Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Contributions to the Design, Conduct and Reporting of the PREVAIL III study

The first draft of the manuscript was prepared by M.C. Sneller, C. Reilly, M.P. Fallah, H.C. Lane and J.D. Neaton. The study was designed by H.C. Lane, M.C. Sneller, M.P. Fallah and J.D. Neaton. The PREVAIL III team, led by M. Badio and Drs. S. Moses, D. Gayedyu-Dennis, K. Johnson, R.J. Bishop and A.O. Eghrari obtained the data. Testing for Ebola RNA and immunogenicity testing was conducted by L.E. Hensley, K. Tuznik, J. Varughese, K. Jensen, and B. Dighero-Kemp. Data analysis was carried out by C. Reilly. All authors reviewed drafts of the manuscript. The writing group vouches for the data and analyses. The decision to publish these results was made by M.C. Sneller, C. Reilly, M.P. Fallah, J.D. Neaton and H.C. Lane.

There were no agreements concerning confidentiality of the data between the sponsor and the authors or the institutions named in the credit line.

1 SUPPLEMENTARY METHODS

PREVAIL III was designed and is being carried out by the Partnership for Research on Ebola Virus in Liberia, a Liberian-U.S. consortium that was formed by the two countries in the midst of the Ebola public health crisis to carry out a program of urgently needed clinical research. Among the other studies conducted and reported by the partnership are PREVAIL I, a randomized phase 2 trial of two vaccines to prevent EVD[1], and PREVAIL II, a randomized trial of investigational therapeutics in patients with acute EVD in collaboration with the governments of Sierra Leone and Guinea[2].

1.1 Baseline Data Collection

The 3 sites used for participant recruitment were John F. Kennedy (JFK) Medical Center, Duport Road Clinic (both in Monrovia), and CH Rennie Hospital (a more rural site about 70 km from Monrovia). Following informed consent, survivors and close contacts received a comprehensive medical examination that included the collection of demographic information, a medical history, collection of symptoms, a physical examination, an eye screen that led to an ophthalmologic examination for most participants, and the measurement of serum chemistries and hematology. In addition to these ophthalmological exams (described more fully in Section 1.3), there were also specialized neurologic assessments on a subset of participants and a birth cohort sub-study evaluating pregnancy outcomes in female survivors. Semen, cerebrospinal fluid, breast milk, vaginal fluid, placenta, and cord blood were tested for the presence of Ebola viral RNA in subsets of participants.

For EVD survivors, information about their Ebola infection, including likely source of infection, symptoms at diagnosis, and dates in the ETU were obtained. For close contacts, the nature of contact with the survivor, and their relationship to the survivor was assessed along with any symptoms the contact may have experienced within 3 weeks of the survivor's illness. Data on the use of condoms was collected on sexual contacts of survivors and survivors.

1.2 Measurement of Antibody Responses to Ebola Glycoprotein

IgG antibody levels against the Ebola surface glycoprotein were measured in serum collected at the baseline examination for survivors and close contacts using the Filovirus Animal Nonclinical Group (FANG) assay. Briefly, 96-well microtiter plates were coated with recombinant EBOV GP produced in Human Embryonic Kidney 293 cells (HEK293, Battelle Memorial Institute (BMI), Columbus, OH/Joint Vaccine Acquisition Program (JVAP), Fort Detrick, MD) diluted in PBS overnight at 4°C. An 11-point standard curve was created by diluting a reference standard (lot number BMIZAIRE102, Battelle Memorial Institute (BMI), Columbus, OH/Joint Vaccine Acquisition Program (JVAP), Fort Detrick, MD) two-fold in ELISA diluent (1X PBS, 5% milk, 0.1% Tween-20), starting at a 1:100 dilution. Patient samples were diluted 6 times, two-fold, in duplicate, starting at a 1:62.5 dilution. In addition, a serum sample from an Ebola virus survivor, a quality control (QC) low, a QC high, and a negative serum sample (BMI/JVAP) were included on each plate as internal controls to monitor assay performance. Diluted samples and controls were transferred to the coated 96-well plates and absorbed for 1 hour at 37°C. Plates were washed three times using ELISA wash buffer (1X PBS, 0.1% Tween-20). 100 µl of goat anti-human IgG HRP conjugate (Jackson Labs 109-035-098) diluted 1:10,000 in ELISA diluent was added to each well, and plates were incubated for 1 hour at 37°C. Plates were then washed five times, and 100 µl of tetramethylbenzidine (Thermo Scientific N301) was added to each well. Plates were incubated in the dark for 10 minutes at room temperature followed by addition

of 100 µl of stop solution (Thermo Scientific N600) to each well. All plates were read within 30 minutes at an absorbance wavelength of 450 nm and a reference wavelength of 650 nm (Spectra Max Plus, Molecular Devices). Data was acquired using SoftMax Pro (v6.5, Molecular Devices) software.

Data from the PREVAIL I vaccine study[1] were used to define a cut-off with which to classify survivors as antibody positive and close contacts as antibody negative. A participant was considered to have elevated antibodies indicative of past Ebola infection if their level was greater than or equal to 548 enzyme-linked immunosorbent assay units (EU)/mL; a value that represents the 95th percentile of the baseline antibody distribution of PREVAIL I participants. The 1,500 adult Liberian participants in PREVAIL I did not have a history of EVD; had a median age of 30 years; 37% were female; and 5.2% were HIV infected[1].

To characterize the diagnostic performance of the 548 EU/ml cut-off , we identified negative and positive samples and used these to construct a received operating characteristics (ROC) curve. For EBOV negative samples, we used serum obtained between 2004 and 2011 from 92 adults in Mali, a country where there had been no reported outbreaks of EBOV infection during that time period. Presumed EBOV antibody-positive samples were from 773 Liberian survivors of the 2014-2016 Ebola epidemic who were listed on the Liberian MOH Ebola Survivor Registry. Diagnosis of EBOV infection in these individuals was based on admission to an ETU with signs and symptoms consistent with EVD and a documented positive EBOV reverse transcriptase-polymerase chain reaction (RT-PCR) result. Using results from these samples, the area under the curve for the ROC curve was 0.98. The sensitivity using 548 EU/ml was 94.4% and the specificity was 96.7%. Any cut-off value between 219 and 2453 EU/ml, gave a sensitivity over 94% and a specificity of over 96% (Figure S1). Sensitivity analyses displayed considerable robustness to the cut-off: while estimates vary slightly as the cut-off varies, the overall

conclusions regarding which symptoms and findings differed significantly between the groups remained the same.

1.3 Ophthalmic Evaluation

A subset of 564 survivors and 635 contacts who enrolled at the JFK site prior to April 1, 2016 had detailed eye examinations at baseline and 1 year from enrollment. These examinations were performed by an ophthalmologist in an eye clinic at JFK Medical Center. The subset of participants receiving ophthalmologic examinations was similar to the rest of the cohort in terms of demographic characteristics. All participants in the eye sub-study underwent comprehensive ophthalmic evaluation including slit-lamp biomicroscopy with Haag-Streit BQ900 LED slit lamp, dilated indirect ophthalmoscopy of the macula and peripheral retina, and optical coherence tomography (OCT) imaging with a Zeiss Cirrus 5000 OCT device.

Uveitis was defined using Standardization of Uveitis Nomenclature[3]. Findings on examination which led to the designation of uveitis (either active or inactive) included: keratic precipitates, anterior segment cell or flare, hypopyon, posterior synechiae, vitreous cell or haze, chorioretinal scars, and vascular sheathing. Vascular sheathing was classified as inflammatory unless clarified as hypertensive in origin and in the absence of additional evidence of intraocular inflammation.

Best-corrected spherical equivalent visual acuity was assessed at the phoropter with guidance from auto-refraction, using an ETDRS Tumbling E chart. Visual impairment was described using criteria as elaborated in the World Health Organization document “Global Data on Visual Impairments 2010”. Best-corrected visual acuity of <20/70 to 20/200 is considered moderate visual impairment, <20/200 to 20/400 is severe visual impairment, and <20/400 is blindness[4].

1.4 Semen Collection

Beginning with the 6-month follow-up visit, males 18 years and older were asked to provide semen samples with a frequency that depended on test results (every 4-6 weeks if negative and every 2 weeks if positive). These participants had similar demographics as other adult male participants except the contacts were slightly older due to the requirement that participants needed to be at least 18 years of age (median age was 29 compared to 23 for the whole cohort of contacts). Samples were tested for the presence of Ebola virus RNA using methods that have been described[5]. Repeat samples of semen were obtained in order to quantify and characterize the number of participants who had viral RNA consistently detected or absent and those who had intermittent viral RNA detected.

1.5 Statistical Methods

Unless otherwise stated, analyses were restricted to survivors with a baseline antibody level greater than or equal to 548 EU/mL and to close contacts with levels less than 548 EU/mL (controls) (Supplementary Appendix, Section 1.2).

Tests for differences between survivors and close contact controls were conducted using generalized estimating equations to account for relationships between survivors and close contacts (using an exchangeable correlation structure). Logistic regression was used to study the association of antibody levels and other factors with presence of symptoms, physical exam findings and viral RNA in the semen. For both types of analyses covariates corresponding to clinical site, age, and gender were included in the models. A pooled odds ratio across all visits and the interaction with study visit were estimated. The former provides a more precise

estimate of the relative difference between survivors and close contacts if there is no variation over time. The latter, while a low power test, provides a measure to assess whether the relative difference between survivors and close contacts in these targeted conditions are increasing or decreasing over time. Odds ratios (ORs) associated with a one standard deviation (SD) higher $\log_{10}$ antibody levels are cited with 95% confidence intervals (CIs).

While strict criteria were used to identify the 11 targeted conditions described in the manuscript, no attempt was made to formally control the family-wide type 1 error across all comparisons. Many comparisons were made and this could be a source of false positives. To provide some context for this, here we describe the tests that were performed in the course of analyzing the large volume of data collected for this study. To examine recalled acute symptoms we conducted 16 hypothesis tests across 2 pairs of groups. To examine self reported symptoms we conducted 89 hypothesis tests across 2 groups at 3 different time points. To examine physical findings we conducted tests for 10 body systems across 2 groups for 3 time points. To provide further insight into these systems we also made comparisons across 2 groups for 50 different specific findings at 3 time points, although we don't report p-values. We also examined 12 laboratory findings at 3 time points for contacts and survivors broken down by age (less than 18 or 18 and older). In addition we report on the prevalence of 4 ophthalmologic outcomes and examine the incidence of 3 of ophthalmologic outcomes. Outcomes of hypothesis tests of associations between the targeted outcomes, serology and shedding in semen are reported. Finally tests for an association of shedding and time since infection are reported. The strict p-value criterion enforced for the identification of our targeted conditions can be interpreted as providing protection from type 1 errors for up to 500 hypothesis tests.

Tests for differences in self-reported symptoms listed on the baseline case report form, systems level abnormalities from the physical exam (e.g. any chest abnormality), ophthalmologic findings

and characterization of EBOV positivity in semen required a p-value of 0.0001 to be reported here while other tests required a p-value of 0.01. These tests included differences between survivors and contacts in recall of symptoms during acute disease, age, body mass index, frequency of pregnancy, specific exam findings (e.g. prevalence of muscle tenderness), laboratory findings, incidence of new symptoms among the identified targeted symptoms as well as differences between antibody-positive close contacts and antibody-negative close contacts and the association between uveitis and the detection of vira RNA in at least 1 semen donation among survivors providing semen samples. Comparisons of self-reported symptoms listed on the baseline case report form and findings on physical exam (including uveitis) were preplanned while others were not.

2 SUPPLEMENTARY RESULTS

2.1 Characteristics of Antibody Positive and Antibody Negative Survivors and Close Contacts

Antibody levels for MOH-reported survivors and self-reported close contacts varied by age: (the medians were 28,017 versus 63 EU/mL for those 12 years of age and less, 22,564 versus 84 EU/mL for those 12-17 years, and 18,288 versus 90 EU/mL for those 18 and older). Antibody levels corresponding to the 25^{th}, 75^{th}, and 95^{th} percentiles for adult close contacts were 56, 240, and 9,593 EU/mL, respectively. In PREVAIL I, the levels corresponding to these percentiles were 47, 139, and 548 EU/mL, respectively (Unpublished data).

To further characterize the antibody positive close contacts, we compared the symptom history they reported at the time of their linked survivor's acute illness with that reported by antibody negative close contacts. Most symptoms were reported with at least 2-fold greater frequency among the antibody positive close contacts compared to the antibody negative close contacts,

with vomiting, unexplained bleeding, red eyes, and sore throat all reported at more than 4-fold greater frequency. Among antibody positive contacts, there was a positive correlation between antibody levels and the proportion of subjects reporting EVD-like symptoms. For those in the top 75 percentile of antibody levels, 52% report EVD-like symptoms (i.e. at least one symptom of those listed in Table S1), for those in the top 50 percentile of antibody levels, 62% report symptoms and for those in the top 25 percentile of antibody levels, 75% report symptoms. By comparison, 99% of antibody positive survivors reported at least one symptom associated with their acute illness (Table S2).

The median antibody concentration for adult survivors of 19,242 EU/mL was much greater than the peak antibody response one month following vaccination observed with the two vaccines studied in PREVAIL I (630 and 1,090 EU/mL, respectively)[1]. For the 13% of MOH-reported survivors with antibody levels below the positive cut-off, our data suggest that some may have been misidentified as having EVD and point to the challenges of diagnostic testing during an Ebola outbreak.

The median antibody level for adult self-reported close contacts enrolled (83 EU/mL) was similar to the median pre-vaccination (baseline) antibody level in the PREVAIL I Ebola vaccine study (78 EU/mL)[1]. However, 11% of adult close contacts in the current study had Ebola antibodies detected above 548 EU/mL compared with 5% in PREVAIL I. Based on the distribution of antibody levels and reported symptoms by the close contacts at the time of the epidemic, these individuals likely represent a heterogeneous group, some of whom likely experienced unidentified symptomatic or possibly asymptomatic Ebola infection.

2.2 Demographic and Baseline Clinical Findings of Antibody Positive Survivors and Antibody Negative Close Contacts

The median time between the onset of acute EVD and the baseline PREVAIL III visit was 358 days (quartiles 313, 405). Enrolled contacts were younger than survivors (Table 1 and Figure 1A). For the survivors, baseline antibody levels were higher in the younger age groups (Table 1). Compared with the close contact group, more survivors in the 12 year and older age groups were pregnant at their baseline visit (Table 1). Twelve (1.4%) survivors and 51 (2.7%) close contacts were HIV positive at their baseline visit. Of the 539 survivors who provided information on condom use, 61% reported never using condoms, 33% sometimes used condoms, and 6% reported always using condoms.

Among close contacts, 318 (14%) reported having sexual contact with a convalescent survivor and 1612 (69%) were living in the same household as the survivor during the survivor's acute illness. Of those close contacts who recounted being in the same household, 85% reported having direct physical contact, contact with clothing or bodily fluids, or being in the same room with the survivor during the survivor's acute illness.

2.3 Clinical Findings at Follow-up Visits

The prevalence of headache and memory loss reported at follow-up visits decreased to a greater degree in contacts than in survivors, leading to an increase over time in the odds ratio for these symptoms (Table 2). In contrast, the prevalence of other targeted symptoms either decreased to a greater degree in survivors than contacts (urinary frequency, muscle pain) or decreased to an approximately equal degree in both groups (fatigue, joint pain; Table 2).

Abnormal targeted physical examination findings observed more frequently in survivors compared to close contacts at baseline also decreased at the 6- and 12-month follow-up visits in both groups, but all remained higher in survivors than close contacts (Table 2). Interaction p-values in Table 2 indicate that relative differences between survivors and close contacts for each physical examination finding are similar over follow-up. Pooled (over the baseline, 6-month and 12-month visits) odds ratios are cited in Figure S3. No additional symptoms or findings emerged during follow-up for which the p-value for the difference between survivors and close contacts was <0.0001. Also, there were no new symptoms for which the difference between survivors and close contacts exceeded 10% (Tables S4-S8).

2.4 Ophthalmologic Findings

The median visual acuity in individual eyes with uveitis was 20/25 (quartiles 20/20 and 20/32) while the median visual acuity in eyes that did not have uveitis was 20/20 (quartiles 20/20 and 20/25); this difference was statistically significant (p<0.0001). Seventeen of the 301 eyes from both groups with uveitis had a visual acuity <20/200; 11 (5.4%) among survivor eyes with uveitis and 6 (6.2%) among contact eyes with uveitis. Having uveitis was significantly associated with blindness (p<0.0001 for having the condition in either eye).

2.5 Association of Baseline Antibody Levels with Symptoms and Examination Findings

We examined the association between self-reported joint pain and antibody levels for survivors. The median level was 19,479 EU/mL among survivors reporting joint pain and 19,152 EU/mL for survivors who did not report joint pain (p=0.72). With adjustment for age and female gender, the OR associated with a SD higher $\log_{10}$ IgG level was 1.01 (95% CI: 0.88 to 1.15; p=0.92).

For survivors, there was no association between the presence of uveitis and levels of Ebola-specific antibody (OR=1.37, 95% CI: 0.76 to 2.47 for a SD higher in $\log_{10}$ IgG level). We also compared antibody levels for survivors with any abnormal finding on abdominal, neurological or musculoskeletal examination (18.4%) with those who had no abnormal findings. The median antibody level was lower among those with an abnormality (18,143 EU/mL) as compared to those without an abnormality (19,761 EU/mL) (p=0.08). With adjustment for site, age and female gender, the latter two of which were associated with an increased risk of an abnormality, antibody levels were lower among survivors with an abnormal finding compared to those who did not have an abnormal finding on abdominal, neurological and musculoskeletal examination (p=0.037).

We found no evidence for a higher rate of EBOV seropositivity among female sexual contacts of men whose semen tested positive for EBOV RNA. We found that 10.70% of sexual contacts of men enrolled in the semen study were seropositive and 10.71% of sexual contacts of men who test positive at least once and report never using condoms are seropositive.

2.6 Correlations of Viral RNA Semen with Examination Findings and Antibody Levels

We found no correlation between persistence of viral RNA in semen and the presence of abdominal, chest, neurologic, musculoskeletal, or urinary symptoms or plasma levels of D-dimer. However, in longitudinal analyses that account for time since acute infection, men testing positive for viral RNA in their semen had significantly higher levels of Ebola-specific IgG antibody when compared to men testing negative (OR=1.50, 95% CI: 1.12 to 2.02 for a SD higher in $\log_{10}$ antibody levels, p=0.03). Older age was also associated with having a positive semen result (p<0.0001) in longitudinal models.

One hundred ninety-one antibody negative close contacts provided one or more semen samples. No RNA positive semen samples were detected in these close contacts.

3 SUPPLEMENTARY FIGURES AND TABLES

3.1 Figure S1

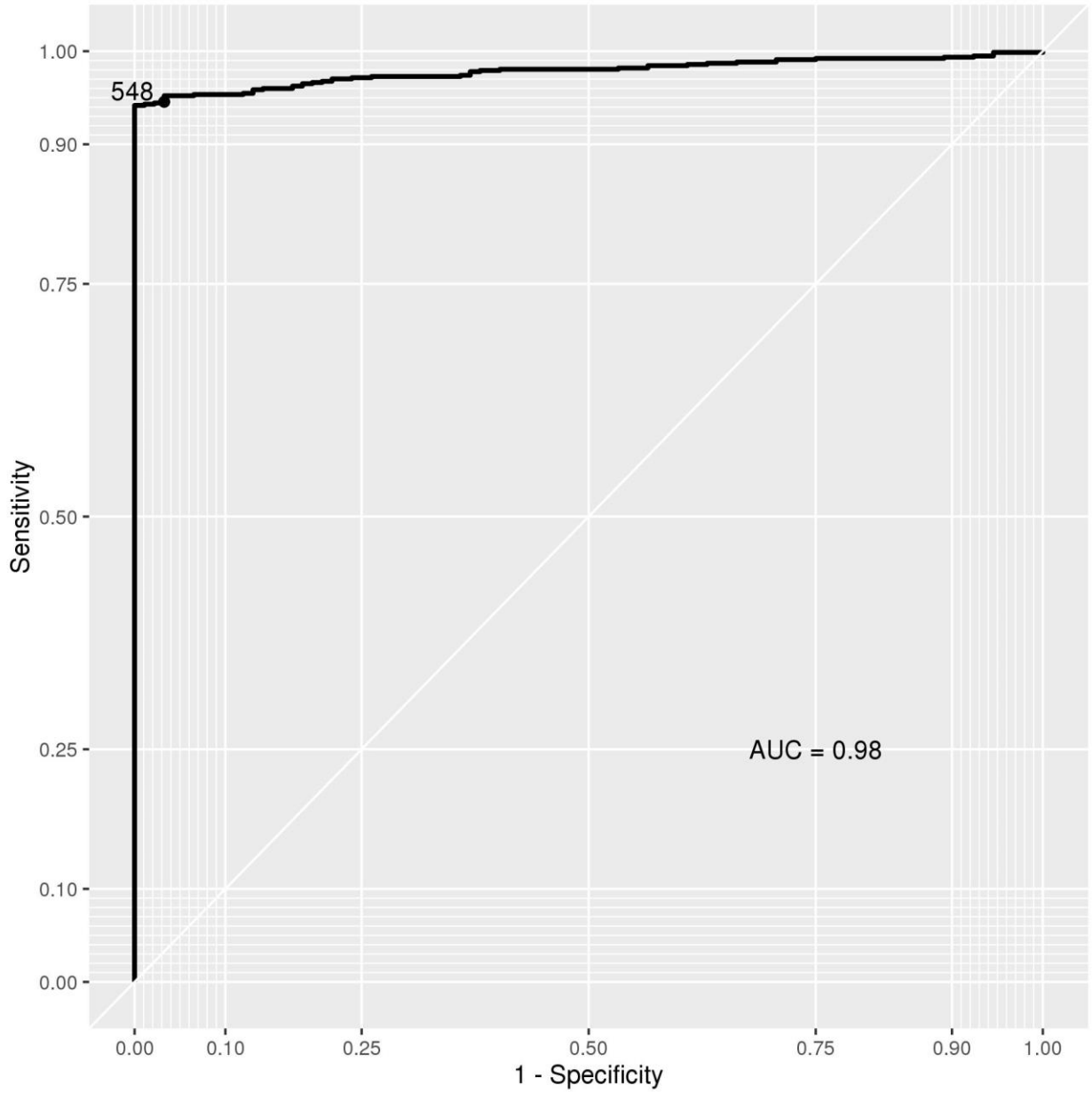

Figure S1: The receiver operating characteristic curve for the FANG assay.

3.2 Figure S2

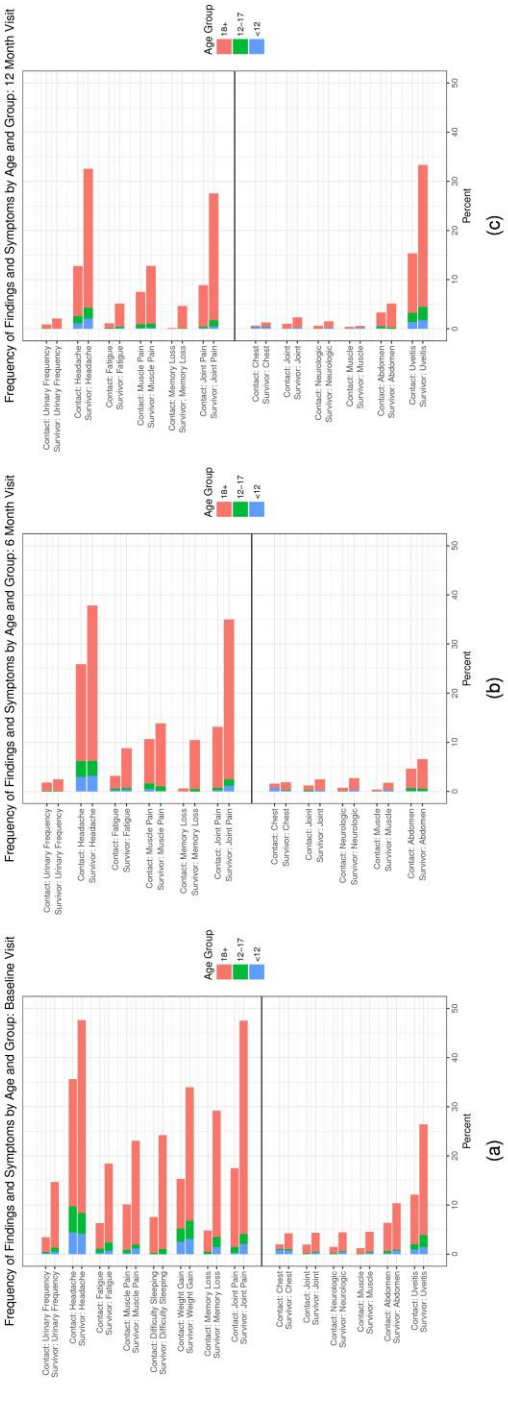

Figure S2: Summary of selected symptoms and physical exam findings for survivors and close contacts enrolled in PREVAIL III over time. All estimates are adjusted for age, gender, site and relations amongs contacts and survivors. Only a subset of participants received eye exams.

3.3 Figure S3

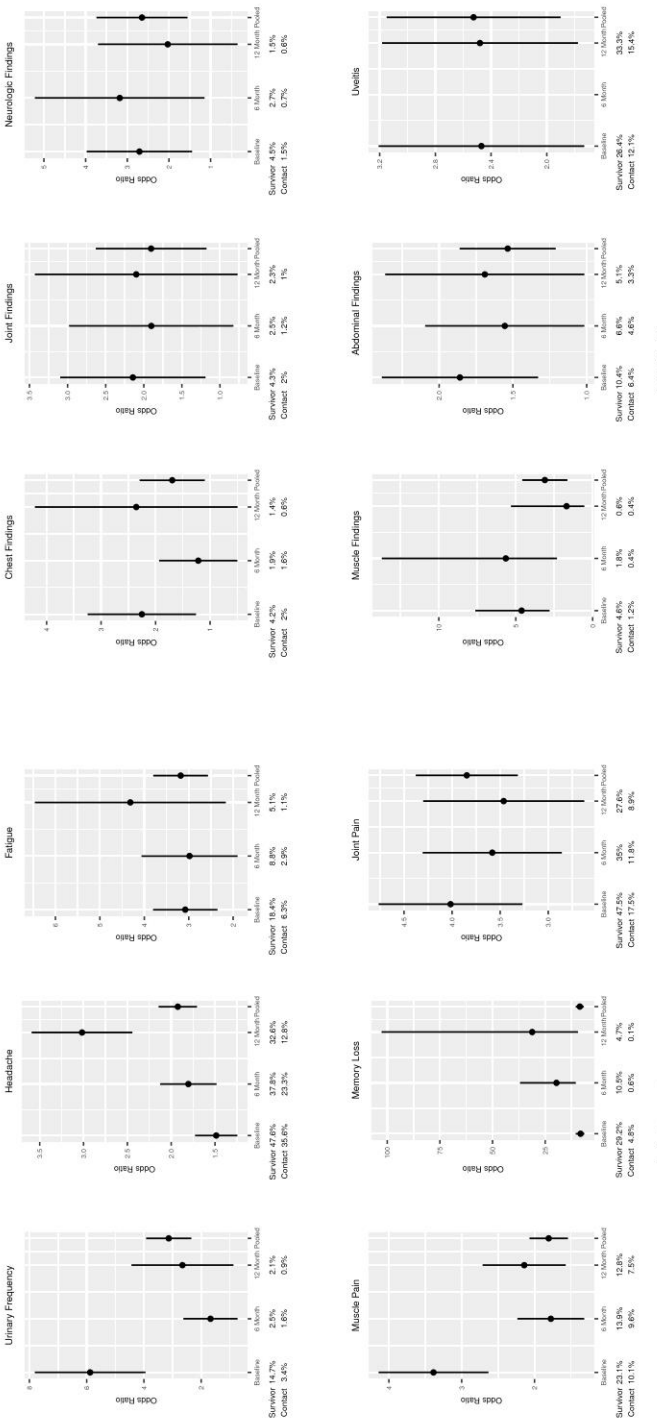

Figure S3: Summary of odds ratios for selected symptoms and physical exam findings for survivors and close contacts enrolled in PREVAIL III over time. All estimates are adjusted for age, gender, site and relations amongs contacts and survivors. Uveitis was not assessed at the 6 month exam.

3.4 Table S1

	Seropositive Contacts		Seronegative Contacts		
Symptom	Number	Percent	Number	Percent	p-value for difference
Fever	75	34.25	304	18.74	< 0.001
Loss of Appetite	71	32.42	201	12.39	< 0.001
Nausea	50	22.83	127	7.83	< 0.001
Vomiting	52	23.74	90	5.55	< 0.001
Diarrhea	43	19.63	110	6.78	< 0.001
Headache	83	37.9	341	21.02	< 0.001
Abdominal Pain	46	21	130	8.01	< 0.001
Unexplained Bleeding	7	3.2	6	0.37	< 0.001
Myalgia	51	23.29	159	9.8	< 0.001
Arthralgia	52	23.74	162	9.99	< 0.001
Breathing Difficulties	25	11.42	54	3.33	< 0.001
Shortness of Breath	25	11.42	48	2.96	< 0.001
Hiccups	12	5.48	23	1.42	< 0.001
Red Eyes	25	11.42	44	2.71	< 0.001
Fatigue	63	28.77	195	12.02	< 0.001
Sore Throat	23	10.5	38	2.34	< 0.001
Any of the Above	102	46.58	497	30.64	< 0.001

Table S1: Summary of self reported symptoms at time of survivor's infection among self reported close contacts. This was the entire collection of acute symptoms for which we collected data across the whole cohort. The test statistics control for age, gender, site and relationships among close contacts.

3.5 Table S2

	Seropositive Survivors		Seronegative Survivors		
Symptom	Number	Percent	Number	Percent	p-value for difference
Fever	865	89.54	126	88.73	0.389
Loss of Appetite	868	89.86	122	85.92	0.040
Nausea	811	83.95	111	78.17	0.012
Vomiting	799	82.71	97	68.31	< 0.001
Diarrhea	804	83.23	94	66.20	< 0.001
Headache	865	89.54	125	88.03	0.299
Abdominal Pain	678	70.19	91	64.08	0.033
Unexplained Bleeding	171	17.70	14	9.86	0.011
Myalgia	844	87.37	121	85.21	0.243
Arthralgia	850	87.99	120	84.51	0.107
Breathing Difficulties	435	45.03	69	48.59	0.641
Shortness of Breath	418	43.27	68	47.89	0.749
Hiccups	242	25.05	41	28.87	0.684
Red Eyes	505	52.28	62	43.66	0.011
Fatigue	920	95.24	127	89.44	0.002
Sore Throat	371	38.41	51	35.92	0.230
Any of the Above	957	99.07	138	97.18	0.019

Table S2: Summary of self reported symptoms at time of infection among self reported survivors. This was the entire collection of acute symptoms for which we collected data across the whole cohort. The test statistics control for age, gender and site.

3.6 Table S3

No. Visits	No. Men	All + No. (%)	All - No. (%)	Mean Percent (Range Percent)
1	16	1 (6.25)	15 (93.75)	NA
2	21	2 (9.52)	17 (80.95)	50 (50, 50)
3	12	0 (0)	8 (66.67)	33.33 (33.33, 33.33)
4	12	0 (0)	8 (66.67)	37.5 (25, 75)
5	9	0 (0)	6 (66.67)	40 (20, 60)
6	19	0 (0)	12 (63.16)	40.48 (16.67, 83.33)
7	14	0 (0)	12 (85.71)	14.29 (14.29, 14.29)
8	11	0 (0)	9 (81.82)	43.75 (25, 62.5)
9	24	0 (0)	16 (66.67)	23.61 (11.11, 55.56)
10	14	0 (0)	11 (78.57)	30 (10, 70)
11	16	0 (0)	14 (87.5)	27.27 (18.18, 36.36)
12 or more	99	0 (0)	58 (58.59)	19.27 (5.88, 91.67)
Total	267	3 (1.12)	186 (69.66)	8.71 (5.88, 91.67)

Table S3: PREVAIL III semen results: + stands for Ebola RNA detected and - stands for Ebola RNA not detected with results presented for all men with a certain number of visits (for example, 16 men had 1 visit, with 15 men having a negative result on this single donation). Among survivors 30% have Ebola RNA detected in semen at least once. These results are based on a total of 2411 samples from 267 survivors. One positive sample was from a survivor who was infected over 40 months prior to sampling and the majority of positive samples were obtained more than a year after the survivor was infected.

3.7 Table S4

Symptom	Survivors (N = 966)	Close Contacts (N = 2350)	Estimated Odds Ratio
Most Common: >5%			
Weight gain	328 (34%)	360 (15.3%)	4.79 (3.79, 6.04)
Trouble sleeping	209 (24.3%)	145 (7.6%)	4.27 (3.3, 5.53)
Joint pain	459 (47.5%)	411 (17.5%)	4.12 (3.42, 4.98)
Fatigue	178 (18.4%)	149 (6.3%)	3.11 (2.46, 3.95)
Muscle pain	223 (23.1%)	238 (10.1%)	3 (2.42, 3.71)
Impotence/decreased libido	66 (15.1%)	55 (5.3%)	2.76 (1.76, 4.32)
Dizziness	129 (13.4%)	164 (7%)	2.32 (1.76, 3.05)
Anorexia	182 (18.8%)	241 (10.3%)	2.1 (1.68, 2.61)
Palpitations	160 (16.6%)	218 (9.3%)	2.03 (1.6, 2.57)
Loss of vision	132 (13.7%)	161 (6.9%)	1.99 (1.5, 2.64)
Chest pain	157 (16.3%)	222 (9.4%)	1.83 (1.45, 2.33)
Amenorrhea	75 (14.2%)	134 (10.2%)	1.76 (1.27, 2.43)
Itching	102 (10.6%)	156 (6.6%)	1.72 (1.32, 2.25)
Headache	460 (47.6%)	837 (35.6%)	1.58 (1.35, 1.85)
Chills	104 (10.8%)	173 (7.4%)	1.55 (1.19, 2.01)
Abdominal pain	224 (23.2%)	430 (18.3%)	1.42 (1.18, 1.71)
Less Common: 1%-5%			
Memory loss	282 (29.2%)	113 (4.8%)	9.28 (7.17, 12)
Tinnitus	69 (7.1%)	24 (1%)	7.79 (4.71, 12.88)
Urinary urgency	66 (6.8%)	38 (1.6%)	6.04 (3.94, 9.26)
Urinary frequency	142 (14.7%)	81 (3.4%)	5.88 (4.26, 8.12)
Female decreased libido	93 (17.6%)	58 (4.4%)	4.34 (3, 6.29)
Paresthesia	117 (12.1%)	74 (3.1%)	3.89 (2.83, 5.35)
Shortness of breath	37 (3.8%)	25 (1.1%)	3.67 (2.14, 6.29)
Diplopia	46 (4.8%)	40 (1.7%)	3.27 (2.05, 5.22)
ENT pain	50 (5.2%)	50 (2.1%)	3.07 (1.98, 4.76)
Decreased hearing	66 (6.8%)	52 (2.2%)	3.07 (2.07, 4.55)
Female Reproductive Odor	30 (5.7%)	35 (2.7%)	2.46 (1.43, 4.23)
Nausea	69 (7.1%)	74 (3.1%)	2.37 (1.66, 3.39)
Nocturia	86 (8.9%)	98 (4.2%)	2.07 (1.53, 2.8)
Rare: <1%			
Orchitis	11 (2.5%)	1 (0.1%)	32.1 (4.15, 248)
Musculoskeletal stiffness	46 (4.8%)	6 (0.3%)	24.59 (10.44, 57.93)
Vertigo	43 (4.5%)	6 (0.3%)	15.21 (6.18, 37.44)
Dyspnea	15 (1.6%)	5 (0.2%)	10.17 (3.27, 31.59)
Musculoskeletal heat	43 (4.5%)	14 (0.6%)	8.9 (4.56, 17.35)
Change in bowel habits	25 (2.6%)	8 (0.3%)	8.26 (3.36, 20.36)
PND	21 (2.2%)	7 (0.3%)	8.06 (3.4, 19.1)
Hair and/or nail changes	34 (3.5%)	12 (0.5%)	7.64 (3.96, 14.75)
Musculoskeletal edema	18 (1.9%)	7 (0.3%)	7.4 (3, 18.25)
Ataxia	24 (2.5%)	11 (0.5%)	5.84 (2.68, 12.73)
Hoarseness	14 (1.4%)	6 (0.3%)	5.78 (2.16, 15.46)
Melena	13 (1.3%)	6 (0.3%)	5.71 (2.2, 14.82)
Polyuria	27 (2.8%)	15 (0.6%)	5.04 (2.63, 9.65)
Enlargement of lymph nodes	10 (1%)	8 (0.3%)	4.35 (1.74, 10.87)
Weakness in any limb	39 (4%)	21 (0.9%)	4.28 (2.41, 7.6)
Wheezing	9 (0.9%)	7 (0.3%)	4.22 (1.69, 10.52)
Tremor	39 (4%)	23 (1%)	3.63 (2.03, 6.48)
Cardiovascular edema	13 (1.3%)	10 (0.4%)	3.05 (1.34, 6.95)
Incontinence	23 (2.4%)	21 (0.9%)	2.94 (1.67, 5.18)

Table S4: Self reported symptoms that differ between survivors and close contacts with a p-value less than 0.01 at the baseline visit. The test statistics control for age, gender, site and relationships among survivors and close contacts.

3.8 Table S5

Symptom	Survivors (N = 966)	Close Contacts (N = 2350)
Fever	198 (20.5%)	483 (20.6%)
Painful periods	91 (17.2%)	199 (15.2%)
Cough/sputum	125 (12.9%)	328 (14%)
Menopause	56 (10.6%)	134 (10.2%)
Weight loss	121 (12.5%)	239 (10.2%)
Dysuria	86 (8.9%)	152 (6.5%)
Night sweats	69 (7.1%)	139 (5.9%)
Rash	50 (5.2%)	97 (4.1%)
Nipple discharge	15 (1.6%)	54 (2.3%)
Dysphagia	25 (2.6%)	54 (2.3%)
Discharge from nose	10 (1%)	41 (1.7%)
Testicular pain or mass	8 (1.8%)	14 (1.3%)
Breast pain	19 (2%)	28 (1.2%)
Diarrhea	21 (2.2%)	28 (1.2%)
Penile discharge	6 (1.4%)	9 (0.9%)
Discharge from ear	9 (0.9%)	20 (0.9%)
Depigmentation	12 (1.2%)	17 (0.7%)
Jaundice	6 (0.6%)	16 (0.7%)
Menarche	1 (0.2%)	8 (0.6%)
Musculoskeletal deformity	9 (0.9%)	11 (0.5%)
Skin lumps and/or bumps	8 (0.8%)	10 (0.4%)
Postmenopausal symptoms	6 (1.1%)	4 (0.3%)
Abnormal vaginal bleeding	7 (1.3%)	4 (0.3%)
Rectal bleeding	12 (1.2%)	7 (0.3%)
Breast lumps	6 (0.6%)	5 (0.2%)
Vomiting	8 (0.8%)	5 (0.2%)
Syncope	1 (0.1%)	5 (0.2%)
Nose bleeds	2 (0.2%)	3 (0.1%)
Positive TB test	4 (0.4%)	3 (0.1%)
Hematuria	2 (0.2%)	3 (0.1%)
Urinary hesitancy	7 (0.7%)	3 (0.1%)
Infertility	0 (0%)	1 (0.1%)
Respiratory congestion	7 (0.7%)	2 (0.1%)
Paralysis	1 (0.1%)	1 (0%)
Orthopnea	11 (1.1%)	0 (0%)
Hemoptysis	1 (0.1%)	0 (0%)
Hematemesis	0 (0%)	0 (0%)
Musculoskeletal redness	0 (0%)	0 (0%)
Muscle tenderness	6 (0.6%)	0 (0%)
Seizures	4 (0.4%)	0 (0%)
Bruising	4 (0.4%)	0 (0%)

Table S5: Self reported symptoms whose differences are not statistically significant between survivors and close contacts at the baseline visit. The test statistics (not shown) control for age, gender, site and relationships among survivors and close contacts.

3.9 Table S6

Symptom	Survivors (N = 851)	Close Contacts (N = 2137)	Estimated Odds Ratio
Most Common: >5%			
Joint pain	298 (35%)	253 (11.8%)	3.55 (2.9, 4.35)
Anorexia	99 (11.6%)	130 (6.1%)	2.02 (1.51, 2.71)
Headache	322 (37.8%)	498 (23.3%)	1.85 (1.54, 2.21)
Muscle pain	118 (13.9%)	205 (9.6%)	1.8 (1.39, 2.35)
Fever	177 (20.8%)	286 (13.4%)	1.56 (1.25, 1.94)
Chest pain	81 (9.5%)	120 (5.6%)	1.56 (1.15, 2.1)
Cough/sputum	96 (11.3%)	188 (8.8%)	1.5 (1.14, 1.96)
Less Common: 1%-5%			
Female decreased libido	50 (10.7%)	17 (1.4%)	6.89 (3.91, 12.11)
Fatigue	75 (8.8%)	61 (2.9%)	2.97 (2.07, 4.25)
Night sweats	49 (5.8%)	38 (1.8%)	2.94 (1.85, 4.65)
Dizziness	67 (7.9%)	81 (3.8%)	2.55 (1.78, 3.65)
Impotence/decreased libido	32 (8.4%)	27 (2.9%)	2.34 (1.34, 4.07)
Palpitations	71 (8.3%)	78 (3.6%)	2.31 (1.62, 3.29)
Itching	58 (6.8%)	80 (3.7%)	1.79 (1.26, 2.55)
Dysuria	50 (5.9%)	70 (3.3%)	1.78 (1.2, 2.65)
Rare: <1%			
Memory loss	89 (10.5%)	12 (0.6%)	16.37 (8.84, 30.3)
Tremor	10 (1.2%)	2 (0.1%)	10.28 (2.17, 48.76)
Weakness in any limb	14 (1.6%)	4 (0.2%)	7.25 (2.27, 23.13)
Decreased hearing	33 (3.9%)	13 (0.6%)	6.03 (2.92, 12.42)
Abnormal vaginal bleeding	6 (1.3%)	3 (0.3%)	5.93 (1.57, 22.46)
ENT pain	23 (2.7%)	12 (0.6%)	5.73 (2.58, 12.74)
Paresthesia	31 (3.6%)	13 (0.6%)	5.34 (2.63, 10.86)
Change in bowel habits	14 (1.6%)	6 (0.3%)	5.09 (2.03, 12.72)
Diarrhea	12 (1.4%)	8 (0.4%)	4.84 (2.07, 11.32)
Diplopia	16 (1.9%)	15 (0.7%)	2.96 (1.41, 6.19)

Table S6: Self reported symptoms that differ between survivors and close contacts with a significance level of 1% at the 6 month visit. The test statistics control for age, gender, site and relationships among survivors and close contacts.

3.10 Table S7

Symptom	Survivors (N = 860)	Close Contacts (N = 2053)	Estimated Odds Ratio
Most Common: >5%			
Joint pain	237 (27.6%)	182 (8.9%)	3.36 (2.64, 4.28)
Headache	280 (32.6%)	262 (12.8%)	2.82 (2.31, 3.44)
Muscle pain	110 (12.8%)	154 (7.5%)	2.55 (1.91, 3.42)
Abdominal pain	100 (11.6%)	130 (6.3%)	2.09 (1.56, 2.8)
Cough/sputum	78 (9.1%)	111 (5.4%)	2 (1.44, 2.76)
Fever	130 (15.1%)	159 (7.7%)	1.77 (1.37, 2.28)
Amenorrhea	59 (12.6%)	117 (10.3%)	1.6 (1.13, 2.27)
Less Common: 1%-5%			
Fatigue	44 (5.1%)	23 (1.1%)	4.22 (2.55, 7)
Palpitations	47 (5.5%)	36 (1.8%)	2.61 (1.63, 4.19)
Nocturia	22 (2.6%)	31 (1.5%)	2.21 (1.31, 3.74)
Chills	61 (7.1%)	62 (3%)	2.19 (1.51, 3.18)
Anorexia	72 (8.4%)	76 (3.7%)	2.15 (1.54, 2.99)
Chest pain	64 (7.4%)	66 (3.2%)	1.98 (1.37, 2.86)
Rare: <1%			
Dysphagia	16 (1.9%)	7 (0.3%)	5.71 (2.21, 14.76)
Impotence/decreased libido	23 (5.9%)	9 (1%)	5.4 (2.25, 12.93)
Decreased hearing	22 (2.6%)	11 (0.5%)	4.24 (1.9, 9.43)
Nausea	17 (2%)	11 (0.5%)	4.21 (1.78, 9.97)

Table S7: Self reported symptoms that differ between survivors and close contacts with a significance level of 1% at the 12 month visit. The test statistics control for age, gender, site and relationships among survivors and close contacts.

3.11 Table S8

Finding	Baseline Visit			6 Month Visit			12 Month Visit		
	Survivor (N = 966)	Close Contact (N = 2350)	p-value for difference	Survivor (N = 851)	Close Contact (N = 2137)	p-value for difference	Survivor (N = 860)	Close Contact (N = 2053)	p-value for difference
Head/face	6 (0.6%)	7 (0.3%)	0.046	3 (0.4%)	4 (0.2%)	0.348	2 (0.2%)	2 (0.1%)	0.348
Head/face: Deformity	1	0		2	0		1	1	
Swelling	2	6		0	4		0	0	
Asymmetry	3	3		2	1		1	1	
Ears, Nose, and Throat	229 (23.7%)	512 (21.8%)	0.307	201 (23.6%)	404 (18.9%)	0.626	233 (27.1%)	382 (18.6%)	0.05
Nose: Mucosa	1	10		3	5		1	3	
Nose: Ulcer	0	2		1	1		0	0	
Ear: TM	6	5		1	1		0	1	
Ear: Ext. Canal	4	2		0	0		0	1	
Ear: Hearing	36	12		17	4		8	3	
Mouth/Throat: Mucosa	1	3		1	1		0	0	
Mouth/Throat: Mass	0	1		0	2		0	1	
Mouth/Throat: Ulcer	5	6		1	4		1	0	
Mouth/Throat: Missing Teeth	90	249		129	238		158	241	
Mouth/Throat: Dental Caries	168	393		140	298		169	275	
Chest	41 (4.2%)	47 (2%)	< 0.0001	16 (1.9%)	34 (1.6%)	0.41	11 (1.3%)	13 (0.6%)	0.027
Wheezes	7	2		3	1		1	2	
Decreased Breath Sounds	9	10		5	4		5	1	
Heart Murmur	9	6		2	3		0	1	
Pericardial Rub	4	1		1	1		0	1	
Rales/Crackles	8	26		3	22		7	7	
Irregular Heartbeat	10	11		4	4		1	1	
Abdomen	100 (10.4%)	150 (6.4%)	< 0.0001	56 (6.6%)	99 (4.6%)	0.041	44 (5.1%)	68 (3.3%)	0.014
Splenomegaly	3	6		1	5		0	3	
Hepatomegaly	7	4		0	1		0	0	
Abdomen: Mass	23	47		18	34		13	28	
Abdomen: Tenderness	54	86		30	48		28	30	
Distention	18	34		12	30		7	20	
Extremities	30 (3.1%)	53 (2.3%)	0.121	16 (1.9%)	28 (1.3%)	0.357	13 (1.5%)	25 (1.2%)	0.731
Extremities: Deformity	12	30		10	17		10	16	
Edema	15	22		5	9		3	9	
Decreased Pulse	7	3		2	1		0	0	
Bruit	1	0		0	1		0	0	
Muscles	44 (4.6%)	29 (1.2%)	< 0.0001	15 (1.8%)	8 (0.4%)	< 0.0001	5 (0.6%)	8 (0.4%)	0.642
Atrophy	4	2		4	3		3	1	
Weakness	5	7		4	3		2	3	
Muscle: Tenderness	40	21		10	2		0	5	
Joints	42 (4.3%)	46 (2%)	< 0.0001	21 (2.5%)	26 (1.2%)	0.091	20 (2.3%)	21 (1%)	0.048
Swelling/Effusion	8	12		4	2		3	5	
Synovial Tenderness	6	3		2	2		1	1	
Deformity	7	12		5	5		5	6	
Decreaesed ROM	26	32		16	17		14	14	
Neurologic	43 (4.5%)	35 (1.5%)	< 0.0001	23 (2.7%)	16 (0.7%)	0.001	13 (1.5%)	13 (0.6%)	0.182
Cognition	3	0		2	0		1	1	
Speech	7	4		5	1		2	1	
Tremor	9	4		6	0		1	1	
Reflexes	14	16		4	4		1	4	
Cranial Nerve(s)	7	2		2	1		1	1	
Focal Weakness	1	1		1	0		1	0	
Gait/Balance	7	21		8	13		10	9	
Sensory	2	0		0	0		0	0	
Skin	93 (9.6%)	173 (7.4%)	0.001	43 (5.1%)	82 (3.8%)	0.042	36 (4.2%)	92 (4.5%)	0.904
Rash	43	86		21	39		14	44	
Skin: Mass	4	9		5	2		0	1	
Lesion	22	28		6	11		6	14	
Jaundice	1	1		0	0		0	0	
Pigmentation	39	68		17	34		17	40	
Breast	14 (1.7%)	56 (2.4%)	0.504	15 (1.8%)	30 (1.4%)	0.358	12 (1.4%)	26 (1.3%)	0.725
Breast: Mass	2	3		1	1		1	0	
Nipple Discharge	12	53		14	29		11	26	

Table S8: Summary of physical exam findings for survivors and close contacts enrolled in PREVAIL III. The test statistics control for age, gender, site and relationships among survivors and close contacts.

3.12 Table S9

	Baseline Visit				6 Month Visit				12 Month Visit			
	Survivor		Contact		Survivor		Contact		Survivor		Contact	
	Age < 18 (N=205)	Age ≥ 18 (N=761)	Age < 18 (N=849)	Age ≥ 18 (N=1500)	Age < 18 (N=180)	Age ≥ 18 (N=670)	Age < 18 (N=795)	Age ≥ 18 (N=1338)	Age < 18 (N=185)	Age ≥ 18 (N=675)	Age < 18 (N=766)	Age ≥ 18 (N=1287)
Renal Function												
Serum creatinine	0.64 (0.54, 0.74)	0.93 (0.8, 1.08)	0.61 (0.5, 0.72)	0.88 (0.75, 1.04)	0.63 (0.54, 0.74)	0.93 (0.8, 1.1)	0.61 (0.5, 0.73)	0.9 (0.76, 1.05)	0.63 (0.53, 0.74)	0.9 (0.76, 1.05)	0.65 (0.54, 0.77)	0.93 (0.79, 1.07)
eGFR[7,8]	88.3 (78.27, 100.56)	104.96 (89.85, 122.15)	90.46 (80.88, 102.96)	111.58 (95.33, 128.6)	88.01 (80.47, 99.59)	105.09 (88.89, 121.7)	90.08 (79.15, 103.76)	109.44 (94.03, 128.45)	88.93 (79.41, 103.84)	107.33 (92.15, 127.54)	84.12 (74.81, 94.76)	106.34 (91.49, 124.02)
eGFR < 60	3 (0.02)	12 (0.02)	17 (0.02)	22 (0.01)	2 (0.01)	13 (0.02)	13 (0.02)	20 (0.01)	1 (0.01)	8 (0.01)	19 (0.03)	21 (0.02)
Hepatic Function												
Total bilirubin	0.5 (0.4, 0.7)	0.7 (0.5, 0.9)	0.5 (0.4, 0.7)	0.7 (0.5, 0.9)	0.5 (0.4, 0.7)	0.7 (0.5, 0.9)	0.5 (0.4, 0.7)	0.7 (0.5, 0.9)	0.5 (0.4, 0.7)	0.7 (0.5, 0.9)	0.5 (0.4, 0.7)	0.7 (0.5, 1)
AST	16 (13, 21)	12 (9, 18)	18 (13, 22)	13 (10, 17)	15 (13, 20)	12 (9, 16)	17 (13, 21)	13 (9, 17)	15 (12, 20)	12 (9, 16)	16 (12, 21)	12 (9, 17)
ALT	6 (4, 10)	7 (3, 13)	6 (4, 10)	7 (4, 12)	5 (3, 8)	7 (3, 12)	6 (4, 10)	7 (4, 12)	6 (3, 9)	7 (3, 13)	6 (3, 9)	7 (4, 11)
APRI[9]	0.14 (0.11, 0.19)	0.14 (0.09, 0.21)	0.16 (0.12, 0.21)	0.14 (0.1, 0.22)	0.14 (0.1, 0.19)	0.14 (0.1, 0.2)	0.15 (0.11, 0.21)	0.14 (0.1, 0.22)	0.15 (0.1, 0.2)	0.13 (0.09, 0.19)	0.15 (0.11, 0.2)	0.14 (0.1, 0.21)
APRI > 0.7	3 (0.01)	18 (0.02)	12 (0.01)	45 (0.03)	2 (0.01)	21 (0.03)	7 (0.01)	43 (0.03)	4 (0.02)	13 (0.02)	11 (0.01)	40 (0.03)
Hematology												
d-Dimer	0.39 (0.29, 0.5)	0.39 (0.27, 0.64)	0.42 (0.29, 0.65)	0.45 (0.27, 0.7)	0.46 (0.33, 0.66)	0.48 (0.29, 0.74)	0.44 (0.28, 0.67)	0.43 (0.27, 0.71)	0.29 (0.27, 0.46)	0.35 (0.27, 0.59)	0.49 (0.32, 0.69)	0.46 (0.29, 0.7)
Prothrombin time	14 (13.5, 14.6)	13.5 (13, 14)	14.4 (13.8, 14.9)	14 (13.5, 14.6)	14.3 (13.8, 14.7)	13.9 (13.3, 14.4)	14.4 (14, 15)	14.1 (13.5, 14.6)	14.4 (13.8, 14.9)	14.1 (13.6, 14.57)	14.3 (13.8, 15)	14 (13.4, 14.6)
Hematocrit	37.59 (34.48, 40.71)	42.17 (38.71, 46.19)	36.5 (33.8, 39)	40.6 (37.58, 44.57)	35.6 (33.3, 37.75)	39.4 (36.2, 43.06)	35.7 (33, 37.99)	39.43 (36.12, 43.13)	36.86 (33.44, 39.32)	40.12 (36.98, 43.56)	35.81 (33.39, 38.27)	39.5 (36.55, 42.84)
Platelet count	293.9 (240.8, 373.9)	237.9 (199.8, 284.8)	288.8 (240.38, 350.07)	234.65 (195.9, 280.68)	292 (236.75, 367.6)	230.85 (192.55, 275.15)	275 (227.4, 338.5)	232.65 (192.72, 273.98)	276.1 (228.7, 343.6)	232.2 (194.7, 276.65)	266.1 (219.1, 329.7)	225.6 (186.55, 267.55)

Table S9: Laboratory results (medians and quartiles for continuous variables and counts and percents for binary variables) for survivors and close contacts separated by age.

4 CASE REPORT FORMS

Enrollment: EVD Survivors

Attach a PID label here:

Enrollment Date: (example: 01-SEP-2015) Day ___ Month ___ Year 2015

Participant Initials: _____

PREVAIL III

Complete this form for survivors of Ebola enrolled in the PREVAIL III: Ebola Natural History Study. If the volunteer is <12 years old, also complete the Pediatric Supplement form.

A. Inclusion criteria (all must be marked "Yes" for participant to be eligible)

	No	Yes
1. In a volunteer of any age, documentation of EVD in the past 2 years based on The Ministry of Health Registry of EVD Survivors.	0 ☐	1 ☐
2. Willingness to participate in examinations at one of the participating health facilities.	0 ☐	1 ☐
3. Willingness to provide informed consent/assent.	0 ☐	1 ☐

B. Exclusion Criterion (must be marked "No" for volunteer to be eligible)

	No	Yes
1. Any condition, in the judgement of study staff, that would make the volunteer unable to participate in the study.	0 ☐	1 ☐

C. Enrollment Documentation

	Check if completed
1. Consent form was signed and dated.	1 ☐
2. Volunteer received copy of consent.	1 ☐

D. EVD History - self-reported

1. When did the volunteer develop symptoms of Ebola? (example: JUL-2015) Month ___ Year 2015 (Estimate the date, if exact date is unknown)

2. Was the volunteer treated in a:

		Record name of center
a. Ebola Treatment Unit (ETU)	0 ☐ No / 1 ☐ Yes →	_____
b. Transit Unit (TU)	0 ☐ No / 1 ☐ Yes →	_____
c. Hospital	0 ☐ No / 1 ☐ Yes →	_____
d. Community Care Center (CCC)	0 ☐ No / 1 ☐ Yes →	_____

Note: also complete EVD Documentation form.

3. What was the total length of stay in treatment center(s)?

1 ☐ < 2 days
2 ☐ 2-5 days
3 ☐ 6-9 days
4 ☐ 10-14 days
5 ☐ > 14 days

4. Were any of the volunteer's household members diagnosed with Ebola?

0 ☐ No
1 ☐ Yes →

5. Mark all that apply:

1 ☐ Spouse/partner
1 ☐ Parent
1 ☐ Other; specify: _____
1 ☐ Sibling
1 ☐ Child

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6. What was the likely source of the volunteer's Ebola infection?

1 ☐ Contact with family or household members
2 ☐ Job related → 7. What best describes the volunteer's role at that time?
3 ☐ Other; specify: _____
4 ☐ Unknown

01 ☐ Doctor	05 ☐ Cleaner	09 ☐ Ambulance driver
02 ☐ Physician's assistant	06 ☐ Laboratory	10 ☐ Other; specify:
03 ☐ Nurse	07 ☐ Transporter	
04 ☐ Nursing assistant	08 ☐ Safe burial team	_____

8. What symptoms (self-reported) did the volunteer experience at the time of diagnosis or during the hospitalization/ETU stay?

a. Fever	0 ☐ No	1 ☐ Yes	i. Myalgia (muscle pain)	0 ☐ No	1 ☐ Yes
b. Loss of appetite	0 ☐ No	1 ☐ Yes	j. Arthralgia (joint pain)	0 ☐ No	1 ☐ Yes
c. Nausea	0 ☐ No	1 ☐ Yes	k. Breathing difficulties	0 ☐ No	1 ☐ Yes
d. Vomiting	0 ☐ No	1 ☐ Yes	l. Shortness of breath	0 ☐ No	1 ☐ Yes
e. Diarrhea	0 ☐ No	1 ☐ Yes	m. Hiccups	0 ☐ No	1 ☐ Yes
f. Headache	0 ☐ No	1 ☐ Yes	n. Red eyes	0 ☐ No	1 ☐ Yes
g. Abdominal pain	0 ☐ No	1 ☐ Yes	o. Fatigue	0 ☐ No	1 ☐ Yes
h. Unexplained bleeding	0 ☐ No	1 ☐ Yes	p. Sore throat	0 ☐ No	1 ☐ Yes

9. Ask the volunteer, "Did you develop eye problems while you were sick with Ebola or after you recovered from Ebola?"

a. Blurry vision	c. Sensitivity to light	e. Discharge from eye
0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes
b. Pain in eye	d. Eye redness	f. Other; specify: _____
0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes

10. Since recovery from Ebola, has the volunteer been hospitalized?

0 ☐ No
1 ☐ Yes → 11. Reason: _____

12. Date of admission: (example: JUL-2015) ☐☐☐–2☐1☐ (Month – Year)

(If multiple, record first hospitalization after discharge from ETU. Estimate the date, if the exact date is unknown)

Enrollment: EVD Survivors

Attach a PID label here:

13. Since the Ebola event, has the volunteer experienced a pregnancy? (include pregnancy at the time of the EVD event, if applicable)

0 ☐ No or not applicable → **Go to Section E.**

1 ☐ Yes

14. Number of pregnancies since Ebola: ☐ (Include pregnancy at the time of the EVD event, if applicable)

15. Was the volunteer pregnant at the time of EVD event?

0 ☐ No

1 ☐ Yes

Answer the following questions for each pregnancy.

	a. 1st pregnancy	b. 2nd pregnancy	c. 3rd pregnancy
16. Outcome of pregnancy:	1 ☐ Still pregnant 2 ☐ Live birth 3 ☐ Live birth with subsequent infant death 4 ☐ Still birth/intrauterine fetal demise (IUFD ≥ 20 weeks) 5 ☐ Spontaneous abortion (IUFD < 20 weeks) 6 ☐ Induced abortion 7 ☐ Other; specify: ________	1 ☐ Still pregnant 2 ☐ Live birth 3 ☐ Live birth with subsequent infant death 4 ☐ Still birth/intrauterine fetal demise (IUFD ≥ 20 weeks) 5 ☐ Spontaneous abortion (IUFD < 20 weeks) 6 ☐ Induced abortion 7 ☐ Other; specify: ________	1 ☐ Still pregnant 2 ☐ Live birth 3 ☐ Live birth with subsequent infant death 4 ☐ Still birth/intrauterine fetal demise (IUFD ≥ 20 weeks) 5 ☐ Spontaneous abortion (IUFD < 20 weeks) 6 ☐ Induced abortion 7 ☐ Other; specify: ________
17. Any medical problems with the fetus or infant?	0 ☐ No 1 ☐ Yes, specify: ________	0 ☐ No 1 ☐ Yes, specify: ________	0 ☐ No 1 ☐ Yes, specify: ________

E. Sexual History

Sexual contacts (since the EVD event) may be invited to participate in this study (have antibody testing) if they are not also EVD survivors. Ask if the volunteer is willing to provide this information.

1. Excluding other survivors, has the volunteer had any sexual partners since the EVD event?

0 ☐ No or not applicable → **Go to Section F.**

1 ☐ Volunteer prefers not to provide information → **Go to Section F.**

2 ☐ Yes → **Close Contacts Form should be completed when the volunteer is willing to provide the names.**

Enrollment: EVD Survivors

Attach a PID label here:

F. Stigma and Discrimination - complete for volunteers ≥ 12 years of age.
Read the following questions to the volunteer and ask which apply to their experience.

	No	Yes
1. Forced to change residence because of social alienation from family and/or friends.	0 ☐	1 ☐
2. Lost a job or another source of income because of being infected.	0 ☐	1 ☐
3. Lost a spouse because of fear of being infected from personal interaction.	0 ☐	1 ☐
4. Deprived from attending gathering (e.g., school, church, social) for fear of infecting others.	0 ☐	1 ☐
5. Isolated yourself from family and/or friends.	0 ☐	1 ☐
6. Withdrew from education/training or did not take up an opportunity for education/training.	0 ☐	1 ☐
7. Afraid that someone would not want to be sexually intimate with you as a survivor.	0 ☐	1 ☐

G. Specimen Documentation

Note: Blood samples are optional for volunteers < 12 years of age.

1. Were the following specimens obtained:

a. Blood 0 ☐ No 1 ☐ Yes →

b. Urine 0 ☐ No 1 ☐ Yes →

Kit Number Label here:

Place 2nd Kit Number label here, if a 2nd kit is used:

2. Has the volunteer had anything to eat or drink (other than water) in the past 8 hours?

0 ☐ No
1 ☐ Yes

Signature: _____ Date: _____

EVD Documentation

Attach a PID label here:

Enrollment Date:
(example: 01-JAN-2016)
Day ___ Month ___ Year 2 0 1 ___

Participant Initials: _____

PREVAIL III

Complete this form using Ministry of Health data and any other available documentation of the volunteer's EVD event. Check unknown for any answer that is not known.

1. Is any documentation of the volunteer's EVD event available?
   - 0 ☐ No → **Stop here. Sign form and submit.**
   - 1 ☐ Yes → **Provide any information below that is available.**

2. Was the volunteer treated in an Ebola Treatment Unit (ETU)?
   - 0 ☐ No
   - 1 ☐ Yes →
   - 2 ☐ Unknown

   3. Name of ETU: _____

   4. Date of admission:
   (example: 01-JAN-2016)
   Day ___ Month ___ Year 2 0 1 ___
   OR 1 ☐ Date unknown

   5. Date of discharge:
   (example: 01-JAN-2016)
   Day ___ Month ___ Year 2 0 1 ___
   OR 1 ☐ Date unknown

   Note: Give date of first admission and last discharge if volunteer had multiple admissions.

6. Was the volunteer treated in a Transit Unit (TU)?
   - 0 ☐ No
   - 1 ☐ Yes →
   - 2 ☐ Unknown

   7. Name of TU: _____

   8. Date of admission:
   (example: 01-JAN-2016)
   Day ___ Month ___ Year 2 0 1 ___
   OR 1 ☐ Date unknown

   9. Date of discharge:
   (example: 01-JAN-2016)
   Day ___ Month ___ Year 2 0 1 ___
   OR 1 ☐ Date unknown

   Note: Give date of first admission and last discharge if volunteer had multiple admissions.

10. Diagnosis certainty (Mark first that applies):
    - 1 ☐ Confirmed, positive PCR
    - 2 ☐ Confirmed, positive ELISA
    - 3 ☐ Probable, no test results available

11. Are any blood RT-PCR test results available?
    - 0 ☐ No
    - 1 ☐ Yes →

Provide any details available.

	a. Date of blood draw* (example: 01-JAN-2016) Day Month Year	b. Result	c. Ct value (Record if positive:)
12.	___ ___ 2 0 1 ___ **OR** 1 ☐ Date unknown	0 ☐ Negative 1 ☐ Positive	___.___ **OR** 1 ☐ Unknown
13.	___ ___ 2 0 1 ___ **OR** 1 ☐ Date unknown	0 ☐ Negative 1 ☐ Positive	___.___ **OR** 1 ☐ Unknown
14.	___ ___ 2 0 1 ___ **OR** 1 ☐ Date unknown	0 ☐ Negative 1 ☐ Positive	___.___ **OR** 1 ☐ Unknown
15.	___ ___ 2 0 1 ___ **OR** 1 ☐ Date unknown	0 ☐ Negative 1 ☐ Positive	___.___ **OR** 1 ☐ Unknown

Signature: _____ Date: _____

Close Contacts

Attach a PID label here:

Date Form Completed:
(example: 01-SEP-2015)

Day	Month	Year
		2015

Participant Initials: _____

Complete this form for each participating Ebola survivor to document close contact with individuals who may be invited to participate in this study. This information is confidential and will not be disclosed to anyone outside of the study. Upon consent, they will be assessed and tested to evaluate their health. The findings from their exams will be compared to EVD survivors to assess the difference.

1. Does the survivor wish to report any close contacts (household or sexual) who may be willing to participate in this study?

   0 ☐ No → **Sign and date this form, and submit.**

   1 ☐ Yes → **Complete questions 2 and/or 3.**

2. Ask for the names of up to 5 household contacts who lived with the volunteer at the time of the Ebola event or since the Ebola event. Only list contacts who are living, and who did not become infected with Ebola. For each, indicate their relationship to the survivor. Choose the 5 closest contacts (e.g., shared bedroom, meals, etc.)

	Name	Relationship				
a.	_____	1 ☐ Spouse/partner	2 ☐ Parent	3 ☐ Child	4 ☐ Sibling	5 ☐ Other; specify: _____
b.	_____	1 ☐ Spouse/partner	2 ☐ Parent	3 ☐ Child	4 ☐ Sibling	5 ☐ Other; specify: _____
c.	_____	1 ☐ Spouse/partner	2 ☐ Parent	3 ☐ Child	4 ☐ Sibling	5 ☐ Other; specify: _____
d.	_____	1 ☐ Spouse/partner	2 ☐ Parent	3 ☐ Child	4 ☐ Sibling	5 ☐ Other; specify: _____
e.	_____	1 ☐ Spouse/partner	2 ☐ Parent	3 ☐ Child	4 ☐ Sibling	5 ☐ Other; specify: _____

3. List sexual contacts since being diagnosed with Ebola. For each, indicate the current status and history of condom use. Do not include contacts who have had Ebola.

	Name	Current partner	History of condom use		
a.	_____	0 ☐ No, 1 ☐ Yes	0 ☐ Never	1 ☐ Sometimes	2 ☐ Always
b.	_____	0 ☐ No, 1 ☐ Yes	0 ☐ Never	1 ☐ Sometimes	2 ☐ Always
c.	_____	0 ☐ No, 1 ☐ Yes	0 ☐ Never	1 ☐ Sometimes	2 ☐ Always
d.	_____	0 ☐ No, 1 ☐ Yes	0 ☐ Never	1 ☐ Sometimes	2 ☐ Always

Signature: _____ Date: _____

Enrollment: Close Contacts

Attach a PID label here:

Enrollment Date:
(example: 01-SEP-2015)

		–				–	2	0	1	
Day			Month				Year			

Participant Initials: _____

Complete this form for close contacts of Ebola survivors enrolled in the PREVAIL III: Ebola Natural History Study. If the volunteer is < 12 years old, also complete the Pediatric Supplement form.

A. Inclusion Criteria (all must be marked "Yes" to be eligible)

	No	Yes
1. Willingness to participate in examinations at one of the participating health facilities.	0 ☐	1 ☐
2. Willingness to provide informed consent/assent.	0 ☐	1 ☐
3. Was named by a participating survivor as one of the following: • Household contact at the time of or since the EVD event. • Sexual contact since being diagnosed with EVD.	0 ☐	1 ☐

B. Exclusion Criteria (all must be marked "No" to be eligible)

	No	Yes
1. History of EVD	0 ☐	1 ☐
2. Any condition, in the judgement of study staff, that would make the volunteer unable to participate in this study.	0 ☐	1 ☐

C. Enrollment Documentation

	Check if completed
1. Consent form was signed and dated.	1 ☐
2. Volunteer received copy of consent.	1 ☐

D. Nature of Contact

1. Close contact of: ☐☐☐–☐☐☐☐–☐ **Record PREVAIL III PID of associated survivor.**

2. The survivor above is this volunteer's:

1 ☐ Spouse or partner
2 ☐ Other sexual contact
3 ☐ Parent
4 ☐ Child
5 ☐ Sibling
6 ☐ Other; specify: _____

3. Was the volunteer living in the same household as the survivor when the survivor developed Ebola?

0 ☐ No → **Go to Question 6.**

1 ☐ Yes → **Ask the volunteer,**

4. "For each item below, indicate the nature of your contact with the survivor at the time of the Ebola event."

	No	Yes
a. Contact with body fluid	0 ☐	1 ☐
b. Slept or ate in same room	0 ☐	1 ☐
c. Contact with clothing	0 ☐	1 ☐
d. Direct physical contact (i.e., touching)	0 ☐	1 ☐

Enrollment: Close Contacts

Attach a PID label here:

5. Did you develop any of the following symptoms within 21 days of the survivor's Ebola event?

a. Fever	0 ☐ No	1 ☐ Yes	i. Myalgia (muscle pain)	0 ☐ No	1 ☐ Yes
b. Loss of appetite	0 ☐ No	1 ☐ Yes	j. Arthralgia (joint pain)	0 ☐ No	1 ☐ Yes
c. Nausea	0 ☐ No	1 ☐ Yes	k. Breathing difficulties	0 ☐ No	1 ☐ Yes
d. Vomiting	0 ☐ No	1 ☐ Yes	l. Shortness of breath	0 ☐ No	1 ☐ Yes
e. Diarrhea	0 ☐ No	1 ☐ Yes	m. Hiccups	0 ☐ No	1 ☐ Yes
f. Headache	0 ☐ No	1 ☐ Yes	n. Red eyes	0 ☐ No	1 ☐ Yes
g. Abdominal pain	0 ☐ No	1 ☐ Yes	o. Fatigue	0 ☐ No	1 ☐ Yes
h. Unexplained bleeding	0 ☐ No	1 ☐ Yes	p. Sore throat	0 ☐ No	1 ☐ Yes

6. Have you had sexual contact with the survivor since his/her Ebola event?

0 ☐ No or not applicable → **Go to Question 8.**

1 ☐ Yes →

7. Since the Ebola event, how often do you use condoms with the survivor?

0 ☐ Never 1 ☐ Sometimes 2 ☐ Always

8. Have you ever been tested for Ebola?

0 ☐ No 1 ☐ Yes

9. Have you been pregnant during or since the survivor's Ebola event?

0 ☐ No or not applicable

1 ☐ Yes →

Answer the following questions for each pregnancy since the survivor's Ebola event.

10. Outcome of pregnancy:	a. 1st pregnancy	b. 2nd pregnancy	c. 3rd pregnancy
	1 ☐ Still pregnant	1 ☐ Still pregnant	1 ☐ Still pregnant
	2 ☐ Live birth	2 ☐ Live birth	2 ☐ Live birth
	3 ☐ Live birth with subsequent infant death	3 ☐ Live birth with subsequent infant death	3 ☐ Live birth with subsequent infant death
	4 ☐ Still birth/intrauterine fetal demise (IUFD ≥ 20 weeks)	4 ☐ Still birth/intrauterine fetal demise (IUFD ≥ 20 weeks)	4 ☐ Still birth/intrauterine fetal demise (IUFD ≥ 20 weeks)
	5 ☐ Spontaneous abortion (IUFD < 20 weeks)	5 ☐ Spontaneous abortion (IUFD < 20 weeks)	5 ☐ Spontaneous abortion (IUFD < 20 weeks)
	6 ☐ Induced abortion	6 ☐ Induced abortion	6 ☐ Induced abortion
	7 ☐ Other; specify: _____	7 ☐ Other; specify: _____	7 ☐ Other; specify: _____
11. Any medical problems with the fetus or infant?	0 ☐ No	0 ☐ No	0 ☐ No
	1 ☐ Yes, specify: _____	1 ☐ Yes, specify: _____	1 ☐ Yes, specify: _____

Enrollment: Close Contacts

Attach a PID label here:

E. Specimen Documentation

Note: Blood samples are optional for volunteers < 12 years of age.

1. Were the following specimens obtained:

a. Blood 0 ☐ No 1 ☐ Yes →

b. Urine 0 ☐ No 1 ☐ Yes →

Kit Number Label here:

Place 2nd Kit Number label here, if a 2nd kit is used:

2. Has the volunteer had anything to eat or drink (other than water) in the past 8 hours?

0 ☐ No

1 ☐ Yes

Signature: _____ Date: _____

Visit 1 (Baseline)

Attach a PID label here:

Enrollment Date:
(example: 01-AUG-2015)
Day ☐☐ Month ☐☐☐ Year 2 0 1 ☐

Participant Initials: _____

Complete this form for survivors of Ebola, close contacts, and others chosen as controls who are enrolled in PREVAIL III.

A. Demographics

1. Date of birth: (example: 03-MAR-1984) Day ☐☐ Month ☐☐☐ Year ☐☐☐☐ **OR** Year ☐☐☐☐ (If only year is known)

2. Gender: 1 ☐ Male 2 ☐ Female

3. Last type of school completed

0 ☐ No formal education completed
1 ☐ Primary school
2 ☐ Junior high
3 ☐ High school
4 ☐ Vocational school
5 ☐ University

B. Clinical Information

1. Weight: ☐☐☐.☐ kg

2. Height: ☐☐☐.☐ cm

3. Blood pressure: ☐☐☐/☐☐☐ mmHg (SBP/DBP)

4. Pulse: ☐☐☐ beats per minute

5. Body temperature: ☐☐.☐ °C

6. Outcome of today's pregnancy test:

0 ☐ Negative
1 ☐ Positive
2 ☐ Not applicable (Male or female without child bearing potential)

C. Review of Systems

For each system, indicate whether the volunteer is experiencing any of the indicated symptoms.

1. Constitutional

0 ☐ No
1 ☐ Yes →

Mark all that apply

1 ☐ Fever
1 ☐ Chills
1 ☐ Night sweats
1 ☐ Weight loss
1 ☐ Weight gain
1 ☐ Fatigue

2. Ears, nose and throat

0 ☐ No
1 ☐ Yes →

1 ☐ Decreased hearing
1 ☐ Tinnitus
1 ☐ Pain
1 ☐ Discharge from ear
1 ☐ Discharge from nose
1 ☐ Hoarseness
1 ☐ Nose bleeds

3. Breast

0 ☐ No
1 ☐ Yes →

1 ☐ Lumps
1 ☐ Nipple discharge
1 ☐ Pain

Attach a PID label here:

Prevail III

Mark all that apply

4. Cardiovascular
- 0 No
- 1 Yes →
  - 1 Palpitations
  - 1 Chest pain
  - 1 Shortness of breath
  - 1 Paroxysmal nocturnal dyspnea
  - 1 Orthopnea
  - 1 Claudication (leg pain with walking)
  - 1 Edema

5. Respiratory
- 0 No
- 1 Yes →
  - 1 Wheezing
  - 1 Dyspnea
  - 1 Cough/sputum
  - 1 Hemoptysis
  - 1 Positive TB skin test
  - 1 Congestion

6. Gastrointestinal
- 0 No
- 1 Yes →
  - 1 Dysphagia
  - 1 Anorexia
  - 1 Nausea
  - 1 Vomiting
  - 1 Hematemesis
  - 1 Diarrhea
  - 1 Melena
  - 1 Rectal bleeding
  - 1 Change in bowel habits
  - 1 Jaundice
  - 1 Abdominal pain

7. Genito-urinary
- 0 No
- 1 Yes →
  - 1 Dysuria
  - 1 Hematuria
  - 1 Frequency
  - 1 Polyuria
  - 1 Urgency
  - 1 Hesitancy
  - 1 Incontinence
  - 1 Nocturia

8. Male reproductive
- 0 No
- 1 Yes →
  - 1 Penile discharge
  - 1 Testicular pain or mass
  - 1 Infertility
  - 1 Impotence/decreased libido
  - 1 Orchitis (pain in groin)
- 2 N/A

9. Female reproductive
- 0 No
- 1 Yes →
  - 1 Menarche
  - 1 Menopause
  - 1 Postmenopausal symptoms
  - 1 Painful periods
  - 1 Odor
  - 1 Decreased libido
  - 1 Amenorrhea
  - 1 Abnormal vaginal bleeding
- 2 N/A

10. Musculoskeletal
- 0 No
- 1 Yes →
  - 1 Joint pain (mono or polyarticular)
  - 1 Edema
  - 1 Heat
  - 1 Redness
  - 1 Stiffness
  - 1 Deformity
  - 1 Muscle pain or tenderness

Attach a PID label here:

Prevail III

Mark all that apply

11. Neurological
0 ☐ No
1 ☐ Yes →
- 1 ☐ Headache
- 1 ☐ Syncope
- 1 ☐ Dizziness
- 1 ☐ Vertigo
- 1 ☐ Seizures
- 1 ☐ Loss of vision
- 1 ☐ Diplopia
- 1 ☐ Paresthesia
- 1 ☐ Paralysis
- 1 ☐ Weakness in any limbs
- 1 ☐ Tremor
- 1 ☐ Ataxia (balance problem)
- 1 ☐ Memory loss

12. Skin
0 ☐ No
1 ☐ Yes →
- 1 ☐ Itching
- 1 ☐ Rash
- 1 ☐ Lumps and/or bumps
- 1 ☐ Hair and/or nail change
- 1 ☐ Depigmentation
- 1 ☐ Bruising

13. Lymphatic
0 ☐ No
1 ☐ Yes →
- 1 ☐ Enlargement of lymph nodes

D. Medical History

1. Based on the medical history available and the physical examination, record whether the volunteer has **EVER** experienced any of the following:

0 ☐ None of the following

OR

- 1 ☐ a. Hypertension
- 1 ☐ b. Stroke
- 1 ☐ c. Ischemic heart disease
- 1 ☐ d. Diabetes mellitus
- 1 ☐ e. Cancer; specify: _____
- 1 ☐ f. Tuberculosis
- 1 ☐ g. Malaria
- 1 ☐ h. Syphilis or other STD
- 1 ☐ i. HIV/AIDS
- 1 ☐ j. Hepatitis B
- 1 ☐ k. Hepatitis C
- 1 ☐ l. Typhoid fever

E. Pregnancy History - complete for girls and women ≥12 years of age

1. Excluding the current pregnancy (if applicable) how many times does the volunteer report:

	Pregnancies
a. Being pregnant?	☐☐ **If 0, go to Section F.**
b. Pregnancies resulting in live births?	☐☐
c. Pregnancies resulting in still birth or fetal demise (IUFD ≥ 20 weeks)?	☐☐
d. Pregnancies resulting in spontaneous abortion (IUFD < 20 weeks)?	☐☐
e. Pregnancies resulting in induced abortion?	☐☐

Note: include pregnancy before and after EVD, if applicable.

Attach a PID label here:

Prevail III

F. Post Traumatic Stress - complete for volunteers ≥ 12 years of age.
Ask the volunteer to consider the following reactions which sometimes occur after a traumatic event. Read each response and ask whether the volunteer experienced it AT LEAST TWICE IN THE PAST WEEK.

	No	Yes , at least twice in the past week
1. Upsetting thoughts or memories about the event that have come into your mind against your will.	0 ☐	1 ☐
2. Upsetting dreams about the event.	0 ☐	1 ☐
3. Acting or feeling as though the event were happening again.	0 ☐	1 ☐
4. Feeling upset by reminders of the event.	0 ☐	1 ☐
5. Bodily reactions (such as fast heartbeat, stomach churning, sweatiness, dizziness) when reminded of the event.	0 ☐	1 ☐
6. Difficulty falling or staying asleep.	0 ☐	1 ☐
7. Irritability or outbursts of anger.	0 ☐	1 ☐
8. Difficulty concentrating.	0 ☐	1 ☐
9. Heightened awareness of potential dangers to yourself and others. (Have you been more concerned or worried about bad things happening to you or you family?)	0 ☐	1 ☐
10. Being jumpy or being startled at something unexpected. (Have you been scared or frightened by something unusual?)	0 ☐	1 ☐

G. Depression - complete for volunteers ≥ 12 years of age.
Read the following questions to the volunteer."During the PAST TWO WEEKS, how often have you been bothered by any of the following?"

	Not at all	Several days (≤ 7 days)	More than half the days (8-11 days)	Nearly every day (≥ 12 days)
1. Little interest or pleasure in doing things.	0 ☐	1 ☐	2 ☐	3 ☐
2. Feeling down, depressed, or hopeless.	0 ☐	1 ☐	2 ☐	3 ☐
3. Trouble falling or staying asleep, or sleeping too much.	0 ☐	1 ☐	2 ☐	3 ☐
4. Feeling tired or having little energy.	0 ☐	1 ☐	2 ☐	3 ☐
5. Poor appetite or overeating.	0 ☐	1 ☐	2 ☐	3 ☐
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down.	0 ☐	1 ☐	2 ☐	3 ☐
7. Trouble concentrating on things, such as reading the newspaper or watching television.	0 ☐	1 ☐	2 ☐	3 ☐
8. Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual.	0 ☐	1 ☐	2 ☐	3 ☐
9. Thoughts that you would be better off dead, or of hurting yourself.	0 ☐	1 ☐	2 ☐	3 ☐

10. If you had any of these problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

0 ☐ Not difficult at all
1 ☐ Somewhat difficult
2 ☐ Very difficult
3 ☐ Extremely difficult

Complete only if any problems are indicated above.

Attach a PID label here:

H. Medications

Ask whether the volunteer takes any of the following types of drugs daily:

	No	Yes
1. Insulin	0 ☐	1 ☐
2. Oral hypoglycemic agents for diabetes	0 ☐	1 ☐
3. Blood pressure lowering drugs	0 ☐	1 ☐
4. Drugs for HIV	0 ☐	1 ☐
5. Amphetamines or other stimulants	0 ☐	1 ☐
6. Librium, Valium or other anti-anxiety agents	0 ☐	1 ☐
7. Acetaminophen	0 ☐	1 ☐
8. Non-steroidal anti-inflammatory agents (excludes aspirin)	0 ☐	1 ☐
9. Aspirin	0 ☐	1 ☐

I. Vision Screening

1. Was vision screening performed?

1 ☐ No → 2. Reason:_____

2 ☐ Yes

Go to Question 5.

3. Method of acuity testing

1 ☐ 10 foot lane
2 ☐ Smart phone
3 ☐ Other; specify: _____

4. Presenting vision

a. Right eye: 20/ ☐☐☐

b. Left eye: 20/ ☐☐☐

Note: Have the volunteer wear their distance glasses, if applicable. Record 999 if the volunteer cannot read the largest character.

c. Was this vision measured wearing spectacles?

0 ☐ No 1 ☐ Yes

Attach a PID label here:

5. Ask the volunteer, "Do you currently have any of the following eye problems?"

a. Blurry vision
0 ☐ No
1 ☐ Yes

b. Pain in eye
0 ☐ No
1 ☐ Yes

c. Sensitivity to light
0 ☐ No
1 ☐ Yes

d. Eye redness
0 ☐ No
1 ☐ Yes

e. Discharge from eye
0 ☐ No
1 ☐ Yes

f. Itchy eyes
0 ☐ No
1 ☐ Yes

g. Other; specify:_____
0 ☐ No
1 ☐ Yes

6. Will the volunteer be referred to the eye clinic at JFK?

0 ☐ No

1 ☐ Yes →

7. Reason (mark all that apply):
1 ☐ a. Vision (presenting vision worse than 20/25, e.g., 20/32)
1 ☐ b. Self-reported current eye problem
1 ☐ c. Self-reported eye problem that developed during or after EVD event (even if currently resolved)
1 ☐ d. Eye abnormality detected upon physical exam
1 ☐ e. No eye problem but referred by staff

2 ☐ Volunteer unwilling or unable to attend eye clinic

8. Pinhole test — Perform for each eye with vision testing (see question I.4) worse than 20/25 (e.g., 20/32).

a. Right eye: 20/ ☐☐☐

b. Left eye: 20/ ☐☐☐

Note: Have the volunteer wear their distance glasses, if applicable. Record 999 if the volunteer cannot read the largest character.

J. Physical Exam

1. Head/face
1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

2. Mark all that apply.
1 ☐ Deformity
1 ☐ Asymmetry
1 ☐ Swelling
1 ☐ Other; specify:_____

3. Eyes
1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

4. Refer to eye clinic;
reason: _____

Attach a PID label here:

5. Ears, nose and throat

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

6a. Nose (Mark all that apply)
1 ☐ Deformity/mass
1 ☐ Mucosa
1 ☐ Ulcer
1 ☐ Other; specify: _____

6b. Ear (Mark all that apply)
1 ☐ TM
1 ☐ Ext. canal
1 ☐ Hearing
1 ☐ Other; specify: _____

6c. Mouth/throat (Mark all that apply)
1 ☐ Mucosa
1 ☐ Mass
1 ☐ Ulcer
1 ☐ Missing teeth
1 ☐ Dental caries
1 ☐ Other; specify: _____

7. Chest

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

8. Mark all that apply.
1 ☐ Wheezes
1 ☐ Decreased breath sounds
1 ☐ Heart murmur
1 ☐ Pericardial rub
1 ☐ Rales/crackles
1 ☐ Other; specify: _____

9. Abdomen

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

10. Mark all that apply.
1 ☐ Splenomegaly
1 ☐ Hepatomegaly
1 ☐ Mass
1 ☐ Tenderness
1 ☐ Distension
1 ☐ Other; specify: _____

11. Extremities

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

12. Mark all that apply.
1 ☐ Deformity
1 ☐ Edema
1 ☐ Cyanosis
1 ☐ Decreased pulse
1 ☐ Bruit
1 ☐ Other; specify: _____

13. Musculoskelatal

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

14a. Muscles (Mark all that apply)
1 ☐ Atrophy
1 ☐ Weakness
1 ☐ Tenderness
1 ☐ Other; specify: _____

14b. Joints (Mark all that apply)
1 ☐ Swelling/effusion
1 ☐ Synovial tenderness
1 ☐ Deformity
1 ☐ Decreased ROM
1 ☐ Other; specify: _____

Attach a PID label here:

15. Neurologic

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

16. Mark all that apply

1 ☐ Cognition
1 ☐ Speech
1 ☐ Tremor
1 ☐ Reflexes
1 ☐ Cranial nerve(s)
1 ☐ Focal weakness
1 ☐ Gait/balance
1 ☐ Sensory
1 ☐ Other; specify:_____

17. Skin

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

18. Mark all that apply.

1 ☐ Rash
1 ☐ Mass
1 ☐ Lesion
1 ☐ Jaundice
1 ☐ Pigmentation
1 ☐ Other; specify:_____

19. Breast

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

20. Mark all that apply.

1 ☐ Mass
1 ☐ Skin retraction
1 ☐ Nipple discharge
1 ☐ Other; specify:_____

Record any additional notes on the Clinical Notes Worksheet.

K. Outcome

1. Will the volunteer be referred to medical care?

0 ☐ No
1 ☐ Yes →

2. Referral to: _____

3. Reason: _____

Signature: _____ Date: _____

Visit 2 (6 Months)

Attach a PID label here:

Date of Visit:
(example: 01-SEP-2016)
Day ___ Month ___ Year 2 0 1 ___

Participant Initials: _____

Site: ___

Complete this form for volunteers enrolled in the Ebola Natural History Study. If the volunteer is < 12 years old, also complete the Pediatric Supplement form.

A. Clinical Information

1. Weight: ___.___ kg

2. Height: ___.___ cm
Complete for volunteers <18 years

3. Blood pressure: ___/___ mmHg (SBP/DBP)

4. Pulse: ___ beats per minute

5. Body temperature: ___.___ °C

6. Outcome of today's pregnancy test:
- 0 ☐ Negative
- 1 ☐ Positive
- 2 ☐ Not applicable (Male or female without child bearing potential)

B. Review of Systems

For each system, indicate whether the volunteer is experiencing any of the indicated symptoms.

		Mark all that apply	
1. Constitutional	0 ☐ No 1 ☐ Yes →	1 ☐ Fever 1 ☐ Chills	1 ☐ Unusual night sweats 1 ☐ Fatigue
2. Ears, nose and throat	0 ☐ No 1 ☐ Yes →	1 ☐ Decreased hearing 1 ☐ Tinnitus 1 ☐ Pain 1 ☐ Discharge from ear	1 ☐ Discharge from nose 1 ☐ Hoarseness 1 ☐ Nose bleeds
3. Breast	0 ☐ No 1 ☐ Yes →	1 ☐ Lumps 1 ☐ Nipple discharge	1 ☐ Pain
4. Cardiovascular	0 ☐ No 1 ☐ Yes →	1 ☐ Palpitations 1 ☐ Chest pain 1 ☐ Shortness of breath 1 ☐ Paroxysmal nocturnal dyspnea	1 ☐ Orthopnea 1 ☐ Claudication (leg pain with walking) 1 ☐ Edema
5. Respiratory	0 ☐ No 1 ☐ Yes →	1 ☐ Wheezing 1 ☐ Dyspnea 1 ☐ Cough/sputum	1 ☐ Hemoptysis 1 ☐ Positive TB skin test 1 ☐ Nasal congestion
6. Gastrointestinal	0 ☐ No 1 ☐ Yes →	1 ☐ Dysphagia 1 ☐ Anorexia 1 ☐ Nausea 1 ☐ Vomiting 1 ☐ Hematemesis 1 ☐ Diarrhea	1 ☐ Melena 1 ☐ Rectal bleeding 1 ☐ Change in bowel habits 1 ☐ Jaundice 1 ☐ Abdominal pain

Attach a PID label here:

Prevail III

Mark all that apply

7. Genito-urinary

0 ☐ No
1 ☐ Yes →

- 1 ☐ Dysuria
- 1 ☐ Hematuria
- 1 ☐ Frequency
- 1 ☐ Polyuria
- 1 ☐ Urgency
- 1 ☐ Hesitancy
- 1 ☐ Incontinence
- 1 ☐ Nocturia

8. Male reproductive

0 ☐ No
1 ☐ Yes →
2 ☐ N/A

- 1 ☐ Penile discharge
- 1 ☐ Testicular pain or mass
- 1 ☐ Infertility
- 1 ☐ Impotence/decreased libido
- 1 ☐ Orchitis (pain in groin)

9. Female reproductive

0 ☐ No
1 ☐ Yes →
2 ☐ N/A

- 1 ☐ Menarche
- 1 ☐ Menopause
- 1 ☐ Postmenopausal symptoms
- 1 ☐ Painful periods
- 1 ☐ Odor
- 1 ☐ Decreased libido
- 1 ☐ Amenorrhea
- 1 ☐ Abnormal vaginal bleeding

10. Musculoskeletal

0 ☐ No
1 ☐ Yes →

- 1 ☐ Joint pain (mono or polyarticular)
- 1 ☐ Edema
- 1 ☐ Heat
- 1 ☐ Redness
- 1 ☐ Stiffness
- 1 ☐ Deformity
- 1 ☐ Muscle pain or tenderness

11. Neurological

0 ☐ No
1 ☐ Yes →

- 1 ☐ Headache
- 1 ☐ Syncope
- 1 ☐ Dizziness
- 1 ☐ Vertigo
- 1 ☐ Seizures
- 1 ☐ Loss of vision
- 1 ☐ Diplopia
- 1 ☐ Paresthesia
- 1 ☐ Paralysis
- 1 ☐ Weakness in any limbs
- 1 ☐ Tremor
- 1 ☐ Ataxia (balance problem)
- 1 ☐ Memory loss

12. Skin

0 ☐ No
1 ☐ Yes →

- 1 ☐ Itching
- 1 ☐ Rash
- 1 ☐ Lumps and/or bumps
- 1 ☐ Hair and/or nail change
- 1 ☐ Depigmentation
- 1 ☐ Bruising

13. Lymphatic

0 ☐ No
1 ☐ Yes →

- 1 ☐ Enlargement of lymph nodes

Visit 2 (6 Months)

Attach a PID label here:

C. Diagnoses Since Baseline

1. Were any of the following conditions diagnosed by a physician or health care worker since the volunteer enrolled in PREVAIL III?

	No	Yes	Date of Diagnosis (e.g., MAY 2016) Month	Year
a. Diabetes (requiring insulin or oral hypoglycemic drugs)	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
b. Malaria	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
c. Tuberculosis	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
d. Typhoid fever	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
e. Pneumonia	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
f. Urinary tract infection	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
g. Hypertension	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
h. Renal failure	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
i. Stroke	0 ☐	1 ☐	☐☐☐	2 0 1 ☐

2. Has the volunteer been hospitalized since the baseline visit?

0 ☐ No
1 ☐ Yes → 3. Reason: _____

D. Sexual Activity - Complete this section for volunteers aged 12 and older.

1. Has the volunteer been sexually active since the last visit?

0 ☐ No
1 ☐ Yes → 2. Since the last visit, how often was a condom used during intercourse?
0 ☐ Never 1 ☐ Sometimes 2 ☐ Always

E. Reproductive History - Females

1. Has the volunteer had a pregnancy outcome since the baseline visit? (ask volunteers of child-bearing potential)

0 ☐ No
1 ☐ Yes → **Complete a Pregnancy Outcome form to document the outcome of this pregnancy.**

2. Is the volunteer currently using any hormonal contraceptive method other than condoms?

0 ☐ No
1 ☐ Yes → 3. Mark all that apply:
1 ☐ Injectable 1 ☐ Oral medication
1 ☐ Implant 1 ☐ Other; specify: _____
2 ☐ Not applicable

4. Was the volunteer asked if she would be willing to provide a vaginal specimen?

0 ☐ No
1 ☐ Yes → 5. Is the volunteer willing to provide this specimen?
0 ☐ No 1 ☐ Yes → **Perform or schedule a vaginal secretion collection visit.**

Attach a PID label here:

F. Reproductive History - Males

Complete this section for every male volunteer aged 18 years and older.

1. Did your wife or partner experience a pregnancy since enrollment?

0 ☐ No
1 ☐ Yes
2 ☐ Not applicable

2. Was the volunteer asked if he would be willing to provide a semen sample?

0 ☐ No
1 ☐ Yes → 3. Is the volunteer willing to provide this specimen?
  0 ☐ No
  1 ☐ Yes → **Perform or schedule a semen collection visit.**

G. Vision Screening

1. Was vision screening performed?

1 ☐ No → 2. Reason:_____
2 ☐ Yes

Go to Section H.

3. Method of acuity testing

1 ☐ 10 foot lane
2 ☐ Smart phone
3 ☐ Other; specify: _____

4. Presenting vision

a. Right eye: 20/ ☐☐☐
b. Left eye: 20/ ☐☐☐

Note: Have the volunteer wear their distance glasses, if applicable. Record 999 if the volunteer cannot read the largest character.

c. Was this vision measured wearing spectacles?

0 ☐ No 1 ☐ Yes

5. Pinhole test — Perform for each eye with vision testing (see question G.4) worse than 20/40.

a. Right eye: 20/ ☐☐☐
b. Left eye: 20/ ☐☐☐

Note: Have the volunteer wear their distance glasses, if applicable. Record 999 if the volunteer cannot read the largest character.

6. Regarding the best vision, either presenting or pinhole:

1 ☐ Both eyes are 20/40 or better
2 ☐ At least one eye is worse than 20/40 but vision has not decreased since baseline
3 ☐ At least one eye is worse than 20/40 and vision has decreased since baseline

Attach a PID label here:

7. Ask the volunteer, "Do you currently have any of the following eye problems?"

a. Blurry vision
0 ☐ No
1 ☐ Yes

b. Pain in eye
0 ☐ No
1 ☐ Yes

c. Sensitivity to light
0 ☐ No
1 ☐ Yes

d. Eye redness
0 ☐ No
1 ☐ Yes

e. Itchy eyes
0 ☐ No
1 ☐ Yes

f. Other; specify: _____
0 ☐ No
1 ☐ Yes

H. Physical Exam

1. Head/face
1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

2. Mark all that apply.
1 ☐ Deformity
1 ☐ Asymmetry
1 ☐ Swelling
1 ☐ Other; specify: _____

3. Eyes
1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

4. Mark all that apply:
1 ☐ Eye redness
1 ☐ Other; specify: _____
1 ☐ Pupil abnormality

5. Ears, nose and throat
1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

6a. Nose (Mark all that apply)
1 ☐ Deformity/mass
1 ☐ Mucosa
1 ☐ Ulcer
1 ☐ Other; specify: _____

6b. Ear (Mark all that apply)
1 ☐ TM
1 ☐ Ext. canal
1 ☐ Hearing
1 ☐ Other; specify: _____

6c. Mouth/throat (Mark all that apply)
1 ☐ Mucosa
1 ☐ Mass
1 ☐ Ulcer
1 ☐ Missing teeth
1 ☐ Dental caries
1 ☐ Other; specify: _____

7. Chest
1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

8. Mark all that apply.
1 ☐ Wheezes
1 ☐ Pericardial rub
1 ☐ Decreased breath sounds
1 ☐ Rales/crackles
1 ☐ Heart murmur
1 ☐ Other; specify: _____

Attach a PID label here:

9. Abdomen
- 1 ☐ Normal
- 2 ☐ Abnormal →
- 3 ☐ Not done

10. Mark all that apply.
- 1 ☐ Splenomegaly
- 1 ☐ Hepatomegaly
- 1 ☐ Mass
- 1 ☐ Tenderness
- 1 ☐ Distension
- 1 ☐ Other; specify:_____

11. Extremities
- 1 ☐ Normal
- 2 ☐ Abnormal →
- 3 ☐ Not done

12. Mark all that apply.
- 1 ☐ Deformity
- 1 ☐ Edema
- 1 ☐ Cyanosis
- 1 ☐ Decreased pulse
- 1 ☐ Bruit
- 1 ☐ Other; specify:_____

13. Musculoskelatal
- 1 ☐ Normal
- 2 ☐ Abnormal →
- 3 ☐ Not done

14a. Muscles (Mark all that apply)
- 1 ☐ Atrophy
- 1 ☐ Weakness
- 1 ☐ Tenderness
- 1 ☐ Other; specify:

_____

14b. Joints (Mark all that apply)
- 1 ☐ Swelling/effusion
- 1 ☐ Synovial tenderness
- 1 ☐ Deformity
- 1 ☐ Decreased ROM
- 1 ☐ Other; specify:

_____

15. Neurologic
- 1 ☐ Normal
- 2 ☐ Abnormal →
- 3 ☐ Not done

16. Mark all that apply
- 1 ☐ Cognition
- 1 ☐ Speech
- 1 ☐ Tremor
- 1 ☐ Reflexes
- 1 ☐ Cranial nerve(s)
- 1 ☐ Focal weakness
- 1 ☐ Gait/balance
- 1 ☐ Sensory
- 1 ☐ Other; specify:_____

17. Skin
- 1 ☐ Normal
- 2 ☐ Abnormal →
- 3 ☐ Not done

18. Mark all that apply.
- 1 ☐ Rash
- 1 ☐ Mass
- 1 ☐ Lesion
- 1 ☐ Jaundice
- 1 ☐ Pigmentation
- 1 ☐ Other; specify:_____

19. Breast
- 1 ☐ Normal
- 2 ☐ Abnormal →
- 3 ☐ Not done

20. Mark all that apply.
- 1 ☐ Mass
- 1 ☐ Skin retraction
- 1 ☐ Nipple discharge
- 1 ☐ Other; specify:_____

Visit 2 (6 Months)

Attach a PID label here:

I. Specimen Documentation

Note: Blood samples are optional for volunteers < 12 years of age.

1. Were the following specimens obtained:

a. Blood 0 ☐ No 1 ☐ Yes →

b. Urine 0 ☐ No 1 ☐ Yes →

Kit Number Label here:

Place 2nd Kit Number label here, if a 2nd kit is used:

2. Has the volunteer had anything to eat or drink (other than water) in the past 8 hours?

0 ☐ No
1 ☐ Yes

J. Outcome

Participants who are part of the longitudinal cohort should be referred to the JFK eye clinic for all new eye abnormalities. The longitudinal cohort is defined as all participants enrolled at JFK on or before March 31, 2016, and seen for a baseline eye exam on or before June 30, 2016.

1. Will the volunteer be referred to an eye clinic?

0 ☐ No
1 ☐ Yes, JFK →

2. Reason (Mark all that apply):
   - 1 ☐ Vision worse than 20/40 in either eye and decreased since baseline
   - 1 ☐ Eye abnormality upon physical exam
   - 1 ☐ Referred by staff, reason: _____

2 ☐ Yes, other eye clinic →

3. Reason: _____

4. Will the volunteer be referred for other medical care?

0 ☐ No
1 ☐ Yes →

5. Reason: _____

Signature: _____ Date: _____

Visit 3 (12 Months)

Attach a PID label here:

Date of Visit:
(example: 01-SEP-2018)

Day ___ Month ___ Year 2 0 1 ___

Participant Initials: _____

Site: ___

Complete this form for volunteers enrolled in the Ebola Natural History Study. If the volunteer is < 12 years old, also complete the Pediatric Supplement form.

A. Clinical Information

1. Weight: ___.___ kg

2. Height: ___.___ cm
Complete for volunteers <18 years

3. Blood pressure: ___/___ mmHg (SBP/DBP)

4. Pulse: ___ beats per minute

5. Body temperature: ___.___ °C

6. Outcome of today's pregnancy test:
- 0 ☐ Negative
- 1 ☐ Positive
- 2 ☐ Not applicable (Male or female without child bearing potential)

B. Review of Systems

For each system, indicate whether the volunteer is experiencing any of the indicated symptoms.

Mark all that apply

1. Constitutional
- 0 ☐ No
- 1 ☐ Yes →
  - 1 ☐ Fever
  - 1 ☐ Chills
  - 1 ☐ Unusual night sweats
  - 1 ☐ Fatigue

2. Ears, nose and throat
- 0 ☐ No
- 1 ☐ Yes →
  - 1 ☐ Decreased hearing
  - 1 ☐ Tinnitus
  - 1 ☐ Pain
  - 1 ☐ Discharge from ear
  - 1 ☐ Discharge from nose
  - 1 ☐ Hoarseness
  - 1 ☐ Nose bleeds

3. Breast
- 0 ☐ No
- 1 ☐ Yes →
  - 1 ☐ Lumps
  - 1 ☐ Nipple discharge
  - 1 ☐ Pain

4. Cardiovascular
- 0 ☐ No
- 1 ☐ Yes →
  - 1 ☐ Palpitations
  - 1 ☐ Chest pain
  - 1 ☐ Shortness of breath
  - 1 ☐ Paroxysmal nocturnal dyspnea
  - 1 ☐ Orthopnea
  - 1 ☐ Claudication (leg pain with walking)
  - 1 ☐ Edema

5. Respiratory
- 0 ☐ No
- 1 ☐ Yes →
  - 1 ☐ Wheezing
  - 1 ☐ Dyspnea
  - 1 ☐ Cough/sputum
  - 1 ☐ Hemoptysis
  - 1 ☐ Positive TB skin test
  - 1 ☐ Nasal congestion

6. Gastrointestinal
- 0 ☐ No
- 1 ☐ Yes →
  - 1 ☐ Dysphagia
  - 1 ☐ Anorexia
  - 1 ☐ Nausea
  - 1 ☐ Vomiting
  - 1 ☐ Hematemesis
  - 1 ☐ Diarrhea
  - 1 ☐ Melena
  - 1 ☐ Rectal bleeding
  - 1 ☐ Change in bowel habits
  - 1 ☐ Jaundice
  - 1 ☐ Abdominal pain

Attach a PID label here:

Prevail III

Mark all that apply

7. Genito-urinary

0 ☐ No
1 ☐ Yes →

- 1 ☐ Dysuria
- 1 ☐ Hematuria
- 1 ☐ Frequency
- 1 ☐ Polyuria
- 1 ☐ Urgency
- 1 ☐ Hesitancy
- 1 ☐ Incontinence
- 1 ☐ Nocturia

8. Male reproductive

0 ☐ No
1 ☐ Yes →
2 ☐ N/A

- 1 ☐ Penile discharge
- 1 ☐ Testicular pain or mass
- 1 ☐ Infertility
- 1 ☐ Impotence/decreased libido
- 1 ☐ Orchitis (pain in groin)

9. Female reproductive (check "N/A" for volunteers <12 years of age)

0 ☐ No
1 ☐ Yes →
2 ☐ N/A

- 1 ☐ Menarche
- 1 ☐ Menopause
- 1 ☐ Postmenopausal symptoms
- 1 ☐ Painful periods
- 1 ☐ Odor
- 1 ☐ Decreased libido
- 1 ☐ Amenorrhea
- 1 ☐ Abnormal vaginal bleeding

10. Musculoskeletal

0 ☐ No
1 ☐ Yes →

- 1 ☐ Joint pain (mono or polyarticular)
- 1 ☐ Edema
- 1 ☐ Heat
- 1 ☐ Redness
- 1 ☐ Stiffness
- 1 ☐ Deformity
- 1 ☐ Muscle pain or tenderness

11. Neurological

0 ☐ No
1 ☐ Yes →

- 1 ☐ Headache
- 1 ☐ Syncope
- 1 ☐ Dizziness
- 1 ☐ Vertigo
- 1 ☐ Seizures
- 1 ☐ Loss of vision
- 1 ☐ Diplopia
- 1 ☐ Paresthesia
- 1 ☐ Paralysis
- 1 ☐ Weakness in any limbs
- 1 ☐ Tremor
- 1 ☐ Ataxia (balance problem)
- 1 ☐ Memory loss

12. Skin

0 ☐ No
1 ☐ Yes →

- 1 ☐ Itching
- 1 ☐ Rash
- 1 ☐ Lumps and/or bumps
- 1 ☐ Hair and/or nail change
- 1 ☐ Depigmentation
- 1 ☐ Bruising

13. Lymphatic

0 ☐ No
1 ☐ Yes →

- 1 ☐ Enlargement of lymph nodes

Visit 3 (12 Months)

Attach a PID label here:

C. Diagnoses Since Last Visit

1. Were any of the following conditions diagnosed by a physician or health care worker since the volunteer's last study visit?

	No	Yes	Date of Diagnosis (e.g., MAY 2018) Month	Year
a. Diabetes (requiring insulin or oral hypoglycemic drugs)	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
b. Malaria	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
c. Tuberculosis	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
d. Typhoid fever	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
e. Pneumonia	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
f. Urinary tract infection	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
g. Hypertension	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
h. Renal failure	0 ☐	1 ☐	☐☐☐	2 0 1 ☐
i. Stroke	0 ☐	1 ☐	☐☐☐	2 0 1 ☐

2. Has the volunteer been hospitalized since the last study visit?

0 ☐ No
1 ☐ Yes → 3. Reason: _____

D. Sexual Activity - Complete this section for volunteers aged 12 and older.

1. Has the volunteer been sexually active since the last visit?

0 ☐ No
1 ☐ Yes → 2. Since the last visit, how often was a condom used during intercourse?
0 ☐ Never 1 ☐ Sometimes 2 ☐ Always

E. Reproductive History - Females

1. Has the volunteer had a pregnancy outcome since the last study visit? (ask volunteers of child-bearing potential)

0 ☐ No
1 ☐ Yes → **Complete a Pregnancy Outcome form to document the outcome of this pregnancy.**

2. Is the volunteer currently using any hormonal contraceptive method other than condoms?

0 ☐ No
1 ☐ Yes → 3. Mark all that apply:
1 ☐ Injectable 1 ☐ Oral medication
1 ☐ Implant 1 ☐ Other; specify: _____
2 ☐ Not applicable

4. Was the volunteer asked if she would be willing to provide a vaginal specimen?

0 ☐ No
1 ☐ Yes → 5. Is the volunteer willing to provide this specimen?
0 ☐ No 1 ☐ Yes → **Perform or schedule a vaginal secretion collection visit.**

Attach a PID label here:

F. Reproductive History - Males

Complete this section for every male volunteer aged 18 years and older.

1. Did your wife or partner experience a pregnancy since enrollment?
   - 0 ☐ No
   - 1 ☐ Yes
   - 2 ☐ Not applicable

2. Was the volunteer asked if he would be willing to provide a semen sample?
   - 0 ☐ No
   - 1 ☐ Yes → 3. Is the volunteer willing to provide this specimen?
     - 0 ☐ No
     - 1 ☐ Yes → **Perform or schedule a semen collection visit.**

G. Medications

Ask whether the volunteer takes any of the following types of drugs daily:

	No	Yes
1. Insulin	0 ☐	1 ☐
2. Oral hypoglycemic agents for diabetes	0 ☐	1 ☐
3. Blood pressure lowering drugs	0 ☐	1 ☐
4. Drugs for HIV	0 ☐	1 ☐
5. Amphetamines or other stimulants	0 ☐	1 ☐
6. Librium, Valium or other anti-anxiety agents	0 ☐	1 ☐
7. Acetaminophen	0 ☐	1 ☐
8. Non-steroidal anti-inflammatory agents (excludes aspirin)	0 ☐	1 ☐
9. Aspirin	0 ☐	1 ☐

H. Vision Screening

1. Was vision screening performed?
   - 1 ☐ No → 2. Reason:_____ **Go to Section I.**
   - 2 ☐ Yes

3. Method of acuity testing
   - 1 ☐ 10 foot lane
   - 2 ☐ Smart phone
   - 3 ☐ Other; specify: _____

Attach a PID label here:

4. Presenting vision

a. Right eye: 20/ ☐☐☐

b. Left eye: 20/ ☐☐☐

Note: Have the volunteer wear their distance glasses, if applicable. Record 999 if the volunteer cannot read the largest character.

c. Was this vision measured wearing spectacles?

0 ☐ No 1 ☐ Yes

5. Pinhole test Perform for each eye with vision testing (see question H.4) worse than 20/40.

a. Right eye: 20/ ☐☐☐

b. Left eye: 20/ ☐☐☐

Note: Have the volunteer wear their distance glasses, if applicable. Record 999 if the volunteer cannot read the largest character.

6. Regarding the best vision, either presenting or pinhole:

1 ☐ Both eyes are 20/40 or better

2 ☐ At least one eye is worse than 20/40 but vision is not worse than the last reported vision

3 ☐ At least one eye is worse than 20/40 and vision is worse than the last reported vision

7. Ask the volunteer, "Do you currently have any of the following eye problems?"

a. Blurry vision
0 ☐ No
1 ☐ Yes

b. Pain in eye
0 ☐ No
1 ☐ Yes

c. Sensitivity to light
0 ☐ No
1 ☐ Yes

d. Eye redness
0 ☐ No
1 ☐ Yes

e. Itchy eyes
0 ☐ No
1 ☐ Yes

f. Other; specify: _____
0 ☐ No
1 ☐ Yes

Visit 3 (12 Months)

Attach a PID label here:

I. Physical Exam

1. Head/face
   - 1 ☐ Normal
   - 2 ☐ Abnormal →
   - 3 ☐ Not done

2. Mark all that apply.
   - 1 ☐ Deformity
   - 1 ☐ Asymmetry
   - 1 ☐ Swelling
   - 1 ☐ Other; specify:_____

3. Eyes
   - 1 ☐ Normal
   - 2 ☐ Abnormal →
   - 3 ☐ Not done

4. Mark all that apply:
   - 1 ☐ Eye redness
   - 1 ☐ Other; specify:_____
   - 1 ☐ Pupil abnormality

5. Ears, nose and throat
   - 1 ☐ Normal
   - 2 ☐ Abnormal →
   - 3 ☐ Not done

6a. Nose (Mark all that apply)
   - 1 ☐ Deformity/mass
   - 1 ☐ Mucosa
   - 1 ☐ Ulcer
   - 1 ☐ Other; specify:

_____

6b. Ear (Mark all that apply)
   - 1 ☐ TM
   - 1 ☐ Ext. canal
   - 1 ☐ Hearing
   - 1 ☐ Other; specify:

_____

6c. Mouth/throat (Mark all that apply)
   - 1 ☐ Mucosa
   - 1 ☐ Mass
   - 1 ☐ Ulcer
   - 1 ☐ Missing teeth
   - 1 ☐ Dental caries
   - 1 ☐ Other; specify:

_____

7. Chest
   - 1 ☐ Normal
   - 2 ☐ Abnormal →
   - 3 ☐ Not done

8. Mark all that apply.
   - 1 ☐ Wheezes
   - 1 ☐ Pericardial rub
   - 1 ☐ Decreased breath sounds
   - 1 ☐ Rales/crackles
   - 1 ☐ Heart murmur
   - 1 ☐ Other; specify:_____

9. Abdomen
   - 1 ☐ Normal
   - 2 ☐ Abnormal →
   - 3 ☐ Not done

10. Mark all that apply.
   - 1 ☐ Splenomegaly
   - 1 ☐ Tenderness
   - 1 ☐ Hepatomegaly
   - 1 ☐ Distension
   - 1 ☐ Mass
   - 1 ☐ Other; specify:_____

11. Extremities
   - 1 ☐ Normal
   - 2 ☐ Abnormal →
   - 3 ☐ Not done

12. Mark all that apply.
   - 1 ☐ Deformity
   - 1 ☐ Decreased pulse
   - 1 ☐ Edema
   - 1 ☐ Bruit
   - 1 ☐ Cyanosis
   - 1 ☐ Other; specify:_____

Attach a PID label here:

13. Musculoskelatal

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

14a. Muscles (Mark all that apply)

1 ☐ Atrophy
1 ☐ Weakness
1 ☐ Tenderness
1 ☐ Other; specify: _____

14b. Joints (Mark all that apply)

1 ☐ Swelling/effusion
1 ☐ Synovial tenderness
1 ☐ Deformity
1 ☐ Decreased ROM
1 ☐ Other; specify: _____

15. Neurologic

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

16. Mark all that apply

1 ☐ Cognition
1 ☐ Speech
1 ☐ Tremor
1 ☐ Reflexes
1 ☐ Cranial nerve(s)
1 ☐ Focal weakness
1 ☐ Gait/balance
1 ☐ Sensory
1 ☐ Other; specify: _____

17. Skin

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

18. Mark all that apply.

1 ☐ Rash
1 ☐ Mass
1 ☐ Lesion
1 ☐ Jaundice
1 ☐ Pigmentation
1 ☐ Other; specify: _____

19. Breast

1 ☐ Normal
2 ☐ Abnormal →
3 ☐ Not done

20. Mark all that apply.

1 ☐ Mass
1 ☐ Skin retraction
1 ☐ Nipple discharge
1 ☐ Other; specify: _____

J. Rheumatology Training

1. Has the doctor performing the physical exam and review of symptoms received NIH-sponsored rheumotology training?

0 ☐ No
1 ☐ Yes

Visit 3 (12 Months)

Attach a PID label here:

K. Specimen Documentation

Note: Blood samples are optional for volunteers < 12 years of age.

1. Were the following specimens obtained:

a. Blood 0 ☐ No 1 ☐ Yes →

b. Urine 0 ☐ No 1 ☐ Yes →

Kit Number Label here:

Place 2nd Kit Number label here, if a 2nd kit is used:

2. Has the volunteer had anything to eat or drink (other than water) in the past 8 hours?

0 ☐ No

1 ☐ Yes

L. Outcome

Participants who are part of the longitudinal cohort should be referred to the JFK eye clinic for all new eye abnormalities. The longitudinal cohort is defined as all participants enrolled at JFK on or before March 31, 2016, and seen for a baseline eye exam on or before June 30, 2016.

1. Will the volunteer be referred to an eye clinic?

0 ☐ No

1 ☐ Yes, JFK →

2. Reason (Mark all that apply):

1 ☐ Vision worse than 20/40 in either eye and decreased since last measurment

1 ☐ Eye abnormality upon physical exam

1 ☐ Referred by staff, reason: _____

2 ☐ Yes, other eye clinic →

3. Reason: _____

4. Will the volunteer be referred for other medical care?

0 ☐ No

1 ☐ Yes →

5. Reason: _____

6. Notes:

Signature: _____ Date: _____

Baseline Ophthalmic Evaluation at JFK

Attach a PID label here:

Visit Date:
(example: 01-APR-2016)
Day ___ Month ___ Year 2 0 1 ___

Participant Initials: _____

PrevailIII

Complete this form for volunteers enrolled in the Ebola Natural History Study. Complete as many fields as possible. Leave non-applicable fields blank.

A. Detailed Eye Survey

Have you had...

a. Condition	b. Eye(s)	c. Specify	d. Onset of 1st occurrence
1. Problems with your eyes?			
0 ☐ No	1 ☐ OD	_____	1 ☐ Prior to EVD event
1 ☐ Yes →	1 ☐ OS	_____	2 ☐ During or after EVD event
			3 ☐ Volunteer is not enrolled as an EVD survivor
2. Eye surgery?			
0 ☐ No	1 ☐ OD	_____	1 ☐ Prior to EVD event
1 ☐ Yes →	1 ☐ OS	_____	2 ☐ During or after EVD event
			3 ☐ Volunteer is not enrolled as an EVD survivor

Indicate any current or past problems with your eyes.

a. Condition	b. Current problem
3. Pain in eye	
0 ☐ No	
1 ☐ Yes, mild →	0 ☐ No
2 ☐ Yes, moderate or severe →	1 ☐ Yes
4. Sensitivity to light	
0 ☐ No	
1 ☐ Yes, mild →	0 ☐ No
2 ☐ Yes, moderate or severe →	1 ☐ Yes
5. Eye redness	
0 ☐ No	
1 ☐ Yes, mild →	0 ☐ No
2 ☐ Yes, moderate or severe →	1 ☐ Yes

a. Condition	b. Current problem
6. Trouble seeing	
0 ☐ No	0 ☐ No
1 ☐ Yes →	1 ☐ Yes
7. Other; specify:	0 ☐ No
_____	1 ☐ Yes

8. Can a visual acuity exam be conducted on BOTH eyes?

0 ☐ No →

9. Reason:

	Eyes Effected OD	Eyes Effected OS
a. Cognition problem	1 ☐	
b. Enucleation	1 ☐	1 ☐
c. Other; specify: _____	1 ☐	1 ☐

If a visual assessment is not possible in EITHER eye, go to section C. If a visual assessment is possible in one eye, go to Section B.

1 ☐ Yes → **Go to Section B.**

Baseline Ophthalmic Evaluation at JFK

Attach a PID label here:

B. Ophthalmic Exam - Part 1

Leave any items that were not assessed blank.

1. Visual acuity (Complete for adults and children for whom VA can be measured. For children in whom visual acuity cannot be measured answer Question 11 on the next page.)

1 ☐ SC
2 ☐ CC

a. Presenting dVA:

OD	OS
20/☐☐☐	20/☐☐☐
OR	**OR**
1 ☐ Count fingers	1 ☐ Count fingers
2 ☐ Hand motion	2 ☐ Hand motion
3 ☐ Light perception	3 ☐ Light perception
4 ☐ No light perception	4 ☐ No light perception

b. Pinhole dVA:

OD	OS
20/☐☐☐	20/☐☐☐
OR	**OR**
1 ☐ Count fingers	1 ☐ Count fingers
2 ☐ Hand motion	2 ☐ Hand motion
3 ☐ Light perception	3 ☐ Light perception
4 ☐ No light perception	4 ☐ No light perception

2. Does the volunteer have an afferent pupillary defect?

0 ☐ No
1 ☐ Yes → 1 ☐ OD, 1 ☐ OS

3. Motility

1 ☐ Full
2 ☐ Restricted: _____

4. Color vision

OD: ☐☐/14
OS: ☐☐/14

5. Alignment:

1 ☐ Normal
2 ☐ Abnormal

6. Confrontational visual fields: (counting fingers in four quadrants):

OD:	OS:
1 ☐ Normal	1 ☐ Normal
2 ☐ Abnormal	2 ☐ Abnormal

7. IOP (mmHg):

OD: ☐☐ OS: ☐☐

Dilated at: _____ *time*

8. Auto-refractor:

Check one:

OD: 1 ☐ - 2 ☐ + ☐☐.☐☐ + ☐.☐☐ x ☐☐☐

OS: 1 ☐ - 2 ☐ + ☐☐.☐☐ + ☐.☐☐ x ☐☐☐

9. Spherical equivalent

a. OD: 1 ☐ - 2 ☐ + ☐☐.☐☐

b. OS: 1 ☐ - 2 ☐ + ☐☐.☐☐

c. PD ☐☐.☐ mm

10. BCSEVA

OD: 20/☐☐☐ using 1 ☐ - 2 ☐ + ☐☐.☐☐

OS: 20/☐☐☐ using 1 ☐ - 2 ☐ + ☐☐.☐☐

ADD: ☐.☐☐ OU; NP: ☐☐ cm

Baseline Ophthalmic Evaluation at JFK

Attach a PID label here:

11. Alternate visual acuity measurements for children (complete for children for whom the VA above could not be measured):

OD	OS
a. Fixes and follows: 0 ☐ No 1 ☐ Yes	c. Fixes and follows: 0 ☐ No 1 ☐ Yes
b. Central, steady and maintained: 0 ☐ No 1 ☐ Yes	d. Central, steady and maintained: 0 ☐ No 1 ☐ Yes

12. Exam notes

	a. Central subfield thickness	b. Intraretinal fluid cysts?	c. Epiretinal membrane?	d. Retinal scar?	e. Vitreous Opacities?
13. OD	☐☐☐ **OR** 0 ☐ Not done	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	1 ☐ None to minimal 3 ☐ Moderate to severe 2 ☐ Mild
14. OS	☐☐☐ **OR** 0 ☐ Not done	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	1 ☐ None to minimal 3 ☐ Moderate to severe 2 ☐ Mild

15. Initials of person performing OCT: ☐☐☐

16. Macula OCT notes:

Baseline Ophthalmic Evaluation at JFK

Attach a PID label here:

C. Ophthalmic Exam - Part 2

Physical	a. Right eye (Mark all that apply)		b. Left eye (Mark all that apply)	
1. Lids and lashes	1 ☐ Normal	1 ☐ Ptosis 1 ☐ Other: _____	1 ☐ Normal	1 ☐ Ptosis 1 ☐ Other: _____
2. Conjunctiva and sclera	1 ☐ White	1 ☐ Injection 1 ☐ Pterygium 1 ☐ Pingueculum 1 ☐ Other: _____	1 ☐ White	1 ☐ Injection 1 ☐ Pterygium 1 ☐ Pingueculum 1 ☐ Other: _____
3. Cornea	1 ☐ Clear	1 ☐ SPK 1 ☐ KPs 1 ☐ Scar 1 ☐ Other: _____	1 ☐ Clear	1 ☐ SPK 1 ☐ KPs 1 ☐ Scar 1 ☐ Other: _____
4. Anterior chamber	1 ☐ Deep/ quiet	1 ☐ Cells 1 ☐ Trace (1-5) 2 ☐ 1 (6-15) 3 ☐ 2 (16-25) 4 ☐ 3 (26-50) 5 ☐ 4+ (>50) 1 ☐ Flare 1 ☐ Trace 2 ☐ 1 (faint, barely detectable) 3 ☐ 2 (moderate; iris/lens clear) 4 ☐ 3 (marked; iris/lens details hazy) 5 ☐ 4+ (intense, fixed coagulated aqueous humor, fibrin present) 1 ☐ Hypopyon: ☐☐ mm 1 ☐ Other: _____	1 ☐ Deep/ quiet	1 ☐ Cells 1 ☐ Trace (1-5) 2 ☐ 1 (6-15) 3 ☐ 2 (16-25) 4 ☐ 3 (26-50) 5 ☐ 4+ (>50) 1 ☐ Flare 1 ☐ Trace 2 ☐ 1 (faint, barely detectable) 3 ☐ 2 (moderate; iris/lens clear) 4 ☐ 3 (marked; iris/lens details hazy) 5 ☐ 4+ (intense, fixed coagulated aqueous humor, fibrin present) 1 ☐ Hypopyon: ☐☐ mm 1 ☐ Other: _____
5. Iris	1 ☐ Round	1 ☐ Synechiae 1 ☐ NV 1 ☐ Atrophy 1 ☐ Other: _____	1 ☐ Round	1 ☐ Synechiae 1 ☐ NV 1 ☐ Atrophy 1 ☐ Other: _____
6. Lens	1 ☐ Clear	1 ☐ Nuclear cataract 1 ☐ PSC 1 ☐ Cortical cataract 1 ☐ IOL 1 ☐ ASC 1 ☐ Other: _____	1 ☐ Clear	1 ☐ Nuclear cataract 1 ☐ PSC 1 ☐ Cortical cataract 1 ☐ IOL 1 ☐ ASC 1 ☐ Other: _____

Baseline Ophthalmic Evaluation at JFK

Attach a PID label here:

Physical	a. Right eye (Mark all that apply)		b. Left eye (Mark all that apply)	
7. Vitreous	1 ☐ Clear 1 ☐ No view	1 ☐ Cells 1 ☐ Trace (2-20) 2 ☐ 1 (21-50) 3 ☐ 2 (51-100) 4 ☐ 3 (101-250) 5 ☐ 4+ (>250) 1 ☐ Haze 1 ☐ Trace 2 ☐ 1 (few opacities, mild blurring) 3 ☐ 2 (significant blurring, still visible) 4 ☐ 3 (Optic nerve visible, no vessels seen) 5 ☐ 4+ (dense opacity obscures optic nerve head) 1 ☐ PVD 1 ☐ Clumping 1 ☐ Syneresis 1 ☐ Other:	1 ☐ Clear 1 ☐ No view	1 ☐ Cells 1 ☐ Trace (2-20) 2 ☐ 1 (21-50) 3 ☐ 2 (51-100) 4 ☐ 3 (101-250) 5 ☐ 4+ (>250) 1 ☐ Haze 1 ☐ Trace 2 ☐ 1 (few opacities, mild blurring) 3 ☐ 2 (significant blurring, still visible) 4 ☐ 3 (Optic nerve visible, no vessels seen) 5 ☐ 4+ (dense opacity obscures optic nerve head) 1 ☐ PVD 1 ☐ Clumping 1 ☐ Syneresis 1 ☐ Other:
8. Optic nerve	1 ☐ Sharp/ pink Cup to disk ratio: ☐.☐ 1 ☐ No view	1 ☐ Swollen 1 ☐ Gliosis 1 ☐ Pale 1 ☐ Cupped 1 ☐ Other:	1 ☐ Sharp/ pink Cup to disk ratio: ☐.☐ 1 ☐ No view	1 ☐ Swollen 1 ☐ Gliosis 1 ☐ Pale 1 ☐ Cupped 1 ☐ Other:
9. Macula	1 ☐ Normal 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ CWS 1 ☐ Edema 1 ☐ Vascular sheathing 1 ☐ ERM 1 ☐ Other: 1 ☐ Scar	1 ☐ Normal 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ CWS 1 ☐ Edema 1 ☐ Vascular sheathing 1 ☐ ERM 1 ☐ Other: 1 ☐ Scar
10. Periphery	1 ☐ Attached 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ Detachment 1 ☐ Scar 1 ☐ Other:	1 ☐ Attached 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ Detachment 1 ☐ Scar 1 ☐ Other:

Baseline Ophthalmic Evaluation at JFK

Attach a PID label here:

11. Assessment - Mark all that apply:

	Eyes affected OD	Eyes affected OS
a. Uveitis	1 ☐	1 ☐
b. Cataract	1 ☐	1 ☐
c. Pseudophakia	1 ☐	1 ☐
d. Macular edema	1 ☐	1 ☐
e. Retinal scar	1 ☐	1 ☐
f. UV sun damage	1 ☐	1 ☐
g. Retinal detachment	1 ☐	1 ☐
h. Dry eye	1 ☐	
i. Presbyopia	1 ☐	
j. Ocular allergy	1 ☐	

12. If present, uveitis is:
1 ☐ Active 2 ☐ Inactive 3 ☐ Unclear

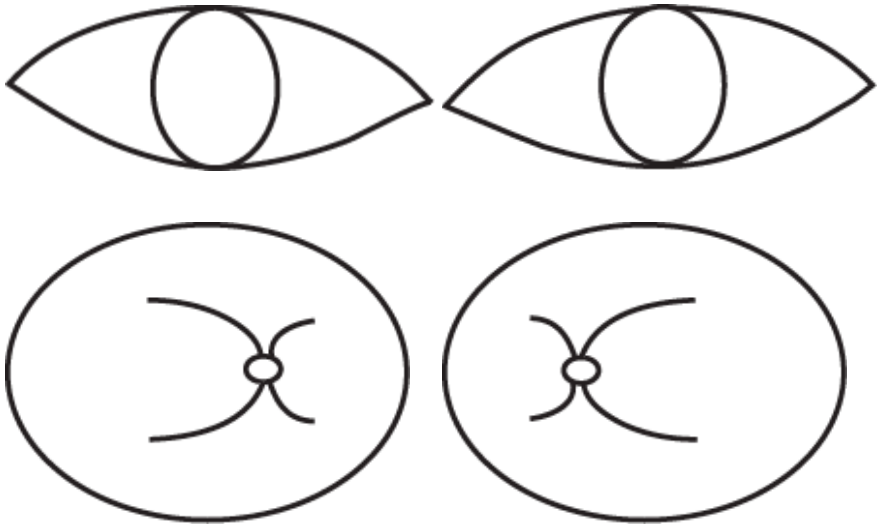
	Eyes affected N/A	Eyes affected OD	Eyes affected OS
k. Other; specify: _____	1 ☐	1 ☐	1 ☐
l. Other; specify: _____	1 ☐	1 ☐	1 ☐
m. Other; specify: _____	1 ☐	1 ☐	1 ☐
n. Other; specify: _____	1 ☐	1 ☐	1 ☐
o. Other; specify: _____	1 ☐	1 ☐	1 ☐

13. Plan (Mark all that apply)

1 ☐ Prednisolone acetate
1 ☐ Artificial tears
1 ☐ Reading glasses
1 ☐ Custom glasses
1 ☐ Surgical consideration

14. Will the volunteer be scheduled for clinical follow-up?

0 ☐ No
1 ☐ Yes



D. Assessment and plan:

E. Follow-up:

F. Notes:

Initials of providers: ☐☐☐ ☐☐☐ ☐☐☐

Signature: _____ Date: _____

Follow-up Ophthalmic Evaluation at JFK

Attach a PID label here:

Timepoint:

1 ☐ Year 1
2 ☐ Year 2
3 ☐ Year 3
4 ☐ Year 4
5 ☐ Year 5

Participant Initials: _____

Complete this form for volunteers of PREVAIL III who are attending annual data collection visits for a follow-up eye evaluation.

(example: 01-FEB-2017)

Visit Date: ☐☐ – ☐☐☐ – 2 0 ☐☐
Day Month Year

A. Interim History

1. Ask the volunteer...

	No	Yes	Note
a. Do you have problems with vision?	0 ☐	1 ☐	
b. Do you have other eye problems?	0 ☐	1 ☐	
c. Are you using any eye medications?	0 ☐	1 ☐	

2. Can a visual acuity exam be conducted on BOTH eyes?

0 ☐ No → 3. Reason:

	Eyes Effected OD	Eyes Effected OS
a. Cognition problem	1 ☐	
b. Enucleation	1 ☐	1 ☐
c. Other; specify: _____	1 ☐	1 ☐

If a visual assessment is not possible in EITHER eye, go to section C. If a visual assessment is possible in one eye, go to Section B.

1 ☐ Yes → **Go to Section B.**

B. Ophthalmic Exam - Part 1

1. Notes:

Follow-up Ophthalmic Evaluation at JFK

Attach a PID label here:

Timepoint:

1 ☐ Year 1 4 ☐ Year 4
2 ☐ Year 2 5 ☐ Year 5
3 ☐ Year 3

Leave any items that were not assessed blank.

2. Visual acuity (complete for adults and children for whom VA can be measured.)

	a. Presenting dVA: OD	a. Presenting dVA: OS	c. Pinhole dVA: OD	c. Pinhole dVA: OS
1 ☐ SC / 2 ☐ CC	20/☐☐☐	20/☐☐☐	20/☐☐☐	20/☐☐☐
	OR	**OR**	**OR**	**OR**
	1 ☐ Count fingers	1 ☐ Count fingers	1 ☐ Count fingers	1 ☐ Count fingers
	2 ☐ Hand motion	2 ☐ Hand motion	2 ☐ Hand motion	2 ☐ Hand motion
	3 ☐ Light perception	3 ☐ Light perception	3 ☐ Light perception	3 ☐ Light perception
	4 ☐ No light perception	4 ☐ No light perception	4 ☐ No light perception	4 ☐ No light perception
b. ETDRS: 1 ☐ SC / 2 ☐ CC	☐☐ letters	☐☐ letters	d. ☐☐ letters	☐☐ letters

3. Alternate visual acuity measurements for children (complete for children for whom the VA above could not be measured):

OD	OS
a. Fixes and follows: 0 ☐ No 1 ☐ Yes	c. Fixes and follows: 0 ☐ No 1 ☐ Yes
b. Central, steady and maintained: 0 ☐ No 1 ☐ Yes	d. Central, steady and maintained: 0 ☐ No 1 ☐ Yes

4. Does the volunteer have an afferent pupillary defect?

0 ☐ No
1 ☐ Yes → 1 ☐ OD, 1 ☐ OS

5. IOP (mmHg): OD: ☐☐ OS: ☐☐

Dilated at: _____ *time*

6. Color plates: OD: ☐☐/14 OS: ☐☐/14

	a. Central subfield thickness	b. Intraretinal fluid cysts?	c. Epiretinal membrane?	d. Retinal scar?	e. Vitreous Opacities?
7. OD	☐☐☐ **OR** 0 ☐ Not done	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	1 ☐ None to minimal 3 ☐ Moderate to severe 2 ☐ Mild
8. OS	☐☐☐ **OR** 0 ☐ Not done	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	0 ☐ No 1 ☐ Yes	1 ☐ None to minimal 3 ☐ Moderate to severe 2 ☐ Mild

9. Initials of person performing OCT: ☐☐☐

10. Macula OCT comments:

Follow-up Ophthalmic Evaluation at JFK

Attach a PID label here:

Timepoint:

1 ☐ Year 1
2 ☐ Year 2
3 ☐ Year 3
4 ☐ Year 4
5 ☐ Year 5

C. Ophthalmic Exam - Part 2

Physical	a. Right eye (Mark all that apply)		b. Left eye (Mark all that apply)	
1. Lids and lashes	1 ☐ Normal	1 ☐ Ptosis 1 ☐ Other: _____	1 ☐ Normal	1 ☐ Ptosis 1 ☐ Other: _____
2. Conjunctiva and sclera	1 ☐ White	1 ☐ Injection 1 ☐ Pterygium 1 ☐ Pingueculum 1 ☐ Other: _____	1 ☐ White	1 ☐ Injection 1 ☐ Pterygium 1 ☐ Pingueculum 1 ☐ Other: _____
3. Cornea	1 ☐ Clear	1 ☐ SPK 1 ☐ KPs 1 ☐ Scar 1 ☐ Other: _____	1 ☐ Clear	1 ☐ SPK 1 ☐ KPs 1 ☐ Scar 1 ☐ Other: _____
4. Anterior chamber	1 ☐ Deep/ quiet	1 ☐ Cells 1 ☐ Trace (1-5) 2 ☐ 1 (6-15) 3 ☐ 2 (16-25) 4 ☐ 3 (26-50) 5 ☐ 4+ (>50) 1 ☐ Flare 1 ☐ Trace 2 ☐ 1 (faint, barely detectable) 3 ☐ 2 (moderate; iris/lens clear) 4 ☐ 3 (marked; iris/lens details hazy) 5 ☐ 4+ (intense, fixed coagulated aqueous humor, fibrin present) 1 ☐ Hypopyon: ☐☐ mm 1 ☐ Other: _____	1 ☐ Deep/ quiet	1 ☐ Cells 1 ☐ Trace (1-5) 2 ☐ 1 (6-15) 3 ☐ 2 (16-25) 4 ☐ 3 (26-50) 5 ☐ 4+ (>50) 1 ☐ Flare 1 ☐ Trace 2 ☐ 1 (faint, barely detectable) 3 ☐ 2 (moderate; iris/lens clear) 4 ☐ 3 (marked; iris/lens details hazy) 5 ☐ 4+ (intense, fixed coagulated aqueous humor, fibrin present) 1 ☐ Hypopyon: ☐☐ mm 1 ☐ Other: _____
5. Iris	1 ☐ Round	1 ☐ Synechiae 1 ☐ NV 1 ☐ Atrophy 1 ☐ Other: _____	1 ☐ Round	1 ☐ Synechiae 1 ☐ NV 1 ☐ Atrophy 1 ☐ Other: _____
6. Lens	1 ☐ Clear	1 ☐ Nuclear cataract 1 ☐ PSC 1 ☐ Cortical cataract 1 ☐ IOL 1 ☐ ASC 1 ☐ Other: _____	1 ☐ Clear	1 ☐ Nuclear cataract 1 ☐ PSC 1 ☐ Cortical cataract 1 ☐ IOL 1 ☐ ASC 1 ☐ Other: _____

Follow-up Ophthalmic Evaluation at JFK

Attach a PID label here:

Timepoint:

1 ☐ Year 1
2 ☐ Year 2
3 ☐ Year 3
4 ☐ Year 4
5 ☐ Year 5

Physical	a. Right eye (Mark all that apply)		b. Left eye (Mark all that apply)	
7. Vitreous	1 ☐ Clear 1 ☐ No view	1 ☐ Cells 1 ☐ Trace (2-20) 2 ☐ 1 (21-50) 3 ☐ 2 (51-100) 4 ☐ 3 (101-250) 5 ☐ 4+ (>250) 1 ☐ Haze 1 ☐ Trace 2 ☐ 1 (few opacities, mild blurring) 3 ☐ 2 (significant blurring, still visible) 4 ☐ 3 (Optic nerve visible, no vessels seen) 5 ☐ 4+ (dense opacity obscures optic nerve head) 1 ☐ PVD 1 ☐ Clumping 1 ☐ Syneresis 1 ☐ Other:	1 ☐ Clear 1 ☐ No view	1 ☐ Cells 1 ☐ Trace (2-20) 2 ☐ 1 (21-50) 3 ☐ 2 (51-100) 4 ☐ 3 (101-250) 5 ☐ 4+ (>250) 1 ☐ Haze 1 ☐ Trace 2 ☐ 1 (few opacities, mild blurring) 3 ☐ 2 (significant blurring, still visible) 4 ☐ 3 (Optic nerve visible, no vessels seen) 5 ☐ 4+ (dense opacity obscures optic nerve head) 1 ☐ PVD 1 ☐ Clumping 1 ☐ Syneresis 1 ☐ Other:
8. Optic nerve	1 ☐ Sharp/ pink Cup to disk ratio: ☐.☐ 1 ☐ No view	1 ☐ Swollen 1 ☐ Gliosis 1 ☐ Pale 1 ☐ Cupped 1 ☐ Other:	1 ☐ Sharp/ pink Cup to disk ratio: ☐.☐ 1 ☐ No view	1 ☐ Swollen 1 ☐ Gliosis 1 ☐ Pale 1 ☐ Cupped 1 ☐ Other:
9. Macula	1 ☐ Normal 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ CWS 1 ☐ Edema 1 ☐ Vascular sheathing 1 ☐ ERM 1 ☐ Other: 1 ☐ Scar	1 ☐ Normal 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ CWS 1 ☐ Edema 1 ☐ Vascular sheathing 1 ☐ ERM 1 ☐ Other: 1 ☐ Scar
10. Periphery	1 ☐ Attached 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ Detachment 1 ☐ Scar 1 ☐ Other:	1 ☐ Attached 1 ☐ No view	1 ☐ Hemorrhage 1 ☐ Detachment 1 ☐ Scar 1 ☐ Other:

Follow-up Ophthalmic Evaluation at JFK

Attach a PID label here:

Timepoint:

1 ☐ Year 1
2 ☐ Year 2
3 ☐ Year 3
4 ☐ Year 4
5 ☐ Year 5

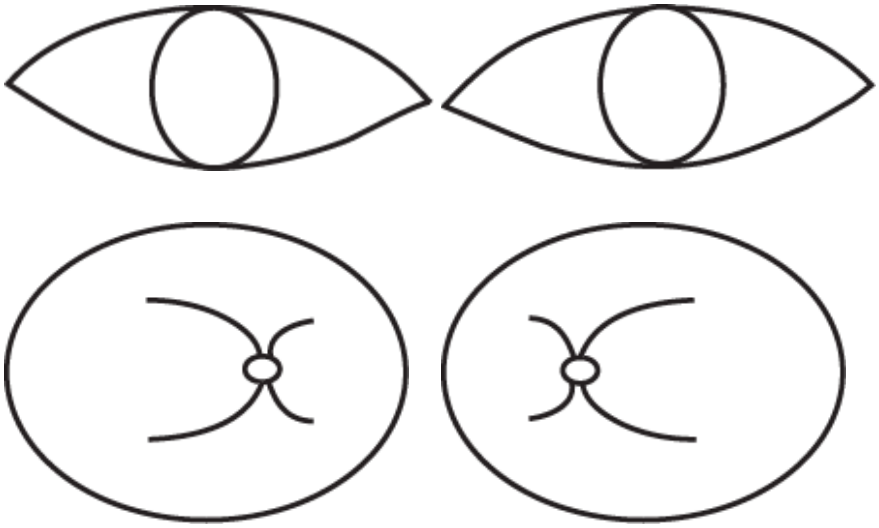
11. Assessment - Mark all that apply:

	Eyes affected OD	Eyes affected OS
a. Uveitis	1 ☐	1 ☐
b. Retinal scar	1 ☐	1 ☐
c. Cataract	1 ☐	1 ☐
d. Pseudophakia	1 ☐	1 ☐
e. Macular edema	1 ☐	1 ☐
f. UV sun damage	1 ☐	1 ☐
g. Hypertensive retinopathy	1 ☐	1 ☐
h. Retinal detachment	1 ☐	1 ☐
i. Glacoma	1 ☐	1 ☐
j. Dry eye	1 ☐	
k. Presbyopia	1 ☐	
l. Ocular allergy	1 ☐	

12. If present, uveitis is:
1 ☐ Active 2 ☐ Inactive 3 ☐ Unclear

13. If present, retinal scar:
1 ☐ Stable 2 ☐ Increasing 3 ☐ Unclear

	Eyes affected N/A	Eyes affected OD	Eyes affected OS
k. Other; specify: _____	1 ☐	1 ☐	1 ☐
l. Other; specify: _____	1 ☐	1 ☐	1 ☐
m. Other; specify: _____	1 ☐	1 ☐	1 ☐
n. Other; specify: _____	1 ☐	1 ☐	1 ☐



13. Plan (Mark all that apply)

1 ☐ Prednisolone acetate
1 ☐ Artificial tears
1 ☐ Reading glasses
1 ☐ Custom glasses
1 ☐ Surgical consideration

14. Will the volunteer be scheduled for interim clinical follow-up?

0 ☐ No 1 ☐ Yes

D. Assessment and plan:

E. Follow-up (Mark only one):

1 ☐ 1 year
2 ☐ As needed

F. Notes:

Initials of providers: ☐☐☐ ☐☐☐ ☐☐☐

Signature: _____ Date: _____

Semen Collection

Attach a PID label here:

Date Form Completed:
(example: 01-SEP-2015)

Day Month Year 2 0 1

Participant Initials: _____

Complete this form each time a male survivor aged 18 and older attempts to provide a sample.

1. Collection site:

1 ☐ Duport Road Clinic
2 ☐ JFK Hospital
3 ☐ Rennie Hospital
4 ☐ Mobile unit

2. Was a semen sample successfully obtained?

0 ☐ No → **Sign form and submit.**

1 ☐ Yes →

3. Date of specimen:
(example: 01-SEP-2015)

Day Month Year 2 0 1

4. Apply specimen label below:

Signature: _____ Date: _____

Death

Attach a PID label here:

Date of Death:
(example: 01-SEP-2015)

Day ☐☐ – Month ☐☐☐ – Year 2 0 1 ☐

Participants initials: _____

Site: ☐☐

1. What is the reported cause of death?

_____

- Enter only one cause (medical condition)
- Be as specific as possible
- DO NOT abbreviate
- DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation, without showing the etiology

2. Was the death certificate obtained?

0 ☐ No
1 ☐ Yes

3. Provide a brief summary of events reported prior to death:

The PREVAIL Site Physician must sign and date this CRF.

Site physician signature: _____

Print name: _____

(example: 01-SEP-2015)

Date signed: Day ☐☐ – Month ☐☐☐ – Year ☐☐☐☐

Clinic name: _____

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