Date: Thursday, August 31, 2017 8:58:20 AM

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**ID:** IRB#11-003579 View: NEW 1.1 - Study Title and Key Personnel

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## Study Title and Key Personnel

*All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.*

**1.0** ***Full Title of the Submission:**
Effectiveness of Peer Navigation to Link Released HIV+ Jail Inmates to HIV Care

**1.1** **Protocol Version Date and/or Number:**
5-9-2014

**2.0** ***Working or Lay Title:**
**Jails LINK LA -- RCT Phase**

**3.0** **Principal Investigator:**

**3.1** ***Name:** WILLIAM CUNNINGHAM
**Degree(s):** If degrees are not shown here, please add them to the next section, Section 1.1a/Item 1.0, which will then update the Principal Investigator's webIRB account information.
MD, MPH

**3.2** **UCLA Title:**

**3.3** ***Will the Principal Investigator conduct the informed consent process with potential study participants?**

- ○ Yes
- ◉ **No**
- ○ Not Applicable

**3.4** ***Is the Principal Investigator an undergraduate student, graduate student, post-doctoral fellow, or resident physician?**

○ Yes ◉ **No**

**3.4.1** **If you answered "yes" to the above question, indicate the Faculty Sponsor for this study.**

**3.5** **UCLA Policy 900 defines types of UCLA employees who may be eligible to serve as a Principal Investigator. Check the policy to see if the Principal Investigator for this study needs an exception to the eligibility requirements.**

**If an exception is needed, either attach the letter of exception here, or indicate a Faculty Sponsor in the above item.**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**4.0** **Study Contact Person: Indicate the person, in addition to the Principal Investigator, who should receive**

**all of the study correspondence.**
DANIELLE SEIDEN

**5.0** **List the key personnel and study staff below.**

**Note: All personnel listed below are required to complete CITI training courses (except for Fund Managers and Regulatory Coordinators). HIPAA training is also required if personnel will be accessing protected health information.**
**Please make sure to have all key personnel update their webIRB profile, contact information. Instructions on how to update the webIRB profile: Click** here**.**

| | Name | Department | Role | Other Role (if applicable) | Will Obtain Consent? | Manage device accountability? | Access to personally identifiable info? | Access to code key? |
|---|---|---|---|---|---|---|---|---|
| View | SUSAN ETTNER, PhD | MEDICINE-DEPT ADMINISTRATION | Co-Investigator | | no | Not Applicable | No | No |
| View | MARK MALEK | EPIDEMIOLOGY | Co-Investigator | | no | Not Applicable | No | No |
| View | JIMMY NGO | MEDICINE-GENERAL MEDICINE & HLTH SRVCS. | Other | study assistant | yes | Not Applicable | Yes | Yes |
| View | DIANE PRECIADO | MEDICINE-GERIATRICS | Other | Interviewer | yes | Not Applicable | Yes | Yes |
| View | DANIELLE SEIDEN | MEDICINE-GENERAL MEDICINE & HLTH SRVCS. | Other | Project director | yes | Not Applicable | Yes | Yes |
| View | STEVEN SHOPTAW, PhD | FAMILY MEDICINE | Other | Significant contributor | no | Not Applicable | No | No |
| View | JASMINE SMITH | MEDICINE-GENERAL MEDICINE & HLTH SRVCS. | Other | Ms. Smith will be the jails coordinator, coordinating all study activities inside the LA County Men's Central Jail. | yes | Not Applicable | Yes | Yes |

**ID:** IRB#11-003579 View: NEW 1.1a - Other Personnel

*This view has been locked by amendment(s)*

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## Other Personnel

*All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.*

**1.0** **Principal Investigator**

**1.1** **Name:** WILLIAM CUNNINGHAM
***Please type the Degree(s):** MD, MPH

**1.2** **Principal Investigator's UCLA Department:** MEDICINE-DEPT ADMINISTRATION

**1.3**

***Protocol's UCLA Home Department:** MEDICINE-DEPT ADMINISTRATION

This response defaults to the PI's payroll department. If you wish to affiliate this protocol with another department, please select the department from the list above.

**For tips on effective search, please see guidance to the right.**

**2.0** **If there will be other types of personnel working directly under the PI's supervision on aspects of the study, provide their name, title and institution, indicate their responsibilities, training and qualifications and complete Item 2.1.**

**Please also indicate, if applicable, whether that person will obtain consent, manage device accountability, have access to personally identifiable information and/or have access to the code key.**

**Please use a new entry to add each individual unless describing a class of individuals who rotate through the study team (see guidance area to the right).**

**Note: If there will not be other types of personnel go to Item 3.0.**

| | Name, title, institution | Study role(s): e.g., conduct interviews/surveys, recruit participants, obtain consent, review records, etc. |
|---|---|---|
| View | Al Brown, UCLA Dept of Medicine, GIM | Health navigator; this incumbant will execute all intervention activities that were designed as part of this study. Mr. Brown will be joining UCLA as of July 1 as a health navigator as a regular UCLA career emplyee. Being a health navigator is Mr. Brown's current affiliation with the study but his affiliation is currently through the Dept of Public Health. |
| View | Christina Wang, Relying PI (CTSI Harbor) | Dr. Wang will be authorizing lab orders to be conducted for this study, as required by Harbor CTSI. Dr. Wang will not be involved in any other human subjects research activities. |
| View | Darlene Hernandez, interviewer/phlebotomist | Study interviewer and phlebotomist; Ms. Hernandez is a certified phlebotomist and will also conduct interviews/surveys, recruit and track participants over time for study retention purposes and obtain consent. She is a staff employee who was officially hired as of 12/13/2013. |
| View | David Hardy, Relying PI (CTSI Cedars) | Dr. Hardy will be authorizing lab orders to be conducted for this study, as required by CSMC. Dr. Hardy will not be involved in any other human subjects research activities. |
| View | Eric Tam, UCLA Medical school | Eric Tam, a UCLA medical student in Dr. Cunningham's CTSI TS1 disparities course this summer will be observing LINK LA study staff conduct study activities in the community. Mr. Tam will not be CONDUCTING any study activities himself. He would simply OBSERVE staff as they, for example, conduct interviews, intervention sessions, perform blood draws, rack participants etc. Mr. Tam will also be helping Dr. Cunningham table results from data analysis but he will NOT have direct access to data. Mr Tam has completed both the HIPAA and CITI training requirements (see section 24.0) |
| View | Fernando Ramirez; Interviewer - UCLA Med Ct. floatpool | Study interviewer; Mr. Ramirez will conduct interviews/surveys, recruit and track participants over time for study retention purposes and obtain consent. |
| View | Garrett Cox, MPH, LA Sheriff's Dept | Research assistant, running all inmate-related statistics |
| View | Jenna Arzinger, study coordinator, UCLA | Ms. Arzinger will coordinate all study activities relating to the intervention of the study as well as the study activities inside the jail. |
| View | Markeisha Craver | Study interviewer; Ms. Craver will conduct interviews/surveys and track participants over time for study retention purposes |
| View | Nina Harawa | Ph.D.; co-investigator; Dual appointment with UCLA and Charles Drew University |
| View | Richard Hamilton, UCLA Dept of Medicine, GIM | Health navigator; this incumbent will execute all intervention activities that were designed as part of this study. Mr. Hamilton will be joining UCLA as of July 1 as a health navigator through the UCLA float pool. Being a health navigator is Mr. Hamilton's current affiliation with the study but his affiliation is currently through the Dept of Public Health. |

| | Name, title, institution | Study role(s): e.g., conduct interviews/surveys, recruit participants, obtain consent, review records, etc. |
|---|---|---|
| View | Sheila Ganjian | Ms. Ganjian will be analyzing data and writing up her findings in manuscripts for publication in academic journals. She has completed the CITI training and the HIPAA module. Please find them, along with her CV, attached to in section 24.0 |

**For existing protocols: Item 2.0 has been modified and this item cannot be edited. When submitting an amendment please use the information found in the text box below to complete Item 2.0 above.**

Briefly describe the other study personnel.

1) Trista Bingham, Ph.D., LACDPH (Co-investigator)
2) Jane Rohde-Bowers, Intervention Director (LACDPH)
3) Garrett Cox, Epidemiologist (Sheriff's Dept)
4) Rangell Oruga, interviewer (LACDPH)
5) Saloniki James, interviewer (LACDPH)
6) Interviewer, TBD
6) Peer navigators (LACDPH) -- TBD

**2.1 Indicate the human subjects research training these personnel have or will receive. If training is required in a language other than English or if research is occurring in a location where research personnel do not have access to the internet (e.g., rural community without internet capability), please describe how human subjects training requirements will be fulfilled.**

**Check all that apply:**

- [x] **CITI Training**
- [x] **UC HIPAA Training**
- [x] **Other**

**2.2 If you indicated "Other" to item 2.1, describe:**

-- Staff at the LA County Dept of Public Health and Sheriff's Dept: These individuals will be completing Human Subjects training provided through The L.A. County Department of Public Health.

-- We have identified Darlene Hernandez, a phlebotomist, who we will do phlebotomy on this study and conduct other study activities, such as tracking of participants and conducting interviews. Ms. Hernandez will work outside of jails with ex-inmates only. She will NOT be in the jail. Mrs. Darlene Hernandez is a staff employee at UCLA (hire date of 12/13). She was not yet in the system at the time of this addendum.

Mr. Ramirez and Ms. Craver are hired through the UCLA Medical Center float pool. All hiring criteria as required by the UCLA Medical Center (i.e. complete background check, complete health check, confidentiality agreement etc. etc etc) will be completed by these candidates. CITI and HIPAA trainings are required of all participants before they may conduct study activities.

All field staff are provided a very comprehensive project-specific training that includes an entire module on the ethical treatment of participants and confidentiality requirements. The overall training is attached in Section 24.0: "Additional Information and/or Attachments"

Please note that none of the UCLA floatpool staff will be reviewing any UCLA medical records. If they were to review any non-UCLA medical records, appropriate approval from the institution that holds the records would be sought. Non-UCLA medical records incldue (as described in the DSMP): CaseWatch, Healthy Way L.A. and LASD electronic health records

Resumes are attached in section 24.0

**3.0** ***Will any of the study procedures or analyses be contracted to a consultant or an organization?**

○ Yes ◉ **No**

**3.1** **If yes, specify the consultant(s) and/or organization(s) and the work that they will do for the study.**

**ID:** IRB#11-003579 View: NEW 1.1b - Type of Study Review

*This view has been locked by amendment(s)*

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## Type of Study Review

**1.0** ***Indicate the level of risk involved with this study.**

**(if there are multiple groups or phases associated with this study, select the highest level of risk.)**

- ◉ **Minimal risk or no known risks - Click here for the OHRPP tip sheet on minimal risk.**
- ○ Greater than minimal risk

**2.0** ***Indicate the type of review that you are requesting for this study.**

- ◉ **IRB Review: Expedited or Full Board**
- ○ Certification of Exemption from IRB Review

**2.1** **If you indicated "IRB Review: Expedited or Full Board" as the type of review in item 2.0, select the IRB that you think best matches your research.**

| | Name | Description |
|---|---|---|
| ○ | Medical Institutional Review Board 1 | **MIRB1 reviews general and internal medicine, infectious diseases and ophthalmologic research.** |
| ○ | Medical Institutional Review Board 2 | **MIRB2 reviews oncology and hematology research.** |
| ○ | Medical Institutional Review Board 3 | **MIRB3 reviews neuroscience, neurology, psychiatric, drug abuse and dental research.** |
| ○ | North General Institutional Review Board | **NGIRB reviews research from the College of Letters & Science and the Professional Schools.** |
| ◉ | **South General Institutional Review Board** | **SGIRB reviews social-behavioral research from the Schools of Public Health, Nursing, and Medicine.** |

***Please note*: The above requests are for initial routing purposes only. The final decision as to committee assignment and type of review, rests with OHRPP and/or the IRBs.**

**ID:** IRB#11-003579 View: NEW 1.2 - Conflict of Interest Information

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Conflict of Interest Information

**1.0** * **Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have a financial interest in the sponsor (profit, non-for-profit) of the research?**

○ Yes ◉ No

**1.1** **If yes, attach a completed copy of the Financial Interests Form for each person who indicates a financial or related interest:**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**2.0** * **Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have any financial interests related to the research sponsored by a government agency?**

○ Yes ◉ No

**2.1** **If yes, attach a completed copy of the Financial Interests Form:**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**3.0** * **Indicate whether any of these financial interests have been submitted to or reviewed by the UCLA campus Conflict of Interest Review Committee (CIRC):**

○ Yes ◉ No

**3.1** **If you have received a response from CIRC, attach it here:**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**ID:** IRB#11-003579 View: NEW 1.3 - Study Locations

*This view has been locked by amendment(s)*

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## Study Locations

**1.0** * **Indicate the locations where any research activities will be performed by the UCLA research team with participants and/or private information obtained.**

**Check all that apply:**

- ☑ **a. UCLA Sites or UCLA Health System Sites**
- ☑ **b. Off Campus (in California)**
- ☐ c. Outside California (in the U.S.)
- ☐ d. Outside the United States ***See note at right**
- ☐ e. Internet

**1.1** **If you selected b, c or d above, please provide your assurance that documentation of each site's permission to**

**conduct the research at the site(s) will be obtained and maintained by the UCLA PI as applicable:**

**Agree** ☑

**2.0** ***Is this a multi-institutional study (i.e., a collaborative project with other sites that have their own IRBs or principal investigators)?**
**(Includes but not limited to UC MOU and CTSI MOU collaborations where UCLA IRB review is requested.)**

◉ **Yes** ○ **No**

***If no, please skip directly to the next page, do not complete the questions below.***
***If yes, please answer items 2.1-2.3:***

**2.1** **Will UCLA be responsible for the overall direction of the study at the other institutions?**

◉ **Yes** ○ No

**2.1.1** **Indicate the measures that will be taken to assure regulatory compliance at each site and that the following types of information will be communicated to the other sites: study procedures; modifications to the protocol and related documents; and safety updates, interim results and other information that may impact risks to study participants.**

**Check all that apply:**

| | |
|---|---|
| ☑ | **Conference calls or meetings with minutes distributed to each site** |
| ☑ | **Timely e-mail communications** |
| ☐ | Postings on the study website |
| ☐ | Other |

**2.1.1.1** **If you chose "other", describe.**

**2.1.2** **If you answered "yes" to item 2.1 above, please provide your assurance that the current IRB approval for each site(s) will be obtained and maintained by the UCLA PI as applicable:**

**Agree** ☑

**2.2** **Will the UCLA principal investigator specified on this application be responsible for the data coordinating center?**
**No/Not Applicable**

**2.3** **Indicate the anticipated total number of study participants that will be enrolled across all of the institutions.**
RCT Phase: 500

**ID:** IRB#11-003579 View: NEW 1.5 - Other Sites and/or Collaborators – Multi-Institutional Research

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## Other Sites and/or Collaborators – Multi-Institutional Research

## Other Sites and/or Collaborators - Multi-Institutional Research

*Use Section 1.5/item 1.0 to list off-campus locations where research activities will be performed by the UCLA research team. If UCLA is the lead institution or responsible for the oversight of the collaborators, please also list these collaborators below.*

**1.0** ***List the research sites or collaborating institutions (including UC/CTSI institutions).**

| | Name of Site | Site(s) Information |
|---|---|---|
| View | HIV clinics where the study will be conducted; A list of sites where study activities may be conducted is attached to section 24.0. | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | HIV clinics where the study will be conducted; A list of sites where study activities may be conducted is attached to section 24.0. |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | Los Angeles area |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | This item is not applicable to this study |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☐ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☑ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | |

| | Name of Site | Site(s) Information |
|---|---|---|
| View | Please see attached Harbor CTSI protocol (attached in section 2.1) - UCLA is serving as IRB of record for Harbor CTSI under UCLA CTSI MOU. | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | Please see attached Harbor CTSI protocol (attached in section 2.1) - UCLA is serving as IRB of record for Harbor CTSI under UCLA CTSI MOU. |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | Los Angeles Biomedical Research Institute and Harbor-UCLA Medical Center - CTSI 1000 W. Carson Street, Torrance CA 90509 |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | This item is not applicable to this study |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☑ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☐ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | The site takes responsibility for any necessary review. The PI will maintain related documentation in the research records (e.g., IRB approval). |

| | Name of Site | Site(s) Information |
|---|---|---|
| View | Please see attached Cedars Sinai CTSI protocol (attached in section 2.1) - UCLA is serving as IRB of record for the CSMC under UCLA CTSI MOU. | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | Please see attached Cedars Sinai CTSI protocol (attached in section 2.1) - UCLA is serving as IRB of record for the CSMC under UCLA CTSI MOU. |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | Cedars-Sinai Medical Center - CTSI 8700 Beverly Blvd. Room 1738 Los Angeles, CA 90024 |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | This item is not applicable to this study |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☑ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☐ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | The site takes responsibility for any necessary review. The PI will maintain related documentation in the research records (e.g., IRB approval). |

| | Name of Site | Site(s) Information |
|---|---|---|
| View | Restaurants/coffee shops, libraries or parks with private sitting areas | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | Restaurants/coffee shops, libraries or parks with private sitting areas |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | Los Angeles, CA, area |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | This item is not applicable to this study |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☐ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☑ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | |

| | Name of Site | Site(s) Information |
|---|---|---|
| View | Los Angeles Sheriff's Department (LASD) | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | Los Angeles Sheriff's Department (LASD) |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | 4700 Ramona Blvd Monterey Park, CA 91754-2169 |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | This item is not applicable to this study |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☐ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☑ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | |

| | Name of Site | Site(s) Information |
|---|---|---|
| View | The Center for Health Justice empowers people affected by incarceration to make healthier choices and advocates for the elimination of disparities between prisoner health and public health. | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | The Center for Health Justice empowers people affected by incarceration to make healthier choices and advocates for the elimination of disparities between prisoner health and public health. |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | 900 Avila Street Client Service Center: Suite 102 Administrative Offices: Suite 301 Los Angeles, CA 90012 |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☐ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☑ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | |

| Name of Site | Site(s) Information |
|---|---|
| View Participants' homes | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | Participants' homes |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | Participants' homes located in the L.A. area |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | This item is not applicable to this study |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☐ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☑ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | |

| | Name of Site | Site(s) Information |
|---|---|---|
| View | SPECTRUM/OASIS Community Services and Research | |

| | |
|---|---|
| **Name or description of the site or collaborating institution:** | SPECTRUM/OASIS Community Services and Research |
| **Name of contact person and address or general location of the site or collaborating institution, as applicable:** | 1748 East 118th Street, Bldg. M Los Angeles |
| **Country** | United States |
| **If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.** | This item is not applicable to this study |
| **If you indicated "Other", describe:** | *No Value Entered* |
| **Indicate the activities that will be conducted by employees of this institution/entity** | ☐ (a)Obtain informed consent<br>☐ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes.<br>☑ (c)None of the above or not applicable to this study. |
| **If you checked (a) or (b) in response to item above, check the applicable item:** | |

**ID:** IRB#11-003579 View: NEW 2.1 - Project Identification Information

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Project Identification Information

**1.0** ***Type of Submission (Select one)**

- ◉ **Research Study**
- ○ Application for Approval of "Research Participant Pool" or recruitment database only

**2.0** ***Type of Submission (Select one)**
**For Amendments, do not undo the response below. Undoing the response may remove sections of the original application.**

- ◉ **New Submission**
- ○ Transfer of Ongoing Research from Another Site from Investigator moving to UCLA. Please complete Item 2.1.

**2.1** **If you selected "Transfer of Ongoing Research" in Item 2.0 indicate the current status of the study and a brief summary**

**of the work to date.**

**3.0** ***Who developed this study?**

**Check all that apply:**

- [x] **UCLA investigator**
- [ ] Investigator from another institution
- [ ] Industry/Pharmaceutical Company
- [ ] Cooperative Group (e.g., Children's Oncology Group, AIDS Clinical Trial Group)
- [ ] Other

**3.1** **If other, specify.**

**4.0** **Review For and Reliance Upon External IRBs.**

***Indicate if one of the following applies to this study. (Select one)**

- ○ None of the options apply.
- ◉ **UCLA IRB to serve as IRB of record for another institution.**
- ○ UCLA to RELY on another IRB.
  This includes reliance using UC MOU, CTSI, NCI, RAND, and Western IRBs.

**5.0** ***Is this study cancer related,** including the recruitment of individuals with cancer, collection of cancer human biological samples, specimens or data, or the recruitment of individuals because they are cancer survivors or at risk of developing cancer?

○ Yes ◉ **No**

**Note:** If you answered "Yes", you must submit an application to the Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC). Click here for instructions for submitting to the ISPRC. The ISPRC approval notice or letter of exemption should be attached in Section 2.1/Item 7.2 of the webIRB application.

**6.0** ***Nurse Involvement:** Does this study involve any nursing time, effort, and/or resources at UCLA Health System sites, including as subjects, investigators, clinical care providers or data or specimen collectors?

○ Yes ○ No

**Note:** If you answer "Yes", please submit an application to the Nursing Practice Research Council (NPRC). For contact information or for more information about NPRC and how to apply, click here. ***IRB approval is not contingent on NPRC approval and you do not need to upload documentation of approval from the NPRC into webIRB.***

**7.0** ***Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review.**
**See http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Scientific_Review.pdf for additional details.**

**Do you want the IRB to consider external scientific or scholarly review?**

○ **Yes** ◉ **No**

**7.1** **If yes, indicate the source of scientific or scholarly review for the study.**

**Check all that apply.**

- [ ] National Institutes of Health (NIH)

- [ ] The funding agency (other than NIH)
- [ ] Faculty Sponsor
- [ ] JCCC – Internal Scientific Peer Review Committee (ISPRC)
- [ ] Clinical Translational Research Center (CTRC)
- [ ] UCLA Department
- [ ] Other

**7.1.1 If you checked "other", describe.**

**7.2 Attach a copy of the scientific or scholarly review, if applicable.**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**ID:** IRB#11-003579 View: NEW 2.2 - Lay Summary and Keywords

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Lay Summary and Keywords

*Please provide the following information about your study.*

**1.0** ***Provide a brief lay summary describing this study. (limit 500 words).**

The HIV epidemic and incarceration are closely linked, especially for low-income men of color. HIV prevalence among incarcerated individuals is five times that of the general population. Despite this recognition, one of the greatest problems is the inability of existing programs to make sure that recently released HIV+ inmates will continue to receive HIV care upon release and re-entry into the community. In other words, once released from jail, former inmates often lack the resources to access HIV care ("linkage") and remain in long-term care ("retention"). Former inmates' inconsistent care and thus non-continuous adherence to HIV medications ("ART") can result in the transmission of a resistant form of HIV, which in turn requires more aggressive and more expensive treatment and follow-up. One of the main barriers to successful linkage to and retention in HIV care is the high prevalence of substance abuse among incarcerated HIV+ populations. Substance abuse not only contributes to HIV risk behaviors but also increases the likelihood of future incarceration ("recidivism").
This study will be among the first to design an intervention tailored specifically to inmates released into the community from jail to improve retention in HIV care, taking into account the effects of substance abuse. The intervention will be carried out by health navigators who will assist participants in getting successfully linked and retained in HIV care upon release from jail. These health navigators will accompany participants to HIV medical visits and substance abuse/mental health visits ("accompaniment sessions") and conduct maintenance meetings between appointments ("navigator meetings"). The study will consist of two phases. In phase 1, which has been previously approved and has now been executed, we conducted qualitative semi-structured interviews with key informants to tailor our existing intervention for HIV+ jail ex-inmates. In the randomized control trial (RCT) phase, for which we are currently seeking approval, we will implement the intervention and test its effectiveness.

**2.0** ***List three to five keywords describing this study (separate the words with commas). The keywords may be used for identifying certain types of studies.**

Jails, HIV, health navigators, HIV clinical markers

**3.0**

***Is this study conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Control and Prevention, etc.)?**

(•) Yes ( ) No

**4.0** * **Is this study regulated by the Food and Drug Administration (FDA)?**

○ Yes ◉ No

**4.1** **If yes, check all that apply:**

- ☐ Human Drugs
- ☐ Medical Devices
- ☐ Biological Products
- ☐ Food Additives
- ☐ Color Additives
- ☐ Other

**4.1.1** **If Other, describe:**

**ID:** IRB#11-003579 View: NEW 2.3 - Methods/Procedures - Descriptors

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Methods/Procedures - Descriptors

*Note: The items listed below are not an inclusive list of methods and procedures that may be used in research studies. The list only includes items that will trigger additional questions related to the research or are needed for the review process*

**1.0** ***Indicate all that apply to this study.**

- ☐ Audio, Visual or Digital Recordings
- ☐ Behavioral Observations (only applicable if you selected Exempt Category 2 in section 5.3)
- ☑ **Certificate of Confidentiality**
- ☑ **Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention**
- ☐ Community Based Research
- ☐ Controlled Substances (Schedule I or II)
- ☐ Deception or Partial Disclosure
- ☐ Devices/Diagnostics (including Humanitarian Devices - HUD)
- ☐ Drugs/Biologics/Dietary Supplements
- ☐ Expanded Access to Drug, Device or Biologic for Treatment Purposes (aka Compassionate Use, Treatment Use)
- ☐ Genetic Analyses/Genotyping
- ☐ Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells
- ☐ Human Gene Transfer/ Recombinant DNA
- ☐ Infectious Agents
- ☐ Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.
- ☐ Radiation (Standard of Care or Investigational use of radioactive materials or ionizing radiation)
- ☐ Substance Abuse Research (with Medication)
- ☐ Treatment in an Emergency Setting (with request to waive consent)
- ☐ **None of the above**

**2.0** ***Will the study require services or resources owned / rented / operated or provided by the UCLA Health System (e.g. clinic and / or hospital visit(s), CTRC, professional medical services, clinical treatment, diagnostics, labs, medical supplies, etc.)?**

***Please direct any questions about this to The Financial Coverage & Activation Team at coverageanalysis@mednet.ucla.edu.***

○ Yes ◉ No

**ID:** IRB#11-003579 View: NEW 3.1 - UCLA IRB Review or Reliance

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## UCLA IRB Review or Reliance

**1.0** ***Please incidate the type of reliance (check all that apply):**

- ☐ UC MOU
  ***Online registration is ALSO required at the UC IRB Reliance Registry.***
- ☐ UCLA/RAND Health Services MOU
  ***UCLA/RAND Request registration form.***
- ☑ **CTSI MOU**
  ***CTSI protocol registration form.***
- ☐ NCI CIRB
- ☐ Western IRB
- ☐ Quorum IRB
- ☐ **NCATS SMART IRB**
- ☐ Chesapeake IRB
- ☐ Copernicus IRB
- ☐ Other IRB(s) not listed above

**Note:**

- Please be sure that you have indicated in section 1.3 of this application that this is a multi-institutional study and whether UCLA is responsible for the overall direction of the study at the other institution(s).
- Regardless of your selection above, please list the collaborating site(s) in section 1.5 (or lead site institution in section 1.6) of this application.
- If you are requesting UCLA to serve as IRB of record for collaborator(s), please also ***complete the required application form*** and submit by email to OHRPP to make a formal request.
- See Reliance of UCLA Investigators on External IRBs for information about existing UCLA agreements and contact OHRPP for assistance.

**1.1** **If you checked "Other IRB(s) not listed above", identify.**

**1.2** **If you selected UC MOU above, please select all involved:**

- ☐ UC Berkeley
- ☐ UC Davis
- ☐ UC Irvine
- ☐ UC Merced
- ☐ UC Riverside
- ☐ UC San Diego
- ☐ UC San Francisco

- [ ] UC Santa Barbara
- [ ] UC Santa Cruz
- [ ] **UC Division of Agriculture and Natural Resources**
- [ ] **Lawrence Berkeley National Laboratory (LBNL)**

**1.3** **If you selected CTSI MOU above, please check all the collaborating institutions:**

- [ ] Cedars-Sinai Medical Center (CSMC)
- [ ] LA BioMed (At Harbor-UCLA Medical Center)
- [x] **Charles R. Drew University**
- [ ] University of Southern California (USC)

**1.4** **Documentation Required for UCLA to Serve as Reviewing IRB for CTSI or UCLA/RAND MOUs**
See Reliance of UCLA Investigators on External IRBs for instructions.

| Document Name | Document Version # |
|---|---|
| Cedars CTSI protocol | 0.04 |
| CTSI protocol (Dr. Harawa) | 0.01 |
| CTSI Protocol (Ganjian) | 0.01 |
| Harbor CTSI protocol | 0.02 |



**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Funding and Other Study Characteristics

**1.0** ***Indicate the funding status for this study**.

- (•) **Funded**
- ( ) Application for funding is pending
- ( ) Departmental funding / Self funding / No funding

**2.0** ***Check all that apply**:

- [ ] The research will be conducted through the UCLA Clinical and Translational Research Center (CTRC)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Defense (DOD)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Energy (DOE)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Justice (DOJ)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Education (ED)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Protection Agency (EPA)
- [x] **None of the above**

**2.1** **If you selected DOD, DOE, DOJ, ED, and/or EPA support/collaboration, please provide your assurances that you will review the additional requirements for research supported by the relevant federal agency.**

**Agree** [ ]

**Note**: Please refer to the Federally-Supported Research section

of the OHRPP guidance document: Funding Considerations for Federally-Funded and Industry-Sponsored Human Research.

**ID:** IRB#11-003579 View: NEW 6.2 - Funding - Description

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Funding - Description

*Based on the response to section 6.1/item1, this study is or will be funded. Please provide the following information.*

The Office of Contract and Grant Administration (OCGA) provides the list of funding sources used by webIRB in this section. Please check your OCGA paperwork to find the correct name of the funding source(s) for this study. Identifying the right funding source is important because:

▪ webIRB will auto-populate the designated funding source name on the approval letter for the study. Many funding sources require an accurate identification of their name on the IRB approval letter before they will release funding;
▪ The Office of Research Administration uses data from webIRB to generate funding reports.

Click here for tips on how to find the funding source name in webIRB.

**1.0** **Identify the funding source(s).**
If a specific funding source has ended, do not delete it, instead please click Update next to the funding entry and **revise item 1.9**.

| Funding Source | Funding Source Information |
|---|---|

View NIH-NIDA NATIONAL INSTITUTE ON DRUG ABUSE

| | |
|---|---|
| **Name of the Funding Source** | NIH-NIDA NATIONAL INSTITUTE ON DRUG ABUSE |
| **If other, specify** | *No Value Entered* |
| **UCLA PI named on the grant, contract, subcontract or gift:** | WILLIAM CUNNINGHAM |
| **Indicate the type of award:** | Grant |
| **If other award, specify** | *No Value Entered* |
| **Indicate the Grant Title:** | Effectiveness of Peer Navigation to Link Released HIV+ Jail Inmates to HIV Care. |
| **Indicate the Award Number assigned by the funding source:** | 1R01DA030781-01 |
| **Indicate the description that applies to the source of funding named in the above item. If this is a subcontract, indicate the original source of funding:** | Federal |
| **If Other, specify** | *No Value Entered* |
| **Attach a copy of the funding proposal, subcontract, or scope of work.** | **Document Name**: NIDA JAILS Proposal<br>**Document Version #**: 0.01 |
| **Does the content of this IRB application differ from the activities described in the attached funding proposal, subcontract, or scope of work?** | No |
| **If yes, describe:** | *No Value Entered* |
| **Check this box to indicate that this specific funding has ended** | *No Value Entered* |

**ID:** IRB#11-003579 View: NEW 8.1 - Study Design

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Study Design

**1.0** ***Check all that apply to the study design.**

- [x] **Direct subject contact ONLY – The research activities involve direct contact with study participants (e.g., collection of data or specimens in person or via internet, phone, mail, etc.)**
- [ ] **No direct subject contact** – None of the research activities involve direct contact with study participants and include only analyses of data, records and/or human biological specimens (e.g., medical record or other record review, study of specimens left over from clinical procedures).
- [x] **BOTH Direct subject contact AND No direct subject contact – Some of the research activities involve direct contact with study participants and some of the research activities involve analyses of data, records and/or human specimens obtained without contact with participants.**

**ID:** IRB#11-003579 View: NEW 8.3 - Clinical Trial of a Behavioral Intervention, Drug, Biologic or Device

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Clinical Trial of a Behavioral Intervention, Drug, Biologic or Device

*You indicated that this study includes a clinical trial (section 2.3/item 1.0). Please provide the following information*

**1.0** ***Indicate the type of clinical trial.**

**Check all that apply:**

- [x] **Randomized**
- [ ] Non-randomized
- [ ] Single Blinded
- [ ] Double Blinded
- [ ] Placebo
- [ ] Sham Control
- [ ] Active/Treatment Control
- [ ] Open Label
- [ ] Crossover
- [ ] Washout Period
- [ ] Dose Escalation
- [ ] Other

**1.1** **If you indicated "other", specify.**

**2.0** ***Indicate the type of clinical trial:**

- ( ) Pilot/Feasibility
- ( ) Phase I
- ( ) Phase I/II
- ( ) Phase II
- ( ) Phase II/III
- ( ) Phase III
- ( ) Phase III/IV
- ( ) Phase IV
- ( ) Open Label Extension/Rollover
- ( ) Expanded Access
- (•) **Behavioral**

**3.0** ***Indicate the status of registration of registering this trial with ClinicalTrials.gov**

- (•) **Registered**
- ( ) Registration Pending
- ( ) Not Registered

**4.0** **If the trial is registered, provide the Trial Registration Number:**
NCT01406626

**ID:** IRB#11-003579 View: NEW 8.10 - Regulatory and Committee Approvals

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Regulatory and Committee Approvals

*Based on the response to section 2.3/item 1.0, you are seeking approval from one or more committees or regulatory agencies. Please complete the following items, as appropriate to this study.*

**1.0** **Certificate of Confidentiality**

***If you indicated that you are obtaining a Certificate of Confidentiality for this study, please respond to the following item.***

**1.1** **Indicate the status of the Certificate of Confidentiality application for this study:**

- (●) **Granted**
- ( ) Pending
- ( ) Application not yet submitted

**1.2** **Upload a copy of the Certificate of Confidentiality once it is granted.**

| Document Name | Document Version # |
|---|---|
| NIH Certificate of Confidentiality | 0.01 |

**2.0** **Controlled Substances or Substance Abuse Research (with Medication)**

***If you indicated that you are conducting research with controlled substances or substance abuse research with medication, approval is needed from the Research Advisory Panel - California. Please complete the following items.***

**2.1** **Indicate the status of approval from the Research Advisory Panel - California (RAP-C).**

- ( ) Approved
- ( ) Pending
- ( ) Application not yet submitted

**2.2** **If the study has been approved by RAP-C, attach the letter here.**

| Document Name | Document Version # |
|---|---|

There are no items to display

**3.0** **Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells**

***If you indicated that this study includes embryonic stem cell research, please provide the following information.***

**3.1** **Indicate the status of approval from the UCLA Embryonic Stem Cell Research Oversight Committee (ESCRO):**

- ( ) Approved

- ◯ Pending
- ◯ Application not yet submitted

**3.2** **Attach a copy of the completed UCLA Embryonic Stem Cell Research Oversight (ESCRO) Application and approval letter.**

| Document Name | Document Version # |
|---|---|

There are no items to display

**4.0** **Non-FDA Approved Medical Equipment with UCLA Patients/Research Participants**

***If you indicated that this study includes using of non-FDA approved medical equipment, please provide the following information.***

**4.1** **If you have a copy of an inspection report from Clinical Engineering, attach it here.**

| Document Name | Document Version # |
|---|---|

There are no items to display

**5.0** **Human Gene Transfer/Recombinant DNA**

***If you indicated that this study includes gene transfer, or recombinant DNA, please provide the following information.***

**5.1** **Attach copies of the following:**

**- One copy of the NIH Guidelines** Appendix M-II: Description of Proposal

**- All RAC correspondence and recommendations:**

**a) RAC approval or exemption letter**
**b) If applicable, a copy of RAC recommendations for the conduct of the trial**
**c) If applicable, one copy of the RAC reviewed protocol and sample consent documents**

| Document Name | Document Version # |
|---|---|

There are no items to display

**5.2** **Indicate the status of approval from the Biosafety Committee**

- ◯ Approved
- ◯ Pending
- ◯ Application not yet submitted

**5.2.1** **If the study has been approved by the Biosafety Committee, attach a copy of the approval.**

| Document Name | Document Version # |
|---|---|

There are no items to display

**5.3** **Post-Approval Reporting**

**5.3.1** **Indicate who is responsible for SAE reporting to the NIH Office Biotechnology Activities (OBA).**

- ◯ Principal Investigator named on this application

○ Other

**5.3.1.1 If you indicated 'Other', attach a copy of the letter of delegation on file with the OBA.**

**5.4 Principal Investigator's Certification**

I certify:

- **I have read the UCLA OHRPP Guidance on "Human Gene Transfer Research/Recombinant DNA Research"**
- **I will ensure that all personnel involved in the conduct of this study are aware of and will follow the UCLA OHRPP Guidance regarding Human Gene Transfer Research/Recombinant DNA Research**

**Agree** ☐

**6.0 Infectious Agents**

***If you indicated that this study includes infectious agents, please provide the following information.***

**6.1 Indicate the status of approval from the Biosafety Committee.**

- ○ Approved
- ○ Pending
- ○ Application not yet submitted

**6.2 If the study has been approved by the Biosafety Committee, attach a copy of the approval.**

| Document Name | Document Version # |
|---|---|

There are no items to display

**ID:** IRB#11-003579 View: NEW 9.2 - Information about Study Data

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Information about Study Data

*This information is needed to determine how you will best protect the confidentiality of data.*

**1.0 * Indicate all that apply to the study data.**

**Check all that apply:**

- ☑ **Obtained from a medical or clinical record**
- ☐ Created or collected as part of health or mental health care
- ☐ Used to make healthcare or mental healthcare decisions and/or provided to other healthcare professionals
- ☑ **Research data will be entered into the participants' medical or clinical record**
- ☐ **None of the above**

**2.0** ***Is it reasonably foreseeable that the study will collect information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse), ethically requires action (e.g., suicidal ideation), or is a reportable disease?**

○ Yes ◉ **No**

**2.1** **If yes, explain below and include a discussion of the reporting requirements in the consent document:**

**3.0** ***Indicate if any of the following are being obtained and used without any direct contact with study participants.**

- ☑ **Records (Not medical)**
- ☐ Human biological specimens
- ☐ **None of the Above**

**4.0** *Indicate all identifiers that may be **accessed or included in the research records** for the study**:**

- ☑ **Names**
- ☑ **Dates**
- ☑ **Age (if over 89 years)**
- ☑ **Postal Address**
- ☑ **Phone Numbers**
- ☑ **Fax Numbers**
- ☑ **E-Mail Address**
- ☑ **Social Security Number**
- ☑ **Medical Record Number**
- ☐ Health Plan Numbers
- ☐ Account Numbers
- ☑ **License/Certificate Numbers**
- ☐ Vehicle ID Numbers
- ☐ Device Identifiers/Serial Numbers
- ☐ Web URLS
- ☐ IP Address Numbers
- ☐ Biometric Identifiers (including finger and voice prints)
- ☑ **Facial Photos/Images**
- ☐ Any Other Unique Identifier (this does not include the code assigned by the investigator to identify the data)
- ☐ **None of the above**

**4.1** **If social security numbers will be collected explain why they are necessary, how they will be used, how they will be protected and how long they will be retained.**
7/19 addition: In the currently approved consent form, participants are asked to provide their consent to release their social security numbers and/or Driver's license numbers/ID numbers. We have now developed an additional consent form that, if signed by the participant, will enable the study team to contact the Social Security Administration and/or the Department of Motor Vehicles for updated participant locator information. This consent form will be administered during enrollment and, if privacy can be assured, at follow-up appointments with study staff.

The form is attached in Section 20.3/Item 5.0 of the application

Social security numbers will be used to track participants over time. Specifically, if participants become lost to follow-up, their

social security numbers will be used to determine participants' current place of residence through the social security administration or public databases. Participant consent as well as a certificate of confidentiality will be procured before social security numbers will be collected as part of the locator form or used for tracking purposes.

SSN will be stored on 128-bit encrypted password protected, computerized files in a locked file cabinet within a locked office at UCLA. Only authorized study staff will have access to these files.

**5.0** ***Select all that apply:**

- ☐ The data and/or specimens will be directly labeled with personal identifying information when acquired by the investigator for this research
- ☑ **The data and/or specimens will be labeled with a code that the research team can link to personal identifying information when acquired by the investigator for this research**
- ☐ The data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information when acquired by the investigator for this research
- ☐ The data are restricted use data (A term used in Social-Behavioral research. See guidance on the right.)

**5.1** **Indicate how the data will be used when this study is completed.**

**Check all that apply:**

- ☐ Use for this study
- ☐ Use for possible future research
- ☐ Use to create a bank or repository at UCLA
- ☐ Add to existing repository
- ☑ **Other**

**5.1.1** **If Other, specify:**
NIDA will create a public-use dataset with de-identified study data.

**ID:** IRB#11-003579 View: NEW 9.2a - Privacy and Confidentiality

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Privacy and Confidentiality

**Important Notes:**

- **Privacy is about people. Privacy refers to a person's wish to control the access of others to themselves.**
- **Confidentiality is about data. Confidentiality refers to the researcher's plan to handle, manage, and disseminate the participant's identifiable private information.**

See OHRPP Quick Guide: Protecting Privacy and Maintaining Confidentiality

**1.0** ***Privacy: How will the investigator maintain privacy in the research setting(s)? (e.g., interviewing participant in a room or area where conversations cannot be overheard by others, or conducting medical procedures in an examination room, or behind a curtain in an emergency room).**

All research activities involving study participants will be conducted in areas in which a participant's complete

privacy can be ensured. All study-related activities conducted in public places will be done at least 10 feet away from any non-study-related personnel.

**2.0** ***Confidentiality: If the protocol will collect and maintain identifiable data, explain how the planned safeguards to maintain confidentiality of identifiable data and data security are appropriate to the degree of risk from disclosure.**

**Note: Other sections of the application (e.g., Sections 9.3, 9.3a, 9.4, 9.5, and 15.3) will request specifications such as identification of persons who will have access to code keys or measures to comply with HIPAA requirements.**

All identifiable data will only be stored on encrypted and password-protected software; data will only be stored on secure network
servers. Any hardcopy materials will be maintained in a locked file cabinet in a locked room with limited access by authorized personnel.
These safeguards have been designed to maintain the highest level of data security, appropriate to the degree of risk from disclosure.

**ID:** IRB#11-003579 View: NEW 9.3 - Data Security

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Data Security

*You indicated that the study team will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items.*

**1.0** ***Do you agree to follow the OHRPP Data Security in Research guidance and procedures?**

- (●) **Yes**
- ( ) I have an alternate equally effective plan (*Note: The plan must be attached to item #2.1*)

**2.0** ***Do you have a data security plan for this study?** *(Note: a plan is not required for all studies; it may be recommended in some instance).*

(●) **Yes** ( ) No

**2.1** **If yes, attach it here:**

| Document Name | Document Version # |
|---|---|
| Data Safety Management Plan (DSMP) | 0.03 |

**3.0** ***Indicate all that apply to personally identifiable information or codes <u>during conduct of the study</u>:**

- [x] **The data and/or specimens will be coded**
- [x] **The personal identifying information will be removed and destroyed**
- [ ] Personally identifying information will be maintained with the data and/or specimens

**3.1** **If you indicated that the personal identifying information will be removed or destroyed or that the data/specimens will be coded, provide the following information:**

- **The process for removing and destroying the personal identifying information or for coding the information, and**
- **Indicate who will perform the task**

a) Each participant will be assigned a personal identification number which will be used to code all study materials, including

blood samples. UCLA research staff will assign the identification number and code all study materials accordingly

b) A master list linking the participant to study materials will be maintained in a locked office on designated, password-protected computers. In addition, a masterlist will be included in DatStat's secure data application and management system (Please see 24.0/1.0 for the attached "DatStat Data Security and Confidentiality" protocol).

c) Only the principal investigator and specially designated research staff will have access to the master list.

d) The only files other than the master list to include personal identifying information is a participant's tracking file. The tracking file will include identifying information (such as name, address, phone number, etc.) and the study ID. The purpose of this file is to track participants over time to ensure the administration of follow-up assessments and intervention activities. These files will be maintained in a locked office on designated, password-protected computers and/or in locked file cabinets. Only the principal investigator and specially designated research staff will have access to the tracking files.

**4.0** ***Will coded or personally identifiable data be collected, transmitted or stored via the internet?**

(●) **Yes** ( ) No

**4.1** **If yes, indicate all that apply:**

- [ ] A mechanism such as Survey Monkey, Zoomerang, or an e-mail anonymizing service will be used to strip off the IP addresses for data submitted via e-mail.
- [x] **The data will be encrypted.**
- [x] **A firewall will be used to protect the research computer from unauthorized access.**
- [x] **Controlled access privileges will be used on the hardware storing the data.**
- [ ] Other.

**4.1.1** **If you indicated "Other", describe:**

The CTSI sites require our interviewers to carry consent forms with them whenever they conduct study activities at the site. In order for the interviewers not to carry hardcopy forms which could be easily lost, consent forms will be scanned and then emailed to the interviewers, so that they have access to them electronically. We will also scan and email the locator forms for easy access to the interviewers in the field. Forms will only be sent on a password-protected and encrypted computer using a UCLA Mednet account.

Please see email communication with Gloria Varghese on 3.18.2013

**5.0** ***Provide your assurances that if there is a data security breach for this study, the PI will notify the IRB and your department's IT Compliance Coordinator.**

**Agree** [x]

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Data Security Plan - During the Study

*You indicated that data and/or specimens for this study will be coded (Section 9.3/item 3). Please complete the following information.*

**1.0** During the study indicate **how data will be stored and secured** including paper records, electronic files, audio/video tapes, specimens. Specify how the **code key** will be securely maintained, as applicable.

**Check all that apply:**

**1.1** ***Electronic Data**

- [x] **Encryption or password protection software will be used**
- [x] **Secure network server will be used to store data**
- [ ] Stand alone desktop computer will be used to store data (not connected to server/internet)
- [ ] A contracted outside vendor will store the code key. The vendor will have a business associate agreement with UCLA.
- [ ] Other
- [ ] **Not Applicable**

**1.2** ***Hardcopy Data, Recordings and Specimens**

- [x] **Locked file cabinet or locked room with limited access by authorized personnel**
- [x] **Locked lab/refrigerator/freezer with limited access by authorized personnel**
- [x] **The code key will be kept in a locked file in a locked room**
- [x] **The coded data and/or specimens will be maintained in a different room**
- [ ] Other
- [ ] **Not Applicable**

**1.3** **If you indicated "Other" in item 1.1 or 1.2 above, describe here.**

**2.0** ***By checking this box, I provide my assurance that all the person(s) who will have access to the code key have been identified in section 1.1 or section 1.1a.**

**Agree** [x]

**ID:** IRB#11-003579 View: NEW 9.5 - Data Security Plan

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Data Security Plan

*You indicated that the study will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items:*

**1.0** ***After the study is completed, indicate how the data codes and/or personal identifying information will be handled.**

**Check all that apply:**

- [x] **All data files will be stripped of personal identifiers and/or the key to the code destroyed.**
- [x] **All specimens will be stripped of personal identifiers and/or the key to the code destroyed.**
- [x] **Personal identifiers and/or codes linking the data and/or specimens to personal identifiers will be maintained for future research.**
- [ ] Audio or Video recordings will be transcribed and then destroyed or modified to eliminate the possibility that study participants could be identified.
- [ ] Photos or Images will be modified to eliminate the possibility that study participants could be identified.
- [ ] Restricted use data will be destroyed or returned to the source.

**1.1 If you indicated that personal identifiers will be maintained for future research, provide the following information:**
**a) How the information will be securely handled and stored**
**b) assure confidentiality, and**
**c) who will have access to the identifiers and/or codes.**

If the participant consents, participant contact information will be maintained for future studies. The contact information will be retained separately from study data.

For all electronically maintained contact information, the following safeguards will be used to ensure confidentiality:
--- Encryption or password protection software will be used
--- Secure network server will be used to store data

All contact information maintained as hardcopies will be stored in a locked file cabinet or locked room with limited access by authorized personnel

--- Only authorized personnel will have access to the contact information.

**2.0 Describe any additional steps, if any, to be taken to assure that the subjects' identities and any personal identifying information are kept confidential.**

**ID:** IRB#11-003579 View: NEW 9.6 - Use of Data and/or Specimens without Direct Contact

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Use of Data and/or Specimens without Direct Contact

*You indicated that some or all of the research activities do not involve direct contact with study participants (Section 8.1/item 1.0). Please provide the following information.*

**1.0** If **all** of your research activities are without direct contact with study participants, provide the following information:

**1.1 Indicate the purpose of the research, specifying the problems and/or hypotheses to be addressed**:

**1.2 Describe the study design and proposed data analyses**:

**1.3 *If you will conduct genetic analysis with specimens, provide your assurance that the results will not be disclosed to subjects or used for clinical care.**

- ○ Agree
- ◉ **Not Applicable**

**2.0** ***Describe specimens and/or data that will be acquired without direct contact with study participants. Complete this item for each type used in the study:**

| | Source | Data and/or Specimens Information |
|---|---|---|

View Division of HIV and STD Programs (DHSP) CaseWatch System

| | |
|---|---|
| **Data and/or Specimens? Indicate all that apply:** | Data |
| **Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective:** | Pre-existing<br>Prospective |
| **Describe the data and/or specimens and indicate the original collection dates:** | HIV primary care visits, dates and values of CD4 counts, dates and values of HIV viral loads, antiretroviral medication prescriptions, emergency room visits, hospitalizations, medical diagnoses and relevant dates, genotypes, substance use and mental health utilization |
| **Indicate the approximate number of data records and/or specimens to be collected:** | 1000 |
| **Will the specimens be used with animals?** | No |
| **If yes, indicate the IACUC Number:** | *No Value Entered* |

View Healthy Way LA

| | |
|---|---|
| **Data and/or Specimens? Indicate all that apply:** | Data |
| **Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective:** | Pre-existing<br>Prospective |
| **Describe the data and/or specimens and indicate the original collection dates:** | HIV primary care visits, dates and values of CD4 counts, dates and values of HIV viral loads, antiretroviral medication prescriptions, emergency room visits, hospitalizations, medical diagnoses and relevant dates, genotypes, substance use and mental health utilization |
| **Indicate the approximate number of data records and/or specimens to be collected:** | 1000 |
| **Will the specimens be used with animals?** | No |
| **If yes, indicate the IACUC Number:** | *No Value Entered* |

| | Source | Data and/or Specimens Information |
|---|---|---|
| View | Los Angeles Sheriff's Department Electronic Medical Records | |

| | |
|---|---|
| **Data and/or Specimens? Indicate all that apply:** | Data |
| **Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective:** | Pre-existing<br>Prospective |
| **Describe the data and/or specimens and indicate the original collection dates:** | HIV primary care visits, dates and values of CD4 counts, dates and values of HIV viral loads, antiretroviral medication prescriptions, emergency room visits, hospitalizations, medical diagnoses and relevant dates, genotypes, substance use and mental health utilization (Collection in progress) |
| **Indicate the approximate number of data records and/or specimens to be collected:** | 1000 |
| **Will the specimens be used with animals?** | *No Value Entered* |
| **If yes, indicate the IACUC Number:** | *No Value Entered* |

**3.0** *** If any sources of data and/or specimens are not at UCLA, provide your agreement that the appropriate institutional approvals for release will be obtained (e.g., IRB approval).**

- (●) **Agree**
- ( ) Not Applicable

**4.0** **Attach any data abstraction tools or lists with the data elements to be collected.**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**ID:** IRB#11-003579 View: NEW 10.1 - Study Summary - Research Study

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Study Summary - Research Study

**1.0** **Study Materials: As applicable to this study, attach the following:**

- **Protocol, Dissertation Proposal or Study Plan**
- **Preliminary Data**
- **Surveys, Questionnaires or other instruments to be used with study participants**
- **References**

| Document Name | Document Version # |
|---|---|
| LINK LA -- Follow-up 2 (English) | 0.01 |
| LINK LA Follow-up Instrument 3 | 0.01 |
| LINK LA Instrument -- Clean | 0.02 |
| LINK LA Instrument --- Follow-up (English) | 0.01 |
| LINK LA Instrument --- Follow-up (Spanish) | 0.01 |
| LINK LA Instrument (Baseline) - Spanish | 0.01 |
| LINK LA Intervention Appendices (1/2) | 0.01 |

| Document Name | Document Version # |
|---|---|
| LINK LA Intervention Appendices (2/2) | 0.01 |
| LINK LA Intervention Manual | 0.02 |
| References | 0.01 |

**2.0** ***Specific Aims: Indicate the purpose of the research, specifying the problems and/or hypotheses to be addressed.**

The primary aim of this study is to develop an effective intervention for recently released male jail inmates who are HIV+, using one-on-one, peer-based learning approaches. While recently released HIV+ inmates are at particularly high risk of failing to access and remain in HIV care following release from jail, few interventions have yet been developed to meet the needs of this population. The first phase of this study, which has been approved an executed, therefore involved formative semi-structured interviews with ex-inmates, case managers, and HIV care providers to examine individual-level and structural-level barriers to HIV care after release from jail. The insights gained from this study
phase will then be used to tailor the intervention to the needs of HIV+ ex-inmates. The intervention will then be evaluated in a two-group experimental RCT design, with the intervention group receiving health navigation services and the control group receiving usual care only. Specifically, the intervention's effectiveness will be evaluated
with regards to improving linkage with and retention in HIV care, self-reported ART adherence, and HIV RNA viral load suppression. Among the study's secondary aims, we will assess the potential moderating effects of substance abuse, the potential mediating effects of substance abuse treatment, and the program's effects on recidivism, and costs.

**3.0** ***Background and Significance: Provide a summary of the background for this study and explain how it will contribute to existing knowledge.**

**For greater than minimal risk biomedical studies, include preliminary data. If necessary, attach in Item 1.0 graphs or tables used to convey information. If there no preliminary data are available, briefly indicate why this proposed study is a reasonable starting point.**

The HIV epidemic and incarceration are closely linked, especially for low-income men of color. HIV prevalence among incarcerated individuals is five times that of the general population (1,2), and 20-26% of the HIV-infected United States (US) population passes through a correctional facility at some point each year (3-6). Despite this recognition, one of the greatest problems is the inability of existing programs to make sure that HIV+ inmates will continue to receive HIV care upon release and re-entry
into the community (6-11). In other words, once released from jail, former inmates often lack the resources to access HIV care ("linkage") and remain in long-term care ("retention"). This gap in care persists, even as medical services during incarceration have improved. Specifically, some studies have found that adherence to HIV medications ("ART") is better while persons are incarcerated than it is after release (12, 13). Observational studies, for example, have found that release from prison is associated with only a 30% likelihood of filling an ART prescription (14), nearly 50% discontinuation of ART with re-incarceration (15), marked increase in viral load (10-12), and increased HIV transmission risk behaviors (15).

Barriers to linkage to and retention in HIV care upon release from jail are multifold. Among common barriers, such as housing, employment, lack of social support and perceived stigma, the high prevalence of substance abuse among incarcerated HIV+ populations is particularly challenging. Substance abuse not only contributes to HIV risk behaviors but also increases the likelihood of future incarceration ("recidivism"). Many studies have shown that substance abuse interferes with care seeking
behavior and ART adherence in HIV+ men and women (16-20). In addition, use of substances ranging from alcohol to cocaine to methamphetamine has been linked to increased HIV risk behavior among HIV+ men, which in turn fuels HIV transmission (21-24). In the L.A. Sheriff's Department (LASD) jails system, 68% of arrests for HIV+ men are for drug- or alcohol-related offenses (25), and many opportunities exist for high risk sex in the setting of substance abuse upon release from jail (26-27). In addition to these barriers, inadequate transitional care at the jails-level may contribute to inefficient linkage to and retention in care. For instance, HIV+ inmates released from the LASD jails system are provided a maximum 3-7 day supply of ART and receive no further direct programming to support linkage to HIV care or other needed services such as substance abuse, mental health, or housing in the community. Upon release from jail, it is entirely up to the inmate to follow through on any referrals received from the jail-based transitional care managers. However, due to unpredictable timing of release (often with no advanced notice), the referral information is often
not available to the inmate, and appointments for care with the community-based providers are not made.

Causing significant delays in accessing HIV care, as well as interruption in ART regimens can lead to subsequent increase in HIV viral load and the transmission of a resistant form of HIV, which in turn requires more aggressive and more expensive treatment and follow-up.

While there is some existing research on linkage to care among recently released HIV+ inmates, most of this research has been conducted on prisons (4, 28, 29). However, far greater numbers pass through jails than prisons (30. 31). Moreover, persons in jails have less opportunity to establish optimal ART regimens given shorter incarceration periods, yet face equal disruption of treatment upon release (13, 33). Former jails inmates also have higher rates of repeated re-incarceration following
release from jail (75%) (30, 34), resulting in a revolving door between jail and the community (35,36). Consequently, the primary aim of this study is to develop and evaluate a newly designed intervention to improve linkage with and retention in HIV care for individuals recently released from the LASD jails system.

The intervention will use one-on-one, peer-based learning approaches, with a trained health navigator a) accompanying the participant to scheduled clinic appointments and mental health/substance use visits (accompaniment sessions) and b) conducting maintenance meetings between appointments. Patient navigation is an approach
that a few investigators have begun to use to address retention in HIV care (37). Patient navigation refers to the assistance offered to underserved populations in “navigating” through the complex health-care system to overcome barriers in accessing quality care and treatment (38). It was originally designed to help poor racial/ethnic minorities with cancer overcome obstacles to timely diagnosis and treatment (39-40). One frequent feature patient navigator programs generally have in
common is accompaniment to doctor appointments. Patient navigators may also address a variety of barriers including difficulties negotiating relationships with health care providers, lack of trust in providers, logistic barriers due to clinic schedules and lack of transportation, and low levels of health literacy (38, 40). Patient navigators are often “culturally matched” and/or have the same illness as the people they help, and are lay people or peers (38-40). A recent multisite study examined patient
navigation among marginalized HIV+ individuals and found that retention in HIV care and viral load suppression improved significantly from baseline to 12 months (37).

If this intervention is found to be effective, then this intervention could prove a useful model for other jurisdictions with large numbers of HIV+ ex-inmates frequently lost to follow-up medical care upon release from jail. Ultimately, this intervention could have substantial, widespread impact on the health care delivered to HIV+ ex-inmates across the US, as well as on public health and the criminal justice system.

--> References are included as an uploaded document

**4.0** ***Research Design and Methods: Describe in detail the design and methodology of the study.**

Overview: We will develop, deliver, and evaluate a health navigation intervention program aimed at linking and retaining inmates released from jail with HIV care, using a randomized design with a usual care control group.

In the RCT phase, for which we are currently seeking approval, we utilize a randomized design for 176 newly released HIV+ ex-inmates assigned to the intervention and 176 control subjects, to implement the intervention and evaluate its effectiveness. The control subjects will receive usual care which involves meetings with transitional case managers who help incarcerated HIV+ inmates transitioning back to the community to connect to relevant services. Intervention subjects will participate in navigator accompaniment sessions as well as navigator meetings:

INTERVENTION
-- Navigator accompaniments:
The health navigators will travel to the home or mutually-agreed-upon meeting place with participants on the day of their clinic appointment, approximately two hours prior to the appointment (unless otherwise requested by the participant). The purpose of having the navigator accompany the participant to the medical appointment is to a) ensure that the participant keeps his scheduled appointment and b) model effective pre-appointment behaviors (i.e. bringing medications to ensure that the participant has a comprehensive medication list, thus averting potentially adverse drug interactions). No confidential or private discussions will take place in any public areas. Furthermore, the participant can freely decide whether to have the navigator present during the actual encounter with the medical provider or not; all navigators will sign confidentiality agreements. Before and after the appointment, the health navigator will review major components of the training program in a private room at the clinic or another private location preferred by the participant. The emphasis in these sessions will be on the health navigator acting as a role-model by literally “walking through” the retention behavior by accompanying the

participant to the medical visit, while also sharing personal experiences relevant to training in a non-didactic manner. Insofar, the health navigator will share his experiences as HIV+ ex-inmate who has maintained good health and quality of life through good retention in care.

There will be a total of 2 navigator accompaniment sessions.

-- Participants may also request monthly accompaniments to any supportive HIV care appointment, including but not limited to substance abuse treatment appointments or mental health appointments. No formal intervention content will be delivered during these sessions. The health navigator's role for these supportive HIV care appointments is to model effective retention behavior by accompanying the participant to the medical visit. A maximum of 6 supportive care accompaniments will be offered to the participant, if requested.

--- Navigator meetings:
Navigator meetings will take place in person, ensuring complete privacy. The first navigator meeting will take place while the participant is still incarcerated. Subsequent meetings will be held in a private location in the community, accommodating the participant's preference of location. If the participant is re-incarcerated subsequent to his release, follow-up sessions may be conducted in jail. The purpose of the navigator meetings is to reinforce and review positive retention behaviors and skills and to maintain regular contact with the participant.

There will be a total of 10 navigator meetings.

NAVIGATOR CARE CALLS
There will be 14 health-navigator calls that will focus on reviewing participants' HIV care goals, employing active problem-solving techniques to help participants achieve these goals (scripts to be submitted for IRB approval in a subsequent submission). In addition, a participant may request daily calls from the navigator during the initial post-release period. These calls are intended to be check-ins to ease the participants' transition into the community.

Participants who have completed the intervention will receive a certificate of completion. No sensitive information, such as the HIV-related content of the intervention will be mentioned in the certificate.

REMINDER SYSTEMS:
Before each study-related activity that is conducted in the community, a participant may request to be reminded of the upcoming activity by a) text message, b) email, and/or c) phone message.

a) TEXT MESSAGES
Two reminder text messages will be sent to each participant who requests this type of reminder system.

b) EMAIL MESSAGES
Two reminder email messages will be sent to each participant who requests this type of reminder system.

c) PHONE MESSAGES
Two reminder phone messages will be delivered to each participant who requests this type of reminder system.

ASSESSMENTS:
All consented and enrolled participants, regardless of treatment arm, will be administered a standardized baseline assessment protocol after enrolment into the study and before the intervention is launched (month 0). The baseline interview will be conducted in jail while the participant is still incarcerated. Follow-up interviews will take place at months 2, 6, 12 after release from jail. If reincarcerated, follow-up interviews will be conducted in jail.

BLOOD SPECIMENS:
Blood specimens of all participants, regardless of treatment arm, will be collected at baseline in jail and months 2 and 12 after release from jail. If a participant is reincarcerated, viral load tests will be performed in jail if study-related viral load blood draws are due during that time (unless already performed by the LASD Medical Services Bureau as part of regular care). The purpose of collecting those blood specimens is to determine viral load levels. Viral load levels are important determinants of successful HIV treatment. Trained phlebotomists will be drawing blood samples; blood samples will be analyzed and stored in labs maintained by the L.A. County Department of Public Health.

The study team will work the LASD Medical Services Bureau (MSB) to obtain current viral load test results from each enrolled participant's medical record whenever possible. This approach will increase cost efficiencies for the study as well as reduce the burden of additional blood draws for the participant. In this event, the MSB will already be providing these results. In the event that a viral load is not performed by the Medical Services Bureau

as part of routine HIV care in the jail setting, the Research Analyst will coordinate with MSB staff to have blood drawn as part of the baseline interview session. The study project will pay for the cost of the viral load test and the results of the test will be provided to the study team as part of the baseline assessment data. The viral load test results will be shared with MSB so that trained MSB staff may disclose these results to the participant as part of a future medical visit.

-- For viral load tests conducted outside of jail, trained phlebotomists or phlebotomists contracted through one of the community sites will conduct the blood tests in a private and safe environment.

(1) will subjects be informed of their test results
-- If study-related viral load tests are conducted during incarceration, the viral load test results will be shared with the Los Angeles Sheriff's Department Medical Services Bureau (MSB) so that trained MSB staff may disclose these results to the participant as part of a future medical visit.

-- For study-related viral load tests conducted outside of jail, the viral load test results will NOT be shared with the Los Angeles Sheriff's Department Medical Services Bureau (MSB). Instead, study staff will inform the participant that he or she may receive his result from the the study's main telephone line. A trained clinician will provide the results to the participant and explain their clinical significance for follow-up care.

(2) how, when, and where and by whom the test results will be managed
The L.A. County Department of Public Health lab will analyze and store blood samples and then enter results in CaseWatch or fax the results to study administrators via a secure fax line. Results will be stored in a locked file cabinet and/or encrypted password-protected computer at UCLA within a locked office. No identifying information will be associated with lab results.

(3) what will be done with the blood samples after testing is completed.
Samples will be destroyed in accordance with L.A. County Department of Public Health lab procedures.

DATA ABSTRACTION:
Data will be abstracted from the following datasets for all participants, regardless of treatment arm:
1. Healthy Way L.A. Medical Records (client-level data) - Data on ambulatory, hospital, outpatient and ER visits will be retrieved; Participant consent will be procured prior to retrieval of data.

2. LASD Electronic Medical Record (client-level data) - Data on ambulatory, hospital, outpatient and ER visits will be retrieved; Participant consent will be procured prior to retrieval of data.

3. DHSP CaseWatch system for uninsured HIV+ patients in LA County - Data on ambulatory, hospital, outpatient and ER visits will be retrieved; Participant consent will be procured prior to retrieval of data.
---
(1) Describe the procedures for contacting and interviewing inmates by study staff while incarcerated.
-- Sheriff's deputies will provide inmates who are participating in this study with a 'medical pass' to meet the health navigator or interviewer/study coordinator at a pre-determined private location within the jail. This type of pass is routinely given to inmates who have a scheduled medical appointment within the jail. Provision of this medical pass does not reveal to third parties what the medical purpose of the pass is.

(2) Describe how subjects' privacy and confidentiality will be maintained, including the measures employed to minimize potential for stigmatization.
-- In order to minimize the risk for stigmatization, no study materials are given to the participant while incarcerated. Furthermore, when the participant meets with the health navigator or other study staff, nobody will know the purpose of the meeting, as the participant is simply given a medical pass (described above). All study activities will be conducted in private areas.

(3) Describe the procedures of re-contact if a participant becomes incarcerated after initial release.
-- Appropriate L.A. Sheriff's Department databases will be checked periodically to determine whether a participant who is lost to follow-up has been re-incarcerated. Study staff will then follow-up with re-incarcerated participants through the study coordinator located within the jails.

---

If the intervention is effective, the L.A. Sheriff's Department in conjunction with the L.A. County Dept of Public Health will consider making the intervention available to all HIV+ inmates upon release from jail. However, the study team does not have any control over the Sheriff's Department's decision whether or not to implement the intervention following the conclusion of the study. Furthermore, due to considerable budgetary constraints and lack of sufficient time in the 5-year study period, the study team is not in a position to offer participation in the intervention to control arm subjects at the end of each control participant's 12-month assessment period.

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TERMINATION OF INTERVENTION ACTIVITIES (October 2015)

----- Summary of Change
Pending approval of this addendum, the LINK LA study no longer provides support from a peer navigator to its participants because the peer navigation piece of the study has ended. This means that no participants, regardless of treatment arm, will receive intervention services as part of the LINK LA study. Consequently, they are no longer eligible to earn up to $40 in incentives for meeting with the navigator.

However, all participants, regardless of treatment arm, will participate in the remaining interviews and viral load blood draws. The incentives associated with the data collection remain the same.

---- Rationale for Change
The study is now in its final year of funding and therefore needs to reduce its operations while finishing up the data collection to evaluate the effectiveness of the peer navigation intervention. To-date, 119/156 (76%) of all eligible participants have finished their participation in the intervention. The retention rate in the study, and thus the ability to draw valid conclusions, is therefore strong and efficacious.

A consent addendum has been created and included in this study addendum for the Board's review. The consent addendum explains to participants enrolled in the intervention arm that intervention services are no longer offered while data collection activities continue. All intervention participants who can be located for follow-up data collection activities will be asked to sign this consent form.

Please note that enrollment is closed at this point and no new participants are enrolled in the study

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TERMINATION OF INTERVENTION ACTIVITIES (November 2015)

----- Summary of Change
Pending approval of this addendum, the LINK LA study no longer provides phone services to the remaining participants in the study. Participants can retain the study-issued phones at no expense but they must cover their own phone service. Participants cannot 'buy in' to the study's T-Mobile phone plan. Participants must find a different phone plan and pay for it out of pocket.

However, all participants will participate in the remaining interviews and viral load blood draws. The incentives associated with the data collection remain the same.

---- Rationale for Change
The study is now in its final year of funding and therefore needs to reduce its operations while finishing up the data collection to evaluate the effectiveness of the peer navigation intervention.

---- New consent procedures
A consent addendum has been created and included in this study addendum for the Board's review. The consent addendum explains to participants that phone service is no longer offered but that the participants can keep their phones at no charge. All participants who can be located for follow-up data collection activities will be asked to sign this consent form.

Please note that enrollment is closed at this point and no new participants are enrolled in the study.

**4.1** * **Will you be providing results of any experimental tests that are performed for the study?**

- ○ Yes - Complete Items 4.1.1 and 4.1.2
- ○ No
- ◉ **Not Applicable**

**4.1.1** **You indicated in Item 4.1 that the research involves experimental tests. Please describe the tests, provide a rationale for providing participants with the experimental test results and explain what, how and by whom participants and**

**their health care provider will be told about the meaning, reliability, and applicability of the test results for health care decisions.**

**4.1.2** **Will tests be performed by a Clinical Laboratory Improvement Amendments (CLIA) approved lab?**

○ Yes ○ No

**5.0** ***Indicate how much time will be required of the subjects, per visit or contact, and in total for the study.**

See attached "LINK LA intervention overview"

**6.0** ***Statistics and Data Analysis: Describe the proposed statistical procedures or descriptive analyses for the study. If applicable, indicate how the sample size was determined.**

All analyses will be conducted using intention to treat. This method minimizes the potential bias introduced by only analyzing participants who are retained in the study, which may inflate the observed benefit in the intervention arm. We will measure the level of participation in the study, and conduct a sensitivity analysis to assess the stability of study outcomes when an intention-to-treat analysis versus an analysis that takes into account level of participation is conducted.

Sample Size/power.
All analyses will be conducted to determine intervention effect sizes with regard to the primary study outcome of HIV RNA VL and retention in HIV care. Based on extensive review of the literature, we have selected 0.5 log VL difference between intervention and control groups as the key effect size upon which to base our sample size and power analysis. We will analyze VL as a continuous variable since VL level has a dose-response relationship with HIV transmission risk, as well as progression of HIV infection to an AIDS diagnosis or death.

In sensitivity analysis, we will also categorize VL as undetectable vs. detectable and use logistic regression to adjust for possible covariates that might influence the likelihood of achieving viral suppression. If we estimate in the control group mean log VL to be 8.54 (standard deviation of 1.25) at 6 months based on the available data in this population and the assumption of the lognormal distribution of VL, a final sample of 500 participants (250 per arm) will have 80% power (using a type I error of 0.05) to detect a mean difference of 0.5 in log VL suppression between intervention and control groups.

**ID:** IRB#11-003579 View: NEW 11.1 - Characteristics of the Study Population

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Characteristics of the Study Population

**1.0** ***Is this an observational or ethnographic study for which the number of participants observed or interviewed cannot be determined in advance.**

○ Yes ◉ **No**

**2.0** **If you answered "no" to item 1.0, indicate the maximum number of study participants you hope to enroll:**
N=352; 0 participants will be recruited at Harbor/LABiomed and CSMC CTSI

**3.0** **How many participants do you expect you will need to recruit, consent and/or screen to meet the target**

**number above?**
N=550; 0 participants will be recruited at Harbor/LABiomed and CSMC CTSI

**4.0** ***Indicate the specific inclusion criteria for enrollment of each of the groups of research participants in this study.**
**If there are any inclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken*, explain the nature of and scientific rationale for the inclusions.**
1. Age: 18 years or older
2. Male or male-to-female transgender
3. Bi-lingual Spanish
4. Residing in LA County upon release

**5.0** ***Indicate the specific exclusion criteria for each of the groups of research participants in this study.**
**If there are any exclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken*, explain the nature of and scientific rationale for the exclusions.**
1. Inability to give informed consent
2. stays in jail <5 days
3. Mono-lingual Spanish

**6.0** ***How (chart review, additional tests/exams for study purposes, etc.), when and by whom will eligibility be determined?**
No medical records or additional tests/exams need to be reviewed to screen for eligibility.

**ID:** IRB#11-003579 View: NEW 11.2 - Characteristics of Study Population

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Characteristics of Study Population

**1.0** ***Indicate the age range of the study participants.**

**Check all that apply:**

- [ ] 0 to 6 years
- [ ] 7 to 11 years
- [ ] 12 to 17 years
- [ ] 17 or younger **in California** who can consent for themselves - see note below
- [ ] 17 or younger **outside California** who can consent for themselves - see note below
- [x] **18 years or older**

**NOTE:**

- For additional information on minors **in California** who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians
- For additional information on minors **outside of California** who are permitted to consent for themselves please refer to the section "Exceptions Outside of California" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians

**2.0** ***Indicate if any of the following populations/specimens will be specifically recruited/obtained for the study.**

- [x] **Adults who are competent to give informed consent**
- [ ] Adults unable to give informed consent

- [ ] Adults with diminished capacity to consent
- [ ] Fetal Tissue
- [ ] Neonates
- [ ] Participants Unable to Read, Speak, or understand English
- [ ] Pregnant Women/Fetuses
- [x] **Prisoners**
- [ ] UCLA Faculty/Staff
- [ ] UCLA Students
- [ ] Wards
- [ ] **Unknown/Not Applicable**

**3.0** * **Is it possible that there may be non-English speakers enrolled in this study or children whose parents are non-English speaking?**

○ Yes ◉ **No**

**ID:** IRB#11-003579 View: NEW 12.8 - Prisoners/Detainees

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Prisoners/Detainees

*You indicated that this study includes prisoners/detainees (Section 11.2/item2). Please provide the following information.*

**1.0** ***The federal regulations specify that research involving prisoners may only be conducted in one of the following categories.**

**Check the description that is applicable to your study:**

- [x] **Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study is no more than minimal risk and no more than inconvenience to the subjects. 45 CFR 46.306(a)(2)(i)**
- [ ] Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study is no more than minimal risk and no more than inconvenience to the subjects. 45 CFR 46.306(a)(2)(ii)
- [ ] Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults). Note: The study may proceed only after the DHHS Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice in the FEDERAL REGISTER of his intent to approved such research. 45 CFR 46.306(a)(2)(iii)
- [ ] Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary [of the DHHS] has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research. 45 CFR 46.306(a)(2)(iv)
- [ ] Epidemiological research conducted or supported by HHS: Epidemiological research, that has as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. The study must pose no more than minimal risk and present no more than an inconvenience to prisoner subjects; prisoners must not be a specific focus of the research.

**1.1** **If you selected more than one description, indicate the groups of prisoners involved in the study and the category for each group.**

**2.0** **Your assurance to the following conditions is required by 45 CFR 406.305 for IRB approval of research involving prisoners:**

2.1 *Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. 45 CFR 46.305(a)(2);

Agree ☑

2.2 *The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers. 45 CFR 46.305(a)(3) ;

Agree ☑

2.3 *Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. 45 CFR 46.305(a)(4);

Agree ☑

2.4 *The information is presented in language which is understandable to the subject population. 45 CFR 46.305(a)(5);

Agree ☑

2.5 *Parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. 45 CFR 46.305(a)(6);

Agree ☑

3.0 * Is there any need for follow-up examination or care of the prisoners after their study participation has ended?

○ Yes ◉ No

3.1 If yes, describe the provisions that have been made for follow-up examination or care, taking into account the varying lengths of the prisoners' sentences and how they will be informed.

4.0 *Indicate where this study will take place:

☑ Inside California

☐ Outside California

5.0 * Does this study include a control group?

◉ Yes ○ No

***If you indicated that this study includes a control group, please respond to the following items (45 CFR 46.306 (a)(2)(iv)).***

5.1 Does this study assign prisoners to a control group that may not benefit from the research?

○ Yes ◉ No

5.2

**Are the control subjects selected randomly from the group of available prisoners who meet the characteristics needed for this study?**

◉ **Yes** ○ No

**5.2.1** **If applicable, provide justification for your proposed selection of control subjects. See guidance in the gray space to the right.**

**ID:** IRB#11-003579 View: NEW 12.8.1 - Prisoners/Detainees - In California

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Prisoners/Detainees - In California

*Based on your response to Section 8.1, this is a treatment study or includes an IND medication and takes place in California. Please provide the following information.*

**1.0** ***Additional approvals and consideration are required to conduct research involving prisoners within California. The regulatory requirements and provisions for conducting research involving prisoners within California are described in the California Code of Regulations (CCR), Title 15, Article 9.1 and California Penal Code, Sections 35000-3524. Research involving California Department of Corrections and Rehabilitation (CDCR) wards, inmates, parolees, and staff, regardless of funding source, requires review and approval by CDCR. Click here for more information on CDCR review and approval**

**Please provide your assurances that you will identify and comply with the applicable requirements for conducting research involving prisoners within California (e.g., California Code of Regulations (CCR), Title 15, Article 9.1; California Penal Code, Sections 3500-3524; CDCR Approval).**

**Agree** ☑

**Important Note: If the research that involves prisoners in California is a treatment study or includes an IND medication, California Penal Code - section 3502.5 applies. Please contact OHRPP for assistance.**

**ID:** IRB#11-003579 View: NEW 14.1 - Risks & Benefits

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Risks & Benefits

**Benefits**

**1.0** ***Are there any potential direct benefits (physical, psychological, social or other) to study participants?**

○ **Yes** ◉ **No**

**1.1** **If yes, describe.**

**2.0** ***Describe the potential benefits to society including the importance of the knowledge to be gained.**

This study benefits society by addressing important public health concerns: Ex-inmates' delays in accessing HIV care, as well as interruption in ART regimens can lead to subsequent increase in HIV viral load and the transmission of a resistant form of HIV, which in turn requires more aggressive and more expensive treatment and follow-up. Thus, our study has important public health benefits beyond the potential benefit of the intervention to the individual HIV+ participant. If the intervention is
successful and adopted by jails systems nationwide, the community to which the ex-inmate returns may benefit from reduced crime and improved public health outcomes.

**Risks**

**3.0** ***Indicate the potential risks/discomforts, if any, associated with each intervention or research procedure.**

**Additionally discuss any measures that will be taken to minimize risks. If data are available, estimate (a) the probability that a given harm may occur, (b) its severity, and (c) its potential reversibility. The information provided should be reflected in risks section of the informed consent documents.**

**If this is an exempt study and there are no risks, indicate N/A. Otherwise, please see the help text.**

RISK AND DISCOMFORTS
Participation in this study poses minimal risks to the participant. There are no physical risks associated with participation, except discomforts associated with needle pricks, and the information obtained during the interviews is not expected be psychologically distressing to the participants. The possibility of personal discrimination as a result of participation in a study of HIV could be a risk, if sensitive information about the participant were released in some untoward breach of confidentiality, or if information were released that could indirectly
identify confidential characteristics of a person.

MINIMIZING RISKS AND DISCOMFORTS:
-- Research staff training: In order to minimize any potential risks and discomforts to participants, extensive staff training and supervision protocols have been devised. The staff, including interviewers, phlebotomists and health navigators, will be trained to be sensitive to the needs of the participants, to be alert to a participant's need to opt out of all or part of any study component, and to take frequent rest periods. Staff will receive initial and ongoing training in: research ethics and confidentiality; study protocols; emergency procedures; and mandated reporting procedures. A minimum of biweekly supervision meetings are conducted for study staff.
-- Phlebotomists will be trained professionals, following all safety procedures
-- Project staff in supervising roles will also randomly monitor all research activities to ensure proper study procedures.
-- All individuals that come in contact with the data will be
required to sign a confidentiality agreement that puts them in violation of the study protocol if they discuss participants' identifying information with anyone outside of the study team.
-- All study materials will be de-indentified and coded.
-- All study activities will only be conducted in private areas
-- Harcopy materials and all computer files will be stored by a unique ID number on 128-bit encrypted password protected computer in a locked file cabinet in locked offices at UCLA. Only select authorized study staff will have access to these offices.

**Risk/Benefit Analysis**

**4.0** ***RISKS/BENEFIT ANALYSIS: Indicate how the *risks to the participants are reasonable in relation to anticipated benefits*, if any, to participants and the importance of the knowledge that may reasonably be expected to result from the study:**

Risk to the study subject from participation in the study is minimal and the potential benefit to society is substantial. Specifically, the intervention may improve participants' own medical care and health

**Alternatives**

**5.0** ***Indicate the alternatives to participating in this study.**

**Check all that apply.**

- [x] **All types of studies - Choose not to participate in the study**
- [ ] Clinical/Intervention Studies - Receive standard of care instead of participating in the study
- [ ] Clinical/Intervention Studies - Medication, device, or other treatment is available off study
- [ ] Item is Not Applicable (e.g., study of existing data)
- [ ] Other

**5.1** **If "other" was selected, specify.**

**5.2** **If this is a clinical/intervention study:**

**Describe the standard of care or activities at UCLA (or study site) that are available to prospective participants who do not enroll in this study. If not applicable to your study, state not applicable (N/A).**
Participants in the control group will be referred to transitional case managers who provide HIV+ inmates with relevant resources in the community upon release.

**ID:** IRB#11-003579 View: NEW 15.1 - Data & Safety Monitoring Plan

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Data & Safety Monitoring Plan

**1.0** ***Is a Data and Safety Monitoring Plan (DSMP) required by the funding agency or other entity?**

(•) **Yes** ( ) **No**

**ID:** IRB#11-003579 View: NEW 15.2 - Data & Safety Monitoring Plan (continued)

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Data & Safety Monitoring Plan (continued)

***Important Note:***
*All interventional studies involving more than minimal risk must include a Data and Safety Monitoring Plan (DSMP). A DSMP is a plan established to assure that each research study has a mechanism for appropriate oversight and monitoring of the conduct of the study to ensure the safety of participants and the validity and integrity of the data. The DSMP should indicate specifically whether or not there will be a formal Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC).*

Most, but not all studies (i.e., non-interventional studies) undergoing full board review will require a DSMP. You will need a DSMP if any of the following apply:
1. This is a Phase I, II or III clinical trial
2. This is an investigator initiated trial (Section 2.1/item 3.0)
3. This study involves treatment in an emergency setting (Section 2.3/item 1.0)
4. A Data/Safety Monitoring Plan is required by the funding agency (Section 15.1/item 1.0)
5. This study is greater than minimal risk (Section 1.1b/item 1.0)

**1.0** ***Indicate who will be responsible for overseeing the study safety. Check all that apply.**

- [x] **The Principal Investigator**
- [ ] Designee of the Principal Investigator
- [x] **The DSMP includes at least one person who is not associated with the study**
- [x] **A formally constituted Data and Safety Monitoring Board (DSMB)**
- [ ] Medical monitor designated by the sponsor
- [ ] Other

**1.1** **If you indicated that a designee would be responsible for overseeing the study safety, or that the DSMP would include at least one person not associated with the study, provide the name(s) of this individual (s). Also, provide a brief explanation of why this person(s) would be appropriate in this role(s).**
Dr. Neil Wenger, an expert ethicist, is serving on the study's DSMB. Dr. Wenger has expertise in clinical and research ethics, and has knowledge of studies of HIV care.

**1.2** **If you indicated "other," describe or indicate where the information can be found in the attached protocol.**

**2.0** ***Provide your assurance that information about serious, unanticipated problems related to the study (e.g., adverse events, incidents and violations) will be reported to the IRB within the time frames specified by the Summary Sheet of Reporting Requirements.**
**Agree** ☑

***Provide the following information as appropriate to the study:***

**3.0** ***Are there plans to perform an interim safety analysis?**
◉ **Yes** ○ **No**

**3.1** **If yes, describe or indicate where the information can be found in the attached protocol.**
Yearly, the Principal Investigator and co-PI, study team and consultants will review trial progress including a data safety monitoring review.

**4.0** ***Have stopping rules been established for the study?**
○ **Yes** ◉ **No**

**4.1** **If yes, describe or indicate where the information can be found in the attached protocol.**

**5.0** ***Are there defined rules for withdrawing participants from study interventions?**
○ **Yes** ◉ **No**

**5.1** **If yes, describe or indicate where the information can be found in the attached protocol.**

**ID:** IRB#11-003579 View: NEW 15.3 - Data & Safety Monitoring Board

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Data & Safety Monitoring Board

*You indicated that there will be a DSMB for this study (Section 15.2.item1) or a DSMB is required because this study involves treatment in an Emergency Setting (with request to waive consent)(Section 8.1/item1). Please provide the following information.*

**1.0** **Describe the proposed composition of the DSMB (e.g. number of members, their qualifications and disciplines, and whether or not they are independent of the study).**
As discussed with and approved by Dr. Shoshana Kahana at the National Institute for Drug Abuse (NIDA), we are in the process of composing a DSMB. The number of members, their qualifications and disciplines are yet to be determined.

**1.1** **If available upload the DSMB Member list here.**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**2.0** ***Describe the type of data to which the DSMB will have access, if this information has been determined (e.g., blinded/unblinded).**
DSMB will have access to all relevant data that is necessary to ensure adherence to the provisions of the DSMP. The DSMB will have access to unblinded data.

**3.0** ***Provide your assurance to the following:**

**1) The DSMB will meet at least annually, or more often if required by the level of risk associated with the study, and**
**2) DSMB reports will be forwarded to the IRB within 10 days of receipt by the study team.**

**Agree** ☑

**3.1** **If the DSMB is planning to meet more frequently than once per year, specify the frequency of the meetings.**

**ID:** IRB#11-003579 View: NEW 16.1 - Payment, Costs, and Injury

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Payment, Costs, and Injury

**1.0** ***Indicate what the participants will receive for their participation in the study.**

**Check all that apply.**

- ☐ No payment will be provided
- ☐ University check
- ☐ Course Credit
- ☑ **Cash**
- ☐ Gift Cards/Bruincard Deposit

☐ Non-Monetary Gifts or Services

☑ **Other (including vouchers for parking)**

**1.1** **If you selected Non-Monetary Gifts or Services or Other, describe:**
Payments will be made to inmate accounts while in jail.

**1.2** **If you selected *Cash* and/or *Gift Cards/Bruincard Deposit* please specify the estimated total amount of money you will require to pay all participants during the length of the entire study. This information is required by UCLA Business and Finance Services (BFS), the office that will provide the cash/gift cards for payment.**
$60,000

**2.0** **If study participants will receive financial or other payment for their participation in the study, please provide the following information:**

- **If applicable, the amount each participant will receive and the payment schedule to be followed including whether partial payment will be provided when the participant does not complete the study.**
- **If there are different plans for different populations or sub-studies, specify the groups and describe the plans.**
- **If families or children will be involved in the research, clarify how the payments, items or services will be apportioned.**

The payment structure for participants in both the control and intervention group is as follows:

1. Participants will receive $25 for participating in the first interview in jail.

2. As part of the second interview, participants will receive a one-time payment of $50 for participating in the interview and having blood drawn.

3. Participants will receive $50 for the third interview.

4. For the fourth and final interview, the participants have a choice: Choice 1: They can either receive $75 for completing both the blood draw and the interview; or choice 2: They can forego the payment of $75 and instead be entered in a lottery. The total payout of the lottery will be based on the number of participants who forego their $75 incentive payment to be included in the lottery. Both the control group and the intervention will have separate grand-prize winners. In each group, the grand-prize is capped at $4400. However, this amount may be less, as it is dependent on the number of participants included in the lottery pool. For participants incarcerated during the final interview, inmates will be made aware that if they are the grand prize winner, they must call the study contact number upon release to receive the money in cash. All other payments will be deposited into the inmate's jail account or given in cash after release, if preferred by the participant.

Participants will be made aware during the informed consent process that their risk to win the pay-out sum is small and that if they decide to enter the lottery, they may not receive any payment for their participation in the final interview. The rationale for the lottery is to reduce study attrition by providing a potentially high payout for participating in the final interview.

Incentives for interviews that are conducted in jail will be made to the inmate account. However, some participants may explicitly request to have their interview incentives withheld until they are released from jail. The participants will be asked to sign a waiver acknowledging that they must contact study staff upon release to receive their incentive payment.

--------- Updating contact information

If participants call the LINK LA staff to update their contact information each month after they are released from jail, they will get an extra $5 payment for each time they call. The study staff will then give

the money at the next study activity.

--------- Navigator in-person meetings outside of jail

Participants are eligible to receive $10 for each in-person meeting with the navigator outside of jail, for a total of up to $40. Participants will receive the $10 incentive amount from the navigator at each in-person session outside of jail.

**3.0** ***Will subjects incur any financial obligations from participation in the study?**

○ **Yes** ◉ **No**

**3.1** **If yes, describe:**

**4.0** ***Indicate below that you are familiar with UCLA policy related to treatment and compensation for injury and that you will use in the consent form for this study the appropriate UC required statement describing "Treatment and Compensation for Injury." Click here to access the UCLA policy: Treatment and Compensation for Research Related Injury.**

***Note:*** Select **Not Applicable** if study is minimal risk.

○ Agree

◉ **Not Applicable**

**ID:** IRB#11-003579 View: NEW 17.1 - HIPAA Authorization

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## HIPAA Authorization

*According to your responses to section 9.2/item 1.0, this study uses protected health information. Please provide the following information.*

**1.0** ***Indicate all that apply to use of or disclosure of PHI in this study:**

- ☐ All UC participants will sign a UC HIPAA Research Authorization for Release of Personal Health Information for Research.
- ☑ **Another Institutions' Healthcare Authorization for Release of Health Information will be used or a waiver for release of health information will be granted from another Institution.**
- ☐ **A Waiver of HIPAA Research Authorization** is requested for **screening** using UC medical records. I assure that the PHI collected for this study will not be reused or disclosed, except as indicated in this application.
- ☐ **A Total Waiver of HIPAA Research Authorization** is requested for the entire study. I assure that the PHI collected for this study from UC records will not be reused or disclosed, except as indicated in this application.
- ☐ **Limited Data Set with a Data Use Agreement** will be obtained from UC medical records. I assure that I will follow the data security plan outlined in this application to protect the identifiers from improper use or disclosure.
- ☐ **None of the above. This study will be conducted outside the United States**

**2.0** ***Indicate to whom or where you will grant access to personal identifying information (including PHI) as part of the study process:**

- ☐ There is no plan to share identifiers outside the study team
- ☐ The study sponsor; on site only (if there is more than one study sponsor, specify below).
- ☐ A foreign country or countries

☑ **Other**

**2.1** **If you checked "other", "a foreign country or countries", or if "there is more than one sponsor", specify.**
Viral load lab results will be shared with L.A. Sheriff's Department Medical Services Bureau to maximize the accuracy and completeness of each participant's medical record. The L.A. Sheriff's Department is a participating partner in this research study.

**3.0** ***The investigator's agreement is needed to the following:**

**- The protected health information requested is the minimum necessary to meet the research objectives**

**- The protected health information that is obtained as part of this study will not be used or disclosed to any other person other than study personnel or to the parties listed in item Section 17.1/item 2, except as required by law.**

**- Study Sponsors will not be provided with personal identifying information (including PHI) to take from the study site at any time, including the end of the study.**

**- Data and specimens shared with outside entities, such as study sponsors, will be coded or de-identified.**

**Agree** ☑



**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Identification/Recruitment Methods

**1.0** ***How will you identify and/or recruit participants for this study.**

**Check all that apply:**

- ☐ Advertisements/Flyers/Information Sheet/Internet Postings
- ☑ **Direct recruitment of potential study participants (e.g., physicians talking with their own or clinic patients about the study, contact between the study team and potential subjects in person, on the phone or on the internet, etc.)**
- ☐ Random or Other Probability Sampling
- ☐ Recruitment Letters/Emails
- ☐ Referrals (e.g., referrals from non-investigator healthcare providers, snowball sampling, participants referring other participants, etc.)
- ☑ **Review of medical records to identify potential research participants**
- ☐ Review of publicly available records
- ☐ Review of other records
- ☐ Participant pool for which potential research participants have given permission for future contact
- ☐ Potential Study Participants are identified from another IRB approved study or IRB approved screening protocol
- ☐ Other

**ID:** IRB#11-003579

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Recruitment Methods

**1.0** **Please upload copies of your recruitment materials below. This includes advertisements, flyers, internet postings, recruitment scripts and letters/emails.**

| Document Name | Document Version # |
|---|---|
| Recruitment script English - Clean | 0.02 |
| Recruitment script Spanish - Clean | 0.02 |
| Study request form -- CLEAN | 0.01 |

**Ads/Flyers/Info Sheets/Internet Postings**

**2.0** **If you have indicated that study participants will be recruited with advertisements/flyers (Section 18.1/Item 1.0), please indicate the type of media that will be used (e.g., newspaper, radio, internet, etc.) and/or where information will be posted or distributed.**

**Direct Recruitment**

**3.0** **If you have indicated that participants will be recruited through direct contact (Section 18.1/Item 1.0), please provide the following information:**

- **A description of how, when, and where initial contact would be made (e.g. in a public setting, in a waiting room, via a phone call, via a letter, via the internet, etc.)**
- **If applicable to the study, indicate how the potential research participant's privacy will be maintained.**
- **Who will make the contact (e.g. the investigator, a patient's physician, etc.)**

The medical personnel and other HIV testing staff within LASD enter the inmates' HIV infection status into the electronic LASD data system. The LASD Epidemiologist has been assigned the task of conducting a routine run of all HIV-positive inmates to identify those individuals who may be eligible for the study. The LASD Epidemiologist will provide this comprehensive list on a weekly or more frequent basis to the Study Coordinator who is based in the jail to facilitate participant recruitment and enrollment. The Study Coordinator will pre-screen the individuals for participation to determine their eligibility (e.g., 18 years or older, HIV-positive status, male or transgender woman, being released to LAC, etc.). Once the individual is deemed eligible, the Study Coordinator, in conjunction with Dr. Mark Malek, a jails-based study co-investigator, will arrange to confidentially screen the inmate for interest and potential participation in the study. If the participant is interested, the Study Coordinator will obtain informed consent, conduct an interviewer-administered baseline questionnaire, arrange for a blood draw to test viral load levels (unless already performed by the LASD MSB) and then will randomize the study participant into the intervention or control arm.

**3.1** **If you will be directly recruiting potential participants who are your patients, students, laboratory workers or any others with whom you have a relationship of authority or unequal power, describe what measures you will put in place to avoid those approached from feeling pressured or unduly influenced to participate in the study.**

**Recruitment Letters/Emails**

**4.0** **If you have indicated that recruitment letters will be distributed to participants (Section 18.1/item 1.0), please indicate who will send out the recruitment letter (i.e. will it be the investigator or other persons**

**who have authorized access to the information), how inquiries will be handled, and if there will be follow-up contacts.**

**Referrals**

**5.0** **If you have indicated that study participants will be identified from referrals (Section 18.1/item 1.0), please indicate the source of the referral (e.g., friends, other participants, healthcare providers) and how the referral will be elicited.**
LASD-based Public Health Nurses and clinicians will provide a study flyer to HIV+ patients to read during private and confidential jails-based clinical encounters. The nurses and clinicians will neither elaborate upon the flyer/study nor provide any encouragement to participate in the study. The nurses and clinicans will simply provide some time for the patient to read the flyer during the clinical encounter. The nurses and clinicians will not answer any questions that the patient may have about the study. The nurses and clinicians will simply tell the patients that if they would like to learn more about the study, they are invited to fill out a study request form which will be confidentially routed to the onsite study coordinator. The study coordinator, in conjunction with Dr. Mark Malek, a jails-based study co-investigator will then arrange to confidentially screen the inmate for potential participation in the study.

b) LASD-based case managers as well as LACDPH coordinators will provide a study flyer to HIV+ inmates to read during private and confidential jails-based case management encounters or other relevant encounters. The case managers will neither elaborate upon the flyer/study nor provide any encouragement to participate in the study. The case managers will simply provide some time for the inmate to read the flyer during the encounter. The case managers will not answer any questions that the inmate may have about the study. The case managers will simply tell the inmates that if they would like to learn more about the study, they are invited to fill out a study request form which will be confidentially routed to the onsite study coordinator. The study coordinator, in conjunction with Dr. Mark Malek, a jails-based study co-investigator will then arrange to confidentially screen the inmate for potential participation in the study.

**Research Participant Pools/Recruitment Databases**

**6.0** **If you have indicated that subjects will be identified and recruited from a subject pool(s) or recruitment database, (Section 18.1/item 1.0), please indicate the name of the Pool or Recruitment Database and UCLA Department. If the Pool or Recruitment Database is not at UCLA, identify the location.**

**ID:** IRB#11-003579 View: NEW 18.7 - Review of Medical Records

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Review of Medical Records

**1.0** ***You have indicated that potential research participants will be identified from medical records (Section 18.1/item 1). Indicate the specific records to be reviewed and the information that will be obtained to identify potential participants for this study.**
The medical personnel and other HIV testing staff within LASD enter the inmates' HIV infection status into the electronic LASD data system. The medical records will be reviewed to pre-screen eligible participants according to the following criteria: HIV status, age and gender.

**1.1** **If you have a data sheet summarizing the information that will be obtained from the records, you can upload it here instead of listing the information above.**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

*Federal and State Regulations require that the IRB review the information below to determine if a waiver of consent and authorization is appropriate for use of medical record information for recruitment purposes.*

**2.0** ***Do you assure the following?**

- **The information that will be reviewed is the minimal necessary to identify potential research participants for this research.**
- **The information that will be obtained for identification of participants will not be reused or disclosed outside the research team, except as required by law.**
- **All study personnel will comply with HIPAA regulations.**
- **Review of the medical records will not result in greater than minimal risk by taking appropriate precautions to protect the confidentiality of the information.**

**Agree** ☑

**3.0** ***Indicate why the potential study participants' rights and welfare would not be adversely affected by waiving consent to review their medical records.**

**Check all that apply.**

- ☑ **Precautions will be taken on protect the confidentiality of the research participants**
- ☑ **The information from the medical records will not be used in any way other than to identify potential research participants**
- ☐ Other

**3.1 If other, describe**

**4.0** ***Indicate why the research could not practicably be carried out without a waiver of consent.**

**Check all that apply.**

- ☑ **The identities of the potential study participants who would meet the criteria for this study would not be known without access to their medical records**
- ☐ Other

**4.1 If other, specify**

**5.0 NON-UC INSTUTITION(S) / AGENCY(IES) HIPAA POLICIES AND PROCEDURES**

If your research will involve access, use, or disclosure of PHI held by a non-UC institution/agency, please provide your assurances that you will comply with that (those) instutition(s)/agency(ies)' HIPAA policies and procedures.

**Agree** ☑

**ID:** IRB#11-003579 View: NEW 19.1 - Eligibility Screening

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Eligibility Screening

**1.0** ***Will you be conducting a preliminary assessment with potential research participants to determine study eligibility during the recruitment process?**

◉ **Yes** ○ No

**ID:** IRB#11-003579 View: NEW 19.2 - Eligibility Screening - Plans

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Eligibility Screening - Plans

*You indicated that eligibility screening will be conducted during the recruitment process (Section 19.1/item 1). Please provide the following information.*

**1.0** ***Will private identifiable information be collected during the screening?**

○ Yes ◉ **No**

**1.1** **If private identifiable information is collected during screening, are there plans to retain data from participants found to be ineligible for the study?**

○ Yes ○ No

**1.2** **If private identifiable data will be collected during the screening, indicate your plans for retaining the data.**

- ☐ The data will be retained with identifiers
- ☐ The data will be retained without identifiers
- ☐ The data will be destroyed

**1.2.1** **If you chose more than one response above, explain.**

**2.0** ***Indicate your plans for obtaining informed consent and/or parental permission for the screening procedures.**

**Check all that apply.**

- ☑ **Oral consent will be obtained for the screening procedures. Participants will not be asked to sign a consent form (Waiver of written consent).**
- ☐ A waiver of informed consent is requested for the screening procedures
- ☐ A waiver of Research Authorization for HIPAA is requested for the screening procedures.
- ☐ Signed consent will be obtained prior to performing any of the screening procedures

**2.1** **If you checked more than one plan above, list the study groups and the plan that you will use for each.**

**3.0** **Describe how screening will be performed.**

**3.1** **Attach screening script(s), if applicable.**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**ID:** IRB#11-003579 View: NEW 19.3 - Oral Consent - For Screening Procedures

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Oral Consent - For Screening Procedures

*You indicated that you are obtaining oral consent for the screening procedures (Section 19.2/Item 2). Please provide the following information.*

**1.0** ***Indicate the reason that you are requesting to conduct an oral consent process and/or parental permission instead of obtaining signed consent.**

- (●) **The research is minimal risk and does not involve any procedures for which written consent is normally required outside the research setting (e.g., in everyday life written consent is not needed for minimal risk surveys, non-invasive health measurements, etc.) (45 CFR 46.117 c2)**
- ( ) The only record linking the participants and the research would be the consent document, and the main risk of research would be a breach of confidentiality (45 CFR 46.117 c1).

e.g., Participants could suffer from social stigma, embarrassment, or other harms if it became known that they participated in research that identified them as having issues including, but not limited to, risky sexual behaviors, HIV, or mental health problems.

**If you indicated that the main risk is a breach of confidentiality, answer 1.1 if appropriate.**

1.1 **According to DHHS regulations at 45 CFR 46.117(c1) when the main risk of the research would be a breach of confidentiality and an oral consent process is used, each participant should be asked whether he/she wants documentation linking the subject with the research and the subject's wishes will govern.**

**Check here if you want the IRB to consider allowing a waiver of this regulation so that you do not need to ask each subject if he/she wishes documentation.**

☐ Request to waive documentation linking the participant with the research

2.0 ***Provide a description of the oral screening procedures for the study.**
The recruitment script which includes a description of the study, consent to ask screening questions and the screening questions will be administered to conduct the oral screening procedures. Screening script is attached in 20.3.



**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Informed Consent Process

*You indicated that adults (and/or minors who are permitted to consent for themselves) are participating in the study (Section 11.2/item 1.0 or Section 12.2/item 1.0).*

**For additional information on minors who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document,** Child Assent and Permission by Parents or Guardians**.**

1.0 ***Indicate your plans for obtaining informed consent for this study.**

**Check all that apply:**

- ☑ **Signed consent will be obtained from the research participant or Legally Authorized Representative.**
  - **Signed consent means research participants will be asked to sign and date a written consent form.**

☐ **A waiver of signed consent is requested for the entire study.** One of the following procedures will be conducted:

- **A written information sheet will** be used. Signed consent will not be obtained from research participants.
- **Oral consent** will be obtained from the research participant or Legally Authorized Representative (LAR)
- This option should be selected if the study involves consenting participants via the internet.

☐ A **waiver of consent** is being requested.

- Research participants will **not** be asked to sign a consent form or give oral consent

☐ Consent will be obtained by a collaborating institution.

**1.1** **- If you checked more than one plan above, list the study groups and the plan that you will use for each.**
**- If you checked "Consent will be obtained by a collaborating institution", explain the consent process and upload a copy of the most recent approved consent document in item 1.2.**

**1.2** **If applicable, attach the consent document(s) from collaborating institution(s).**

| Document Name | Document Version # |
|---|---|
| There are no items to display | |

**ID:** IRB#11-003579 View: NEW 20.3 - Description of the Consent Process

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Description of the Consent Process

**1.0** ***Indicate the type of setting(s) in which the consent process will be conducted.**

**Check all that apply.**

☐ In a private home
☑ **In a private room**
☐ In a waiting room
☐ In a public setting
☐ In a group setting
☐ On the internet
☐ Over the telephone
☐ Other

**1.1** **If you checked more than one response, or indicated other, describe.**

**1.2** **If the setting is not private, describe the measures to protect confidentiality or indicate "not applicable."**

**2.0** ***Indicate the measures that will be taken to provide prospective research participants with sufficient**

**opportunity to consider whether or not to participate in the study.**

**Check all that apply.**

- [x] **Member(s) of the study staff will meet with the prospective participants/families to review the consent document(s) and/or provide an oral explanation of the study. Individuals will be given a chance to ask questions before making a considered decision about whether or not to participate in the study.**
- [ ] Prospective participants/families will have the opportunity to take the consent form(s) home and may discuss the documents with others prior to deciding whether or not to participate in the study.
- [ ] Prospective participants will self-administer the consent and send it back if they decide to participate in the study.
- [ ] Other

**2.1 If you indicated other, describe.**

**3.0** ***Indicate the length of time subjects are given to decide whether they wish to participate in the study.**
1 week

**4.0** ***How will you assess whether subjects understand the information conveyed during the consent process?**

**Check all that apply.**

- [ ] Use the Subject Comprehension Tool form for research
- [x] **Investigator or study team member will evaluate during the consent process**
- [ ] Other
- [ ] Not Applicable

**4.1 If you indicated other, describe.**

**5.0** ***Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.**

| Document Name | Document Version # |
|---|---|
| Consent form Addendum (October 2015) | 0.01 |
| LINK LA Consent Addendum (Phones) | 0.02 |
| RCT Consent Addendum -- Clean | 0.02 |
| RCT Consent form (English) -- CLEAN | 0.15 |
| RCT Consent form (Spanish) -- CLEAN | 0.04 |
| SSN Consent form | 0.01 |

**ID:** IRB#11-003579 View: NEW 22.1 - Cultural Considerations

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Cultural Considerations

*The following items are designed to acquaint the IRB with cultural features of the population that you are studying that may require procedures to ensure truly informed consent.*

**1.0** ***Check all that apply to the population(s) with which this study will be conducted.**

- [ ] Participants may be illiterate or insufficiently literate to be able to comprehend a conventional written informed consent form.

- [ ] The participants may be reluctant or unwilling to sign a written informed consent form.
- [ ] The husbands make decisions for their wives.
- [ ] Elders make decisions for younger adult family members.
- [ ] Elders make decisions for their community.
- [ ] It is considered impolite to refuse a request.
- [ ] People are fearful of refusing requests that they regard as coming from authorities.
- [x] **None of the above are applicable to this study.**

**1.1** **If any of the above items are applicable to this study, indicate the steps that you will take to ensure voluntary participation after providing the study information, and if applicable, any planned involvement with the community regarding the consent process.**

**ID:** IRB#11-003579 View: NEW 24.0 - Additional Information and/or Attachments

*This view has been locked by amendment(s)*

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."**

## Additional Information and/or Attachments

**1.0** **Attach any other documents that have not been specifically requested in previous items, but are needed for IRB Review.**

| Document Name | Document Version # |
|---|---|
| Darlene Hernandez - Resume | 0.03 |
| DatStat Data and Security Protocol | 0.01 |
| Eric Tam -- CITI/HIPAA certificates | 0.01 |
| Incentive hold waiver | 0.01 |
| Jasmine Smith Resume | 0.01 |
| Jenna Arzinger Resume | 0.01 |
| LINK LA Intervention Certificate | 0.01 |
| LINK LA Intervention Overview (Participant time involvement) | 0.01 |
| LINK LA Interviewer Training - Emergency procedures | 0.03 |
| LINK LA Interviewer Training - Overall training | 0.01 |
| List of clinics | 0.02 |
| Locator form - CLEAN January 2015 revised | 0.04 |
| March Olmos Florez Resume | 0.02 |
| Markeisha Craver - Resume | 0.01 |
| OHRP Approval | 0.01 |
| Reminder scripts | 0.01 |
| Richard Hamilton - Resume | 0.01 |
| Sheila Ganjian -- CV | 0.01 |
| Sheila Ganjian -- IRB certificate 1 | 0.01 |
| Sheila Ganjian -- IRB certificate 2 | 0.01 |
| Sheila Ganjian -- IRB certificate 3 | 0.01 |
| Sheila Ganjian -- IRB certificate 4 | 0.01 |
| Sheriff's Dept Letter of Support | 0.01 |
| Stephen Armstead - Resume | 0.01 |
| UCLA Med Ctr. hiring requirements (Checklist) | 0.01 |

**2.0** **If there is any additional information that you want to communicate about this study, include it in the area provided. Note: this section should not be used instead of the standard application items.**

**ID:** IRB#11-003579 View: NEW 100.0 - Instructions for Study Submission

**Instructions for Study Submission**

**You have completed your application, but it has *not yet been submitted*.**

**FOLLOW THESE STEPS TO SUBMIT THE APPLICATION TO THE IRB FOR REVIEW:**

1. **Click the Finish button to return to exit the SmartForm and return to the study workspace.**
2. **Use the View SmartForm Progress function to make sure that the application is complete.**
3. **If you are the PI or PI Proxy, click Submit Study under My Activities. If you are a member of the study team, you can let the PI know that the study is ready to submit by clicking Send Ready Notification.**
4. **Once the study is submitted, the state indicator at the top of the page will no longer display Pre-Submission.**
5. **After submission of the study, the PI Assurances activity will immediately become available under My Activities. The PI should provide his/her assurances at that time. If the PI is not available, the study can be submitted by a PI Proxy and the assurances provided at a later time. The study will be reviewed by the IRB while the PI Assurances are pending; however, it will not be approved until the PI assurances are completed.**
6. ***If there is a Faculty Sponsor for the study*: The study can not be submitted to the IRB until the Faculty Sponsor provides his/her assurances through FS Assurances activity.**

**ID:** IRB#11-003579 View: Display - Method Description

Audio, Visual or Digital Recordings

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Behavioral Observations (only applicable if you selected Exempt Category 2 in section 5.3)

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Certificate of Confidentiality

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. The project does not need to be funded by NIH to obtain a Certificate of Confidentiality. For additional information see http://grants.nih.gov/grants/policy/coc/

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention

A clinical trial is a research study designed to answer specific questions about medical or behavioral treatments. The trial may be interventional or observational. Interventional studies are those in which the research participants are assigned by the investigator to a treatment or other intervention, and the outcomes measured. Observational studies are those in which individuals are observed and the outcomes are measured by the investigators.

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Community Based Research

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Controlled Substances (Schedule I or II)

Check here only if you are using a Schedule I or II Controlled substance in this study. Research using Schedule I or Schedule II controlled Substances must be submitted to the Research Advisory Panel of California for review and approval prior to initiation. Research using Schedule III, IV, or V Controlled Substances as a study drug do not require review by the Research Advisory Panel. For further information see: http://ag.ca.gov/research/guide.php o Schedule I Controlled Substances are drugs or substances with a high potential for abuse, that have no currently accepted medical use in treatment in the United States. Examples of Schedule I Controlled Substances are: heroin, lysergic acid diethylamide (LSD), methylenedioxy-methamphetamine (MDMA), marijuana, and psilocybin. o Schedule II Controlled Substances are drugs or substances with a high potential for abuse, that have a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions. Examples of Schedule II Controlled Substances are: fentanyl, methadone, methylphenidate, morphine, and oxycodone. For further information see: http://www.deadiversion.usdoj.gov/schedules/index.html

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Deception or Partial Disclosure

Deception includes withholding information about the real purpose of the study or purposely giving subjects false information about some aspect of the research to prevent bias. Some professions, such as the American Psychological Association (APA) have ethical codes regarding the use of deception in research. ( See sections 8.07 and 8.08 at http://www.apa.org/ethics/code/index.aspx#807 ) If deception is included in the study, you must also apply for approval of a waiver of the informed consent process (Section 20.1) in addition to selecting the other consent procedures planned for the study (e.g., written or oral consent).

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Devices/Diagnostics (including Humanitarian Devices - HUD)

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy. For further information see: http://www.fda.gov/oc/ohrt/irbs/irbreview.pdf

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Drugs/Biologics/Dietary Supplements

- **Drug: The term "drug" means: articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.**
- **Biologics vs. Drugs: Most drugs consist of pure chemical substances and their structures are known. Most biologics, however, are complex mixtures that are not easily identified or characterized. Biological products differ from conventional drugs in that they tend to be heat-sensitive and susceptible to microbial contamination. This requires sterile processes to be applied from initial manufacturing steps. For more information see:** http://www.fda.gov/consumer/updates/biologics062608.html#drugs
- **Dietary Supplements are products that are intended to supplement the diet and have one of the following ingredients:**
  - **A vitamin**
  - **A mineral**
  - **An herb or other botanical**
  - **An amino acid**
  - **A dietary substance for use by man to supplement the diet by increasing the total daily intake**
  - **A concentrate, metabolite, constituents, or an extract of combinations of these ingredients.**

**For additional information see:** http://www.foodsafety.gov/~dms/supplmnt.html

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Expanded Access to Drug, Device or Biologic for Treatment Purposes (aka Compassionate Use, Treatment Use)

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Genetic Analyses/Genotyping

Genetic analyses/genotyping include, but are not limited to, studies of inheritable conditions or traits, gene markers or mutations, and pedigrees.

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells

Research with human embryonic stem cells (hESC) and related lines requires IRB review under the following conditions: o Clinical research in which human subjects are given hESCs or related products. o When the UCLA research team will have a research related direct interaction or intervention with the cell donors, including donation of blastocysts or gametes for the purpose of creating hESCs,. o Cells provided to the UCLA research team that have identifiers or codes that can be linked back to the donor. Research involving hESC requires review and approval by the ESCRO Committee. For further information see: http://www.stemcell.ucla.edu/research

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Human Gene Transfer/ Recombinant DNA

Studies involving gene transfer and/or recombinant DNA require approval of the UCLA Institutional Biosafety Committee ( IBC) and the NIH Recombinant DNA Advisory Committee (RAC) . Human gene transfer is an investigational method for correcting defective genes responsible for disease development through one of the following techniques: o A normal gene may be inserted into a nonspecific location within the genome to replace a nonfunctional gene. o An abnormal gene could be swapped for a normal gene. o The abnormal gene could be repaired through selective reverse mutation, which returns the gene to its normal function. o The regulation of a particular gene could be altered. Recombinant DNA molecules, according to the NIH Guidelines, are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Infectious Agents

Studies involving the use of Risk Group 2 or 3 infectious agents (such as bacteria, fungi, parasites, prions, rickettsia, viruses, etc.) require approval of the UCLA Institutional Biosafety Committee (IBC).

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.

Clinical Engineering is responsible for completing incoming inspections on investigational devices that are used to diagnose, treat or monitor a patient and that are used in the patient care area on site at UCLA, but *not* in other hospitals such as Cedars Sinai, CHLA, or Drew. If a device is FDA and/or testing - laboratory approved for the purpose it was designed, then evaluation is not required of the device. If you have a copy of an inspection report from Clinical Engineering, please attach here. As appropriate, please contact Clinical Engineering at 310-267-9000 to arrange an inspection.

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Radiation (Standard of Care or Investigational use of radioactive materials or ionizing radiation)

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Substance Abuse Research (with Medication)

Research for the treatment of controlled substance addiction or abuse that uses any drug (scheduled or not) as treatment, requires the review and approval of the Research Advisory Panel of California prior to initiation. For further information see: For further information see: http://ag.ca.gov/research/guide.php

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

Treatment in an Emergency Setting (with request to waive consent)

Federal regulations allow certain research activities to be conducted in emergency settings with waiver of informed consent - in the interest of facilitating potentially life-saving and life-enhancing research with protecting the rights and welfare of participants. For further information see: o OHRP Guidance: http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc97-01.htm o FDA Guidance: http://www.fda.gov/oc/ohrt/irbs/except.html

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Display - Method Description

**None of the above**

**Click "OK" below to return to the SmartForm page where you can select the appropriate response.**

**ID:** IRB#11-003579 View: Specimens and/or data that will be acquired without direct contact with study participants

## Specimens and/or Data that will be Acquired without direct contact with study participants

**1.1** *__Data and/or Specimens? Indicate all that apply:__

- [x] **Data**
- [ ] Specimens

**1.2** *__Indicate the source of the data and/or specimens. If the source is UCLA or a previous study, also indicate the IRB#:__
Division of HIV and STD Programs (DHSP) CaseWatch System

**1.3** ***Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective. Check all that apply:**

- [x] **Pre-existing**
- [x] **Prospective**

**1.4** ***Describe the data and/or specimens and indicate the original collection dates. If collection is in progress, indicate the planned end date or "continuing." (*e.g., academic records for children 6-12 years for the time period between 1995-2005, or tumor samples collected from adults between January 1, 2009 to December 31, 2009*).**

HIV primary care visits, dates and values of CD4 counts, dates and values of HIV viral loads, antiretroviral medication prescriptions, emergency room visits, hospitalizations, medical diagnoses and relevant dates, genotypes, substance use and mental health utilization

**1.5** ***Indicate the approximate number of data records and/or specimens to be collected.**
1000

**1.6** **If you indicated that you will be using specimens, provide the following information.**

**1.6.1** **Will the specimens be used with animals?**
○ Yes ◉ **No**

**1.6.1.1** **If yes, indicate the IACUC Number:**

**ID:** IRB#11-003579 View: Specimens and/or data that will be acquired without direct contact with study participants

## Specimens and/or Data that will be Acquired without direct contact with study participants

**1.1** ***Data and/or Specimens? Indicate all that apply:**

- [x] **Data**
- [ ] Specimens

**1.2** ***Indicate the source of the data and/or specimens. If the source is UCLA or a previous study, also indicate the IRB#:**
Healthy Way LA

**1.3** ***Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective. Check all that apply:**

- [x] **Pre-existing**
- [x] **Prospective**

**1.4** ***Describe the data and/or specimens and indicate the original collection dates. If collection is in progress, indicate the planned end date or "continuing." (*e.g., academic records for children 6-12 years for the time period between 1995-2005, or tumor samples collected from adults between January 1, 2009 to December 31, 2009*).**

HIV primary care visits, dates and values of CD4 counts, dates and values of HIV viral loads, antiretroviral medication prescriptions, emergency room visits, hospitalizations, medical diagnoses and relevant dates, genotypes, substance use and mental health utilization

**1.5** ***Indicate the approximate number of data records and/or specimens to be collected.**
1000

**1.6** **If you indicated that you will be using specimens, provide the following information.**

**1.6.1** **Will the specimens be used with animals?**

○ Yes ◉ **No**

**1.6.1.1** **If yes, indicate the IACUC Number:**

**ID:** IRB#11-003579 View: Specimens and/or data that will be acquired without direct contact with study participants

## Specimens and/or Data that will be Acquired without direct contact with study participants

**1.1** ***Data and/or Specimens? Indicate all that apply:**

- ☑ **Data**
- ☐ Specimens

**1.2** ***Indicate the source of the data and/or specimens. If the source is UCLA or a previous study, also indicate the IRB#:**

Los Angeles Sheriff's Department Electronic Medical Records

**1.3** ***Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective. Check all that apply:**

- ☑ **Pre-existing**
- ☑ **Prospective**

**1.4** ***Describe the data and/or specimens and indicate the original collection dates. If collection is in progress, indicate the planned end date or "continuing." (*e.g., academic records for children 6-12 years for the time period between 1995-2005, or tumor samples collected from adults between January 1, 2009 to December 31, 2009*).**

HIV primary care visits, dates and values of CD4 counts, dates and values of HIV viral loads, antiretroviral medication prescriptions, emergency room visits, hospitalizations, medical diagnoses and relevant dates, genotypes, substance use and mental health utilization (Collection in progress)

**1.5** ***Indicate the approximate number of data records and/or specimens to be collected.**

1000

**1.6** **If you indicated that you will be using specimens, provide the following information.**

**1.6.1** **Will the specimens be used with animals?**

○ Yes ○ No

**1.6.1.1** **If yes, indicate the IACUC Number:**