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Section: 1 Study Background Information

**Study #:2016-0940\_AM03**

Last Update from Study Team: Wed Oct 25 14:36:56 PDT 2017

**1A Study Introduction****1A1 Study Description****1A1.1 \*\* Title:**

A Randomized Controlled Trial of an Antiretroviral Treatment Adherence Intervention for HIV+ African Americans

**1A1.2 \*\* Provide a brief summary or abstract for this study. Describes its purposes, study methods (i.e., participants, procedures, data sources), and expected results. (5,000 character limit)**

Compared to Whites, Black people living with HIV are less likely to adhere to antiretroviral treatment (ART) and be virally suppressed. Our research has identified culturally relevant factors contributing to disparities among HIV-positive Black Americans, including stigma and medical mistrust (e.g., "conspiracy beliefs," that ART is poison), in addition to structural and psychosocial factors related to poverty, healthcare access, and mental health. However, ART adherence interventions have rarely been culturally congruent, which may explain why relatively few interventions have shown robust effects on adherence or viral suppression. We propose to conduct a randomized controlled trial (RCT) of Rise, a culturally congruent adherence counseling intervention for HIV-positive Black men and women. Rise counselors possess specialized HIV treatment knowledge and are trained in motivational interviewing (MI) skills to overcome culturally relevant barriers to adherence and retention in care; they also assist with linkage to social services. Rise is ideally implemented in community organizations, enabling clients to seek services in non-medical settings, which helps to overcome mistrust of healthcare, and increase readiness for adherence. In a pilot RCT, Rise led to increased adherence (measured by electronic monitoring) relative to a wait-list control group over time, showing a large effect size (Cohen's  $d=.87$ ). However, the pilot did not evaluate effects on viral suppression or include long-term follow-up. Thus, we propose to conduct an RCT of Rise that follows best practices for evidence-based HIV treatment adherence intervention design and testing. The Specific Aims are: (1) To conduct a randomized controlled trial to examine the effects of a culturally congruent adherence intervention on antiretroviral treatment adherence, retention in care, and viral suppression among Black men and women living with HIV; (2) To examine culturally relevant mediators (e.g., medical mistrust, stigma) that may help to explain the effects of the intervention on antiretroviral treatment adherence, retention in care, and viral suppression among Black men and women living with HIV; and (3) To conduct a cost effectiveness analysis of the intervention. A total of 350 Black men and women will be randomly assigned to the intervention or usual care control group (175 per group). Adherence will be electronically monitored daily (and downloaded bi-monthly) from 1-month pre-enrollment to 12-months post-baseline. Viral load will be assessed through venipuncture at baseline and 6- and 12-months post-baseline. If Rise is found to be effective, the next step would be to conduct research to determine effective and feasible methods for intervention implementation and dissemination to community settings.

**1A1.3 \*\* Who is the intended audience for the results of this study? Where and in what form will you disseminate results? What are the potential benefits of the study to society?**

Intended audience: Community stakeholders and academic researchers in the HIV

Dissemination: via community and academic conference presentations, and journal articles

Benefits: to help reduce health disparities and ultimately make available an evidence-program that communities can use to help people living with HIV be healthier through suppressed viral load and to be less likely to transmit HIV to others

**1A1.4 \*\* Research Unit(s):** Arroyo Center Child Policy Education Health Homeland Security Division

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- Justice, Infrastructure, and Environment \*
- Labor and Population
- National Security Research Division
- Project AIR FORCE
- Pardee RAND Graduate School
- Other
- N/A

\* JIE includes all work formerly done under ISE, ICJ, and LBR.

**1A2 Study Staff**

**1A2.1 \*\* Principal Investigator.** (If there are multiple PIs, please designate one PI here as being responsible for human subjects protection. Include the other PIs in the study staff list asked for in the next question.) The PI will receive all emails on the project from the HSPC. The PI in [OASIS](#) is the PI in RHINO.  
Laura Bogart

**1A2.2 Study Staff List.** Enter the names of all study staff whom you want to have view and edit privileges for the study file in RHINO. Note that these staff will receive all emails on the project from the HSPC.

Last Name	First Name	Organization
Armenta	Gabriela	PRGS Fellows

**1A2.3 Primary HSPC Contact.** You can designate only one person as the primary contact. This can be the PI or a study staff member listed above or anyone else you choose. The Primary HSPC Contact should be someone who can be reached quickly if there is a question. The person designated a primary contact will receive all emails on the project from the HPSC.  
Gabriela Armenta

**1A2.4 Other Key Personnel.** In order to (1) determine the experience of the study staff and (2) avoid reviewer assignment conflicts, please identify other key personnel involved in the study. The individuals you list here will not receive email notifications or have view/edit rights on the study in RHINO. *Note: To avoid reviewer assignment conflicts, you can see if staff on your study would potentially be reviewers by looking at the [HSPC membership list](#).*

Last Name	First Name	Organization	Role
<a href="#">View</a> Ghosh Dastidar	Bonnie	Economics, Sociology and Statistics	Key Researcher
<a href="#">View</a> Linnemayr	Sebastian	Economics, Sociology and Statistics	Key Researcher
<a href="#">View</a> Wagner	Glenn	Behavioral and Policy Sciences	Key Researcher

**1A2.5 Email List.** Specify any other RAND staff (i.e., beyond the study staff) who should receive email notifications about this study. The persons you list here will have read-only access privileges to the study file.

Last Name	First Name	Organization	E-Mail
There are no items to display			

**1A3 Screen for Involvement of Human Subjects and Eligibility for Exemption**

**1A3.1 \*\* Before completing the full set of review questions, would you like to see if any of the population-procedure components of your study do not require review or are exempt from review?**

- A. Yes - I want to see if all of the population-procedure components are exempt or do not require review.
- B. Yes - I want to see if some of the population-procedure components are exempt or do not require review.
- C. No - Take me to the full set of the review questions.

**1A3.4** You will be asked to list all of the component(s) of your study and then proceed to the full set of review questions for each component. Each population and procedure combination that will be used will be defined as a *component*. A study that has only one component will be routed through the population and procedure questions only one time.

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## 1B Study Funding

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### 1B1 Funding Status

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**1B1.1 \* Funding Status:**

- Proposed
- Sponsor requires review before funding (Just in Time Review)
- Funded**
- Initiated, but not yet funded

**1B2 \* Funding Sources.**

Click Add to list a funding source. To edit, click on the [Edit] link. To delete, check the checkbox next to the funding source to be removed, then click Delete.

Name	Project Task Number	Proposal Number	Funding Institution Type	Institution Other	Status
<a href="#">View</a> NIMH	HOH0175-1000	20161317	Federal Govt		Completed

### 1B3 Prime Contractor

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**1B3.1 \* Which institution is the prime contractor or grantee?**

RAND

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## 1C Populations and Procedures

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**1C1 \*\* Specify Populations - Click Add to list a population. To edit, click on the link. To delete, check the checkbox and click Delete.**

Population	Created
<a href="#">People Living with HIV</a>	11/21/2016

**1C2 \*\* Specify Procedures - Click Add to list a procedure. To edit, click on the link. To delete, check the checkbox and click Delete.**

Procedure	Created
<a href="#">Cost Data</a>	11/30/2016
<a href="#">Electronic Adherence Assessment (MEMS)</a>	11/29/2016
<a href="#">Intervention</a>	11/21/2016
<a href="#">Medical Records Assessment</a>	11/21/2016
<a href="#">Surveys</a>	11/21/2016
<a href="#">Viral Load Assessment</a>	11/21/2016

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## 1D Populations and Procedures Matrix

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**Population Procedures:**

Population	Procedure	Check here if this procedure applies to this population	Check here to see if your study meets the criteria for the <u>abridged set of review questions</u>
People Living with HIV	Cost Data	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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Section: 2 Is This Reviewable

**2 Is This Reviewable?**

Population	Procedure	Complete screeners by clicking on all active links below	Status
People Living with HIV	Cost Data	2A Determining Human Subjects Involvement <a href="#">Follow up questions not required</a>	Completed
	Electronic Adherence Assessment (MEMS)	On screen 1D you did not indicate that you wanted to answer the screening questions for this component. The full set of review questions will be asked for this component.	
	Intervention	On screen 1D you did not indicate that you wanted to answer the screening questions for this component. The full set of review questions will be asked for this component.	
	Medical Records Assessment	On screen 1D you did not indicate that you wanted to answer the screening questions for this component. The full set of review questions will be asked for this component.	
	Surveys	On screen 1D you did not indicate that you wanted to answer the screening questions for this component. The full set of review questions will be asked for this component.	
	Viral Load Assessment	On screen 1D you did not indicate that you wanted to answer the screening questions for this component. The full set of review questions will be asked for this component.	

Your project may not involve human subjects of research. For each component above that indicates "[Follow up questions not required](#)" please go to Screen 7A and attach a data safeguarding plan as a Miscellaneous Document. For those components that involve the collection of new data, please also attach the consent protocol and questions.

**People Living with HIV: Cost Data**

**2A Determining Human Subjects Involvement**

**2A1 Activities That Do Not Involve Human Subjects**

2A1.1 \* Will you be doing any of the following activities which *would not* be classified as involving [human subjects](#)?

You will be asked about other research activities later.

- A. Providing advisory services or expert consultation without additional data collection (e.g., surveys) or use of previously collected data (e.g., school records).

## Section: 2 Is This Reviewable

- B. Convening a conference or meeting with no data collection other than an anonymous evaluation (for example, the conference may not be used as a focus group).
- C. Preparing a concept paper or op-ed piece, or otherwise developing an article that doesn't require any new research activity.
- D. Conducting a review of published literature or historical research that doesn't involve reviewing identifiable information (unpublished) about living individuals.
- E. Using existing anonymous unrestricted data from publicly available sources (e.g., Census, Current Population Survey).
- F. Using previously collected data not provided at the individual person level (e.g., aggregate data, data recorded at the transaction or event level that does not contain any indicator about individuals, data recorded on operations or systems that does not contain any indicator about individuals).
- G. Interviewing individuals to gather factual information about organizations and their activities (e.g., weapons acquisitions program, logistics workflow) if it would not lead to damage to employability if there was a breach of confidentiality (e.g., identifying a whistleblower).
- H. None of the above

2A1.2 \* Are you doing any activities not covered by 2A1.1?  
no

2A1.3 If the reviewer determines that only the activities checked in 2A1.1 are being performed, they may determine that the study component does not involve human subjects.

**2A4 Proprietary Information**

2A4.1 \* Could the research involve proprietary information (i.e., trade or business information that belongs to an organization)?  
No

## Section: 3 Research Overview

**3A Research Overview - Dates****3A1 Start Dates**

3A1.1 \* Project Start Date ([mm/dd/yyyy](#)): (Grant and non-FFRDC research should use the award date as the project start date. FFRDC research should use the date on which the project task number was opened.)  
5/1/2017

3A1.2 \* Anticipated Data Acquisition Start Date ([mm/dd/yyyy](#)): (Note: This should include pilot/pretest activities)  
11/1/2017

**3A2 End Dates**

3A2.1 \* Anticipated Data Acquisition End Date ([mm/dd/yyyy](#)):  
10/31/2021

3A2.2 \* Anticipated Data Analysis End Date ([mm/dd/yyyy](#)): (The date on which data analysis is completed and reports or articles have been published.)  
3/31/2024

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**3B Research Overview - External Organizations Collaborating in the Research**

3B If a collaborating institution is participating in human subjects research as defined by the regulations, either its own IRB must review its activities or it must arrange to have a registered IRB (e.g., RAND's HSPC) do the

Section: 3 Research Overview

**review.**

Organization	Status
<a href="#">AIDS Project Los Angeles</a>	Completed
<a href="#">Children's Mercy Hospitals and Clinics (Kansas City, MO)</a>	Completed

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### 3B Research Overview - External Organizations Collaborating in the Research

**3B1    \*\* Name of external organization.**  
AIDS Project Los Angeles

#### **3B2 External Organization Staff Activities**

**3B2.1    \* External organization staff will be involved in the following (Check all that apply):**

- A. Give RAND names and contact information to assist in subject recruitment without their prior written consent
- B. Obtaining informed consent**
- C. Collecting data**
- D. Receive identifiable person-level data**
- E. Sharing responsibility for research design, data analysis, and/or interpreting and reporting results**
- F. Performing other activities
- G. None of the above

**3B2.4**    If you check options A - E, it may be necessary for this external organization to obtain an IRB review because the activities this organization will be performing could be considered to be human subjects research.

#### **3B3 IRB Review**

**3B3.1    \* Will the external organization be carrying out its own IRB review?**  
No

**3B3.2    \* Will the external organization be deferring IRB review?**

- A.            Yes - to RAND's HSPC**
- B.            Yes - to another IRB
- C.            No
- D.            Don't know

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### 3B Research Overview - External Organizations Collaborating in the Research

**3B1    \*\* Name of external organization.**  
Children's Mercy Hospitals and Clinics (Kansas City, MO)

#### **3B2 External Organization Staff Activities**

**3B2.1    \* External organization staff will be involved in the following (Check all that apply):**

- A. Give RAND names and contact information to assist in subject recruitment without their prior written consent
- B. Obtaining informed consent
- C. Collecting data

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**D. Receive identifiable person-level data**

E. Sharing responsibility for research design, data analysis, and/or interpreting and reporting results

F. Performing other activities

G. None of the above

**3B2.4** If you check options A - E, it may be necessary for this external organization to obtain an IRB review because the activities this organization will be performing could be considered to be human subjects research.

**3B3 IRB Review**

**3B3.1** \* Will the external organization be carrying out its own IRB review?

No

**3B3.2** \* Will the external organization be deferring IRB review?

**A. Yes - to RAND's HSPC**

B. Yes - to another IRB

C. No

D. Don't know

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Section: 4 Populations

**4A - Populations**

Click on the link for each Population to answer the questions for that population.

Population	Status
<a href="#">People Living with HIV</a>	Completed

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**People Living with HIV**

Related procedures:

- *Medical Records Assessment (Pending - as with Just in Time reviews)*
- *Viral Load Assessment (Pending - as with Just in Time reviews)*
- *Surveys (Pending - as with Just in Time reviews)*
- *Cost Data (Pending - as with Just in Time reviews)*
- *Electronic Adherence Assessment (MEMS) (Pending - as with Just in Time reviews)*
- *Intervention (Pending - as with Just in Time reviews)*

Required fields are indicated with a red asterisk (\*) to the left of the question.

**4A1 Piloting or Pretesting Procedures**

**4A1.1** \* Will you be piloting or pre-testing procedures or instruments for this population?

no

**4A2 Inclusion Criteria**

**4A2.1**

Section: 4 Populations

**\* Please give the inclusion or selection criteria for participation in the research.** *Note: questions on exclusion criteria will be asked later.*

Eligibility criteria include: (1) age ≥18 years; (2) self-identified as African American/Black (if mixed race, primarily identify as Black); (3) currently prescribed antiretroviral treatment (ART) for at least 6 months; and (4a) any self-reported adherence problems (i.e., missed at least 1 ART dose in the past week or <90% of doses in the past month) and/or (4b) detectable viral load (verified by medical records). Participants also (5) must be willing to use MEMS for electronic adherence monitoring.

**4A2.2 \* Please indicate which, if any, of the following vulnerable populations would be intentionally included among your research subjects as part of your study design. Do not check any that may be included incidentally.**

A. Children/minors

B. Prisoners, incarcerated individuals, detainees, parolees, probationers

C. Cognitively impaired persons

**D. Seriously or terminally ill individuals, including those with serious mental illnesses**

E. Illegal immigrants

F. Economically or educationally disadvantaged individuals

G. Other potentially vulnerable participant groups

H. None of the above

**4A2.5 \* Could children/minors be included in your sample either inadvertently or by chance?**

no

**4A2.7 \* Could prisoners, incarcerated individuals, detainees, parolees, or probationers be included in your sample either inadvertently or by chance?**

no

**4A3 Exclusion Criteria**

**4A3.1 \* Are you going to intentionally exclude anyone because of gender, racial/ethnic groups, or language fluency?**

yes

**4A3.2 \* If "Yes", please explain why you are going to intentionally exclude someone on the basis of gender, racial/ethnic groups, or language fluency:**

The intervention has been specifically tailored for African Americans and thus we are excluding those of other racial/ethnic groups

**4A3.3 \* Are there additional criteria for excluding individuals from participation not described above (such as minimum time in current job, specific health conditions, cognitive impairment, literacy)?**

no

**4A4 Coercion or Undue Pressure to Participate**

**4A4.1 \* Are any of the participants in a situation, role, or position where they could be coerced or feel undue pressure to participate (e.g., employer/employee, doctor/patient, supervisor/subordinate, student/teacher)?**

no

**4A5 Participant Recruitment**

**4A5.1 \* Next we will be asking questions related to communication or interaction with potential study participants. These questions will cover number of participants, recruitment procedures, recruitment materials to be used, obtaining informed consent, and contact after the research ends.**

How will the study staff (including subcontractors and vendors) be communicating or interacting with individuals from this population?

A. Recruiting/contacting participants

B. Obtaining informed consent

**4A5.2 Please answer the remaining questions based on your best estimates at this time.**

**4A5.3**



Section: 4 Populations

- \* **What is the earliest date at which you expect the project will have first contact with potential participants?**  
(mm/dd/yyyy)  
10/3/2016
- 4A5.4 \* **How many potential participants does the study staff expect to contact or screen regarding participation (i.e., your starting sample size)?**  
1000
- 4A5.5 \* **How many participants do you expect to have (i.e., number of respondents or participants)?**  
350
- 4A5.6 \* **Please describe the recruitment procedure. Include who, what, where, when, and how. Note: questions on informed consent will be asked later in Section 6.**  
Participants will be recruited via fliers in waiting areas and on bulletin boards at APLA, clinics, and other AIDS service organizations (ASOs); radio, metro, newspaper, newsletter, and online ads; and fliers disseminated by APLA program staff to their clients (e.g., case managers). APLA and RAND staff will also hold brief information sessions at client gatherings (e.g., support groups) and staff meetings in different clinics and organizations. We will hire a staff member from the local community for recruitment and tracking who is well-connected with the local HIV population and community organizers, and familiar with local HIV services in Los Angeles County (LAC). In addition, we will recruit through several of APLA's programs (housing, food bank) that attract a wide variety of clients, including those not fully engaged in care. Interested participants will be screened in person or by phone by APLA study staff, and they will be asked to bring proof of viral load to the first study visit. Prior to the baseline survey, the study coordinator will describe the details of the study, including the nature of involvement in the study, the possible risks and benefits of participation, and the ability to withdraw from the study at any time without consequence. The participant will have the opportunity to ask questions about the study, after which informed consent will be obtained and documented by having the participant read and sign a consent form, which will be stored in a locked file cabinet. Each participant will be given a copy of the consent form to keep.  
We have used these recruitment procedures successfully for several prior studies.
- 4A5.7 \* **Do you have recruitment materials (e.g., advertisements, flyers, letters of introduction) in draft or final form ready to upload?**  
yes
- 4A5.8 You will be asked to upload these recruitment materials in section 7.

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Section: 5 Procedures

**5 - Procedures**

Procedure	Answer questions by clicking on all active links below	Status
Electronic Adherence Assessment (MEMS)	<a href="#">5C Procedures - Interactions with Participants</a>	Completed
	<a href="#">5E Procedures - Risks</a>	Completed
	<a href="#">5F Procedures - Benefits, Incentives, Costs</a>	Completed
	<a href="#">5G Procedures - Confidentiality</a>	Completed
Intervention	<a href="#">5A Procedures - Interventions: Overview</a>	Completed
	<a href="#">5E Procedures - Risks</a>	Completed
	<a href="#">5F Procedures - Benefits, Incentives, Costs</a>	Completed
	<a href="#">5G Procedures - Confidentiality</a>	Completed
Medical Records Assessment	<a href="#">5D Procedures - Secondary Data</a>	Completed
	<a href="#">5E Procedures - Risks</a>	Completed
	<a href="#">5G Procedures - Confidentiality</a>	Completed

Section: 5 Procedures

Surveys	<a href="#">5C Procedures - Interactions with Participants</a>	Completed
	<a href="#">5E Procedures - Risks</a>	Completed
	<a href="#">5F Procedures - Benefits, Incentives, Costs</a>	Completed
	<a href="#">5G Procedures - Confidentiality</a>	Completed
Viral Load Assessment	<a href="#">5A Procedures - Interventions: Overview</a>	Completed
	<a href="#">5B Procedures - Interventions: Biologic Samples or Specimens</a>	Completed
	<a href="#">5E Procedures - Risks</a>	Completed
	<a href="#">5F Procedures - Benefits, Incentives, Costs</a>	Completed
	<a href="#">5G Procedures - Confidentiality</a>	Completed

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## Electronic Adherence Assessment (MEMS)

### 3C Research Overview - Procedures

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Related Populations:

- *People Living with HIV (Pending - as with Just in Time reviews)*

### 3C1 Procedure Description

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**3C1.1 \* Which of the following describes this procedure? (Check all that apply)**

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> A.            | Acquiring previously collected person-level information                   | (e.g., medical records, census data, employment records, education records, other existing datasets) |
| <input type="checkbox"/> B.            | Interview   | (e.g., phone interview)  |
| <input type="checkbox"/> C.            | Survey (either oral or written)   | (e.g., mail survey, web survey)  |
| <input type="checkbox"/> D.            | Group discussion  | (e.g., focus group, expert panel)  |
| <input type="checkbox"/> E.            | Observation of individuals or groups                                      | (e.g., in-person visual observation, video observation)  |
| <input type="checkbox"/> F.            | Educational testing   | (e.g., aptitude testing, military/vocational training assessment)                                    |
| <input type="checkbox"/> G.            | Psychological testing, measurement, or assessment                         |  |
| <input type="checkbox"/> H.            | Physical exam, testing, measurement, assessment (w/o specimen collection) | (e.g., blood pressure, weight measurement,)  |
| <input type="checkbox"/> I.            | Biologic sample collection  | (e.g., tissue, blood, urine, saliva)   |
| <input type="checkbox"/> J.            | Testing of existing biological samples                                    | (e.g., testing for the presence of disease or drugs)   |
| <input type="checkbox"/> K.            | Socio-behavioral or educational intervention                              | (e.g., randomized trials, quasi-experimental designs, demonstration projects)                        |
| <input type="checkbox"/> L.            | Clinical treatment  | (e.g., administering drugs, therapy)   |
| <input type="checkbox"/> M.            | Other intervention research procedures                                    | (e.g., physical procedures, manipulating environment to evaluate impact on outcome)                  |
| <input checked="" type="checkbox"/> N. | <b>Other interaction research procedures</b>                              | <b>(e.g., obtaining information from individuals)</b>  |

**3C1.4** You will be asked to answer the questions on screen 5C "Procedures – Interactions." If those questions seem inappropriate for this procedure, please contact the RHINO Helpdesk for assistance at ext 4772.

## Section: 5 Procedures

**\* If "N" above, please describe the interaction procedure.**

**3C1.5** Adherence will be measured continuously and electronically from 1 month prior to the baseline survey to 12-month follow-up using MEMS. One and a half months prior to the baseline session (to decrease reactance to the adherence measurement for a valid baseline measure), interviewers will assist clients with dispensing the medication with the most complex dosing schedule or the base medication of the regimen if all medications have the same schedule (e.g., non-nucleoside reverse transcriptase inhibitor, protease inhibitor, integrase inhibitor), into a MEMS bottle. Bi-monthly, starting at baseline, interviewers will download adherence data and participants will complete a brief survey to assess instances in which the cap was not used as intended in the past two weeks (i.e., how often the bottle was opened without removing a dose, a dose was taken from a source other than the bottle, such as a pillbox, and whether multiple doses were removed at a time and pocketed for later ingestion). Data for the past two weeks at each time-point will be adjusted using these responses for a more valid assessment. MEMS software can calculate the percentage of total scheduled doses actually taken, which will be dichotomized at  $\geq 85\%$  of doses taken at each time-point, following research suggesting that moderate adherence can have clinically significant effects.

**3C3** You will be asked to complete the following screens in section 5 for this procedure based on your answers given above:

- 5C Procedures - Interactions
- 5E Procedures - Risks
- 5F Procedures - Benefits, Incentives, Costs
- 5G Procedures - Confidentiality

## 5C Procedures - Interactions with Participants

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### 5C1 Research Team Interaction with Participants

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*Note: Do not repeat details of interactions that apply only to recruitment procedures. Those details are addressed for the related populations in 4A5.*

**5C1.1** **\* How will the research team be interacting with the participants for the purposes of data collection? (Check all that apply)**

A. In person

B. By phone

C. Via mail

D. Over the web (e.g., email, chat, blog)

**5C1.3** **\* Will the research team be audio or video recording the interaction procedure?**

no

**5C2** **\* Provide a step-by-step description of this procedure.** *Note: Details regarding whether the interaction procedure will be repeated are covered in 5C4.*

Adherence will be measured continuously and electronically from 1-month prior to the enrollment and randomization visit to 12-months post-intervention using MEMS. One month prior to the baseline session (to decrease reactance to the adherence measurement for a valid baseline measure), interviewers will assist clients with dispensing the medication with the most complex dosing schedule or the base medication of the regimen if all medications have the same schedule (e.g., non-nucleoside reverse transcriptase inhibitor, protease inhibitor, integrase inhibitor), into a MEMS bottle. Bi-monthly, starting at enrollment, interviewers will download adherence data and participants will complete a brief survey to assess instances in which the cap was not used as intended in the past two weeks (i.e., how often the bottle was opened without removing a dose, a dose was taken from a source other than the bottle, such as a pillbox, and whether multiple doses were removed at a time and pocketed for later ingestion). Data for the past two weeks at each time-point will be adjusted using these responses for a more valid assessment. MEMS software can calculate the percentage of total scheduled doses actually taken, which will be dichotomized at  $\geq 85\%$  of doses taken at each time-point, following research suggesting that moderate adherence can have clinically significant effects.

In addition to in person, interviewers will interact with participants by phone, mail, and over the internet to set up appointments and to remind participants about appointments.

### 5C3 Participant Questions

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**5C3.1** **\* Do you have the questions you will be asking participants (e.g., the interview protocol, survey instrument, focus group guide) in draft or final form or a list of domains to be covered?**  
yes

**5C3.2** If "Yes" and you did not upload the questions in Section 2, you will be asked to upload them in Section 7.

Section: 5 Procedures

**5C4 Repetition of the Interaction Procedure**

**5C4.1** \* Will this interaction procedure be repeated with the same participants? *Note: If the repetition is described in another procedure, indicate that below.*

- A. Yes - described below in 5C4.2
- B. Yes - is or will be described in another procedure
- C. No
- D. Possibly

**5C4.2** \* If "A" or "D", indicate how often this interaction procedure will occur and at what intervals. *Note: If you already provided this detail in 5C2, please indicate that below.*  
Please see 5C2

**5C5 Previously Developed and Validated Surveys, Tests, or Assessments**

**5C5.1** \* Will previously developed and validated surveys, tests, or assessments be administered as part of this interaction procedure?

- Yes
- No
- Don't know

**5C5.2** \* If "Yes," please list the previously developed and validated surveys, tests, or assessments to be administered, noting what each measures. Please indicate whether the standardized test or assessment has been altered.  
MEMS adherence past-two weeks diary: Bangsberg DR, Hecht FM, Charlebois ED, et al. Adherence to protease inhibitors, HIV-1 viral load, and development of drug resistance in an indigent population. AIDS. 2000;14(4):357-366.

**5E Procedures - Risks****5E1 Breach of Confidentiality Risk**

**5E1.1** \* In the event a breach of confidentiality allowing someone outside of the research team to identify participants in this study, which of the following types of harm might result? (Check all that apply)

- A. Legal (i.e., criminal or civil liability)
- B. Financial/economic (e.g., damage to employability)
- C. Psychological (e.g., embarrassment, distress)
- D. Social (e.g., damage to reputation)
- E. Other
- F. No anticipated risk

**5E2 Participation Risk**

**5E2.1** \* Aside from the risks associated with a breach of confidentiality, which of the following types of harm might result from participation in the procedure? (Check all that apply)

- A. Financial/economic (e.g., damage to employability)
- B. Physical consequences (e.g., pain, discomfort)
- C. Psychological consequences (e.g., distress, embarrassment, pressure to participate)
- D. Social (e.g., stigma of participation, damage to reputation)
- E. Other
- F. No anticipated risk

**5E3** In the questions that follow, the phrase "individuals in the general U.S. population" refers to healthy individuals in the United States who are not incarcerated. Thus, the high standard of minimal risk is based on the amount of risk typically encountered in everyday life by healthy individuals in the United States. If the study population is unhealthy individuals, incarcerated individuals, or individuals in another country, the appropriate comparison is now how much risk "healthy individuals" would face. The comparison is what the actual subject population would face in comparison to minimal risk

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as defined by everyday life for healthy individuals in the United States. *If a breach of confidentiality or participation would be dangerous in the study population, it is above minimal risk.*

**5E5 Financial/Economic Risks Associated with a Breach of Confidentiality**

---

- 5E5.1** \* Might the degree or amount of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
yes
- 5E5.2** \* Might the likelihood of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
no
- 5E5.3** \* Please explain the nature of the financial/economic harm, what might cause it, and steps that would be taken to mitigate it.  
Participants could experience financial harm if their HIV-positive serostatus became known to others, potentially leading to employment discrimination. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E6 Psychological Risks Associated with a Breach of Confidentiality**

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- 5E6.1** \* Might the degree or amount of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
yes
- 5E6.2** \* Might the likelihood of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
no
- 5E6.3** \* Please explain the nature of the discomfort or distress, what might cause it, and steps that would be taken to mitigate it.  
Participants could experience psychological harm if their HIV-positive serostatus became known to others, potentially leading to HIV stigma and discrimination. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E7 Social Risks Associated with a Breach of Confidentiality**

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- 5E7.1** \* Might the degree or amount of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
yes
- 5E7.2** \* Might the likelihood of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
no
- 5E7.3** \* Please explain the nature of the social harm, what might cause it, and steps that would be taken to mitigate it.  
Participants could experience social harm if their HIV-positive serostatus became known to others, potentially leading to HIV stigma and discrimination. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5F Procedures - Benefits, Incentives, and Costs**

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**5F2 Incentives and Other Forms of Compensation**

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- 5F2.1** \* Will the participants receive incentives or some other form of compensation (e.g., cash, voucher, meals, reimbursements)?  
yes
- 5F2.2** \* If "Yes", what will the participants receive as an incentive or other forms of compensation?  
Participants will receive \$20 per visit to download adherence data and update their contact information
- 5F2.3** \* If "Yes", how and when will the incentives or other forms of compensation be distributed to participants?  
Include any detail about conditions under which they might *not* receive the incentive or other form of compensation.  
All participants who visit APLA for a study visit to download adherence data will receive \$20

**5F3 Costs**

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- 5F3.1** \* Might the participants incur any financial costs that will not be reimbursed and that they would otherwise not incur?  
no

**5G Procedures - Confidentiality**

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**5G1 Sensitive Information**

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- 5G1.1** \* Will any of the following types of sensitive information be intentionally accessed, acquired, or recorded as part of data collection about an individual? (Check all that apply) *Note: You may have answered this question 2H with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be sensitive with regard to another population in your study that you have associated with this procedure.*
- |                                     |                           |  |
|-------------------------------------|---------------------------|--|
| <input type="checkbox"/>            | A. Substance use          | including alcohol, drugs, and tobacco  |
| <input checked="" type="checkbox"/> | <b>B. Physical health</b> | <b>including diagnosis, treatment, or any other private physical health information</b>  |
| <input type="checkbox"/>            | C. Mental health          | including diagnosis, treatment, current mental health status (e.g., suicidality), or any other private mental health information |
| <input type="checkbox"/>            | D. Traumatic events       | including victimization, bereavement, accidents, natural disasters, and military combat  |
| <input type="checkbox"/>            | E. Illegal activity       | including illicit drug use, human trafficking, and terrorism   |
| <input type="checkbox"/>            | F. Immigration status     |  |
| <input type="checkbox"/>            | G. Sexual behavior        |  |
| <input type="checkbox"/>            | H. Abuse/neglect          | including child, elder, domestic, and partner  |
| <input type="checkbox"/>            | I. Educational records    | including status, history, or performance  |
| <input type="checkbox"/>            | J. Employment records     | including status, history, or performance  |
| <input type="checkbox"/>            | K. Financial information  |  |
| <input type="checkbox"/>            | L. Other                  |  |
| <input type="checkbox"/>            | M. None of the above      |  |

**5G2 Identifying Information**

---

- 5G2.1** \* Check all types of identifying information that your research will acquire about these participants. *Note: You may have answered this question on screens 2B or 2C with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be identifiable with regard to another population in your study that you have associated with this procedure.*
- |                                     |  |   |
|-------------------------------------|--|---|
| <input type="checkbox"/>            | A. Names                               | including names appearing on consent forms, payment receipts, medical records, and emergency contact lists                  |
| <input type="checkbox"/>            | B. Location and contacting information | including any address information smaller than state, telephone or fax numbers, email addresses, web URLs, and IP addresses |
| <input checked="" type="checkbox"/> | <b>C. Dates</b>                        | <b>including birth date, marriage date, and treatment or visit dates from medical records</b>                               |
| <input type="checkbox"/>            | D.                                     |   |

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- Identification numbers including Social Security Numbers, medical record or health plan beneficiary numbers, account numbers, student ID numbers, certificate or license numbers (e.g., driver's license), vehicle identifiers and serial numbers (e.g., license plates), and device identifiers and serial numbers (e.g., serial numbers on surgical implants)

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- Audio, video, or E. biometric indicators including photographic or video images, audio recordings, and finger or voice prints

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- None of the F. identifiers listed above by checking this box you certify that you are not obtaining any of the information listed above

**5G3 Disclosure of Identifiable Person Level Data**

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**5G3.1** \* Will any information that you collect go into person level non-research records (e.g., medical, educational, employment records) that are not maintained and controlled solely by the research team? *Note: This is a relatively rare occurrence for research done at RAND and would require HSPC approval.*

- Yes
- No
- Don't know

**5G4 Reasons for Breaking Confidentiality**

---

**5G4.1** \* Could the procedure yield information potentially of importance to individual participants that they otherwise would be unlikely to know? This includes information specifically gathered or spontaneously provided or observed.  
yes

**5G4.2** \* If "Yes", will participants or others (e.g., doctors, teachers, parents) be notified?  
yes

**5G4.3** Note: If "Yes", this information must be included in the consent form.

**5G4.4** \* If "Yes", please provide a detailed explanation of who will be notified, what information will be provided (e.g., abnormal test results, reportable diseases), and how.  
At the end of their participation in the study, all participants will be presented with their electronically monitored adherence data and will go over it with the study research assistant.

**5G5 Promise of Confidentiality**

---

**5G5.1** \* Is confidentiality being promised to participants with no additional exceptions aside from those noted in 5G4?

- A. Yes
- B. No, participants can choose to allow potentially identifiable information (e.g., quotes, performance information) to be included in published reports
- C. No, participants must agree to be attributable in published reports (this is a rare exception and might only occur in studies of a single organization)
- D. No, there will be other exceptions (e.g., intent to harm self or others, suspected child abuse)

**5G5.4** \* If "D" on 5G5.1, please describe the exceptions and why they are necessary.  
There will be legal exceptions of suicidal ideation or harm to self or others and intent to harm others or child or elder abuse/neglect.

**5G5.5** \* Do you plan to apply for a Certificate of Confidentiality? Please note that such applications can be filed only after consent protocols have been approved.

- Yes
- No
- Don't know

**5G6 Identifiability by Inference in Published Reports**

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**5G6.1** \* Might comments or other information included in published reports be identifiable by inference for participants who do not agree to be identified and are being assured of confidentiality?  
no

**5G7 Data Safeguarding Plan**

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**5G7.1** \* Based on previous answers, a Data Safeguarding Plan (DSP) is required. Are you ready to upload it in draft or final form at this time?  
yes

**5G7.2** You will be able to upload the Data Safeguarding Plan (DSP) later in Section 7

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**Intervention**

**3C Research Overview - Procedures**

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Related Populations:

- *People Living with HIV (Pending - as with Just in Time reviews)*

**3C1 Procedure Description**

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**3C1.1** \* Which of the following describes this procedure? (Check all that apply)

- |                             |   |  |
|-----------------------------|---|--|
| <input type="checkbox"/> A. | Acquiring previously collected person-level information                   | (e.g., medical records, census data, employment records, education records, other existing datasets) |
| <input type="checkbox"/> B. | Interview   | (e.g., phone interview)  |
| <input type="checkbox"/> C. | Survey (either oral or written)   | (e.g., mail survey, web survey)  |
| <input type="checkbox"/> D. | Group discussion  | (e.g., focus group, expert panel)  |
| <input type="checkbox"/> E. | Observation of individuals or groups                                      | (e.g., in-person visual observation, video observation)  |
| <input type="checkbox"/> F. | Educational testing   | (e.g., aptitude testing, military/vocational training assessment)                                    |
| <input type="checkbox"/> G. | Psychological testing, measurement, or assessment                         |  |
| <input type="checkbox"/> H. | Physical exam, testing, measurement, assessment (w/o specimen collection) | (e.g., blood pressure, weight measurement,)  |
|                             | I. Biologic sample collection   | (e.g., tissue, blood, urine, saliva)   |



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<input type="checkbox"/>		
<input type="checkbox"/>	J. Testing of existing biological samples	(e.g., testing for the presence of disease or drugs)
<input checked="" type="checkbox"/>	<b>K. Socio-behavioral or educational intervention</b>	<b>(e.g., randomized trials, quasi-experimental designs, demonstration projects)</b>
<input type="checkbox"/>	L. Clinical treatment	(e.g., administering drugs, therapy)
<input type="checkbox"/>	M. Other intervention research procedures	(e.g., physical procedures, manipulating environment to evaluate impact on outcome)
<input type="checkbox"/>	N. Other interaction research procedures	(e.g., obtaining information from individuals)

**3C3** You will be asked to complete the following screens in section 5 for this procedure based on your answers given above:

- [5A Procedures - Interventions: Overview](#)
- [5E Procedures - Risks](#)
- [5F Procedures - Benefits, Incentives, Costs](#)
- [5G Procedures - Confidentiality](#)

## 5A - Procedures - Interventions: Overview

**5A1** \* Provide a step-by-step description of this procedure for the studied groups of participants. Include both alterations of their experiences (e.g., novel educational practices, new health services) and administration of any treatments they might not otherwise receive (e.g., medications, nutritional supplements). *Note: you will be asked below in 5A2 about assignment of participants to different groups (e.g., different data collection or treatment/control groups).*

Rise consists of a one-month intensive intervention (with three core 60-minute counseling sessions at weeks 1, 2, and 4) followed by two booster sessions (at weeks 12 and 20). If participants show treatment nonadherence during booster sessions, they are offered up to four additional booster sessions (i.e., extra booster sessions if <85% of prescribed doses were taken in the past month). Thus, participants receive three core sessions in the first month, followed by 2-6 booster sessions over the next four months.

**One-Month Intensive Intervention Period. Session 1:** In the first session, the counselor provides information about the importance of adherence and consequences of missed doses and appointments, provides education about viral load and drug resistance, and explains the connection between dosing schedules and viral suppression. To address culturally relevant factors, the counselor acknowledges health care discrimination and health disparities, and shares reasons for medical mistrust and HIV misconceptions in Black communities. The counselor encourages the client to share any experiences and perceptions they may have in this regard. To enhance instrumental (e.g., finding transportation to clinic) and emotional (e.g., encouraging/reinforcing adherence) support, the counselor assesses the availability of social supports to the client (e.g., whether individuals in clients' social networks are aware of their HIV status). The counselor explores with the client whether HIV disclosure is an option for obtaining social support, in the context of reviewing possible benefits as well as risks. The counselor supplies accurate information to dispel any HIV-related misconceptions.

**Adherence Feedback/Review:** Together with the client, the counselor reviews adherence and attendance at scheduled medical appointments to provide a baseline of adherence levels that will be revisited in future sessions. Adherence will be measured electronically and continuously using MEMS caps, which record times when the medication bottle is opened. (See Assessment section for a full description.) MEMS software yields daily medication-taking reports and calculates percentage of scheduled doses taken. Intervention counselors download MEMS data and generate and print out adherence summary statistics and graphic depictions of patterns of doses taken and missed since baseline in Session 1 or since the last session in later sessions.

After the counselor identifies instances of nonadherence using MEMS data, clients identify barriers that may contribute to missed appointments and doses, such as lack of accurate treatment information (or belief in misconceptions), low motivation, presence of or concern about side effects, mental health issues or substance use, internalized stigma, medical mistrust and/or negative experiences with health care (e.g., discrimination). Stages of problem solving are reviewed: defining the problem, deciding on a goal, generating possible solutions, selecting a potential solution, planning the solution's implementation, and evaluating the solution's effectiveness (at the subsequent session). The counselor identifies contextual cues that influence adherence (what occurred immediately before and after a missed dose/appointment) to derive strategies for managing and controlling cues. Clients describe daily routines and together with the counselor determine optimal ways to integrate medication into routines. Doses are connected with routine daily activities that can serve as reminder triggers for taking medications. Strategies for coping with and reducing side effects are discussed.

The counselor conducts a needs assessment and provides referrals for any unmet basic needs (housing, food, transportation) and mental health issues (depression, substance use), using pre-screeners for mental health and substance use (PHQ-2 for depression; NIDA Quick Screen for substance use). Session 1 closes with the development of an Individual Service Plan (ISP) of short- and long-term goals (e.g., following up on referrals, engaging a friend to support adherence), which is revisited and updated in each session.

**Sessions 2-3:** These sessions are similar to Session 1, but with greater targeting of barriers to adherence and retention

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in care. Together with the client, the counselor reviews adherence and attendance at scheduled medical appointments since the last session, and discusses barriers and reasons for missed doses. The counselor assesses whether clients followed up on referrals, offers new referrals as needed, and evaluates progress toward ISP goals. The counselor assesses the client's relationship with his/her HIV care provider in terms of satisfaction with care and trust in provider. With consent from the client, the counselor contacts the provider via phone or email to inform him/her that the client is participating in Rise and working with the counselor over the next 6 months to support the adherence and care retention. The client and counselor agree on any adherence barriers that the counselor can convey to the provider (e.g., about housing status).

**Booster Sessions. Booster Sessions 4 & 5:** The goal of the booster sessions is to help clients sustain optimal adherence. Clients who achieve  $\geq 85\%$  adherence (as measured by MEMS) during the 2 weeks preceding Weeks 12 and 20 receive a session only at those weeks; others receive up to two biweekly added sessions at each time point. For example, if adherence from Weeks 10-12 is  $\geq 85\%$ , the client receives a session at Week 12, and then returns again at Week 20 for the next booster session. If the client's adherence from Weeks 10-12 is  $< 85\%$ , the client receives booster sessions at Weeks 12 and 14, and if adherence from Weeks 12-14 is  $< 85\%$ , then s/he receives another session at Week 16. All clients return at Week 20, but only clients with adherence  $< 85\%$  during Weeks 18-20 return at Week 22, and those with adherence  $< 85\%$  during Weeks 20-22 have another session at Week 24. We use 85% adherence as the cutoff for determining good adherence based on research suggesting that this level of adherence is associated with optimal treatment response and viral suppression. The dose regulation (of 0-4 extra booster sessions) is intended to promote efficient use of limited community resources by varying intensity depending on client need. Booster sessions are similar to the initial core sessions, with continued emphasis on identification and resolution of barriers, use of MI to improve attitudes and motivation related to adherence, side effect management, monitoring of adherence-related social support and self-efficacy, and medical mistrust.

**5A2 Administered to All Members****5A2.1 \* Will any subgroups of the population(s) referenced above receive different interventions? (Check all that apply)**

A. Yes - not all participants will receive the same intervention (e.g., physical exams or biologic samples will be collected/tested from only a subset)

B. Yes - some participants will receive the socio-behavioral or clinical intervention and others will be in the control group

C. No - all participants will receive the same procedure(s) listed above

**5A2.4 \* If "B", please describe how individuals will be selected into the intervention/treatment and control groups (e.g., random assignment of individuals/groups or quasi-experimental designs comparing existing groups). If already described above in 5A1, please indicate that below.**

A blocked 1:1 randomization design with stratification by viral suppression (with randomly alternating blocks of 2, 4, and 6 to prevent anticipation of condition) will help to ensure balance across arms. The statistician will use a random numbers generator to devise a randomization log and a set of numbered randomization envelopes. In the log, treatment assignment specifications will be left blank to prevent condition foreknowledge. After the project director records each ID in the log (immediately after the baseline survey, using results from pre-baseline confirmation of viral load via medical records for stratification), s/he will open the corresponding randomization envelope.

**5A3 \* Describe the qualifications and/or training for those who will conduct the intervention.**

Counselors are trained peers with similar backgrounds and experiences as clients, with in-depth knowledge of local communities and the experience of living with HIV; thus, they are seen as credible sources to address mistrust. Counselors use an motivational interviewing (MI) style. MI is used to change behaviors and attitudes that are barriers to adherence and care retention, and to develop positive attitudes and beliefs about treatment efficacy, expected treatment outcomes, and adherence self-efficacy; counselors help clients to develop problem-solving skills to identify key barriers, and to implement and evaluate strategies to overcome barriers. MI maximizes feelings of autonomy and increases the likelihood that strategies will be adopted. Counselors are trained to ask open questions, use reflective listening, and motivate change by highlighting discrepancies between behavior or thoughts and stated health goals, as well as respecting client autonomy.

Counselor training and ongoing supervision will ensure consistency in intervention implementation and protocol fidelity. The training (conducted by Co-Is Goggin and Wagner) includes instruction on basic HIV disease, the importance of protecting confidentiality and complying with HIPAA regulations, crisis intervention, referral resources, issues that can influence ART adherence and retention in care among Black clients, and mental health and substance abuse assessment. The counselor is trained to establish rapport and effective working relationships with clients and medical providers, and to locate community resources, referrals, and linkages. The counselor is provided with and encouraged to further develop a comprehensive referral list to HIV-related and supportive services (e.g., housing, mental health). All counseling sessions are recorded with consent from the client. The supervisor listens to all sessions of the first two clients receiving the intervention, and then all recorded sessions of every fifth participant. This serves as the basis for provision of feedback to the counselor during biweekly supervision. Supervision also provides a time for the counselor to discuss challenging cases and review treatment plans for newly enrolled participants. Co-I Goggin will work with Co-I Wagner to develop a detailed supervision protocol. Wagner will supervise the counselor for the first six months while training the MA-level Project Director (who will have a counseling or social work degree) to conduct supervision

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for the remaining sessions. Wagner and the Project Director will complete a rating form after reviewing session transcripts for fidelity, for use in supervision. Goggin may listen to recordings of initial participants to assist with the trainings and provide feedback. (She will receive recordings through a secure SharePoint site, as noted in the DSP.)

**5A4 Interim Outcome Monitoring**

**5A4.1 \* Will interim outcomes be monitored in any way? For example, some intervention studies may have or be required to have a Data and Safety Monitoring Plan (DSMP) to assess that the intervention is not harmful and/or is having a positive effect.**

yes

**5A4.2 \* If "Yes", explain what will be monitored, when, how, and why.**

Given the low risk of the experimental intervention, we believe that a multiple-person data safety monitoring board (DSMB) is an unnecessarily intensive approach to monitoring this trial. We propose here an alternative, less intensive approach which we believe will effectively ensure the welfare of study subjects and the continued scientific validity of the study. Specifically, we propose that a single, independent, behavioral HIV researcher to serve as an independent monitor for the study. The monitor will be an expert in the treatment of substance use among people living with HIV who does not have a conflict of interest with anyone on the study team, i.e., who does not have a prior (within 3 years) collaborative or financial relationship with any of the study investigators and who is not employed currently or within 3 years in any of the primary study institutions.

To allow effective monitoring, the independent monitor will be provided with periodic reports which include subject enrollment, subject retention, the number of patients who drop out of the study with reasons for dropping out, and a listing of all adverse events (AEs) that are plausibly related to study procedures. Reports will be provided to the independent monitor at 6-month intervals. After review of the periodic reports, the independent monitor may ask for clarification or additional information from the principal investigator (PI). After such information is provided, if requested, the independent monitor will make a recommendation regarding the continuation, modification, or termination of the study. All communications from the independent monitor will be shared with the study institutional review boards (IRBs), as well as NIH. By utilizing a single independent monitor rather than a multi-person DSMB, we believe the oversight of the study will be easier to implement, more efficient, and more responsive to issues as they arise.

**5A4.3 \* Does your funder or the RAND HSPC require a Data and Safety Monitoring Plan (DSMP) for your study? The RAND HSPC will make its determination during the review process.**

**Yes - by the funder and/or the HSPC**

No (including not yet determined by the HSPC)

**5A4.4 \* Do you have the DSMP for this study ready to upload in draft or final form?**

yes

**5A4.5** You will be asked to upload the DSMP in section 7. A DSMP is typically done at the study level and you will be able to upload a single DSMP in section 7 and associate it with as many components as necessary. This is done to ensure that all components that should be covered are addressed in the DSMP.

**5E Procedures - Risks****5E1 Breach of Confidentiality Risk**

**5E1.1 \* In the event a *breach of confidentiality* allowing someone outside of the research team to identify participants in this study, which of the following types of harm might result? (Check all that apply)**

**A. Legal (i.e., criminal or civil liability)**

**B. Financial/economic (e.g., damage to employability)**

**C. Psychological (e.g., embarrassment, distress)**

**D. Social (e.g., damage to reputation)**

**E. Other**

**F. No anticipated risk**

**5E2 Participation Risk**

**5E2.1 \* Aside from the risks associated with a breach of confidentiality, which of the following types of harm might result from participation in the procedure? (Check all that apply)**

**A. Financial/economic (e.g., damage to employability)**

**B. Physical consequences (e.g., pain, discomfort)**

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C. Psychological consequences (e.g., distress, embarrassment, pressure to participate)

D. Social (e.g., stigma of participation, damage to reputation)

E. Other

F. No anticipated risk

**5E3** In the questions that follow, the phrase "individuals in the general U.S. population" refers to healthy individuals in the United States who are not incarcerated. Thus, the high standard of minimal risk is based on the amount of risk typically encountered in everyday life by healthy individuals in the United States. If the study population is unhealthy individuals, incarcerated individuals, or individuals in another country, the appropriate comparison is now how much risk "healthy individuals" would face. The comparison is what the actual subject population would face in comparison to minimal risk as defined by everyday life for healthy individuals in the United States. ***If a breach of confidentiality or participation would be dangerous in the study population, it is above minimal risk.***

**5E4 Legal Risks Associated with a Breach of Confidentiality**

**5E4.1** \* Might the degree or amount of legal harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
yes

**5E4.2** \* Might the likelihood of legal harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
no

**5E4.3** \* Please explain the nature of the legal harm, what might cause it, and steps that would be taken to mitigate it.  
Participants will be discussing barriers to adherence with the intervention counselor, which could include illegal substance use. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E5 Financial/Economic Risks Associated with a Breach of Confidentiality**

**5E5.1** \* Might the degree or amount of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
yes

**5E5.2** \* Might the likelihood of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
no

**5E5.3** \* Please explain the nature of the financial/economic harm, what might cause it, and steps that would be taken to mitigate it.  
Participants could experience financial/economic harm if their HIV-positive serostatus became known to others. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E6 Psychological Risks Associated with a Breach of Confidentiality**

**5E6.1** \* Might the degree or amount of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
yes

**5E6.2** \* Might the likelihood of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?  
no

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**5E6.3 \* Please explain the nature of the discomfort or distress, what might cause it, and steps that would be taken to mitigate it.**

Participants could experience psychological harm if their HIV-positive serostatus became known to others, potentially leading to HIV stigma and discrimination. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E7 Social Risks Associated with a Breach of Confidentiality**

---

**5E7.1 \* Might the degree or amount of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

yes

**5E7.2 \* Might the likelihood of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

no

**5E7.3 \* Please explain the nature of the social harm, what might cause it, and steps that would be taken to mitigate it.**

Participants could experience social harm if their HIV-positive serostatus became known to others, due to HIV stigma. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E11 Psychological Risks Resulting from Participation**

---

**5E11.1 \* Might the degree or amount of psychological harm *resulting from participation in the procedure itself* (i.e., other than from a breach of confidentiality) be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

no

**5E11.2 \* Might the likelihood of psychological harm *resulting from participation in the procedure itself* (i.e., other than from a breach of confidentiality) be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

no

**5E11.3 \* Please explain the nature of the psychological harm, what might cause it, and steps that would be taken to mitigate it.**

Participants may experience psychological distress while talking about issues raised during individual sessions. Participating in the intervention could also lead to self-awareness about the limitations of one's knowledge of HIV and/or techniques related to HIV treatment care. There is also a possibility that participants who have not disclosed their HIV status to individuals in their social network will do so (due to prompting from the counselor); depending on how the individual they disclose to responds, it could either increase or decrease the participant's psychological distress. If participants express a great deal of psychological distress during the sessions, the intervention facilitator will provide appropriate referrals to local mental health resources, including information about APLA's mental health program, and answer any questions the participant may have about these services.

**5F Procedures - Benefits, Incentives, and Costs**

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**5F2 Incentives and Other Forms of Compensation**

---

**5F2.1 \* Will the participants receive incentives or some other form of compensation (e.g., cash, voucher, meals, reimbursements)?**

yes

**5F2.2 \* If "Yes", what will the participants receive as an incentive or other forms of compensation?**

\$10 to compensate for transportation costs

**5F2.3 \* If "Yes", how and when will the incentives or other forms of compensation be distributed to participants?**

Include any detail about conditions under which they might *not* receive the incentive or other form of compensation.

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Participants will get the incentive if they show up to an intervention session. The incentive will be distributed at the end of the session.

**5F3 Costs**

- 5F3.1** \* Might the participants incur any financial costs that will not be reimbursed and that they would otherwise not incur?  
no

**5G Procedures - Confidentiality****5G1 Sensitive Information**

- 5G1.1** \* Will any of the following types of sensitive information be intentionally accessed, acquired, or recorded as part of data collection about an individual? (Check all that apply) *Note: You may have answered this question 2H with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be sensitive with regard to another population in your study that you have associated with this procedure.*

- A. Substance use** including alcohol, drugs, and tobacco
- B. Physical health** including diagnosis, treatment, or any other private physical health information
- C. Mental health** including diagnosis, treatment, current mental health status (e.g., suicidality), or any other private mental health information
- D. Traumatic events** including victimization, bereavement, accidents, natural disasters, and military combat
- E. Illegal activity** including illicit drug use, human trafficking, and terrorism
- F. Immigration status**
- G. Sexual behavior**
- H. Abuse/neglect** including child, elder, domestic, and partner
- I. Educational records** including status, history, or performance
- J. Employment records** including status, history, or performance
- K. Financial information**
- L. Other**
- M. None of the above**

- 5G1.2** \* If "Other", please explain.  
electronically monitored HIV medication adherence data will be downloaded at each session. Participants may also bring medical records information (e.g., viral load values) to go over with the intervention counselor.

**5G2 Identifying Information**

- 5G2.1** \* Check all types of identifying information that your research will acquire about these participants. *Note: You may have answered this question on screens 2B or 2C with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be identifiable with regard to another population in your study that you have associated with this procedure.*

- A. Names** including names appearing on consent forms, payment receipts, medical records, and emergency contact lists
- B. Location and contacting information** including any address information smaller than state, telephone or fax numbers, email addresses, web URLs, and IP addresses
- C. Dates** including birth date, marriage date, and treatment or visit dates from medical records
- D. Identification numbers** including Social Security Numbers, medical record or health plan beneficiary numbers, account numbers, student ID numbers, certificate or license numbers (e.g., driver's license), vehicle identifiers and serial numbers (e.g., license plates), and device identifiers and serial numbers (e.g., serial numbers on surgical implants)
- E. Audio, video, or biometric indicators** including photographic or video images, audio recordings, and finger or voice prints
- F.**

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None of the identifiers listed above by checking this box you certify that you are not obtaining any of the information listed above

**5G3 Disclosure of Identifiable Person Level Data**

---

**5G3.1** \* Will any information that you collect go into person level non-research records (e.g., medical, educational, employment records) that are not maintained and controlled solely by the research team? *Note: This is a relatively rare occurrence for research done at RAND and would require HSPC approval.*

- Yes
- No
- Don't know

**5G4 Reasons for Breaking Confidentiality**

---

**5G4.1** \* Could the procedure yield information potentially of importance to individual participants that they otherwise would be unlikely to know? This includes information specifically gathered or spontaneously provided or observed.  
yes

**5G4.2** \* If "Yes", will participants or others (e.g., doctors, teachers, parents) be notified?  
yes

**5G4.3** Note: If "Yes", this information must be included in the consent form.

**5G4.4** \* If "Yes", please provide a detailed explanation of who will be notified, what information will be provided (e.g., abnormal test results, reportable diseases), and how.  
Participants will be presented with their electronically monitored adherence data since the last session and will go over it with the counselor. Counselors will also review with participants their medical information (e.g., viral load) and explain how to read it. We will not notify participants' healthcare providers, since their healthcare providers will be already be aware if their viral load is not suppressed. However, as part of the intervention, with consent from the client, the counselor will contact the provider via phone or email to inform him/her that the client is participating in Rise and working with the counselor over the next 6 months to support the adherence and care retention. The client and counselor agree on any adherence barriers that the counselor can convey to the provider (e.g., about housing status).

**5G5 Promise of Confidentiality**

---

**5G5.1** \* Is confidentiality being promised to participants with no additional exceptions aside from those noted in 5G4?

- A. Yes
- B. No, participants can choose to allow potentially identifiable information (e.g., quotes, performance information) to be included in published reports
- C. No, participants must agree to be attributable in published reports (this is a rare exception and might only occur in studies of a single organization)
- D. No, there will be other exceptions (e.g., intent to harm self or others, suspected child abuse)

**5G5.4** \* If "D" on 5G5.1, please describe the exceptions and why they are necessary.  
There will be legal exceptions of suicidal ideation or harm to self or others and intent to harm others or child or elder abuse/neglect.

**5G5.5** \* Do you plan to apply for a Certificate of Confidentiality? Please note that such applications can be filed only after consent protocols have been approved.

- Yes
- No
- Don't know

**5G6 Identifiability by Inference in Published Reports**

---

Section: 5 Procedures

**5G6.1** \* Might comments or other information included in published reports be identifiable by inference for participants who do not agree to be identified and are being assured of confidentiality?  
no

**5G7 Data Safeguarding Plan**

---

**5G7.1** \* Based on previous answers, a Data Safeguarding Plan (DSP) is required. Are you ready to upload it in draft or final form at this time?  
yes

**5G7.2** You will be able to upload the Data Safeguarding Plan (DSP) later in Section 7

---

**Medical Records Assessment**

**3C Research Overview - Procedures**

---

Related Populations:

- *People Living with HIV (Pending - as with Just in Time reviews)*

**3C1 Procedure Description**

---

**3C1.1** \* Which of the following describes this procedure? (Check all that apply)

- |                                     |   |  |
|-------------------------------------|---|--|
| <input checked="" type="checkbox"/> | <b>A. Acquiring previously collected person-level information</b> | (e.g., medical records, census data, employment records, education records, other existing datasets) |
| <input type="checkbox"/>            | B. Interview  | (e.g., phone interview)  |
| <input type="checkbox"/>            | C. Survey (either oral or written)                                | (e.g., mail survey, web survey)  |
| <input type="checkbox"/>            | D. Group discussion   | (e.g., focus group, expert panel)  |
| <input type="checkbox"/>            | E. Observation of individuals or groups                           | (e.g., in-person visual observation, video observation)  |
|                                     | F. Educational testing  | (e.g., aptitude testing, military/vocational training assessment)                                    |



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- 
- G. Psychological testing, measurement, or assessment
- H. Physical exam, testing, measurement, assessment (w/o specimen collection) (e.g., blood pressure, weight measurement,)
- I. Biologic sample collection (e.g., tissue, blood, urine, saliva)
- J. Testing of existing biological samples (e.g., testing for the presence of disease or drugs)
- K. Socio-behavioral or educational intervention (e.g., randomized trials, quasi-experimental designs, demonstration projects)
- L. Clinical treatment (e.g., administering drugs, therapy)
- M. Other intervention research procedures (e.g., physical procedures, manipulating environment to evaluate impact on outcome)
- N. Other interaction research procedures (e.g., obtaining information from individuals)

**3C2 Secondary Data Follow-Up Questions**

We will ask a few secondary data questions at this point to determine whether some of the population and procedure questions on the later screens can be skipped.

**3C2.1** \* Will the secondary data received by this RAND project (including RAND subcontractors) include any of the following types of identifiers? (Check all that apply) *Note: You may have answered this question on screens 2B or 2C if you applied for an exemption for one or more population-procedure components of your study. However, your information is not carried over automatically because your prior answer was not at the procedure level and this may differ.*

- A. Names** including names appearing on consent forms, payment receipts, medical records, and emergency contact lists
- B. Location and contacting information** including any address information smaller than state, telephone or fax numbers, email addresses, web URLs, and IP addresses
- C. Dates** including birth date, marriage date, and treatment or visit dates from medical records
- D. Identification numbers** including Social Security Numbers, medical record or health plan beneficiary numbers, account numbers, student ID numbers, certificate or license numbers (e.g., driver's license), vehicle identifiers and serial numbers (e.g., license plates), and device identifiers and serial numbers (e.g., serial numbers on surgical implants)
- E. Audio, video, or biometric indicators** including photographic or video images, audio recordings, and finger or voice prints
- F. None of the identifiers listed above** by checking this box you certify that you are not obtaining any of the information listed above

**3C2.6** \* Who will be able to identify a participant in the dataset? (Check all that apply)

- A. Research team members (whether or not they are RAND associates)**
- B. Person or organization providing the data (i.e., data provider)**
- C. Subcontractors, vendors, or other service providers hired by RAND (other than the data provider)**
- D. Anyone else who is not on the research team**

**3C2.7** \* Is there a written agreement involved in obtaining the data (e.g. data use agreement, web based agreement, other conditions on use)?

- Yes
- No**
- Don't know

**3C3** You will be asked to complete the following screens in section 5 for this procedure based on your answers given above:

## Section: 5 Procedures

- 5D Procedures - Secondary Data
- 5E Procedures - Risks
- 5G Procedures - Confidentiality

**5D Procedures - Secondary Data**

---

- 5D1 \* Which previously collected person-level information (e.g., medical records, census data, employment records, education records, other existing datasets) will you acquire? If unsure, please list what you are considering.**

Participants will provide consent for paper and electronic medical record data extraction from their usual HIV clinic. During screening, we will obtain permission to extract the two most recent viral loads from medical records, for use in stratification by viral suppression for the randomization process. After the 12-month follow-up, we will extract past 2-year viral load, CD4 counts, ART prescriptions, clinic visits, and associated dates. We have successfully used multiple methods to obtain such data from multiple different clinics across Los Angeles County (e.g., confidential faxes, multiple calls, in-person clinic visits, asking participants to bring lab print-outs to study visits) in prior studies.

**5D2 Private Health Information**

---

- 5D2.1 \* Will private health information (e.g., medical records, health-related administrative data, health insurance claims, pharmaceutical data) be acquired?**

Yes

No

Don't know

- 5D2.2 \* If "Yes", from whom will the private health information be acquired?**

A. Participant (including participant's parent/guardian)

B. Medical care provider/insurer (e.g., a doctor or other health care provider, hospital, insurance company, managed care company, other covered entity under HIPAA)

C. Other

- 5D2.3 \* If "Other", please describe from which other individuals will the private health information be acquired.**

Both A and B - Participant and Medical care provider. Participants will be asked for permission to contact their medical provider to obtain medical records data; they will also be told that they can bring in the data if they obtain it themselves.

**5D4 Merging Data**

---

- 5D4.1 \* Do you plan to merge and retain person-level secondary data with person-level data from other sources (e.g., other existing records, datasets, interview data from this study)? Note: Do not consider data that will be used only to contact participants and will not be retained in the study data**  
yes

- 5D4.2 \* If "Yes", what other information will be merged with the person-level data? Note: This doesn't include data that will not be retained in the data file, such as name or telephone number.**  
Surveys, viral load assessments, and electronically monitored adherence data

**5D5 Destroying Data Identifiers/Link File**

---

- 5D5.1 \* Will the data identifiers or link file maintained by the project ever be destroyed?**

Yes

No

Don't know

- 5D5.2 \* If "Yes", when do you estimate that the data identifiers or link files will be destroyed? (mm/dd/yyyy)**  
3/31/2023

**5E Procedures - Risks**

---

**5E1 Breach of Confidentiality Risk**

---

**5E1.1**

## Section: 5 Procedures

**\* In the event a *breach of confidentiality* allowing someone outside of the research team to identify participants in this study, which of the following types of harm might result? (Check all that apply)**

- A. Legal (i.e., criminal or civil liability)
- B. Financial/economic (e.g., damage to employability)
- C. Psychological (e.g., embarrassment, distress)
- D. Social (e.g., damage to reputation)
- E. Other
- F. No anticipated risk

**5E3** In the questions that follow, the phrase "individuals in the general U.S. population" refers to healthy individuals in the United States who are not incarcerated. Thus, the high standard of minimal risk is based on the amount of risk typically encountered in everyday life by healthy individuals in the United States. If the study population is unhealthy individuals, incarcerated individuals, or individuals in another country, the appropriate comparison is now how much risk "healthy individuals" would face. The comparison is what the actual subject population would face in comparison to minimal risk as defined by everyday life for healthy individuals in the United States. ***If a breach of confidentiality or participation would be dangerous in the study population, it is above minimal risk.***

#### 5E5 Financial/Economic Risks Associated with a Breach of Confidentiality

---

**5E5.1** \* Might the degree or amount of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

**5E5.2** \* Might the likelihood of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

no

**5E5.3** \* Please explain the nature of the financial/economic harm, what might cause it, and steps that would be taken to mitigate it.

Participants could experience financial/economic harm if their HIV-positive serostatus became known to others. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

#### 5E6 Psychological Risks Associated with a Breach of Confidentiality

---

**5E6.1** \* Might the degree or amount of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

**5E6.2** \* Might the likelihood of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

no

**5E6.3** \* Please explain the nature of the discomfort or distress, what might cause it, and steps that would be taken to mitigate it.

Participants could experience psychological harm from HIV stigma if their HIV-positive serostatus became known to others. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

#### 5E7 Social Risks Associated with a Breach of Confidentiality

---

**5E7.1** \* Might the degree or amount of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

Section: 5 Procedures

**5E7.2 \* Might the likelihood of social harm resulting from a breach of confidentiality be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

no

**5E7.3 \* Please explain the nature of the social harm, what might cause it, and steps that would be taken to mitigate it.**

Participants could experience social harm from HIV stigma if their HIV-positive serostatus became known to others. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5G Procedures - Confidentiality**

**5G1 Sensitive Information**

**5G1.1 \* Will any of the following types of sensitive information be intentionally accessed, acquired, or recorded as part of data collection about an individual? (Check all that apply) Note: You may have answered this question 2H with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be sensitive with regard to another population in your study that you have associated with this procedure.**

- A. Substance use including alcohol, drugs, and tobacco
- B. Physical health including diagnosis, treatment, or any other private physical health information
- C. Mental health including diagnosis, treatment, current mental health status (e.g., suicidality), or any other private mental health information
- D. Traumatic events including victimization, bereavement, accidents, natural disasters, and military combat
- E. Illegal activity including illicit drug use, human trafficking, and terrorism
- F. Immigration status
- G. Sexual behavior
- H. Abuse/neglect including child, elder, domestic, and partner
- I. Educational records including status, history, or performance
- J. Employment records including status, history, or performance
- K. Financial information
- L. Other
- M. None of the above

**5G3 Disclosure of Identifiable Person Level Data**

**5G3.1 \* Will any information that you collect go into person level non-research records (e.g., medical, educational, employment records) that are not maintained and controlled solely by the research team? Note: This is a relatively rare occurrence for research done at RAND and would require HSPC approval.**

- Yes
- No
- Don't know

**5G4 Reasons for Breaking Confidentiality**

**5G4.1 \* Could the procedure yield information potentially of importance to individual participants that they otherwise would be unlikely to know? This includes information specifically gathered or spontaneously provided or observed.**

no

**5G4.2 \* If "Yes", will participants or others (e.g., doctors, teachers, parents) be notified?**

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**5G5 Promise of Confidentiality**

---

- 5G5.1 \* Is confidentiality being promised to participants with no additional exceptions aside from those noted in 5G4?
- A. Yes
- B. No, participants can choose to allow potentially identifiable information (e.g., quotes, performance information) to be included in published reports
- C. No, participants must agree to be attributable in published reports (this is a rare exception and might only occur in studies of a single organization)
- D. No, there will be other exceptions (e.g., intent to harm self or others, suspected child abuse)
- 5G5.5 \* Do you plan to apply for a Certificate of Confidentiality? Please note that such applications can be filed only after consent protocols have been approved.
- Yes
- No
- Don't know

**5G6 Identifiability by Inference in Published Reports**

---

- 5G6.1 \* Might comments or other information included in published reports be identifiable by inference for participants who do not agree to be identified and are being assured of confidentiality?
- no

**5G7 Data Safeguarding Plan**

---

- 5G7.1 \* Based on previous answers, a Data Safeguarding Plan (DSP) is required. Are you ready to upload it in draft or final form at this time?
- yes
- 5G7.2 You will be able to upload the Data Safeguarding Plan (DSP) later in Section 7

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**Surveys**

**3C Research Overview - Procedures**

---

Related Populations:

- *People Living with HIV (Pending - as with Just in Time reviews)*

**3C1 Procedure Description**

---

- 3C1.1 \* Which of the following describes this procedure? (Check all that apply)
- A. Acquiring previously collected person-level information (e.g., medical records, census data, employment records, education records, other existing datasets)

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- B. Interview (e.g., phone interview)
- C. Survey (either oral or written)** (e.g., mail survey, web survey)
- D. Group discussion (e.g., focus group, expert panel)
- E. Observation of individuals or groups (e.g., in-person visual observation, video observation)
- F. Educational testing (e.g., aptitude testing, military/vocational training assessment)
- G. Psychological testing, measurement, or assessment
- H. Physical exam, testing, measurement, assessment (w/o specimen collection) (e.g., blood pressure, weight measurement.)
- I. Biologic sample collection (e.g., tissue, blood, urine, saliva)
- J. Testing of existing biological samples (e.g., testing for the presence of disease or drugs)
- K. Socio-behavioral or educational intervention (e.g., randomized trials, quasi-experimental designs, demonstration projects)
- L. Clinical treatment (e.g., administering drugs, therapy)
- M. Other intervention research procedures (e.g., physical procedures, manipulating environment to evaluate impact on outcome)
- N. Other interaction research procedures (e.g., obtaining information from individuals)

**3C3** You will be asked to complete the following screens in section 5 for this procedure based on your answers given above:

- 5C Procedures - Interactions
- 5E Procedures - Risks
- 5F Procedures - Benefits, Incentives, Costs
- 5G Procedures - Confidentiality

**5C Procedures - Interactions with Participants**

**5C1 Research Team Interaction with Participants**

*Note: Do not repeat details of interactions that apply only to recruitment procedures. Those details are addressed for the related populations in 4A5.*

**5C1.1** \* How will the research team be interacting with the participants for the purposes of data collection? (Check all that apply)

- A. In person
- B. By phone
- C. Via mail
- D. Over the web (e.g., email, chat, blog)

**5C1.3** \* Will the research team be audio or video recording the interaction procedure?

no

**5C2** \* Provide a step-by-step description of this procedure. *Note: Details regarding whether the interaction procedure will be repeated are covered in 5C4.*

At the pre-enrollment visit, and at 6-and 12-month post-intervention start (7 and 13 months after the first study visit), participants will complete surveys using the Questionnaire Development System for audio computer-assisted self-interviews. Surveys will be completed in a private space on a computer at APLA project offices, and a study interviewer will be available to answer questions or administer the survey as needed for those of lower literacy.

Interviewers will also interact with participants by phone, mail, and over the internet to set up appointments and to remind participants about appointments.

**5C3 Participant Questions**

**5C3.1** \* Do you have the questions you will be asking participants (e.g., the interview protocol, survey instrument, focus group guide) in draft or final form or a list of domains to be covered?

yes

Section: 5 Procedures

**5C3.2** If "Yes" and you did not upload the questions in Section 2, you will be asked to upload them in Section 7.**5C4 Repetition of the Interaction Procedure****5C4.1** \* Will this interaction procedure be repeated with the same participants? *Note: If the repetition is described in another procedure, indicate that below.*

- A. Yes - described below in 5C4.2
- B. Yes - is or will be described in another procedure
- C. No
- D. Possibly

**5C4.2** \* If "A" or "D", indicate how often this interaction procedure will occur and at what intervals. *Note: If you already provided this detail in 5C2, please indicate that below. Please see 5C2 above.***5C5 Previously Developed and Validated Surveys, Tests, or Assessments****5C5.1** \* Will previously developed and validated surveys, tests, or assessments be administered as part of this interaction procedure?

- Yes
- No
- Don't know

**5C5.2** \* If "Yes," please list the previously developed and validated surveys, tests, or assessments to be administered, noting what each measures. Please indicate whether the standardized test or assessment has been altered.

Secondary Outcomes/Potential Mediators will be collected in surveys at baseline and at 6- and 12-month follow-up. The LifeWindows IMB ART Adherence Questionnaire (LW-IMB-AAQ) includes measures of Adherence-related Information (perceived knowledge and misinformation;  $\alpha = .70$ ); Adherence Motivation (negative consequences of medications,  $\alpha = .74$ ; negative beliefs about medication taking,  $\alpha = .76$ ); and Behavioral Adherence Skills ( $\alpha = .88$ ). Internalized Racism will be assessed with the Cross Racial Identity Scale-Self-Hatred subscale ( $\alpha = .89$ ). We will also include the Internalized-Homophobia Scale-Revised ( $\alpha = .88$ ). We will use an Internalized Stigma subscale validated for HIV-positive adults by Co-Investigator Cunningham ( $\alpha = .91$ ). We will also adapt the Chronic illness Anticipated Stigma Scale ( $\alpha = .95$ ) for people living with HIV. Medical Mistrust will be measured with validated subscales (racism  $\alpha = .76$ ; mistrust  $\alpha = .74$ ),<sup>39</sup> as well as our HIV Conspiracy Beliefs Scale ( $\alpha = .85$ ). Participants will rate the perceived severity of 20 Side Effects associated with ART ( $\alpha = .89$ ). Mental health will be assessed with the PHQ-9, a valid screening tool for Depression. We will use the Risk Behavior Survey to assess substance use in the past 30 days. Problematic drinking will be measured with the RAPS4-QF. Unmet Needs (financial/benefits, housing, mental health, food, transportation, substance abuse) will be assessed with HCSUS items.

Potential Covariates will be assessed at baseline, and 6-and 12-months post-baseline. We will assess potential covariates that have previously been related to HIV outcomes. Socio-demographics include race/ethnicity, gender, education level, age, income, employment status, housing status, marital/relationship status, sexual orientation, and incarceration history. Spirituality and Religiosity will be assessed with items from HCSUS. We will use the 6-item Social Support Questionnaire, Revised ( $\alpha = .94$ ). To assess Trauma History, participants will indicate lifetime traumatic experiences on a checklist of 9 traumas from the Posttraumatic Stress Diagnostic Scale. We will assess Usual Care by asking participants to complete a checklist of Standard Clinic Practices for Adherence (e.g., pill boxes). To assess Exposure to Other Adherence Programs, we will ask participants whether they received adherence counseling through medical case management (a Ryan White Care Act program) and extent of exposure (number of sessions, information covered). They will complete a checklist of other Social Services Resources accessed at APLA or elsewhere. We will assess self-reported adherence using items validated against viral load and pill counts: number of doses missed last week; percentage of prescribed medications taken last month (on a visual analogue scale), and ability to take all medications as prescribed in the past 4 weeks.

**5E Procedures - Risks****5E1 Breach of Confidentiality Risk****5E1.1** \* In the event a *breach of confidentiality allowing someone outside of the research team to identify participants in this study, which of the following types of harm might result? (Check all that apply)*

- A. Legal (i.e., criminal or civil liability)
- B. Financial/economic (e.g., damage to employability)
- C. Psychological (e.g., embarrassment, distress)

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 D. Social (e.g., damage to reputation) E. Other F. No anticipated risk**5E2 Participation Risk****5E2.1 \* Aside from the risks associated with a breach of confidentiality, which of the following types of harm might result from participation in the procedure? (Check all that apply)** A. Financial/economic (e.g., damage to employability) B. Physical consequences (e.g., pain, discomfort) C. Psychological consequences (e.g., distress, embarrassment, pressure to participate) D. Social (e.g., stigma of participation, damage to reputation) E. Other F. No anticipated risk

**5E3** In the questions that follow, the phrase "individuals in the general U.S. population" refers to healthy individuals in the United States who are not incarcerated. Thus, the high standard of minimal risk is based on the amount of risk typically encountered in everyday life by healthy individuals in the United States. If the study population is unhealthy individuals, incarcerated individuals, or individuals in another country, the appropriate comparison is now how much risk "healthy individuals" would face. The comparison is what the actual subject population would face in comparison to minimal risk as defined by everyday life for healthy individuals in the United States. **If a breach of confidentiality or participation would be dangerous in the study population, it is above minimal risk.**

**5E4 Legal Risks Associated with a Breach of Confidentiality**

**5E4.1 \* Might the degree or amount of legal harm resulting from a breach of confidentiality be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**  
yes

**5E4.2 \* Might the likelihood of legal harm resulting from a breach of confidentiality be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**  
no

**5E4.3 \* Please explain the nature of the legal harm, what might cause it, and steps that would be taken to mitigate it.**

Participants could experience legal harm if their illegal behaviors related to substance use become known to others. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E5 Financial/Economic Risks Associated with a Breach of Confidentiality**

**5E5.1 \* Might the degree or amount of financial/economic harm resulting from a breach of confidentiality be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**  
yes

**5E5.2 \* Might the likelihood of financial/economic harm resulting from a breach of confidentiality be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**  
no

**5E5.3 \* Please explain the nature of the financial/economic harm, what might cause it, and steps that would be taken to mitigate it.**

Participants could experience financial harm if their HIV-positive serostatus became known to others, potentially leading to employment discrimination. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant



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name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E6 Psychological Risks Associated with a Breach of Confidentiality**

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- 5E6.1** \* Might the degree or amount of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

- 5E6.2** \* Might the likelihood of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

no

- 5E6.3** \* Please explain the nature of the discomfort or distress, what might cause it, and steps that would be taken to mitigate it.

Participants could experience psychological harm if their HIV-positive serostatus became known to others, potentially leading to HIV stigma and discrimination. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E7 Social Risks Associated with a Breach of Confidentiality**

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- 5E7.1** \* Might the degree or amount of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

- 5E7.2** \* Might the likelihood of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

no

- 5E7.3** \* Please explain the nature of the social harm, what might cause it, and steps that would be taken to mitigate it.

Participants could experience social harm if their HIV-positive serostatus became known to others, potentially leading to HIV stigma and discrimination. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E11 Psychological Risks Resulting from Participation**

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- 5E11.1** \* Might the degree or amount of psychological harm *resulting from participation in the procedure itself* (i.e., other than from a breach of confidentiality) be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

- 5E11.2** \* Might the likelihood of psychological harm *resulting from participation in the procedure itself* (i.e., other than from a breach of confidentiality) be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

no

- 5E11.3** \* Please explain the nature of the psychological harm, what might cause it, and steps that would be taken to mitigate it.

Participants could experience psychological harm and distress from responding to questions about their serostatus, as well as mental health and trauma. If participants express a great deal of psychological distress during the sessions, the interviewer will provide appropriate referrals to local mental health resources, including information about APLA's mental health program, and answer any questions the participant may have about these services.

**5F Procedures - Benefits, Incentives, and Costs**

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**5F2 Incentives and Other Forms of Compensation**

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**5F2.1 \* Will the participants receive incentives or some other form of compensation (e.g., cash, voucher, meals, reimbursements)?**

yes

**5F2.2 \* If "Yes", what will the participants receive as an incentive or other forms of compensation?**

Participants will receive \$30 for the baseline survey (i.e., pre-enrollment, which will also include screening, consent, and starting on MEMS), and \$40 at 6-months, and \$50 at 12-months for the follow-ups (which will also include venipuncture for viral load assessment and downloading of MEMS data).

**5F2.3 \* If "Yes", how and when will the incentives or other forms of compensation be distributed to participants? Include any detail about conditions under which they might not receive the incentive or other form of compensation.**

Participants will receive cash incentives if they attend the study visit, even if they do not finish the entire survey assessment. If they choose to do the MEMS download (at enrollment) or survey (at followup) but not undergo the venipuncture, they will receive \$20.

**5F3 Costs**

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**5F3.1 \* Might the participants incur any financial costs that will not be reimbursed and that they would otherwise not incur?**

no

**5G Procedures - Confidentiality**

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**5G1 Sensitive Information**

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**5G1.1 \* Will any of the following types of sensitive information be intentionally accessed, acquired, or recorded as part of data collection about an individual? (Check all that apply) Note: You may have answered this question 2H with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be sensitive with regard to another population in your study that you have associated with this procedure.**

- A. Substance use** including alcohol, drugs, and tobacco
- B. Physical health** including diagnosis, treatment, or any other private physical health information
- C. Mental health** including diagnosis, treatment, current mental health status (e.g., suicidality), or any other private mental health information
- D. Traumatic events** including victimization, bereavement, accidents, natural disasters, and military combat
- E. Illegal activity** including illicit drug use, human trafficking, and terrorism
- F. Immigration status
- G. Sexual behavior**
- H. Abuse/neglect including child, elder, domestic, and partner
- I. Educational records including status, history, or performance
- J. Employment records including status, history, or performance
- K. Financial information**
- L. Other
- M. None of the above

**5G2 Identifying Information**

---

**5G2.1 \* Check all types of identifying information that your research will acquire about these participants. Note: You may have answered this question on screens 2B or 2C with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be identifiable with regard to another population in your study that you have associated with this procedure.**

- A. Names** including names appearing on consent forms, payment receipts, medical records, and emergency contact lists
- B. Location and contacting information** including any address information smaller than state, telephone or fax numbers, email addresses, web URLs, and IP addresses
- C. Dates** including birth date, marriage date, and treatment or visit dates from medical records

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D. Identification numbers

including Social Security Numbers, medical record or health plan beneficiary numbers, account numbers, student ID numbers, certificate or license numbers (e.g., driver's license), vehicle identifiers and serial numbers (e.g., license plates), and device identifiers and serial numbers (e.g., serial numbers on surgical implants)

E. Audio, video, or biometric indicators

including photographic or video images, audio recordings, and finger or voice prints

F. None of the identifiers listed above

by checking this box you certify that you are not obtaining any of the information listed above

**5G3 Disclosure of Identifiable Person Level Data**

**5G3.1** \* Will any information that you collect go into person level non-research records (e.g., medical, educational, employment records) that are not maintained and controlled solely by the research team? *Note: This is a relatively rare occurrence for research done at RAND and would require HSPC approval.*

Yes

No

Don't know

**5G4 Reasons for Breaking Confidentiality**

**5G4.1** \* Could the procedure yield information potentially of importance to individual participants that they otherwise would be unlikely to know? This includes information specifically gathered or spontaneously provided or observed.

no

**5G4.2** \* If "Yes", will participants or others (e.g., doctors, teachers, parents) be notified?

**5G5 Promise of Confidentiality**

**5G5.1** \* Is confidentiality being promised to participants with no additional exceptions aside from those noted in 5G4?

A. Yes

B. No, participants can choose to allow potentially identifiable information (e.g., quotes, performance information) to be included in published reports

C. No, participants must agree to be attributable in published reports (this is a rare exception and might only occur in studies of a single organization)

D. No, there will be other exceptions (e.g., intent to harm self or others, suspected child abuse)

**5G5.4** \* If "D" on 5G5.1, please describe the exceptions and why they are necessary.

There will be legal exceptions of suicidal ideation or harm to self or others and intent to harm others or child or elder abuse/neglect.

**5G5.5** \* Do you plan to apply for a Certificate of Confidentiality? Please note that such applications can be filed only after consent protocols have been approved.

Yes

No

Don't know

**5G6 Identifiability by Inference in Published Reports**

**5G6.1** \* Might comments or other information included in published reports be identifiable by inference for participants who do not agree to be identified and are being assured of confidentiality?

no

**5G7 Data Safeguarding Plan**

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**5G7.1** \* Based on previous answers, a Data Safeguarding Plan (DSP) is required. Are you ready to upload it in draft or final form at this time?

yes

**5G7.2** You will be able to upload the Data Safeguarding Plan (DSP) later in Section 7

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## Viral Load Assessment

### 3C Research Overview - Procedures

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Related Populations:

- *People Living with HIV (Pending - as with Just in Time reviews)*

### 3C1 Procedure Description

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**3C1.1** \* Which of the following describes this procedure? (Check all that apply)

- |                                     |  |  |
|-------------------------------------|--|--|
| <input type="checkbox"/>            | A. Acquiring previously collected person-level information                   | (e.g., medical records, census data, employment records, education records, other existing datasets) |
| <input type="checkbox"/>            | B. Interview   | (e.g., phone interview)  |
| <input type="checkbox"/>            | C. Survey (either oral or written)   | (e.g., mail survey, web survey)  |
| <input type="checkbox"/>            | D. Group discussion  | (e.g., focus group, expert panel)  |
| <input type="checkbox"/>            | E. Observation of individuals or groups                                      | (e.g., in-person visual observation, video observation)  |
| <input type="checkbox"/>            | F. Educational testing   | (e.g., aptitude testing, military/vocational training assessment)                                    |
| <input type="checkbox"/>            | G. Psychological testing, measurement, or assessment                         |  |
| <input type="checkbox"/>            | H. Physical exam, testing, measurement, assessment (w/o specimen collection) | (e.g., blood pressure, weight measurement,)  |
| <input checked="" type="checkbox"/> | <b>I. Biologic sample collection</b>   | <b>(e.g., tissue, blood, urine, saliva)</b>  |
| <input type="checkbox"/>            | J. Testing of existing biological samples                                    | (e.g., testing for the presence of disease or drugs)   |
| <input type="checkbox"/>            | K. Socio-behavioral or educational intervention                              | (e.g., randomized trials, quasi-experimental designs, demonstration projects)                        |
| <input type="checkbox"/>            | L. Clinical treatment  | (e.g., administering drugs, therapy)   |

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- M. Other intervention research procedures (e.g., physical procedures, manipulating environment to evaluate impact on outcome)
- N. Other interaction research procedures (e.g., obtaining information from individuals)

**3C3** You will be asked to complete the following screens in section 5 for this procedure based on your answers given above:

- 5A Procedures - Interventions: Overview
- 5B Procedures - Interventions: Biologic Samples
- 5E Procedures - Risks
- 5F Procedures - Benefits, Incentives, Costs
- 5G Procedures - Confidentiality

**5A - Procedures - Interventions: Overview**

**5A1** \* Provide a step-by-step description of this procedure for the studied groups of participants. Include both alterations of their experiences (e.g., novel educational practices, new health services) and administration of any treatments they might not otherwise receive (e.g., medications, nutritional supplements). *Note: you will be asked below in 5A2 about assignment of participants to different groups (e.g., different data collection or treatment/control groups).*

At study enrollment and 6- and 12-months post-enrollment (and post-intervention start), a member of the study team (trained in phlebotomy) will draw participants' blood for viral load assessment at the APLA Health and Wellness clinic. Viral load suppression will be defined as <200 copies of virus per milliliter of blood plasma.

**5A2 Administered to All Members**

**5A2.1** \* Will any subgroups of the population(s) referenced above receive different interventions? (Check all that apply)

- A. Yes - not all participants will receive the same intervention (e.g., physical exams or biologic samples will be collected/tested from only a subset)
- B. Yes - some participants will receive the socio-behavioral or clinical intervention and others will be in the control group
- C. No - all participants will receive the same procedure(s) listed above

**5A3** \* Describe the qualifications and/or training for those who will conduct the intervention.

The team member will be trained and certified in phlebotomy.

**5A4 Interim Outcome Monitoring**

**5A4.1** \* Will interim outcomes be monitored in any way? For example, some intervention studies may have or be required to have a Data and Safety Monitoring Plan (DSMP) to assess that the intervention is not harmful and/or is having a positive effect.

yes

**5A4.2** \* If "Yes", explain what will be monitored, when, how, and why.

Given the low risk of the experimental intervention, we believe that a multiple-person data safety monitoring board (DSMB) is an unnecessarily intensive approach to monitoring this trial. We propose here an alternative, less intensive approach which we believe will effectively ensure the welfare of study subjects and the continued scientific validity of the study. Specifically, we propose that a single, independent, behavioral HIV researcher to serve as an independent monitor for the study. The monitor will be an expert in the treatment of depression and/or substance use among people living with HIV who does not have a conflict of interest with anyone on the study team, i.e., who does not have a prior collaborative or financial relationship with any of the study investigators and who is not employed currently or within 3 years in any of the primary study institutions.

To allow effective monitoring, the independent monitor will be provided with periodic reports which include subject enrollment, subject retention, the number of patients who drop out of the study with reasons for dropping out, and a listing of all adverse events (AEs) that are plausibly related to study procedures. Reports will be provided to the independent monitor at 6-month intervals. After review of the periodic reports, the independent monitor may ask for clarification or additional information from the principal investigator (PI). After such information is provided, if requested, the independent monitor will make a recommendation regarding the continuation, modification, or termination of the study. All communications from the independent monitor will be shared with the study institutional review boards (IRBs), as well as NIH. By utilizing a single independent monitor rather than a multi-person DSMB, we believe the oversight of the study will be easier to implement, more efficient, and more responsive to issues as they arise.

**5A4.3** \* Does your funder or the RAND HSPC require a Data and Safety Monitoring Plan (DSMP) for your study? The RAND HSPC will make its determination during the review process.

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**Yes - by the funder and/or the HSPC**

No (including not yet determined by the HSPC)

**5A4.4 \* Do you have the DSMP for this study ready to upload in draft or final form?**

yes

**5A4.5** You will be asked to upload the DSMP in section 7. A DSMP is typically done at the study level and you will be able to upload a single DSMP in section 7 and associate it with as many components as necessary. This is done to ensure that all components that should be covered are addressed in the DSMP.

## 5B Procedures - Interventions: Biologic Samples or Specimens

### 5B1 Biologic Sample or Specimen Types

**5B1.1 \* Please indicate which biological sample types will be collected. (Check all that apply)**

A. Urine

B. **Blood**

C. Saliva

D. Hair

E. Tissue/cell sample

F. Other, specify:

**5B2 \* Please provide an account of how, where, and when the samples or specimens will be collected. Include the methods, the qualifications of and/or training provided to those who will collect the samples or specimens, and other details (e.g., volume collected, how stored, safety considerations).**

At enrollment and 6- and 12-months post-enrollment (post intervention start), a member of the study team (trained in phlebotomy) will draw participants' blood for viral load assessment at the APLA Health and Wellness clinic.

APLA Health and Wellness Clinic staff regularly perform venipuncture for viral load assessment and the clinic has mechanisms for storage and procedures for safety. Our study staff will be trained on the clinic's protocols as well as certified in phlebotomy.

### 5B3 Biologic Sample or Specimen Testing

**5B3.1 \* Will any of the samples or specimens be tested?**

**Yes - during this study**

Yes - but testing will be done later

No

Don't know

**5B3.2 \* List the types of testing to be performed (e.g., specific biomarkers or diseases to be tested, generic tests to be conducted) and why.**

We will conduct viral load assessments. Viral load suppression, a main study outcome, will be defined as <200 copies of virus per milliliter of blood plasma.

### 5B4 Biologic Sample or Specimen Disposition

**5B4.1 \* What will be the ultimate disposition of the sample(s) or specimen(s) collected during this study?**

A. **Destroyed at the end of this study**

B. Anonymous sample(s) banked for future research

C. Identifiable sample(s) banked for future research

## 5E Procedures - Risks

### 5E1 Breach of Confidentiality Risk

## Section: 5 Procedures

**5E1.1** \* In the event a **breach of confidentiality** allowing someone outside of the research team to identify participants in this study, which of the following types of harm might result? (Check all that apply)

- A. Legal (i.e., criminal or civil liability)
- B. Financial/economic (e.g., damage to employability)
- C. Psychological (e.g., embarrassment, distress)
- D. Social (e.g., damage to reputation)
- E. Other
- F. No anticipated risk

**5E2 Participation Risk**

**5E2.1** \* Aside from the risks associated with a breach of confidentiality, which of the following types of harm might result from participation in the procedure? (Check all that apply)

- A. Financial/economic (e.g., damage to employability)
- B. Physical consequences (e.g., pain, discomfort)
- C. Psychological consequences (e.g., distress, embarrassment, pressure to participate)
- D. Social (e.g., stigma of participation, damage to reputation)
- E. Other
- F. No anticipated risk

**5E3** In the questions that follow, the phrase "individuals in the general U.S. population" refers to healthy individuals in the United States who are not incarcerated. Thus, the high standard of minimal risk is based on the amount of risk typically encountered in everyday life by healthy individuals in the United States. If the study population is unhealthy individuals, incarcerated individuals, or individuals in another country, the appropriate comparison is now how much risk "healthy individuals" would face. The comparison is what the actual subject population would face in comparison to minimal risk as defined by everyday life for healthy individuals in the United States. **If a breach of confidentiality or participation would be dangerous in the study population, it is above minimal risk.**

**5E5 Financial/Economic Risks Associated with a Breach of Confidentiality**

**5E5.1** \* Might the degree or amount of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

**5E5.2** \* Might the likelihood of financial/economic harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

no

**5E5.3** \* Please explain the nature of the financial/economic harm, what might cause it, and steps that would be taken to mitigate it.

Participants could experience financial/economic harm if their HIV-positive serostatus became known to others. To protect confidentiality, the following steps will be taken: All samples will be stored according to standard clinic confidentiality protocols. Test results will be provided to study staff and participants only and recorded in participants' confidential study files. All hard copy research data will be kept in locked file cabinets and all hard and soft copy data will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E6 Psychological Risks Associated with a Breach of Confidentiality**

**5E6.1** \* Might the degree or amount of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

yes

**5E6.2** \* Might the likelihood of psychological harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?

no

## Section: 5 Procedures

- 5E6.3 \* Please explain the nature of the discomfort or distress, what might cause it, and steps that would be taken to mitigate it.**

Participants could experience psychological harm from HIV stigma if their HIV-positive serostatus became known to others. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E7 Social Risks Associated with a Breach of Confidentiality**

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- 5E7.1 \* Might the degree or amount of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

yes

- 5E7.2 \* Might the likelihood of social harm *resulting from a breach of confidentiality* be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

no

- 5E7.3 \* Please explain the nature of the social harm, what might cause it, and steps that would be taken to mitigate it.**

Participants could experience social harm from HIV stigma if their HIV-positive serostatus became known to others. To protect confidentiality, the following steps will be taken: All research data will be kept in locked file cabinets and will be available only to research staff directly involved in this project and state regulatory agency personnel. Data will be identifiable only by study numbers and client initials. HIV status will not appear along with any personal identifying information. Personal information used for tracking, including participant name, address, and phone number, will be stored separately from all research data. To further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

**5E11 Psychological Risks Resulting from Participation**

---

- 5E11.1 \* Might the degree or amount of psychological harm *resulting from participation in the procedure itself* (i.e., other than from a breach of confidentiality) be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

no

- 5E11.2 \* Might the likelihood of psychological harm *resulting from participation in the procedure itself* (i.e., other than from a breach of confidentiality) be greater than ordinarily encountered in daily life by individuals in the general U.S. population?**

no

- 5E11.3 \* Please explain the nature of the psychological harm, what might cause it, and steps that would be taken to mitigate it.**

Collection of blood samples could cause some physical discomfort and consequent psychological distress. However, participants will routinely be going to a clinic for blood draws as part of their usual medical care, and the venipuncture in the proposed study will take place in a clinic setting with trained and certified phlebotomists who have experience working with the research population.

**5F Procedures - Benefits, Incentives, and Costs**

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**5F2 Incentives and Other Forms of Compensation**

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- 5F2.1 \* Will the participants receive incentives or some other form of compensation (e.g., cash, voucher, meals, reimbursements)?**

yes

- 5F2.2 \* If "Yes", what will the participants receive as an incentive or other forms of compensation?**

Participants will receive \$30 for the first venipuncture visit, \$40 at the 6-month follow-up and \$50 at 12-month followup.

- 5F2.3 \* If "Yes", how and when will the incentives or other forms of compensation be distributed to participants? Include any detail about conditions under which they might *not* receive the incentive or other form of compensation.**

Participants will receive cash at these study visits. If they complete the venipuncture only, they will receive \$20.

**5F3 Costs**

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Section: 5 Procedures

**5F3.1 \* Might the participants incur any financial costs that will not be reimbursed and that they would otherwise not incur?**

no

## 5G Procedures - Confidentiality

### 5G1 Sensitive Information

**5G1.1 \* Will any of the following types of sensitive information be intentionally accessed, acquired, or recorded as part of data collection about an individual? (Check all that apply) Note: You may have answered this question 2H with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be sensitive with regard to another population in your study that you have associated with this procedure.**

- |                                     |                           |  |
|-------------------------------------|---------------------------|--|
| <input type="checkbox"/>            | A. Substance use          | including alcohol, drugs, and tobacco  |
| <input checked="" type="checkbox"/> | <b>B. Physical health</b> | <b>including diagnosis, treatment, or any other private physical health information</b>  |
| <input type="checkbox"/>            | C. Mental health          | including diagnosis, treatment, current mental health status (e.g., suicidality), or any other private mental health information |
| <input type="checkbox"/>            | D. Traumatic events       | including victimization, bereavement, accidents, natural disasters, and military combat  |
| <input type="checkbox"/>            | E. Illegal activity       | including illicit drug use, human trafficking, and terrorism   |
| <input type="checkbox"/>            | F. Immigration status     |  |
| <input type="checkbox"/>            | G. Sexual behavior        |  |
| <input type="checkbox"/>            | H. Abuse/neglect          | including child, elder, domestic, and partner  |
| <input type="checkbox"/>            | I. Educational records    | including status, history, or performance  |
| <input type="checkbox"/>            | J. Employment records     | including status, history, or performance  |
| <input type="checkbox"/>            | K. Financial information  |  |
| <input type="checkbox"/>            | L. Other                  |  |
| <input type="checkbox"/>            | M. None of the above      |  |

### 5G2 Identifying Information

**5G2.1 \* Check all types of identifying information that your research will acquire about these participants. Note: You may have answered this question on screens 2B or 2C with regard to a specific population if you applied for an exemption for one or more population-procedure components of your study. However, we are asking this question again because the information may be identifiable with regard to another population in your study that you have associated with this procedure.**

- |                                     |  |   |
|-------------------------------------|--|---|
| <input checked="" type="checkbox"/> | <b>A. Names</b>                          | <b>including names appearing on consent forms, payment receipts, medical records, and emergency contact lists</b>   |
| <input type="checkbox"/>            | B. Location and contacting information   | including any address information smaller than state, telephone or fax numbers, email addresses, web URLs, and IP addresses   |
| <input checked="" type="checkbox"/> | <b>C. Dates</b>                          | <b>including birth date, marriage date, and treatment or visit dates from medical records</b>   |
| <input checked="" type="checkbox"/> | <b>D. Identification numbers</b>         | <b>including Social Security Numbers, medical record or health plan beneficiary numbers, account numbers, student ID numbers, certificate or license numbers (e.g., driver's license), vehicle identifiers and serial numbers (e.g., license plates), and device identifiers and serial numbers (e.g., serial numbers on surgical implants)</b> |
| <input type="checkbox"/>            | E. Audio, video, or biometric indicators | including photographic or video images, audio recordings, and finger or voice prints  |
| <input type="checkbox"/>            | F. None of the identifiers listed above  | by checking this box you certify that you are not obtaining any of the information listed above   |

### 5G3 Disclosure of Identifiable Person Level Data

**5G3.1 \* Will any information that you collect go into person level non-research records (e.g., medical, educational, employment records) that are not maintained and controlled solely by the research team? Note: This is a**

Section: 5 Procedures

*relatively rare occurrence for research done at RAND and would require HSPC approval.*

Yes

No

Don't know

**5G3.2** \* If "Yes", please provide details regarding information that you collect that will go into non-research records that are not maintained and controlled solely by the research team.  
 If the participant is already a patient at APLA's Health and Wellness Clinic (where the blood will be drawn), their viral load values will be put into their medical records. Participants will be notified of this.

**5G4 Reasons for Breaking Confidentiality**

**5G4.1** \* Could the procedure yield information potentially of importance to individual participants that they otherwise would be unlikely to know? This includes information specifically gathered or spontaneously provided or observed.

yes

**5G4.2** \* If "Yes", will participants or others (e.g., doctors, teachers, parents) be notified?

yes

**5G4.3** Note: If "Yes", this information must be included in the consent form.

**5G4.4** \* If "Yes", please provide a detailed explanation of who will be notified, what information will be provided (e.g., abnormal test results, reportable diseases), and how.

Participants in the intervention condition will be notified of the results of the blood draw, and the results will be discussed with the intervention facilitator. Participants in the control condition will not be told of the results of the blood draw because it could serve as an intervention that influences their adherence behavior (a primary study outcome). However, all participants will be on medication and in medical care, and thus should be receiving regular viral load assessments from their medical provider (outside of the study procedures). Thus, they will likely already be aware of their viral load status. The purpose of assessing viral load as part of the study (in addition to the regular assessments provided by participants' clinics) is for the timing of the viral load assessments from medical records to match the timing of the study survey and adherence assessments, which fall before and after the intervention sessions. This will allow us to have a definitive test of the effects of the intervention on viral suppression.

**5G5 Promise of Confidentiality**

**5G5.1** \* Is confidentiality being promised to participants with no additional exceptions aside from those noted in 5G4?

A. Yes

B. No, participants can choose to allow potentially identifiable information (e.g., quotes, performance information) to be included in published reports

C. No, participants must agree to be attributable in published reports (this is a rare exception and might only occur in studies of a single organization)

D. No, there will be other exceptions (e.g., intent to harm self or others, suspected child abuse)

**5G5.4** \* If "D" on 5G5.1, please describe the exceptions and why they are necessary.

There will be legal exceptions of suicidal ideation or harm to self or others and intent to harm others or child or elder abuse/neglect.

**5G5.5** \* Do you plan to apply for a Certificate of Confidentiality? Please note that such applications can be filed only after consent protocols have been approved.

Yes

No

Don't know

**5G6 Identifiability by Inference in Published Reports**

**5G6.1** \* Might comments or other information included in published reports be identifiable by inference for participants who do not agree to be identified and are being assured of confidentiality?

no

Section: 5 Procedures

**5G7 Data Safeguarding Plan**

- 5G7.1 \* Based on previous answers, a Data Safeguarding Plan (DSP) is required. Are you ready to upload it in draft or final form at this time?  
yes
- 5G7.2 You will be able to upload the Data Safeguarding Plan (DSP) later in Section 7

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Section: 6 Informed Consent

**6 - Informed Consent**

Population	Procedure	Answer questions by clicking on all active links below	Name	Status
People Living with HIV	Cost Data	Component does not require review		Not Required
	Electronic Adherence Assessment (MEMS)	<a href="#">6A Informed Consent</a>	<a href="#">Consent Form 10 16 17for HSPC.docx</a> 10/16/2017	Consent Will Be Performed - Document Uploaded
	Intervention	<a href="#">6A Informed Consent</a>	<a href="#">Consent Form 10 16 17for HSPC.docx</a> 10/16/2017 (duplicate)	Consent Will Be Performed - Document Uploaded
	Medical Records Assessment	<a href="#">6A Informed Consent</a>	<a href="#">Consent Form 10 16 17for HSPC.docx</a> 10/16/2017 (duplicate)	Consent Will Be Performed - Document Uploaded
	Surveys	<a href="#">6A Informed Consent</a>	<a href="#">Consent Form 10 16 17for HSPC.docx</a> 10/16/2017 (duplicate)	Consent Will Be Performed - Document Uploaded
	Viral Load Assessment	<a href="#">6A Informed Consent</a>		

Section: 6 Informed Consent

Population	Procedure	Answer questions by clicking on all active links below	Name	Status
			<a href="#">Consent Form 10 16 17for HSPC.docx</a> 10/16/2017 (duplicate)	Consent Will Be Performed - Document Uploaded

**6A Informed Consent**

**6A1 Informed Consent Applies to Multiple Components**

6A1.1 Which of the following population-procedure components does this Informed Consent apply to? (Check all that apply)

Population	Procedure	This Informed Consent applies to this population-procedure component
People Living with HIV	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**6A2 Plan to Obtain Informed Consent**

6A2 \* Please explain how you plan to obtain informed consent (and/or assent from youth) for the population-procedure component(s) checked above. Describe the processes and methods involved (e.g., written, oral, implicit, passive). For additional explanation of these methods, refer to <http://intranet.rand.org/groups/hspc/consent.html>.

Prior to the baseline survey (during the pre-baseline study visit), the study coordinator will meet with the participant in a confidential space. After confirming eligibility criteria, he/she will describe the details of the study, including the nature of involvement in the study, the possible risks and benefits of participation, and the ability to withdraw from the study at any time without consequence. Participants will be told that their data, including data regarding their HIV status, will be kept confidential. They will also be told that intervention counselors will not have access to their survey data. Participants will be informed that they can skip any survey questions they prefer not to answer. The participant will have the opportunity to ask questions about the study, after which informed consent will be obtained and documented by having the participant read and sign a consent form, which will be stored in a locked file cabinet. Each participant will be given a copy of the consent form to keep.

**6A3 Informed Consent Material Upload**

6A3.1 \* Do you have informed consent material(s) to upload now?

A. Yes - ready to upload now

6A3.2 \* Do you have variations (e.g., for students at different schools) of the informed consent material?

A. Yes - the variations are minor

6A3.4 \* Please upload the informed consent material (e.g., consent form to be signed or script for oral consent).

Note: If you have variations that are substantive, refer to 6A3.3 before uploading.

[Consent Form 10 16 17for HSPC.docx\(0.01\)](#)

6A3.7 \* Please explain the variations. If you are uploading multiple variations in 6A3.6, please include references to the specific documents in explaining the variations.

The Consent form attached will be used for different procedures or components of this study; while the HIPPA form will be used to authorize the release of medical information by the participant. The HIPPA form has been uploaded under additional materials.

Note that the consent form was revised on 10/16/17 to reflect changes suggested by the reviewer as well as

Section: 6 Informed Consent

community stakeholder (to simplify the text),and new timing of study procedures (i.e., baseline survey will be given 1 month earlier).

**6A4 Elements Included**

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You must provide individuals with the information they need to make an informed decision about participating in your study. The list of elements normally included in an informed consent is shown below. If you wish NOT to include any elements that are normally included, you will need to ask the HSPC to grant a waiver..

**6A4.1 \* Check all of the following required elements that are/will be included in the informed consent document. (Check all that apply)**

- A. That the project is a research study**
- B. Purpose of the research**
- C. What organizations are conducting and sponsoring it**
- D. That participation is voluntary**
- E. Clear description of procedures (nature, duration, etc.)**
- F. Risks from participation, if any**
- G. Benefits to the individual from participation, if any**
- H. How the project will treat confidential data**
- I. Point of contact for questions or problems regarding the study**
- J. Point of contact for the HSPC**
- K. Signature of participant and/or legally authorized representative (e.g., parent, guardian)**

**6A4.2 \* Will any of the elements of informed consent that are checked above be altered or involve deception?**  
no

**6A6 Language Translation**

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**6A6.1 \* Will informed consent be administered in languages other than English?**  
no

**6A8 Future Contract After Research Ends**

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**6A8.1 \* After the project ends, is there a possibility that the participants will be contacted to participate any in future research (including research conducted on other topics or by other research teams)?**  
Yes

**6A8.2 \* If "Yes" or "Maybe", you are advised to include a request for permission to recontact in your study's informed consent document. Otherwise you or another researcher may face a situation in the future when the HSPC will not approve recontact. Please describe when and for what purpose the study staff might re-contact this population of participants. How likely is this to happen and when are the study staff be likely to know whether it will happen?**  
It is possible that we will get funded for another similar project with the same population during the study timeframe, in which case we would re-contact participants for participation in another study. There are no plans to do so right now, although we will be submitting other proposals in the next 1-2 years that would be relevant to this study population.

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Section: 7 Documents

**7A - Main Documents to Upload**

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Section: 7 Documents

Based on your prior answers, below RHINO displays a matrix that indicates the documents you need to upload for review. Here you may be asked to upload documents related to any of the following as applicable to your study: participant questions, recruitment material, Data and Safety Monitoring Plan (DSMP), Data Use Agreement (DUA), Data Safeguarding Plan (DSP), and miscellaneous documents other than consent (which can be uploaded in section 6). A DSMP is not the same as a DSP.

Click on the hyperlink in the first column to add or replace a specific document. You can click on the hyperlink in the second column to directly open uploaded documents. You will be able to associate a document with multiple population-procedure components (e.g., questionnaire, or DSP that applies to different populations or procedures) when you upload it. Note: The reviewer may also ask to see documents in addition to those you load below.

Population	Procedure	Upload documents by clicking on all active links below	View Uploaded Documents	Document Status
People Living with HIV		<a href="#">7A2 Recruitment Material</a>	<a href="#">Phone and in-person recruitment Script 10.25.17.docx</a> 10/25/2017	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Flyer Rise 2.0 09-25-17.docx</a> 9/26/2017	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Internet Recruitment Script 9-25-17.docx</a> 9/26/2017	Uploaded
Cost Data		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">Patient Instructions for use of cap 09-25-17.doc</a> 9/26/2017	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx</a> 11/30/2016	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH RAND HIV Adherence IAA Goggin Feb^17.pdf</a> 2/14/2017	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH Request to Rely on External IRB has been Approved 2:14:17.pdf</a> 2/14/2017	Uploaded
Electronic Adherence Assessment (MEMS)		<a href="#">7A1 Participant Questions</a>	<a href="#">Cost effectiveness.xlsx</a> 10/16/2017	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Phone and in-person recruitment Script 10.25.17.docx</a> 10/25/2017 <u>(duplicate)</u>	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Flyer Rise 2.0 09-25-17.docx</a> 9/26/2017 <u>(duplicate)</u>	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Internet Recruitment Script 9-25-17.docx</a> 9/26/2017 <u>(duplicate)</u>	Uploaded
		<a href="#">7A5 Data Safeguarding Plan (DSP)</a>	<a href="#">DSPforRiserev 10 11 17.docx</a> 10/11/2017	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">Patient Instructions for use of cap 09-25-17.doc</a> 9/26/2017 <u>(duplicate)</u>	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CheckinvisitsandRandomizationform10-16-17.docx</a> 10/16/2017	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx</a> 11/30/2016 <u>(duplicate)</u>	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH RAND HIV Adherence IAA Goggin Feb^17.pdf</a> 2/14/2017 <u>(duplicate)</u>	Uploaded

Section: 7 Documents

Population	Procedure	<a href="#">Upload documents by clicking on all active links below</a>	<a href="#">View Uploaded Documents</a>	<a href="#">Document Status</a>
Intervention	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH Request to Rely on External IRB has been Approved 2:14:17.pdf</a> 2/14/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">HIPPA Form 09-25-17.docx</a> 9/26/2017		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Phone and in-person recruitment Script 10.25.17.docx</a> 10/25/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Flyer Rise 2.0 09-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Internet Recruitment Script 9-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A3 Data and Safety Monitoring Plan (DSMP)</a>	<a href="#">DSMPforRise 11 30 16.docx</a> 11/30/2016		Uploaded
	<a href="#">7A3 Data and Safety Monitoring Plan (DSMP)</a>	<a href="#">DSMPforRise 10 12 17.docx</a> 10/16/2017		Uploaded
	<a href="#">7A3 Data and Safety Monitoring Plan (DSMP)</a>	<a href="#">DSMPforRise 10 12 17.docx</a> 10/12/2017		Uploaded
	<a href="#">7A5 Data Safeguarding Plan (DSP)</a>	<a href="#">DSPforRiserev 10 11 17.docx</a> 10/11/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">Rise2.0InterventionManual 9 26 17.docx</a> 9/26/2017		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">Patient Instructions for use of cap 09-25-17.doc</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx</a> 11/30/2016 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH RAND HIV Adherence IAA Goggin Feb^17.pdf</a> 2/14/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH Request to Rely on External IRB has been Approved 2:14:17.pdf</a> 2/14/2017 <a href="#">(duplicate)</a>		Uploaded
Medical Records Assessment	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH FWA letter exp 01-2019 RM.pdf</a> 1/20/2017		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">HIPPA Form 09-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Phone and in-person recruitment Script 10.25.17.docx</a> 10/25/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Flyer Rise 2.0 09-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded

Section: 7 Documents

Population	Procedure	<a href="#">Upload documents by clicking on all active links below</a>	<a href="#">View Uploaded Documents</a>	<a href="#">Document Status</a>
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Internet Recruitment Script 9-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A5 Data Safeguarding Plan (DSP)</a>	<a href="#">DSPforRiserev 10 11 17.docx</a> 10/11/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">Patient Instructions for use of cap 09-25-17.doc</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CheckinvisitsandRandomizationform10-16-17.docx</a> 10/16/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx</a> 11/30/2016 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH RAND HIV Adherence IAA Goggin Feb^17.pdf</a> 2/14/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH Request to Rely on External IRB has been Approved 2:14:17.pdf</a> 2/14/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">HIPPA Form 09-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
Surveys	<a href="#">7A1 Participant Questions</a>	<a href="#">Pre-enrollment and baseline 10-09-2017.docx</a> 10/16/2017		Uploaded
	<a href="#">7A1 Participant Questions</a>	<a href="#">Participant Tracking and Locator Form 09-25-17.docx</a> 9/26/2017		Uploaded
	<a href="#">7A1 Participant Questions</a>	<a href="#">Rise 10 13 17 Follow-up.docx</a> 10/16/2017		Uploaded
	<a href="#">7A1 Participant Questions</a>	<a href="#">Pre-enrollment assessment 9 25 17lmb Submitted to HSPC.docx</a> 9/26/2017		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Phone and in-person recruitment Script 10.25.17.docx</a> 10/25/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Flyer Rise 2.0 09-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A2 Recruitment Material</a>	<a href="#">Internet Recruitment Script 9-25-17.docx</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A5 Data Safeguarding Plan (DSP)</a>	<a href="#">DSPforRiserev 10 11 17.docx</a> 10/11/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">Patient Instructions for use of cap 09-25-17.doc</a> 9/26/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CheckinvisitsandRandomizationform10-16-17.docx</a> 10/16/2017 <a href="#">(duplicate)</a>		Uploaded
	<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx</a> 11/30/2016 <a href="#">(duplicate)</a>		Uploaded



Section: 7 Documents

Population	Procedure	<a href="#">Upload documents by clicking on all active links below</a>	<a href="#">View Uploaded Documents</a>	<a href="#">Document Status</a>
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH RAND HIV Adherence IAA Goggin Feb^17.pdf</a> 2/14/2017 (duplicate)	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH Request to Rely on External IRB has been Approved 2:14:17.pdf</a> 2/14/2017 (duplicate)	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">HIPPA Form 09-25-17.docx</a> 9/26/2017 (duplicate)	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Phone and in-person recruitment Script 10.25.17.docx</a> 10/25/2017 (duplicate)	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Flyer Rise 2.0 09-25-17.docx</a> 9/26/2017 (duplicate)	Uploaded
		<a href="#">7A2 Recruitment Material</a>	<a href="#">Internet Recruitment Script 9-25-17.docx</a> 9/26/2017 (duplicate)	Uploaded
		<a href="#">7A3 Data and Safety Monitoring Plan (DSMP)</a>	<a href="#">DSMPforRise 11 30 16.docx</a> 11/30/2016 (duplicate)	Uploaded
		<a href="#">7A3 Data and Safety Monitoring Plan (DSMP)</a>	<a href="#">DSMPforRise 10 12 17.docx</a> 10/16/2017 (duplicate)	Uploaded
	Viral Load Assessment	<a href="#">7A5 Data Safeguarding Plan (DSP)</a>	<a href="#">DSPforRiserev 10 11 17.docx</a> 10/11/2017 (duplicate)	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">Patient Instructions for use of cap 09-25-17.doc</a> 9/26/2017 (duplicate)	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx</a> 11/30/2016 (duplicate)	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH RAND HIV Adherence IAA Goggin Feb^17.pdf</a> 2/14/2017 (duplicate)	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">CMH Request to Rely on External IRB has been Approved 2:14:17.pdf</a> 2/14/2017 (duplicate)	Uploaded
		<a href="#">7A6 Miscellaneous Documents</a>	<a href="#">HIPPA Form 09-25-17.docx</a> 9/26/2017 (duplicate)	Uploaded

## 7A1 Participant Questions

7AX.1b \* Which of the following population-procedure study components does this document apply to? (Check all that apply)

Section: 7 Documents

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Surveys	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[Pre-enrollment and baseline 10-09-2017.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This document combines what was previously the pre-enrollment and baseline survey questions. No questions have been changed. The documents have been combined because all questions will now be asked at the first study visit, rather than splitting the survey across the first 2 study visits. This will decrease participant burden in the second study visit (which will also include MEMS downloading, blood draws, and a possible first intervention session).

## 7A1 Participant Questions

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Surveys	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[Participant Tracking and Locator Form 09-25-17.docx\(0.02\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 The participant tracking and location form will be used during the pre-enrollment assessment and during check-ins.

## 7A1 Participant Questions

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Surveys	<input checked="" type="checkbox"/>

Section: 7 Documents

**7AX.2a** **\*\* Please upload the document.**  
[Rise\\_10\\_13\\_17\\_Follow-up.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This document is the follow-up survey. These questions were previously contained in the baseline survey and were already approved. We have simply separated out the followup questions into a new document.

## 7A1 Participant Questions

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
<a href="#">People Living with HIV</a>	<a href="#">Electronic Adherence Assessment (MEMS)</a>	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[Cost effectiveness.xlsx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This spreadsheet will be used to collect data from APLA (on intervention costs and salaries), the intervention counselor regarding how long each session takes, and the intervention supervisor (on how long supervision takes). No participant identifying information will be included in this spreadsheet.

## 7A1 Participant Questions

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
<a href="#">People Living with HIV</a>	<a href="#">Surveys</a>	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[Pre-enrollment assessment 9 25 17lmb Submitted to HSPC.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This is the pre-enrollment assessment and we have clarified its use in the consent form

Section: 7 Documents

**7A2 Recruitment Material**

**7AX.1b \* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Cost Data	<input checked="" type="checkbox"/>
	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a \*\* Please upload the document.**  
[Phone and in-person recruitment Script 10.25.17.docx\(0.01\)](#) | [History](#)

**7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Revised recruitment script that specifies participants must be prescribed antiretroviral treatment (not necessarily taking it)

**7A2 Recruitment Material**

**7AX.1b \* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Cost Data	<input checked="" type="checkbox"/>
	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>

Section: 7 Documents

Population	Procedure	This document applies to this population-procedure component
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[Flyer Rise 2.0 09-25-17.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This flyer will be used to recruit participants for different study procedures.

## 7A2 Recruitment Material

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Cost Data	<input checked="" type="checkbox"/>
	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[Internet Recruitment Script 9-25-17.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This script will be used to recruit people using Facebook and Twitter. This script will be used to recruit people for different procedures.

## 7A3 Data and Safety Monitoring Plan (DSMP)

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Section: 7 Documents

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Intervention	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[DSMPforRise 11 30 16.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**

### 7A3 Data and Safety Monitoring Plan (DSMP)

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Intervention	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[DSMPforRise 10 12 17.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Minor changes: clarified that Kiteworks will be used and that the independent data and safety monitor is a behavioral HIV researcher (who has been approved by NIH)

### 7A3 Data and Safety Monitoring Plan (DSMP)

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Intervention	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[DSMPforRise 10 12 17.docx\(0.01\)](#) | [History](#)

**7AX.3a**

Section: 7 Documents

**Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Minor revisions, to clarify (1) that the independent data safety monitor, who has been approved by NINR, is a behavioral HIV researcher but not a clinical psychologist, and (2) that Kiteworks will be used for data transfers

### 7A5 Data Safeguarding Plan (DSP)

**7AX.1b \* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a \*\* Please upload the document.**  
[DSPforRise 11 30 16.docx\(0.01\)](#) | [History](#)

**7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Original version inadvertently re-uploaded

### 7A5 Data Safeguarding Plan (DSP)

**7AX.1b \* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

Section: 7 Documents

**7AX.2a** \*\* Please upload the document.  
[DSPforRiserev 10 11 17.docx\(0.01\)](#) | [History](#)

**7AX.3a** Please enter any comments that you wish to share with the reviewer regarding this document.  
 Updated Data Safeguarding Plan that references a project Kiteworks site for secure data transfer and that updates wording around a federal certificate of confidentiality

### 7A6 Miscellaneous Documents

**7AX.1b** \* Which of the following population-procedure study components does this document apply to? (Check all that apply)

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Intervention	<input checked="" type="checkbox"/>

**7AX.2a** \*\* Please upload the document.  
[Rise2.0InterventionManual 9 26 17.docx\(0.02\)](#) | [History](#)

**7AX.3a** Please enter any comments that you wish to share with the reviewer regarding this document.  
 APLA's FWA letter; APLA will defer to the RAND HSPC.  
 We are also including the intervention manual.

### 7A6 Miscellaneous Documents

**7AX.1b** \* Which of the following population-procedure study components does this document apply to? (Check all that apply)

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Cost Data	<input checked="" type="checkbox"/>
	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>



Section: 7 Documents

Population	Procedure	This document applies to this population-procedure component
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[Patient Instructions for use of cap 09-25-17.doc\(0.02\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Signed APLA reliance agreement  
 We have also included the patient instructions for use of CAP

### 7A6 Miscellaneous Documents

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>

**7AX.2a** **\*\* Please upload the document.**  
[CheckinvisitsandRandomizationform10-16-17.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Document for checking in with participants about updating contact information, downloading electronic adherence data, and randomizing (1-month session only)  
 Replaces check-in and use of MEMS form combined (which was similar but did not include the randomization for the first check-in)

### 7A6 Miscellaneous Documents

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Section: 7 Documents

Population	Procedure	This document applies to this population-procedure component
People Living with HIV		

**7AX.2a** **\*\* Please upload the document.**  
[R01Rise 9 1 16 310pmFINAL\\_UPDATEDFORHSPC.docx\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This is the NIH R01 proposal

### 7A6 Miscellaneous Documents

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV		

**7AX.2a** **\*\* Please upload the document.**  
[CMH RAND HIV Adherence IAA Goggin Feb^17.pdf\(0.01\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Children's Mercy Hospital IRB Reliance Agreement

### 7A6 Miscellaneous Documents

**7AX.1b** **\* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV		

**7AX.2a** **\*\* Please upload the document.**  
[CMH Request to Rely on External IRB has been Approved 2:14:17.pdf\(0.03\)](#) | [History](#)

**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Children's Mercy Hospital IRB approval of reliance agreement

Section: 7 Documents

### 7A6 Miscellaneous Documents

**7AX.1b \* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV		

**7AX.2a \*\* Please upload the document.**  
[CMH\\_FWA letter exp 01-2019 RM.pdf\(0.01\)](#) | [History](#)

**7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.**  
 Children's Mercy Hospital's (CMH) FWA letter; CMH will defer to the RAND HSPC for Co-I Goggin. Co-I Goggin will train the intervention counselor; as part of the training, she may be sent recordings of counseling sessions of participants through a secure SharePoint site. This will allow her to provide guidance about specific issues that may arise on which the team would like her input.

### 7A6 Miscellaneous Documents

**7AX.1b \* Which of the following population-procedure study components does this document apply to? (Check all that apply)**

Population	Procedure	This document applies to this population-procedure component
People Living with HIV	Electronic Adherence Assessment (MEMS)	<input checked="" type="checkbox"/>
	Intervention	<input checked="" type="checkbox"/>
	Medical Records Assessment	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>

**7AX.2a \*\* Please upload the document.**  
[HIPPA Form 09-25-17.docx\(0.01\)](#) | [History](#)

**7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.**  
 This HIPPA form authorizes the release of medical information. It is also a consent form, but we already have another consent form, so we are uploading the HIPPA in miscellaneous documents instead.

Section: 7 Documents

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Section: 8 Conclusion

## 8A Conclusion

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### 8A1 Other Ethical Issues

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**8A1.1** \* Does the proposed study involve any ethical issues not already discussed in the study application?  
no

**8A2** Please enter any other comments or information that you would like to share with the HSPC reviewer that would be relevant to the review.

This study was funded on May 1, 2017. All study documents have now been uploaded (post-JIT review).

Note that this study is very closely related to 2011-0744-CR05, with similar procedures, setting, and study team.

Version 2.10