Wait time too long
- Conflict with work
- Financial problems
- Unwilling to attend because of health problems
- Family problems
- Client will go to faith healer
- Not willing to disclose HIV status
- Referred elsewhere
- Unknown
- Other (specify)

9. Did you refer the client to any of the following (tick all that apply)

- Clinic
- Counselor
- Nutritionist
- HBC
- None

Comments

For the data use only (tick after scanning the form)

Scanned Date ___/___/_____ Name of data person

HOPE CLINIC

Counseling General Session

HOPE ID Number

Site Code

Today's Date (DD/MM/YYYY)

Interviewer number

Notes

What was the focus of the session? (tick all that apply)

- Pretest
- Hygiene
- Family planning
- Crisis
- Discordance
- Sex and sexuality

- Post-test
- PMTCT
- Child(ren)
- Opportunistic infection
- Welfare
- Drug therapy

- HIV/STD Prevention
- Nutrition
- Bereavement
- Spirituality
- Disclosure
- Child transfer to Adult Clinic
- Other (specify)

For the data use only (tick after scanning the form)

Scanned Date ___ / ___ / _____ Name of data person

HOPE CLINIC

COUNSELOR SCREENING

HOPE ID Number

Site Code

Today's date (DD.MM.YYYY)

Interviewer number

1. How many children do you have or care for? *If = 0 go to 2*

1a. Describe HIV test results and HIV care for each child.

	Test Result	Receiving HIV care?	Receiving HAART?	Receiving HAART and/or HIV care at Hope Clinic?
1	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Not tested	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A
2	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Not tested	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A
3	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Not tested	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A
4	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> not tested	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> N/A

2. Have you revealed your serostatus to:

- a. Spouse(s) or steady partner(s) All Some None Has no spouse
- b. Casual or non-casual partner(s) All Some None Has no partner
- c. Parents All Some None Has no parents
- d. Siblings All Some None Has no siblings
- e. Children All Some None Has no children
- f. Friends All Some None Has no friends
- g. Others All Some No one else Specify

3. Who forms your closest social support (tick one)

- Spouse/steady partner Sibling
- Mother Other (specify)
- Father No social supporter
- Friend

3a. Have you informed this person of your serostatus?

- Yes No N/A

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4. Have you ever had sex? Yes No (If YES, go to 5, If NO go to 13)

5. How many spouse(s) or steady partner(s) do you have? (If = 0 go to 6)

5a. Describe HIV test results and HIV care for each spouse(s) or steady partner(s)

	Relationship	Test Result	Receiving HIV care?	Receiving HAART?	Receiving HAART and/or HIV care at Hope Clinic?
1	<input type="checkbox"/> Spouse <input type="checkbox"/> Steady partner	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> not tested	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
2	<input type="checkbox"/> Spouse <input type="checkbox"/> Steady partner	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Not tested	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
3	<input type="checkbox"/> Spouse <input type="checkbox"/> Steady partner	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Not tested	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
4	<input type="checkbox"/> Spouse <input type="checkbox"/> Steady partner	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> not tested	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
5	<input type="checkbox"/> Spouse <input type="checkbox"/> Steady partner	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Not tested	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
6	<input type="checkbox"/> Spouse <input type="checkbox"/> Steady partner	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Not tested	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A

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6. How many different casual or non-steady partner(s) did you have in the past year?
7. In the past year, how many different sexual partners have you had, including your spouse(s) and steady partner(s)?
8. During your lifetime have you had sex with
 Men Only Women Only Both None Refused to answer
9. Describe your condom use in the past 12 months todate:-
 a. Spouse(s) or steady partners *(Tick one)*
 Never Sometimes Always No sex in past 12 months No spouse/steady partner
 b. Non- steady partners. *(Tick one)*
 Never Sometimes Always No sex in past 12 months No Non-steady partner
10. Did you use a condom during your last sexual encounter
 No Yes Refused to answer
11. Are you able to talk about using condoms with your spouse(s) or steady partner(s)?
 No Yes Refused to answer No spouse/steady partner Dont know
- 11a. Are you able to say NO to sex if your spouse or steady partner will not use a condom?
 No Yes No spouse/steady partner Refused to answer Don't know
12. Are you able to talk about condoms with your casual or non-steady partner(s)?
 Yes No No non-steady partner(s) Refused to answer Don't know
- 12a. Are you able to say NO to sex if your casual or non-steady partner(s) will not use a condom?
 No Yes No non-steady partner(s) Refused to answer Don't know
13. Are you Circumcised ? *(Ask Male client only)*
 Yes No Refused to answer Female client
14. Do you feel neglected by anyone *(tick all that apply)*
 Family Friends Health care workers None Others (specify)
15. Counselor, does the client need a treatment supporter? Yes No *(If yes go to 15a, if no go 16)*
- 15a. If YES why? specify (Tick all that apply)
 Client requests treatment supporter
 Physically disabled
 Mentally disabled
 Other (specify)

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16. Counselor is this client recommended for homecare? Yes No

16a. If YES, specify why? (Tick all that apply)

- Physically or mentally disabled adult
- Adult dependent on care-giver
- Client requests a home visit
- Disclosure (patient would like help disclosing status to family members)
- Family testing (client would like other family members to be tested)
- Other (specify)

17. Have you explained/discussed or checked the following with the Client?

Checklist	Tick (if Yes)	Tick (if No)
1. Overview of HOPE Center Program and Services	<input type="radio"/>	<input type="radio"/>
2. Importance of commitment to the program	<input type="radio"/>	<input type="radio"/>
3. Policy for adherence and clinic attendance	<input type="radio"/>	<input type="radio"/>
4. Patients enrollment status in other programs or facilities	<input type="radio"/>	<input type="radio"/>
5. Patients long term goals for health management at our program	<input type="radio"/>	<input type="radio"/>

Notes / Assessment

For the data use only (tick after scanning the form)

Scanned Date ___ / ___ / _____ Name of data person

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**HOPE CLINIC
ADULT LOCATOR FORM**

HOPE ID Number

Site Code

Today's Date (DD/MM/YYYY)

Interviewer number

1. Name (Last, First, Middle)

2. Gender Male Female

3. Age (Years)

CLIENT'S RESIDENTIAL AND TELEPHONE CONTACT INFORMATION

4. Public Transportation to the house:

4a. Type

Bus Citi Hoppa Matatu Taxi Other(specify)

4b. Number

4c. Stage Name

4d. General name of the area

5. Walking directions to house from the stage?

6. Landmarks that aide in locating the household: (Schools, churches, businesses etc.)

7. How is the Client or Caregiver called or referred to in home area:

8. Primary Telephone Contact:

Mobile Landline Unknown

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Hope Clinic

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8a. Line belongs to:

- Client
- Parent
- Caregiver
- Other household member
- Relative
- Friend
- Neighbour
- Nerby Simu ya Jamii
- Guardian Institution or organisation
- Other(specify)

8b. If the phone is not the client's does the owner know of the client's status?

- Yes
- No
- Unknown

9. Secondary Telephone Contact:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

- Mobile
- Landline
- Unknown

9a. Line belongs to:

- Client
- Parent
- Caregiver
- Other household member
- Relative
- Other(specify)
- Friend
- Neighbour
- Nearby Simu ya Jamii
- Guardian Institution or organisation

9b. If the phone is not the client's does the owner know of the client's status?

- Yes
- No
- Unknown

10. How long has the client been living at this residence:

		Years		Months
--	--	-------	--	--------

10a. This residence is:

- Permanent
- Temporary
- Unknown

For the data use only (tick after scanning the form)

Scanned Date ___ / ___ / _____ Name of data person

HOPE CLINIC

ADULT MEDICAL FOLLOW-UP

HOPE ID Number

Site Code

Today's Date (DD.MM.YYYY)

/

/

Interviewer number

HISTORY OF PRESENT ILLNESS

MEDICAL REVIEW

1. Does the patient currently have Extra pulmonary TB? Yes No
2. Does the Patient have Pulmonary TB? Yes No *(If YES go to 2a, If NO go to 4)*
 - 2a. If YES, what was the diagnosis based on (tick all that apply)
 - Chest X-ray
 - Sypmtoms (persistent cough >2 weeks, fever, night sweats, etc)
 - Failure to respond to empirical antibiotics
 - Sputum
 - Other (specify)
 - Unknown
3. Is the patient currently on treatment for TB(PTB & ETB) *(If YES go to 3a, If NO or Unknown go to 4)*
 - Yes No Unknown
 - 3a. If yes, specify treatment start date (DD.MM.YYYY) / /
 - 3b. If YES, specify treatment

S=streptomycine
H=Isoniazid
R=Rifampicin
Z=Pyrazinamid
E=Ethambutol

 - EH SHRZE
 - RHZ unknown
 - RHZE Other (specify)
 - RH
 - 3c. Is the patient currently being treated for TB at coptic? Yes No *(If YES go to 4, If NO go to 3d)*
 - 3d. If NO, specify where:
 - Private hospital
 - Public hospital
 - Other government facility
 - Other (specify)
4. In the past month, has the patient experienced any of the following? (tick all that apply)

<input type="checkbox"/> Dysparenuia	<input type="checkbox"/> Testicular pain or swelling
<input type="checkbox"/> Genital sores or ulcers	<input type="checkbox"/> Urethral discharge
<input type="checkbox"/> Lower Abdominal pain	<input type="checkbox"/> Vaginal discharge
<input type="checkbox"/> Painful micturation(Dysuria)	<input type="checkbox"/> Vaginal itching/burning
<input type="checkbox"/> None	

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Modified December 2009

Hope Clinic

Version 5.0

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MEDICATIONS

5. Is the patient currently taking HAART or ARVs, excluding PMTCT & PEP? Yes No (If YES go to 5a, If NO go to 7)

5a. If yes, specify (tick one)

- AZT-3TC-EFV d4T(40mg)-DDI-LPV/rit
- AZT-3TC-NVP TDF 3TC EFV
- AZT-3TC-LPV/rit TDF 3TC NVP
- d4T(30mg)-3TC-EFV TDF-ABC-LPV/rit
- d4T(30mg)-3TC-NVP Unknown
- d4T(30mg)-DDI-LPV/rit Other (specify)

5b. Has the patient had any recent side effects due to HAART or ARV medications? Yes No (If Yes go to 5c, If NO go to 6)

5c. If YES, describe the symptoms and severity of possible side effects (Tick for each symptom)

Symptom	Frequency of Symptom	If YES, severity of symptom
a. Nausea or vomiting	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
b. Rash	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
c. Fat changes	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
d. Diarrhea	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
e. Anemia	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
f. Cough	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
g. Fatigue	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
h. Abdominal pain	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
i. CNS - dizziness, anxiety, nightmares	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
j. Headache	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
k. Jaundice	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
l. Difficulty breathing	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
m. Burning/numbness/tingling	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
n. Fever	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
o. Heartburn	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
p. Other (specify) <input style="width: 80px; height: 15px;" type="text"/>	<input type="checkbox"/> Sometimes <input type="checkbox"/> Often	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe

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6. During the last 7 days how many ARV pills did the patient MISS taking? (tick one)

- None Very Few Half Most All

6a. If patient MISSED doses, please specify reasons (tick all that apply).

- Alcohol Forgot Too ill
 Depression Inability to pay Toxicity/side effect
 Drug stock out - dispensary Patient lost or ran out of pills Other (specify)
 Delivery/travel problems Stigma, disclosure or privacy issues
 Felt better Share with others

7. Is patient taking any of the following medications? (tick all that apply)

- Cotrimoxazole Antimalarial medications None of the above
 Dapsone Herbal traditional medications
 Fluconazole Multivitamin supplements

8. What other medications is patient currently taking?

Medication	Dose (mg)	Frequency (per day)	Start date	Stop date
1.				
2.				
3.				

9. PHYSICAL EXAMINATION

Nurse number

Temp (F) HR BP / RR Wt (Kg) HGT Sa O2

BMI BMI > 18.5 BMI < 18.5 BMI Unknown Gender MALE Female

10.

System (tick one)	Normal	Abnormal	Not done	Findings (if abnormal)
General	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Psychological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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ASSESSMENT AND PLAN

11. What diagnoses does the patient have on today's visit (tick all that apply)?

- | | | | |
|---|--|--|--|
| <input type="checkbox"/> Anaemia | <input type="checkbox"/> Dermatitis | <input type="checkbox"/> Myalgia | <input type="checkbox"/> URTI |
| <input type="checkbox"/> Asthma | <input type="checkbox"/> Extra Pulmonary TB | <input type="checkbox"/> Neuropathy | <input type="checkbox"/> UTI |
| <input type="checkbox"/> Candidiasis (thrush) - oral | <input type="checkbox"/> Gonorrhoea | <input type="checkbox"/> Peptic Ulcer disease | <input type="checkbox"/> Zoster |
| <input type="checkbox"/> Candidiasis (thrush) - vaginal | <input type="checkbox"/> Genital Ulcer disease | <input type="checkbox"/> Pneumonia | <input type="checkbox"/> None |
| <input type="checkbox"/> Chancroid | <input type="checkbox"/> Hypertension | <input type="checkbox"/> Side effects due to ARV | <input type="checkbox"/> Other (specify) |
| <input type="checkbox"/> Conjunctivitis | <input type="checkbox"/> HSV - genital | <input type="checkbox"/> Soft tissue infection | <input type="text"/> |
| <input type="checkbox"/> Diarrhea | <input type="checkbox"/> IRIS | <input type="checkbox"/> Syphilis | |
| <input type="checkbox"/> Dementia | <input type="checkbox"/> Malaria | <input type="checkbox"/> Ulcers - oral | |

12. What is the patients current Pulmonary TB diagnosis?

- Pulmonary TB suspected *(If suspected go to 13)*
- Pulmonary TB diagnosed today *(If diagnosed go to 14)*
- Currently on pulmonary TB treatment *(If currently on TB treatment go to 15)*
- Previously diagnosed with TB, not on Treatment *(skip to 14a)*
- No Pulmonary TB *(If NO TB go to 15)*
- Other(specify)

13. If pulmonary TB suspected, what is the suspected pulmonary TB based on (tick all that apply)?

- Abnormal X-ray
- Symptoms (persistent cough >2 weeks, fever, night sweats, etc)
- Failure to respond to empirical antibiotics
- Recent contact with people with Pulmonary TB
- Other (specify)

13a. Will the patient be sent for pulmonary TB testing? Yes NO *(If yes, go to 13b, if no go to 15)*

13b. If YES, which of the following tests will the patient be sent for:

- Sent for sputum
- Sent for X-ray
- Other (specify)
- (Go to 15)*

14. If Pulmonary TB is diagnosed today, what is it based on (tick all that apply)?

- Abnormal X-ray Failure to respond to empirical antibiotics
- Symptoms (persistent cough >2 weeks, fever, night sweats, etc) Sputum
- Other (specify)

14a. Specify treatment to be started: S=streptomycine

- | | | |
|--|--------------------------------|---------------|
| <input type="checkbox"/> RHZE | <input type="checkbox"/> SHRZE | H=Isoniazid |
| | | R=Rifampicin |
| <input type="checkbox"/> RHZ | <input type="checkbox"/> EH | Z=Pyrazinamid |
| | | E=Ethambutol |
| <input type="checkbox"/> Other (specify) | <input type="text"/> | |

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Section B: Female Patients Only (If Male go to 19)

15. Is the patient currently pregnant?
 Yes No Unknown *(If YES, complete Pregnancy Monitoring Form)*
16. Is the patient currently breastfeeding? Yes No *(If YES, go to 16a, if no go to 17)*
 16a. If yes, specify what type of breastfeeding (tick one)
 Exclusive breastfeeding *(Child given ONLY mother's milk and NO water, tea, formula, cow's milk or food of any kind)*
 Mixed feeding *(Child given mother's milk and water, tea formula, cow's milk or food)*
- 16b. If YES, has she had a session with the nutritionist since she started breast feeding?
 Yes No ***(If NO, refer patient to Nutritionist)***
17. Has the patient delivered in the past 18 Months? Yes No *(If yes go to 17a, If No go to 18)*
 17a. If yes, is this the first time the patient has returned to the Hope Center since delivery?
 Yes ***(If yes, complete pregnancy Close -Out form)***
 No
- 17b. Age of the child Months Days Child not Alive
- 17c. If not currently breastfeeding, at what age did the child stop breastfeeding?
 Months Days Unknown NA, Child never breastfed
- 17d. Has the child ever had a PCR test? Yes No
- 17e. If Yes, what was the result of the last PCR test?
 HIV Positive *(Go to 18)*
 HIV Negative
 Indeterminate
 Result not yet available
(Complete Infant PCR form; If Q17e is HIV Negative, Indeterminate or Result not yet available)
- 17f. Will an Infant PCR test be ordered today? Yes No
18. Is the patient being referred for Cervical Cancer screening at Hope? Yes No *(If yes go to 19, If NO go to 18a)*
 18a. If NO, reasons why patient NOT referred for Cervical Cancer Screening *(tick all that apply)*
 Patient is younger than 18 years
 Patient has had total hysterectomy, LEEP or cryotherapy
 Patient is currently pregnant
 Patient has had a screening test in the last year
 No service available at this time
 Patient wishes to defer until a later time Specify reason
 Patient does not accept screening Specify reason
 Other(specify)

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19. Is the Client currently on HAART, excluding PMTCT and PEP? Yes No *(If YES go to 19a, If No go to 19b)*

19a. If yes, did you continue current HAART? Yes No *(If YES go to 20, If No go to 19a1)*

19a1. If no, did you change or stop HAART today? Changed Stopped

19a2. Specify why HAART was changed or stopped *(Tick all that apply)*

- Toxicity / Side effects
- Clinical treatment failure
- Pregnancy
- Immunologic treatment failure
- Risk of pregnancy
- Virologic treatment failure
- Newly diagnosed TB
- Poor adherence
- New drug available
- Illness, hospitalization
- Drug not available
- Other (specify)
- Patient lacks finances

(Skip to 20)

19b. If no, is patient ELIGIBLE for therapy? Yes No Not yet determined *(If Eligible go to 19b1; if NOT eligible or NYD go to 22)*

19b1. If ELIGIBLE for therapy then by what criteria *(tick all that apply)?*

- CD4 count CD4 % Date (DD/MM/YYYY) / /
- WHO Clinical Stage 1 2 3 4 Viral Load
- Patient on HAART/ARV in past

19c. Did you initiate HAART/ARV treatment at this clinic visit, excluding PMTCT and PEP? Yes No *(If YES go to 19c1 If No go to 19c2)*

19c1. If yes, what was the WHO stage 1 2 3 4

19c2. If NO, specify:

- Patient has not completed HAART protocol
- Patient preference
- Patient currently on drugs which may interact with HAART/ARV
- Patient too ill to begin HAART today
- Other (specify)

20. Has the patient completed HAART protocol? Yes No

21. What ARV medications were prescribed or continued today

- AZT-3TC-EFV
- TDF-ABC -LPV/rit
- AZT-3TC-NVP
- TDF 3TC EFV
- AZT-3TC- LPV/rit
- TDF 3TC NVP
- d4T(30mg)-3TC-EFV
- None
- d4T(30mg)-DDI-LPV/rit
- Other (specify)
- d4T(30mg)-3TC-NVP

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22. Did you initiate or continue Cotrimoxazole today? Yes No (If YES go to 23, If NO go to 22a)

22a. If no, why?

- Side effects/ toxicity Patient preference
 Stockout/drug supply interruption Other (Specify)

23. Did you initiate or continue any of the following medications today (tick all that apply)?

- Dapsone Fluconazole Multivitamin supplement None of the above

24. Other medications prescribed during this visit

Medication	Dose (mg)	Frequency (per day)	Start date	
1.				
2.				
3.				
4.				

25. What laboratory tests were ordered today (tick all that apply)

- ALT Hgb Viral Load
 cd4 HIV ELISA Confirmatory test Widal Test
 Chest X-ray LFT None
 Creatinine Lactic Test Other (specify)
 Complete Blood Count Urinalysis

Comments

For the data use only (tick after scanning the form)

Scanned Date ___/___/_____ Name of data person

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HOPE CLINIC ADULT MEDICAL SCREENING

HOPE ID Number

Site Code Today's date (DD.MM.YYYY) Interviewer number

 / /

HISTORY OF PRESENT ILLNESS

PAST MEDICAL HISTORY

1. Has the patient ever had pulmonary TB in the past? *(If YES go to 1a, If NO or unknown go to 2)?*
 Yes No Unknown

1a. If YES, what was the diagnosis based on *(tick all that apply)*

- Chest X-ray
- Sypmtoms (persistent cough >2 weeks, fever, night sweats, etc)
- Failure to respond to empirical antibiotics
- Sputum
- Other (specify)
- Unknown

1b. Was the patient treated

- Yes No Unknown *(If YES go to 1c, If NO or unknown go to 2)*

1c. If YES, specify treatment

- EH SHRZE
- RHZ unknown
- RHZE Other (specify)
- RH

S=streptomycine
 H=Isoniazid
 R=Rifampicin
 Z=Pyrazinamid
 E=Ethambutol

1d. If YES, did the patient (tick one)?

- Never completed full treatment
- Doesn't know if received full treatment
- Completed Full Treatment

Date started (DD/MM/YYYY) / /

Date stopped (DD/MM/YYYY) / /

2. Does the patient currently have Extra pulmonary TB? Yes No

3. Does the Patient have Pulmonary TB? Yes No *(If YES go to 3a, If NO go to 4)*

3a. If YES, what was the diagnosis based on (tick all that apply)

- Chest X-ray
- Symptoms (persistent cough >2 weeks, fever, night sweats, etc)
- Failure to respond to empirical antibiotics
- Sputum
- Other (specify)
- Unknown

4. Is the patient currently on treatment for TB (either PTB or EPTB) *(If YES go to 4a If NO or Unknown go to 5)*

Yes No Unknown

4a. If yes, specify treatment start date (DD.MM.YYYY) / /

4b. If YES, specify treatment

- EH SHRZE
- RHZ unknown
- RHZE Other (specify)
- RH

S=streptomycine
H=Isoniazid
R=Rifampicin
Z=Pyrazinamid
E=Ethambutol

4c. Is the patient currently being treated for TB at coptic? Yes No *(If YES go to 5, If NO go to 4d)*

4d. If NO, specify where:

- Private hospital
- Public hospital
- Other government facility
- Other (specify)

5. In the past month, has the patient experienced any of the following? (tick all that apply)

- Dyspareunia Vaginal itching/burning
- Genital sores or ulcers Vaginal discharge
- Lower Abdominal pain Urethral discharge
- Painful micturation(Dysuria) None
- Testicular pain or swelling

6. Has the patient ever had or been told he/she had a sexually transmitted infection? Yes No Unknown

6a. If yes, specify (tick all that apply)

- Chlamydia Trichomonas vaginalis
- Chancroid Syphilis
- Herpes Unknown
- Neisseria gonorrhoea Other specify

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7. Does the patient currently have, or has the patient ever had, any of the following conditions (tick all that apply)

WHO stage 1	
Asymptomatic HIV infection	<input type="checkbox"/>
Persistent generalized lymphadenopathy (PGL)	<input type="checkbox"/>
WHO stage 2	
Herpes Zoster (within last 5 years)	<input type="checkbox"/>
Minor Mucocutaneous Manifestations	<input type="checkbox"/>
Recurrent Upper Respiratory Infections	<input type="checkbox"/>
Weight loss < 10% of Body weight	<input type="checkbox"/>
WHO stage 3	
Severe Bacterial infections (i.e Pneumonia, pyomyositis)	<input type="checkbox"/>
Oral Candidiasis (Thrush)	<input type="checkbox"/>
Unexplained chronic diarrhea (> 1 month)	<input type="checkbox"/>
Unexplained Prolonged Fever (intermittent or constant, > 1 month)	<input type="checkbox"/>
Oral Hairy Leukoplakia	<input type="checkbox"/>
Tuberculosis, Pulmonary (within last 12 months from today)	<input type="checkbox"/>
Weight loss > 10% of body weight	<input type="checkbox"/>
WHO stage 4	
Candidiasis (Esophageal, Bronchi, Trachea, or lungs)	<input type="checkbox"/>
Cryptococcosis, Extrapulmonary	<input type="checkbox"/>
Cryptosporidiosis with Diarrhea (> 1 month duration)	<input type="checkbox"/>
Herpes Simplex (mucocutaneous > 1 months, or visceral or any duration)	<input type="checkbox"/>
HIV Encephalopathy	<input type="checkbox"/>
HIV Wasting Syndrom	<input type="checkbox"/>
Kaposi's Sarcoma (KS)	<input type="checkbox"/>
Lymphoma	<input type="checkbox"/>
Atypical Mycobacteriosis, Disseminated	<input type="checkbox"/>
Tuberculosis, Extrapulmonary	<input type="checkbox"/>
Progressive Multifocal Leukoencephalopathy (PML)	<input type="checkbox"/>
Mycosis, disseminated endemic (i.e., histoplasmosis, coccidiomycosis)	<input type="checkbox"/>
Pneumocystis Carinii Pneumonia (PCP)	<input type="checkbox"/>
Salmonella Septicemia, Non-typhoid	<input type="checkbox"/>
Toxoplasmosis, CNS	<input type="checkbox"/>

5875 8. What is the WHO Clinical Stage of the patient? (tick one) 1 2 3 4

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9. Last CD4 count Unknown Not tested
 9a. Last CD4 count date (DD.MM.YYYY) / / Unknown
 9b. Last Viral load undetectable Unknown Not tested
 9c. Last viral load date (DD.MM.YYYY) / / Unknown

MEDICATIONS

10. Has the patient ever taken or is the patient presently on HAART excluding for the purpose of PMTCT and PEP?

Yes No (If YES go to 10a, if NO go to 11)

10a. If YES, specify history below

	Medication (tick all that apply)										
	d4T	3TC	AZT	DDI	ABC	NVP	EFV	LPV/rit	TDF	Truvada	Other (Specify)
First regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Second regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Third regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

	Generic or brand (tick one)	CD4 count at time of regimen initiation (if known)	Adherence (1=V. poor, 2=poor, 3=Fair, 4= Good, 5=Excellent)	Date started (DD/MM/YYYY)	Did patient stop?	If yes, Date stopped (DD/MM/YYYY)
First regimen	<input type="checkbox"/> Generic <input type="checkbox"/> Brand <input type="checkbox"/> Unknown	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> Unknown	<input type="checkbox"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Second regimen	<input type="checkbox"/> Generic <input type="checkbox"/> Brand <input type="checkbox"/> Unknown	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> Unknown	<input type="checkbox"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Third regimen	<input type="checkbox"/> Generic <input type="checkbox"/> Brand <input type="checkbox"/> Unknown	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> Unknown	<input type="checkbox"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

If stopped why? (tick all that apply)

	Costs	Side effects	Failure of therapy	New diagnosis TB	Drug out of stock	Doctor orders	Unknown	Other (Specify)
First regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Second regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Third regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

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11. Is patient taking any of the following medications? (tick all that apply)

- Antimalarial medications
 Dapsone
 Herbal traditional medications
 None of the above
 Cotrimoxazole
 Fluconazole
 Multivitamin supplements

12. What other medications is patient currently taking?

Medication	Dose (mg)	Frequency (per day)	Start date	Stop date
1.				
2.				
3.				

13. PHYSICAL EXAMINATION

Nurse number

Temp (F)
 HR
 BP /
 RR
 Wt (Kg)
 Height (cm)
 Sa O2

BMI BMI>18.5
 BMI<18.5
 BMI Unknown
 Gender MALE
 Female

14.

System (tick one)	Normal	Abnormal	Not done	Findings (if abnormal)
General	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Psychological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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ASSESSMENT AND PLAN

15. What new diagnoses does the patient have on today's visit (tick all that apply)?

- | | | | |
|---|--|--|--|
| <input type="checkbox"/> Anaemia | <input type="checkbox"/> Dermatitis | <input type="checkbox"/> Malaria | <input type="checkbox"/> Syphilis |
| <input type="checkbox"/> Asthma | <input type="checkbox"/> Extra Pulmonary TB | <input type="checkbox"/> Myalgia | <input type="checkbox"/> Ulcers genital |
| <input type="checkbox"/> Candidiasis (thrush) - oral | <input type="checkbox"/> Gonorrhoea | <input type="checkbox"/> Neuropathy | <input type="checkbox"/> Ulcers - oral |
| <input type="checkbox"/> Candidiasis (thrush) - vaginal | <input type="checkbox"/> Genital Ulcer disease | <input type="checkbox"/> Peptic Ulcer disease | <input type="checkbox"/> URTI |
| <input type="checkbox"/> Chancroid | <input type="checkbox"/> Hypertension | <input type="checkbox"/> Pneumonia | <input type="checkbox"/> UTI |
| <input type="checkbox"/> Conjunctivitis | <input type="checkbox"/> HSV - genital | <input type="checkbox"/> Side effects due to ARV | <input type="checkbox"/> Zoster |
| <input type="checkbox"/> Diarrhea | <input type="checkbox"/> IRIS | <input type="checkbox"/> Soft tissue infection | <input type="checkbox"/> None |
| <input type="checkbox"/> Dementia | | | <input type="checkbox"/> Other (specify) |

16. What is the patients current TB diagnosis?

- TB suspected *(If suspected go to 17)*
- TB diagnosed today *(If diagnosed go to 18)*
- Currently on pulmonary TB treatment *(If currently on TB treatment go to 19)*
- No TB *(If NO TB go to 19)*
- Other(specify)

17. If TB suspected, what is the suspected TB based on (tick all that apply)?

- Abnormal X-ray
- Symptoms (persistent cough >2 weeks, fever, night sweats, etc)
- Failure to respond to empirical antibiotics
- Recent contact with people with TB
- Other (specify)

17a. Will the patient be sent for TB testing? Yes NO *(If YES, go to 17b, If NO go to 19)*

17b. If YES. which of the following tests will the patient be sent for:

- Sent for sputum
- Sent for X-ray
- Other (specify)
- (Go to 19)***

18. If TB is diagnosed today, what is it based on(tick all that apply)?

- Abnormal X-ray
- Symptoms (persistent cough >2 weeks, fever, night sweats, etc)
- Failure to respond to empirical antibiotics
- Sputum
- Other (specify)

18a. Specify treatment to be started:

- | | |
|-------------------------------|---|
| <input type="checkbox"/> EH | <input type="checkbox"/> SHRZE |
| <input type="checkbox"/> RHZE | <input type="checkbox"/> Other (specify) <input type="text"/> |
| <input type="checkbox"/> RHZ | |

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SECTION B: FEMALE PATIENTS ONLY

19. In the past, has the patient ever taken any antiretroviral drugs for PMTCT?

Yes No Unknown (If YES go to 19a, If NO or Unknown go to 20)

19a. If YES, how many times did the patient take PMTCT?

19b. Specify history for each pregnancy in which the patient had PMTCT, beginning with the youngest child:

	Date of delivery (DD/MM/YYYY)	Regimen	Specify when the drug was taken (Tick all that apply)	Location of delivery	Mode of delivery
1.	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/> AZT	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum	<input type="checkbox"/> Hospital <input type="checkbox"/> Home <input type="checkbox"/> Other (specify) <input type="text"/>	<input type="checkbox"/> C-section <input type="checkbox"/> Unassisted vaginal <input type="checkbox"/> Assisted vaginal (use of forceps or vacuum)
		<input type="checkbox"/> 3TC	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> NVP	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> HAART	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> Other (Specify) <input type="text"/>	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> Unknown			
2.	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/> AZT	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum	<input type="checkbox"/> Hospital <input type="checkbox"/> Home <input type="checkbox"/> Other (specify) <input type="text"/>	<input type="checkbox"/> C-section <input type="checkbox"/> Unassisted vaginal <input type="checkbox"/> Assisted vaginal (use of forceps or vacuum)
		<input type="checkbox"/> 3TC	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> NVP	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> HAART	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> Other (Specify) <input type="text"/>	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum		
		<input type="checkbox"/> Unknown			

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	Date of delivery (DD/MM/YYYY)	Regimen	Specify when the drug was taken (Tick all that apply)	Location of delivery	Mode of delivery
3.	<input type="text"/> / <input type="text"/> / <input type="text"/> 	<input type="checkbox"/> AZT <input type="checkbox"/> 3TC <input type="checkbox"/> NVP <input type="checkbox"/> HAART <input type="checkbox"/> Other (Specify) <input type="text"/> <input type="checkbox"/> Unknown	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum <input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum <input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum <input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum <input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum	<input type="checkbox"/> Hospital <input type="checkbox"/> Home <input type="checkbox"/> Other (specify) <input type="text"/>	<input type="checkbox"/> C-section <input type="checkbox"/> Unassisted vaginal <input type="checkbox"/> Assisted vaginal (use of forceps or vacuum)
4.	<input type="text"/> / <input type="text"/> / <input type="text"/> 	<input type="checkbox"/> AZT <input type="checkbox"/> 3TC <input type="checkbox"/> NVP <input type="checkbox"/> HAART <input type="checkbox"/> Other (Specify) <input type="text"/> <input type="checkbox"/> Unknown	<input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum <input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum <input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum <input type="checkbox"/> Antepartum <input type="checkbox"/> Labor & Delivery <input type="checkbox"/> Postpartum	<input type="checkbox"/> Hospital <input type="checkbox"/> Home <input type="checkbox"/> Other (specify) <input type="text"/>	<input type="checkbox"/> C-section <input type="checkbox"/> Unassisted vaginal <input type="checkbox"/> Assisted vaginal (use of forceps or vacuum)

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20. Is the patient currently pregnant?
 Yes No Unknown *(If YES also complete Pregnancy Monitoring Form)*

21. Is the patient currently breastfeeding? Yes No *(If YES go to 21a, if NO go to 22)*

21a. If yes, specify what type of breastfeeding (tick one)
 Exclusive breastfeeding *(Child given ONLY mother's milk and NO water, tea, formula, cow's milk or food of any kind)*
 Mixed feeding *(Child given mother's milk and water, tea formula, cow's milk or food)*

21b. If YES, has she had a session with the nutritionist since she started breastfeeding.
 Yes No ***(If NO refer to Nutritionist)***

22. Is the patient currently on HAART, excluding PMTCT and PEP? Yes No *(If YES, go to 22a, If NO go to 22b)*

22a. If yes, did you continue current HAART today? Yes No *(If YES, go to 23, If NO go to 22a1)*

22a1. If no, did you change or stop HAART today? Changed Stopped

22a2. Specify why HAART was changed or stopped (Tick all that apply) :

<input type="checkbox"/> Toxicity / Side effects	<input type="checkbox"/> Clinical treatment failure
<input type="checkbox"/> Pregnancy	<input type="checkbox"/> Immunologic treatment failure
<input type="checkbox"/> Risk of pregnancy	<input type="checkbox"/> Virologic treatment failure
<input type="checkbox"/> Newly diagnosed TB	<input type="checkbox"/> Poor adherence
<input type="checkbox"/> New drug available	<input type="checkbox"/> Planned treatment interruption
<input type="checkbox"/> Drug not available	<input type="checkbox"/> Illness, hospitalization
<input type="checkbox"/> Patient lacks finances	<input type="checkbox"/> Other (specify) <input type="text"/>

(Go To 23)

22b. If NO, is patient ELIGIBLE for therapy? Yes No Not yet determined *(If Eligible=NO or NYD >>24)*

22b1. If ELIGIBLE for therapy then by what criteria (tick all that apply)?

CD4 count Date (DD/MM/YYYY) / /

WHO Clinical Stage 1 2 3 4 Viral Load copies

Patient on HAART/ARV in past

22c. Did you initiate HAART/ARV treatment at this clinic visit, excluding PMTCT and PEP? Yes No

(If YES go to 23, If NO go to 22c1)

22c1. If NO, specify:

<input type="checkbox"/> Patient has not completed HAART protocol	<input type="checkbox"/> Patient preference
<input type="checkbox"/> Patient currently on drugs which may interact with HAART/ARV	<input type="checkbox"/> Patient pregnant
<input type="checkbox"/> Patient too ill to begin HAART today	<input type="checkbox"/> Other (specify) <input type="text"/>

23. What ARV medications were prescribed or continued today

<input type="checkbox"/> AZT-3TC-EFV	<input type="checkbox"/> TDF-ABC -LPV/rit
<input type="checkbox"/> AZT-3TC-NVP	<input type="checkbox"/> TDF 3TC EFV
<input type="checkbox"/> AZT-3TC- LPV/rit	<input type="checkbox"/> TDF 3TC NVP
<input type="checkbox"/> d4T(30mg)-3TC-EFV	<input type="checkbox"/> None
<input type="checkbox"/> d4T(30mg)-DDL-LPV/rit	<input type="checkbox"/> Other (specify) <input type="text"/>
<input type="checkbox"/> d4T(30mg)-3TC-NVP	

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24. Did you initiate or continue Cotrimoxazole today? Yes No *(If yes go to 25, if no go to 24a)*

24a. If no, why?

Side effects/ toxicity

Patient preference

Stockout/drug supply interruption

Other (Specify)

25. Did you initiate or continue any of the following medications today (tick all that apply)?

Dapsone

Fluconazole

Multivitamin supplement

None of the above

26. Other medications prescribed during this visit

Medication	Dose (mg)	Frequency (per day)	Start date	Stop date
1.				
2.				
3.				
4.				
5.				

27. What laboratory tests were ordered today (tick all that apply)

ALT

Hgb

Viral Load

cd4

HIV ELISA Confirmatory test

Widal Test

Chest X-ray

LFT

None

Creatinine

Lactic Test

Other (specify)

Complete Blood Count

Urinalysis

Additional Comments

For the data use only (tick after scanning the form)

Scanned

Date ___ / ___ / _____

Name of data person

HOPE CLINIC VERBAL AUTOPSY FORM

HOPE ID Number

Site Code

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Today's Date (DD.MM.YYYY)

--	--	--	--	--	--	--	--

Interviewer number

--	--	--

1. Gender Female Male

2. Age at death

--

--

--

 Years

3. Date of death (DD/MM/YYYY)

--

 /

--

 /

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4. The information source for the cause of death was (Tick all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Hospital records/Staff | <input type="checkbox"/> Mother or Father |
| <input type="checkbox"/> Partner/Spouse | <input type="checkbox"/> Other family member/relative |
| <input type="checkbox"/> Neighbour | <input type="checkbox"/> Caregiver |
| <input type="checkbox"/> Friend | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Other (Specify) <table border="1" style="display: inline-table; width: 200px; height: 20px;"></table> | |

5. Was the deceased seeking other medical treatment (other than Hope Center) during that last 3 months before his/her death?

- Yes No Unknown *(If YES go to 5a, If NO go to 6)*

5a. If YES, where specifically was the deceased receiving other medical care?

Name of facility:

5b. What type of care was the deceased receiving at these other facilities? (Tick all that apply)

- | | | |
|--|----------------------------------|--|
| <input type="checkbox"/> General medical care | <input type="checkbox"/> TB | <input type="checkbox"/> STD |
| <input type="checkbox"/> HIV/AIDS | <input type="checkbox"/> Malaria | <input type="checkbox"/> Other infectious disease(s) |
| <input type="checkbox"/> Other (Specify) <table border="1" style="display: inline-table; width: 200px; height: 20px;"></table> | | |

6. Respondent's detailed account of the illness of the deceased:

7. Did a health care worker tell you the cause of death? *(If YES go to 7a, If NO go to 8)*

- Yes No Unknown

7a. What did the health care worker say was the cause of death?

8. Did s/he have any operation for the illness? (If YES go to 8a, If NO go to 9)

- Yes No Unknown

8a. How long before the death was the operation? : Months

8b. On what part of the body was the operation?

- Abdomen Chest Head

Other(specify)

9. Has the deceased's spouse or partner died in the past in the past 5 years? (If YES go to 9a, If NO go to 10)

- Yes No Unknown Had no spouse

9a. If YES, what is the perceived cause(s) of death of the partner(s)

9a1. Partner 1:

9a2. Partner 2:

Injury/accident/suicide

10. Did s/he suffer from any injury or accident that led to her/his death? (If YES go to 10a, If NO go to 11)

- Yes No Unknown

10a. What kind of injury or accident did the deceased suffer?

- Road traffic accident Fall
 Burns Violence/assault
 Unknown Poisoning
 Drowning Other:

10b. Was the injury or accident intentionally inflicted by someone else?

- Yes No Unknown

10c. Do you think that s/he committed suicide?

- Yes No Unknown

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History of previously known conditions

11. Did the deceased suffer from any of the following conditions?

- a. High blood pressure Yes No Unknown
- b. Diabetes Yes No Unknown
- c. Asthma Yes No Unknown
- d. Epilepsy Yes No Unknown
- e. Malnutrition Yes No Unknown
- f. Cancer Yes No Unknown

f1. If YES, specify type or site

g. Tuberculosis Yes No Unknown

h. Any other medically diagnosed illness? Yes No Unknown

h1. If YES, specify

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12. Signs, symptoms and their severity during the last illness:

Symptom	Symptom present?	If present, duration of symptom
a. Fever	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
b. Loss of weight	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
c. Diarrhea	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
d. Vomiting/associated abdominal pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
e. Constipation/associate abdominal pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
f. Cough	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
g. Cough followed by vomiting	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
h. Breathing trouble (chest indrawing/difficult /rapid/wheezing)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
i. Neck stiffness	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
j. Unconscious episodes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
k. Fits	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
l. Jerking of individual limbs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
m. History of epileptic illness in earlier years	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
n. Paralysis of limbs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
o. Rigid body stiffness, unable to open mouth	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
p. Red and sore eyes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
q. Skin rash and itching	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
r. Herpes zoster (at any time in life)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
s. Abscesses/body sores	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
t. White patches on the inside of mouth and tongue	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
u. Oedema	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
v. Hair changes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
w. Yellowing of eyes or passing of brown urine	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
x. Chest pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
y. Other (specify) <input style="width: 100px; height: 15px;" type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown

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Women only:

z. unexpected vaginal bleeding or discharge	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown
aa.Pelvic or vaginal pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> =<2 weeks <input type="checkbox"/> >2 weeks <input type="checkbox"/> Unknown

14. Records available in home e.g. death certificate (extract findings):

Comments (if the form is incomplete or any other comments)

For the data use only (tick after scanning the form)

Scanned Date ___/___/_____ Name of data person

5906

HOPE CLINIC ADULT NURSING SCREENING

HOPE ID Number

Site Code

Today's date (DD.MM.YYYY)

Interviewer number

Section A: All Patients

1. Who referred patient here? (tick one)

- | | |
|--|--|
| <input type="radio"/> Hope VCT
<input type="radio"/> Other VCT
<input type="radio"/> PMTCT
<input type="radio"/> CCC Clinic or HIV Clinic
<input type="radio"/> Hope TB clinic
<input type="radio"/> Other TB clinic
<input type="radio"/> Self-referral
<input type="radio"/> Child welfare Clinic | <input type="radio"/> Family member, spouse or friend
<input type="radio"/> Other patients
<input type="radio"/> NGO
<input type="radio"/> Coptic ward
<input type="radio"/> Other hospital ward (specify) <input style="width: 150px; height: 15px;" type="text"/>
<input type="radio"/> Coptic Pharmacy
<input type="radio"/> Private doctor
<input type="radio"/> Other (specify) <input style="width: 250px; height: 15px;" type="text"/> |
|--|--|

2. Does the client have a NASCOP referral number? Yes No *(If YES go to 2a, If NO go to 3)*

2a. If Yes, specify the client's NASCOP referral number with date

NASCOP Referral Number

Referral Date (DD/MM/YYYY) / /

NASCOP referral number unknown

3. Has client ever been on antiretroviral drugs, excluding for PMTCT and PEP? Yes No *(If YES go to 3a, If NO go to 4)*

3a. If YES, where did the client receive antiretroviral drugs ?

- | | |
|---|---|
| <input type="radio"/> CCC Clinic or HIV Clinic
<input type="radio"/> Private Doctor
<input type="radio"/> Hospital ward | <input type="radio"/> NGO
<input type="radio"/> Other (specify) <input style="width: 250px; height: 15px;" type="text"/> |
|---|---|

3b. What is the reason for transfer of care (tick all that apply)

- | | |
|--|--|
| <input type="radio"/> Financial
<input type="radio"/> Client's preference
<input type="radio"/> Distance to clinic
<input type="radio"/> Doctors advice | <input type="radio"/> Poor management
<input type="radio"/> Client was asked to leave
<input type="radio"/> Facility unable to <input style="width: 150px; height: 15px;" type="text"/>
<input type="radio"/> Other (specify) |
|--|--|

4. In the past, has the patient ever taken any antiretroviral drugs for PMTCT?

- Yes No Unknown N/A, Male Client

4a. If YES, how many times did the patient take PMTCT?

5. Has the patient been tested for HIV? Yes No (If Yes go to 5a, If NO go to 6)

5a. If yes, where was the test performed? (Tick one) (If **PITC**, go to 5ai, else go to 5b)

- PITC (ProviderInitiated HIV Testing and Counseling)
- VCT
- PMTCT
- Postnatal Clinic
- CWC(Child welfare Clinic)
- TB clinic
- Other (Specify)

5ai. Where was the PITC done ?

- Coptic Hospital-Outpatient Coptic Hospital-inpatient
- Hope TB clinic Private Hospital
- Hope Home-base care program Public Hospital
- Muangalizi Program Other(specify)

5b. When was the test done (DD/MM/YYYY) / /

5c. What were the test results? Positive Negative Unknown

6. Has the patient been hospitalized in the last 1 year? Yes No

6a. If yes, how many times?

7. Does patient have Penicillin allergy? Yes No Dont Know

8. Does patient have Sulfa allergy? Yes No Dont Know (Medical and non-medical allergies)

9. Does the patient have anv other Yes No Dont Know

9a. If yes, please specify

(If Patient ticked any "YES" in Q7, 8 or 9 highlight allergy in chart)

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Section B: Female patients only [If Male go to 12]

10. How many times has the patient been pregnant? IF = 0 go to 13

11. How many children has patient given birth to? IF = 0 go to 13

12. How many of the children the patient has given birth to are alive? IF = 0 go to 13

12a) What is the age of the first child? Years Month Weeks

12b) What is the age of the last child? Years Month Weeks

13. Is the patient or partner using any form of family planning? Yes No

13a. If YES (tick all that apply)

Condoms

Oral contraceptive pills

Injectable/implantable hormones

Diaphragm/Cervical cap

Intrauterine device

Vastectomy/tubal ligation/hysterectomy

Natural method (specify)

Other (specify)

Other Comments

Scanned Date ___/___/___ Name of data person

(Q7. applies to those initiated/or already on food supplement)

7. How would you Classify today's case? Severe Cases Moderate/Mild Cases

8. Assessment and Recommendations

For the data use only (tick after scanning the form)

Scanned Date ___/___/_____ Name of data person

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HOPE CLINIC NUTRITION SCREENING

HOPE ID Number

Site Code **Today's date (DD.MM.YYYY)** **Interviewer number**
 / /

1. Anthropometric Assessment

Weight Kgs Height cm Hip Circ. cm BMI
 Waist circ. cm Waist:Hip ratio cm MUAC cm

2. Medical

Nausea No Yes Vomiting No Yes
 Diarrhoea No Yes Constipation No Yes
 Weight loss greater than 10% No Yes Chewing/teeth problem No Yes
 Swallow difficulty No Yes Taste changes No Yes
 Poor appetite No Yes
 Other medical conditions No Yes

If patient has other medical conditions, specify

1	
2	
3	
4	

Medications? Yes No (specify)

Medication	Time	with food?	Time	with food?	Time	with food?

3. Social History

Permanent housing No Yes
 Adequate food resources No Yes
 Adequate cooking facilities No Yes
 Activity/exercise No Yes
 Smoking No Yes specify
 Alcohol No Yes specify
 Drugs No Yes specify

4. Dietary History

4a. Number of meals or snacks per day
 4b. Times per week eat out

4c. Who prepares food?

- Self Relative
 Spouse Caregiver
 Child/children Other (specify)
 Neighbour

- 4d. Special or alternative diets No Yes specify
 4e. Food intolerances or allergies No Yes specify
 4f. Food likes No Yes specify
 4g. Food dislikes No Yes specify

5. Is the client currently on multivitamins? Yes NO (If YES go to 5a, If NO go to 6)

5a. If YES, did you continue the multivitamins today? Yes NO

6. Is the client on food supplement? Yes NO (If YES go to 6a, If NO go to 7)

6a. If YES, which type of food supplement?

- First Food Advantaged Foundation Other (specify)

6b. If YES, what is the qualifying criteria

- BMI < 18.5 Pregnant Breastfeeding mother Other (specify)

7. 24 hour recall /usual diet

B/Fast	M. Morning	Lunch	M. Afternoon	Dinner

8. Is the client initiating food supplements today? Yes No (If YES go to 8a, If NO go to 10)

8a. If yes, why?

- BMI < 18.5 Pregnant Breastfeeding mother Other (specify)

8b. If YES, which type of food supplement is client initiating today?

- First food Advantaged Foundation Other (specify)

8c. If yes, has the patient been on food supplement before? Yes No

(Q9. applies to those initiated/or already on food supplement)

9. How would you Classify today's case? Severe Cases Moderate/Mild Cases

10. Assessment and Recommendations

For the data use only (tick after scanning the form)

Scanned Date ___/___/_____ Name of data person

HOPE CLINIC SOCIAL WORK SCREENING

HOPE ID Number

Site Code	Today's date (DD/MM/YYYY)	Interviewer number															
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	/		/														

Client's Residential and Telephone Contact Information

1. Public Transport to the House:

First trip

Ia. Type

Bus
 Citi Hoppa
 Matatu
 Taxi
 Other(specify)

Ib. Number

Ic. Stage Name

Id. General name of the area

Second trip

IIa. Type

Bus
 Citi Hoppa
 Matatu
 Taxi
 Other(specify)

IIb. Number

IIc. Stage Name

IId. General name of the area

2. Walking directions to house from the stage?

3. Landmarks that aid in locating the household: (Names of schools, Churches, businesses etc.)

4. How is the client called or referred to in the home area:

4a. How is the caregiver called or referred to in the home area: N/A

5. Does the patient have a treatment supporter? Yes No *(If yes, go to 5a, if no go to 6)*

5a. Treatment supporter name (Last, First, Middle)

5b. Treatment supporter home address

5c. Treatment supporter postal address (P.O Box)

5d. Treatment supporter number (Cell) .

5e. Treatment supporter number (Landline) .

6. Upcountry name for the client? N/A

6a. Upcountry contact home address? N/A

6b. Upcountry contact postal address? N/A

6c. Upcountry contact phone number (Cell) . N/A

6d. Upcountry contact phone number (Landline) . N/A

7. During the last year from today, have you been hit, slapped, Kicked, or hurt by someone?

Yes No Refused to answer

7a. If yes Who?

Spouse Steady Partner

Casual Partner Sibling

Parent Other(specify)

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8. During the last year from today, have you ever hit, slapped, Kicked, or hurt someone?

Yes No Refused to answer

8a. If yes Who?

Spouse Steady Partner

Casual Partner Sibling

Parent Other(specify)

9. In the past 12 months have you:

9a1. Smoked? Yes No Refused to answer

9a2. If yes, number of cigarettes per day

9b1. Chewed Miraa Yes No Refused to answer

9b2. If yes, number of times per month

9c1. Smoked marijuana ? Yes No Refused to answer

9c2. If yes, number of times per month

9d1. Used cocaine? Yes No Refused to answer

9d2. If yes, number of times per month

9d3. If yes, how? Sniff Inject

smoke Other (specify)

9e1. Used intravenous drugs? Yes No Refused to answer

9e2. If yes, number of times per month

9e3. If yes, do you share needles? yes No Refused to answer

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10. Do you drink alcohol? Yes No

10a. If yes, number of drinks per week

10b. In the last month, how often did you get drunk?

Never Daily Weekly 1-3 times a month

10c. In the last month, have you experienced any of the following after drinking alcohol?

- Gotten in to a fight No Yes Refused to answer
- Had accident/ Injured No Yes Refused to answer
- Been arrested No Yes Refused to answer
- Been raped (sex was forced on you) No Yes Refused to answer
- Sexually assaulted someone No Yes Refused to answer

11. Can you use a condom during sex after you have been drinking or taking drugs?

Yes No Do not drink or use drugs Refused to answer

12. What is your Current Marital Status (tick one)

- Married (monogamous) Separated
- Married (Polygamous) Widowed
- Cohabiting (come we stay) Single
- Divorced

13. What is your occupation?

- Unemployed Housewife
- Employed Casual labourer
- Self-employed Student

14. Housing roof type?

- Corrugated iron sheet Makuti
- Tiles Asbestos
- Concrete Tin
- Grass Other (specify)

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15. How many adults live in the home?

16. How many children live in the home?

17. How much do you or your spouse earn in one month? (Ksh)

- 0 - 2,000 Ksh
- 2,001 - 5000 Ksh
- 5,001 - 10,000 Ksh
- 10,001 - 20,000 Ksh
- 20,001 - 30,000 Ksh
- 30,001 - 50,000 Ksh
- > 50,001 Ksh
- Refused to answer

18. What is your highest level of education?(Tick one)

- No education
- Lower primary education (< 5years education)
- Five to eight years of primary education
- Some secondary education
- Beyond secondary education

19. How long does it take for you to travel to the clinic from home one way (Hrs/ Minutes)

Hours	Minutes
<input type="text"/>	<input type="text"/>

20. Do you have piped water in your home? Yes No

21. Do you have electricity at home? Yes No

22. What is your main source of cooking at home?

- Electricity
- Paraffin
- Firewood
- Solar Energy
- Other (Specify)

23. Social worker, does the client require home assessment Yes No

23a. If YES, why?

- Physically or mentally disabled adult
- Adult dependent on care-giver
- Client requests a home visit
- Disclosure (patient would like help disclosing status to family members)
- Family testing (patient would like other family members to be tested)
- Other (specify)

For the data use only (tick after scanning the form)

Scanned Date ___ / ___ / _____ Name of data person

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HOPE CLINIC ADULT TRACING AND HOME CARE FOLLOW-UP FORM

HOPE ID Number

Site Code

Today's Date (DD.MM.YYYY)

 /
 /

Interviewer number

REASONS FOR FOLLOW-UP VISIT

1. What is the reason for today's follow-up visit, as specified by previous visit (Check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Clinic attendance and/or ART adherence monitoring | <input type="checkbox"/> PMTCT Client |
| <input type="checkbox"/> Follow-up on physical health, HBC or first aid | <input type="checkbox"/> Hospital Admission |
| <input type="checkbox"/> Monitoring consistency of caregiver | <input type="checkbox"/> Lost to follow up client |
| <input type="checkbox"/> Follow-up on psycho-social issue or referral made(specify referral) | |
| <input type="checkbox"/> Counseling <input type="checkbox"/> Social work <input type="checkbox"/> Clinic <input type="checkbox"/> Pharmacy | |

Homebased counseling for patient or caregiver/household members (*Specify all that apply*):

<input type="checkbox"/> Patient	<input type="checkbox"/> Counseling for the Caregiver/Household
<input type="checkbox"/> ART and Adherence	<input type="checkbox"/> Care and support for PLWHA
<input type="checkbox"/> Management of side effects	<input type="checkbox"/> General HIV: Prevention, Transmission and management
<input type="checkbox"/> Disclosure	<input type="checkbox"/> knowing HIV status: Testing and care options
<input type="checkbox"/> General counseling	<input type="checkbox"/> Management of side effects for client needs
<input type="checkbox"/> Hygiene	<input type="checkbox"/> ART and Adherence
<input type="checkbox"/> Client basic care	<input type="checkbox"/> Disclosure
<input type="checkbox"/> Nutrition	<input type="checkbox"/> General counseling
<input type="checkbox"/> HIV prevention	<input type="checkbox"/> Hygiene
<input type="checkbox"/> PMTCT and Family Planning	<input type="checkbox"/> Nutrition
<input type="checkbox"/> Other (specify) <input style="width: 100px;" type="text"/>	<input type="checkbox"/> Other (specify) <input style="width: 100px;" type="text"/>

1a. This visit is taking place at the client's

- Place of residence
- Place of work or school
- Central market, shop or other public meeting place
- Hospital due to client's admission

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HOPE CLINIC ADULT TRACING AND HOME CARE FOLLOW-UP FORM

PHYSICAL HEALTH MONITORING

2. During this visit how would you describe the client's physical condition/health?

- Stable and self dependent
- Immobile
- Sought medical attention for health complaints from previous visit *(Specify outcome)*
 - Condition improving No change Condition worsening
- Did not seek medical attention for health complaints from previous visit *(Specify outcome)*
 - Condition improving No change Condition worsening
- Presenting new health complaints at this visit *(Specify in question 3)*

3. Current symptoms or complaints assessed during this visit:

<input type="checkbox"/> None	<input type="checkbox"/> Minor Health Complaints	<input type="checkbox"/> Severe Health Complaints
	<input type="checkbox"/> Low grade fever (below 38)	<input type="checkbox"/> Bedridden/immobile
	<input type="checkbox"/> Headaches	<input type="checkbox"/> Severe coughing (2 weeks or more) with difficulty breathing
	<input type="checkbox"/> Fatigue	<input type="checkbox"/> Severe Burning/tingling in extremities
	<input type="checkbox"/> Nausea and or occasional vomiting	<input type="checkbox"/> Poor feeding
	<input type="checkbox"/> Mild diarrhea (occasional and loose stool)	<input type="checkbox"/> Severe Diarrhea (frequent and watery)
	<input type="checkbox"/> Abdominal pain	<input type="checkbox"/> Severe vomiting
	<input type="checkbox"/> Cough	<input type="checkbox"/> Persistent or high grade fever (above 39)
	<input type="checkbox"/> Fat changes	<input type="checkbox"/> Jaundice
	<input type="checkbox"/> Burning tingling in extremities	<input type="checkbox"/> Sores or skin lesions
	<input type="checkbox"/> Skin rash	<input type="checkbox"/> Mental confusion/Dementia
	<input type="checkbox"/> Other (specify) <input style="width: 150px;" type="text"/>	<input type="checkbox"/> Other (specify) <input style="width: 150px;" type="text"/>

4. How many meals does the client eat per day?

- One
 Two
 Three
 More than three
 None

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HOPE CLINIC ADULT TRACING AND HOME CARE FOLLOW-UP FORM

CAREGIVER/HOUSEHOLD MONITORING

5. Has the caregiver changed since the last visit? Yes No (If NO, go to Q6)

5a. If YES, specify reason

- No longer able or willing to care for the patient
 Found more suitable long term caregiver
 Patient refused care from this person
 Patient's condition no longer requires the need of a caregiver
 Patient's condition now requires the help of a caregiver
 Other (Specify)

5b. If YES, who is the new caregiver?

- Self (No caregiver needed)
 Parent
 Spouse
 Relative
 Neighbour
 Friend
 Social worker/Institution
 Other (Specify)

5c. If YES, is the new caregiver aware of the clients HIV status? Yes No

6. At this visit are there areas of counseling or education which are needed in the household? (Tick all that apply)

<input type="checkbox"/> Patient	<input type="checkbox"/> Counselling for the Caregiver/Household
<input type="checkbox"/> ART and Adherence	<input type="checkbox"/> Care and support for PLWHA
<input type="checkbox"/> Management of side effects	<input type="checkbox"/> General HIV: Prevention, Transmission and management
<input type="checkbox"/> Disclosure	<input type="checkbox"/> Knowing HIV status: Testing and care options
<input type="checkbox"/> General counselling	<input type="checkbox"/> Management of side effects for client needs
<input type="checkbox"/> Hygiene	<input type="checkbox"/> ART and Adherence
<input type="checkbox"/> Client basic care	<input type="checkbox"/> Disclosure
<input type="checkbox"/> Nutrition	<input type="checkbox"/> General counseling
<input type="checkbox"/> HIV prevention	<input type="checkbox"/> Hygiene
<input type="checkbox"/> PMTCT and Family Planning	<input type="checkbox"/> Nutrition
<input type="checkbox"/> Opportunistic Infections and STIs	<input type="checkbox"/> Opportunistic Infections and STIs
<input type="checkbox"/> Other (specify) <input style="width: 100px;" type="text"/>	<input type="checkbox"/> Other (specify) <input style="width: 100px;" type="text"/>

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HOPE CLINIC ADULT TRACING AND HOME CARE FOLLOW-UP FORM

PSYCO-SOCIAL MONITORING

7. Was referral made at the previous visit? Yes No *(If NO go to Q8)*

7a. If YES, specify

- Domestic violence Food Insecurity
 Drug or Alcohol abuse Legal aid
 Sexual violence Other (Specify)

7b. If YES did the client seek referral services? Yes No

- Transportation costs Client went but was turned away
 Client refused to go Forgot or lost referral slip
 Other (specify)

8. Have there been any noticeable changes from the last visit in the psycho-social issues that were identified?

- No noticeable change Improvement Issues are worsening Cannot assess

9. During this visit were there any concerns in the household regarding any of the following? (Tick all that apply)

Physical abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Sexual abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Emotional abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Alcohol abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Drug abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Potential to self-inflict harm	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Depression	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Stigma and isolation	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Food insecurity	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Neglect by caregiver	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
NO CONCERNS	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported

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HOPE CLINIC ADULT TRACING AND HOME CARE FOLLOW-UP FORM

CLINIC ATTENDANCE AND ADHERENCE MONITORING

10. Is the client on ARVs? Yes No

11. Since the last visit has the client refilled their prescription? Yes No (If YES go to Q 12)

11a. If NO specify reason:

- | | |
|--|---|
| <input type="checkbox"/> Client was not due for a refill since the last home visit | <input type="checkbox"/> Lacked someone to assist to clinic |
| <input type="checkbox"/> Unable to get to clinic due to transport costs | <input type="checkbox"/> Forgot |
| <input type="checkbox"/> Unable to get to the clinic due to illness or weakness | <input type="checkbox"/> Refused to go |
| <input type="checkbox"/> Travelled | <input type="checkbox"/> Other (specify) <input style="width: 150px; height: 15px;" type="text"/> |

12. Since the last visit, has the client missed any doses?

- One Two Three More than three None

12a. If doses were missed specify reason:

- | | |
|--|---|
| <input type="checkbox"/> Refused to take medications | <input type="checkbox"/> Was stopped by physician |
| <input type="checkbox"/> Forgot | <input type="checkbox"/> Side effects |
| <input type="checkbox"/> Doses were administered by caregiver who did not give | <input type="checkbox"/> Felt too ill or too weak to take |
| <input type="checkbox"/> Ran out of medication and could not refill prescription | <input type="checkbox"/> Medications lost or stolen |
| <input type="checkbox"/> Felt better and decided to stop | <input type="checkbox"/> Sharing medications with others |
| <input type="checkbox"/> Drug or alcohol use affecting adherence | <input type="checkbox"/> Other (specify) <input style="width: 150px; height: 15px;" type="text"/> |
| <input type="checkbox"/> Stigma, disclosure or privacy issues | |

13. Is the client/caregiver able to recall critical information related to thier ARV regime?

Drug names	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Doses	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Times taken	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Side effects	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Food related indications	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None

14. Client adherence since the last visit has

- No change Improved Worsened Refer to clinician for review

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HOPE CLINIC ADULT TRACING AND HOME CARE FOLLOW-UP FORM

15. Since the last visit, has the client attended all their scheduled clinic visits? Yes No Not due for visit

15a. If NO, Specify

- | | |
|---|--|
| <input type="checkbox"/> Too ill to come
<input type="checkbox"/> Forgot
<input type="checkbox"/> Lost appointment card
<input type="checkbox"/> Stigma within the household related to disclosure or privacy
<input type="checkbox"/> Need assistance from care-giver and none was available
<input type="checkbox"/> Traveled
<input type="checkbox"/> Depression | <input type="checkbox"/> Alcohol or drug use affected ability to come
<input type="checkbox"/> Refused to come or continue with program
<input type="checkbox"/> Could not afford transport
<input type="checkbox"/> Was seen at another clinic
<input type="checkbox"/> Work
<input type="checkbox"/> Other (specify) <input style="width: 200px; height: 15px;" type="text"/> |
|---|--|

FOLLOW - UP PLAN

16. Is the client eligible for discharge from the tracer and home care services Yes No

16a. If NO, Next visit scheduled for:

- One week
 Two weeks
 One month
 Two months

Specify date of next visit((DD/MM/YYYY) / /

16b. What actions will be taken as follow-up to this visit?

- Follow-up counseling in the home for client or caregiver/household
- Follow-up on physical health
- Adherence monitoring
- Referral for household member for site based VCT services
- Referral for suspected TB of client or household member
- Follow-up and monitoring of social conditions and actions previously taken
- Alert authorities for further investigation of neglect, sexual or domestic violence
- PMTCT
- Organise Hospital ambulatory services for immediate and urgent medical needs
- HIV positive Family /Household member for HIV/AIDS management
- Home based VCT for household member
- Organization referral or accompaniment
- Accompany client to clinic
- Counselor assisted disclosure
- No Action

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HOPE CLINIC

ADULT TRACING AND HOME CARE FOLLOW-UP FORM

17. During this visit, was an appointment booked for the client at the clinic? Yes No

If YES, Specify date of next appointment((DD/MM/YYYY)) / /

If YES, specify the appointment type:

Doctor Social worker

Counselor Nutritionist

Pharmacy

Comments

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Scanned Date ___ / ___ / _____ Name of data person

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HOPE CLINIC ADULT TRACING AND HOME CARE SCREENING FORM

HOPE ID Number

Page 1

Site Code

Today's Date (DD.MM.YYYY)

Interviewer number

1. The reason for this client to be monitored through the tracer and Home Care program is

- Adult on ARVs not adhering to medications or clinic appointments Lost to follow up client
 Adult dependent on care-giver
 Post-partum mother
 Staff referred for other reason: (Specify)

1a. This visit is taking place at the client's

- Place of residence Central market, shop or other public meeting place
 Place of work or school Other(specify)
 Hospital due to client's admission

PHYSICAL HEALTH ASSESSMENT

2. At this initial screening in what physical condition did you find the client?

- Stable , mobile and able to take care of self
 Weak but mobile and able to take care of self
 Immobile or needs assistance to walk or move, reliant on caregiver

2a. Current symptoms or complaints assessed during this visit:

<input type="checkbox"/> None	<input type="checkbox"/> Minor Health Complaints	<input type="checkbox"/> Severe Health Complaints
	<input type="checkbox"/> Low grade fever (below 38)	<input type="checkbox"/> Bedridden/immobile
	<input type="checkbox"/> Headaches	<input type="checkbox"/> Severe coughing (2 weeks or more) with difficulty breathing
	<input type="checkbox"/> Fatigue	<input type="checkbox"/> Severe Burning/tingling in extremities
	<input type="checkbox"/> Nausea and or occasional vomiting	<input type="checkbox"/> Poor feeding
	<input type="checkbox"/> Mild diarrhea (occasional and loose stool)	<input type="checkbox"/> Severe Diarrhea (frequent and watery)
	<input type="checkbox"/> Abdominal pain	<input type="checkbox"/> Severe vomiting
	<input type="checkbox"/> Cough	<input type="checkbox"/> Persistent or high grade fever (above 39)
	<input type="checkbox"/> Fat changes	<input type="checkbox"/> Jaundice
	<input type="checkbox"/> Burning tingling in extremities	<input type="checkbox"/> Sores or skin lesions
	<input type="checkbox"/> Skin rash	<input type="checkbox"/> Mental confusion/Dementia

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Skip to Question 4 if the residence is an institution/organisation

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HOUSEHOLD ASSESSMENT

3. Describe the type of residence this is: (*Skip to Question 4 if the residence is an institution/organisation*)

Private residential home

Institution/organization (specify name):

3a. Who is the head of the household

Patient (Self)

Patient's Father

Patient's mother

Both parents

Patient's sibling (Specify age) years

Neighbour

Patient's relative (Aunt, Uncle, grandparent, cousin)

Friend

Other (Specify)

3b. How many individuals living in the household?

3b1. Adults (Age 15 and over) :

3b2. Children (Age 14 and below) :

3c. Number of rooms in the house:

One

Two

Three

More than three

3d. Does the house have electricity? Yes No

3e. What is the household's water source?

Piped to the house

Communal water tank within the vicinity

Water tank and piping to the house

Water from river, pool or open water source

Communal water tap within the vicinity

No water source in the vicinity

3f. What is the household's sanitation system?

Own flush toilet in the house

Shared pit latrine in vicinity of house

Private pit latrine

None

Shared toilet in vicinity of house

3g. What is the source of Energy for cooking?

Gas

Paraffin

Wood

Electricity

Charcoal

None

4. Does the patient have any special needs? Yes No Unknown

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4a. If YES specify:

4a. If YES specify:

- Advanced illness
- Physically handicapped or disabled
- Mentally handicapped or disabled
- Emotionally/psychologically unstable or unwell
- Other(specify)

4b. If YES does the client currently have a caregiver? Yes No Unknown

4b1. If YES specify

- Spouse Friend
- Partner Neighbour
- Parent Social worker/local community health worker
- Relative Other(specify)

5. Is the client living in an environment where hygiene is neglected? Yes No

5a. If YES specify:

- Foul smell in the room where the client is staying Client has not had a bath for more than 2 days
- Client is sleeping in soiled beddings Other(Specify)

6. How many meals is the client eating per day?

- One Two Three More than three None

7. Does the client have access to food? Always Sometimes Never

NO CONCERNS

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8. Are there there any concerns in the household regarding any of the following? (Tick all that apply)

Physical abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Sexual abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Emotional abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Alcohol abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Drug abuse	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Potential of self-inflict harm	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Depression	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Stigma and isolation	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Food insecurity	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
Neglect by caregiver	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported
NO CONCERNS	<input type="checkbox"/> Client Reported	<input type="checkbox"/> Staff Assessed	<input type="checkbox"/> Household Reported

COUNSELLING AND DISCLOSURE ASSESSMENT

9. Is the client aware of his or her status? Yes No Unknown
 9a. If NO, is the caregiver willing to begin the disclosure process with the patient? Yes No Unknown
10. If the client has a caregiver, is the current caregiver aware of the patient's status?
 Yes No Unknown There is no caregiver
 10a. If NO, is the patient willing to begin the disclosure process with the caregiver?
 Yes No Unknown
11. Are other household members aware of the client's status? All Some None
 11a. If NO, is the patient/caregiver willing to begin the disclosure process with other household members?
 Yes No
12. Is there a need for HIV counseling and testing of other household members? (Tick all that apply)
 Spouse/Partner Siblings
 Mother Other household members of unknown status in need of testing
 Father None

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13. What areas of counselling and education are necessary for the Patient and household?

<input type="checkbox"/> Patient	<input type="checkbox"/> Counselling for the Caregiver/Household
<input type="checkbox"/> ART and Adherence	<input type="checkbox"/> Care and support for PLWHA
<input type="checkbox"/> Management of side effects	<input type="checkbox"/> General HIV: Prevention, Transmission and management
<input type="checkbox"/> Disclosure	<input type="checkbox"/> Knowing HIV status: Testing and care options
<input type="checkbox"/> General counselling	<input type="checkbox"/> Management of side effects for client needs
<input type="checkbox"/> Hygiene	<input type="checkbox"/> ART and Adherence
<input type="checkbox"/> Client basic care	<input type="checkbox"/> Disclosure
<input type="checkbox"/> Nutrition	<input type="checkbox"/> General counseling
<input type="checkbox"/> HIV prevention	<input type="checkbox"/> Hygiene
<input type="checkbox"/> PMTCT and family planning	<input type="checkbox"/> Nutrition
<input type="checkbox"/> Other (specify) <input type="text"/>	<input type="checkbox"/> Other (specify) <input type="text"/>

CLINIC ATTENDANCE AND ARV ADHERENCE ASSESSMENT

14. Is the client on ARVs? Yes No (If NO, skip to question 16)

14a. If yes, is the client able to tell you the following information?

Drug names	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Doses	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Times taken	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Side effects	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None
Food related indications	<input type="checkbox"/> All	<input type="checkbox"/> Some	<input type="checkbox"/> None

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14b. During the last 7 days, how many doses did the client miss?

- One Two Three More than three None

14c. During the last 30 days, how many doses did the client miss?

- One Two Three More than three None

14c1. If the patient missed any doses, please specify reasons (Check all that apply)

<input type="checkbox"/> Refused to take medication	<input type="checkbox"/> Medications lost or stolen
<input type="checkbox"/> Forgot	<input type="checkbox"/> Sharing medications with others
<input type="checkbox"/> Doses are administered by caregiver who did not give	<input type="checkbox"/> Felt better and decided to stop
<input type="checkbox"/> Ran out of medication and could not refill prescription	<input type="checkbox"/> Stigma, disclosure or privacy issues
<input type="checkbox"/> Was stopped by physician	<input type="checkbox"/> Drug or alcohol use affecting adherence
<input type="checkbox"/> Side effects	<input type="checkbox"/> Other (specify)
<input type="checkbox"/> Felt too ill or too weak to take	<input type="text"/>

14d. When is the client due for a refill (check prescription)

- Date passed in a previous month
 Within the current month
 Next month
 Last month
 2 months or more
 No prescription available to confirm

15. Has the client/caregiver missed the client's last clinic visit? Yes No

15a. If YES, what reason did the client/caregiver fail to return to the clinic for your appointments?

- | | |
|---|---|
| <input type="checkbox"/> Too ill to come | <input type="checkbox"/> Alcohol or drug use affected ability to come |
| <input type="checkbox"/> Forgot | <input type="checkbox"/> Refused to come or continue with program |
| <input type="checkbox"/> Lost appointment card | <input type="checkbox"/> Was seen at another clinic |
| <input type="checkbox"/> Stigma within the household related to disclosure or privacy | <input type="checkbox"/> Depression |
| <input type="checkbox"/> Could not afford transport | <input type="checkbox"/> work |
| <input type="checkbox"/> Need assistance from care-giver and none was available | <input type="checkbox"/> Travel |
| <input type="checkbox"/> Other (specify) <input type="text"/> | |

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FINAL ASSESSMENT AND FOLLOW-UP PLAN

16. Based on this initial assessment, what actions will be taken as follow-up to this visit? (check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Follow-up counseling for client or caregiver/household (refer to Question 13) | <input type="checkbox"/> Home based VCT for household member |
| <input type="checkbox"/> Referral for household member for site based VCT services | <input type="checkbox"/> Counselor assisted disclosure |
| <input type="checkbox"/> HIV+ family/household member for HIV/AIDS management | <input type="checkbox"/> Organization referral or accompaniment |
| <input type="checkbox"/> Referral for suspected TB of client/household member | <input type="checkbox"/> Accompany client to clinic |
| <input type="checkbox"/> Follow-up on physical health | <input type="checkbox"/> Adherence monitoring |
| <input type="checkbox"/> PMTCT | <input type="checkbox"/> No Action |
| <input type="checkbox"/> Organize hospital ambulatory services for immediate and urgent medical needs | |
| <input type="checkbox"/> Alert authorities for further investigation of neglect, sexual or domestic violence | |
| <input type="checkbox"/> Follow-up and monitoring of social conditions and actions previously taken | |

17. Next home visit scheduled for:

- One week
 Two weeks
 One month
 Two months

Specify date of next home visit((DD/MM/YYYY)) / /

18. During this visit, was an appointment booked for the client at the clinic? Yes No

If YES, Specify date of next appointment((DD/MM/YYYY)) / /

If YES, specify the appointment type:

- Doctor
 Counselor
 Pharmacy
 Social worker
 Nutritionist

Comments

For the data use only (tick after scanning the form)

Scanned Date ___ / ___ / _____ Name of data person

For the data use only (tick after scanning the form)

Scanned Date ___ / ___ / _____ Name of data person

Modified March 2008

**Hope
Clinic**

Version

5960

5961

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