

Clinicaltrials.gov Cover Sheet

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

NCT03331978

Date: 4.5.22



HSPC Information Online (RHINO)

Date: 11/10/2022, 12:39:01 AM

ID: 2016-0940

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Study #:2016-0940

Last Update from Study Team: Tue Apr 5 14:39:40 PDT 2022

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

☐ Education and Labor

☐ Global Research Talent

☒ Health Care

☐ HSOAC

☐ Justice, Infrastructure, and Environment *

☐ Labor and Population (Archive)

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☐ National Security Research Division☐ Project AIR FORCE☐ Pardee RAND Graduate School☐ RAND Europe☐ Social and Economic Well-Being☐ 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
There are no items to display		

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.
Terry Marsh

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
View Ghosh Dastidar	Bonnie	Economics, Sociology and Statistics	Key Researcher
View Linnemayr	Sebastian	Economics, Sociology and Statistics	Key Researcher
View 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.

1B Study Funding

1B1 Funding Status

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	Instiution Other	Status
View NIMH	HPH0175-1000	20161317	Federal Govt		Completed

1B3 Prime Contractor

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

RAND

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1C Populations and Procedures

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
People Living with HIV	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
Cost Data	11/30/2016
COVID-19 Survey Items	4/29/2020
Electronic Adherence Assessment (MEMS)	11/29/2016
Intervention	11/21/2016
Medical Records Assessment	11/21/2016
Recruitment Discussion Groups	11/28/2018
Surveys	11/21/2016
Viral Load Assessment	11/21/2016

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1D Populations and Procedures Matrix

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"/>
	COVID-19 Survey Items	<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"/>
	Recruitment Discussion Groups	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Surveys	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Viral Load Assessment	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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2 Is This Reviewable?

Population	Procedure	Complete screeners by clicking on all active links below	Status
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Population

Procedure	Complete screeners by clicking on all active links below	Status
People Living with HIV	Cost Data	2A Determining Human Subjects Involvement <u>Follow up questions not required</u> Completed
	COVID-19 Survey Items	2A Determining Human Subjects Involvement <u>Follow up questions required</u> 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.
	Recruitment Discussion Groups	2A Determining Human Subjects Involvement <u>Follow up questions not required</u> Completed
	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).
- ☐ 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.

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2A4 Proprietary Information

2A4.1 * Could the research involve proprietary information (i.e., trade or business information that belongs to an organization)?

No

People Living with HIV: COVID-19 Survey Items**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).
- ☐ 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

2A1.5 Since you selected "None of the above" on 2A1.1, an answer needs to be provided on 2A2.1 below. If you do not believe that you are doing any of the activities listed below in 2A2.1, please contact the HSPC Helpdesk at x4772.

2A2 Activities That Are Typically Classified to Involve Human Subjects

2A2.1 * Will you be doing any of the following activities which are typically considered to involve human subjects? (Check all that apply)

- ☐ A. Expert panel or workshop to discuss current or future concepts and systems (e.g., meetings of experts to arrive at shared advice, decisions and recommendations; obtain views on their utility; issues for system design)
- ☒ B. Interview (e.g., oral or background interviews with key individuals)
- ☒ C. Survey (e.g., written, internet, mail)
- ☐ D. Focus group or group discussion for data collection purposes
- ☐ E. Observation of public behavior
- ☐ F. Analysis of person-level data from extant records or previously collected datasets (extant records such as educational, criminal, military, or medical records)
- ☐ G. Tests or assessments related to education/training
- ☐ H. Psychological tests or assessments
- ☐ I. Physical exams or measurements

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- | | |
|---|--|
| <input type="checkbox"/> J. Social-behavioral intervention | (e.g., effect of counseling on drug use, effect of innovative educational practices on learning, effects of training or new procedures on individual performance, assignment to experimental conditions, or pilot demo programs) |
| <input type="checkbox"/> K. Clinical treatment or intervention | (e.g., nutritional supplementation) |
| <input type="checkbox"/> L. Specimen collection | (e.g., collection of blood, urine, hair, or other material for tests, including genetic testing) |
| <input type="checkbox"/> M. Any other activities which will gather person-level information | |

2A3 - Information Acquired/Accessed

2A3.1 * Please specify the information that you will be acquiring, accessing, or recording as part of data collection. (Check all that apply)

- | | |
|--|---|
| <input checked="" type="checkbox"/> A. Attitudes, opinions, judgments from a living individual, including opinions about organizations and performance | |
| <input type="checkbox"/> B. Facts about organizations, programs, and systems, such as their policies and procedures | (e.g., statistics whether estimated or measured) |
| <input checked="" type="checkbox"/> C. Personal data about or personal experiences of a living individual | (i.e., private information that is recorded as part of data collection) |
| <input type="checkbox"/> D. Other (specify below) | |

2A3.3 * Do you have the questions you will be asking participants (e.g., the interview protocol, survey instrument, or focus group guide) in draft or final form or a list of domains to be covered?
yes

2A3.4 If "Yes", you will be able to upload in section 6 the questions you will be asking participants.

2A3.7 This study component does involve human subjects of research because attitudes, opinions, judgements, or personal data/experiences will be collected. In order for a reviewer to determine whether this study component is exempt, please select an exemption category below. This will expose questions on other screens that the reviewer will need to make this determination.

2A4 Proprietary Information

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

2A5 Choose Exemptions to Qualify For

2A5.1 This component may qualify for one of the exemptions listed below. Please check any boxes to see which exemptions the component may qualify for.


- | |
|--|
| <input type="checkbox"/> A. <u>Adult Interviews and Surveys Exemption</u> (Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior) |
| <input type="checkbox"/> B. <u>Existing Data Exemption</u> (Category 4: Secondary Research for Which Consent is Not Required) |
| <input type="checkbox"/> C. <u>Regular Educational/Training Practices Exemption</u> (Category 1: Research in Established or Commonly Accepted Educational Settings) |
| <input type="checkbox"/> D. <u>Public Benefit Program Research Exemption</u> (Category 5: Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency) |
| <input type="checkbox"/> E. <u>Taste and Food Evaluation Exemption</u> (Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies) |
| <input type="checkbox"/> F. <u>Elected Officials, Political Appointees Exemption</u> (Needed for older studies only) |
| <input checked="" type="checkbox"/> G. <u>None of the Above</u> |
| <input type="checkbox"/> H. <u>Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information From Adult Subjects (NEW)</u> |
| <input type="checkbox"/> I. <u>Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required (NEW)</u> |
| <input type="checkbox"/> J. <u>Category 8: Secondary Research for Which Broad Consent is Required (NEW)</u> |

2A5.2-0940 Because you selected "None of the Above" for 2A5.1, you will be asked the reviewable questions for this component.

People Living with HIV: Recruitment Discussion Groups

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).
- ☒ 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

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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 activites)

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 review.	
	Organization	Status
	AIDS Project Los Angeles	Completed
	Children's Mercy Hospitals and Clinics (Kansas City, MO)	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
- ☒ 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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4A - Populations

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

Population	Status
People Living with HIV	Completed

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People Living with HIV

Related procedures:

- *Recruitment Discussion Groups (Does not involve human subjects)*
- *Viral Load Assessment (Full Committee - Approved)*
- *Intervention (Full Committee - Approved)*
- *Electronic Adherence Assessment (MEMS) (Full Committee - Approved)*

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- *Surveys (Full Committee - Approved)*
- *Medical Records Assessment (Full Committee - Approved)*
- *COVID-19 Survey Items*
- *Cost Data (Full Committee - Approved)*

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 * 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 <100% 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.

Participants will be ineligible if they are unable to understand or communicate in spoken English.

If individuals are screened via an online screener, we will also require that participants live in LA County, so that they can attend study appointments in person, as required by the protocol.

Participants will have similar eligibility criteria for the discussion groups: 18 years or older, living with HIV, be prescribed medications for at least 6 months, self-described adherence issues, and identify as Black/African American.

If participants wish, after they screen as eligible, we will offer ride assistance through the confidential Circulation program (a program of Lyft) for their first study visit.

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)?

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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** * 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).

Discussion Groups: 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. APLA staff will also hold discussion groups to help with recruitment; the discussion groups will be conducted as focus groups, in which we will ask participants about their feedback on the Rise intervention, and then offer study screening after the discussion group (data from the discussion groups will not be collected).

Fliers: The study fliers were designed by a graphic artist, with input from the community advisory board (CAB). Based on CAB feedback, we are also creating fliers with pictures of CAB members (which includes HIV service organization staff and clients), along with slogans that are developed by the CAB (e.g., Get back on track; Are you forgetting something...?; Take time for yourself...; Rise up for yourself or life; Rise and shine...; Being undetectable is important for my health). Using community members as models in social media campaigns was suggested by the CAB, who felt that such images would resonate with potential participants, who may find comfort in seeing people who look like them being affiliated with the study. Permission to take photos through APLA Health & Wellness is collected through the APLA Health Communications department, who provide a waiver to be signed by the interested CAB member that states the likeness will not be shared with any other department within the organization, or outside the organization, for any purpose. Whatever photos are taken will only be used for the purpose of promoting Project Rise. In providing consent for being photographed, the CAB member has the right to rescind their permission, and it will not affect their relationship with Project Rise, APLA Health, or any other organization/person/entity. All signed paper copies are kept by the Communications department in a secure locked folder and office at APLA Health, which cannot be accessed by anyone outside the department.

Recruitment Staffing: We hired 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). We also 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.

Screening: 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.

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We have used these recruitment procedures successfully for several prior studies.

Online Recruitment: Participants who are recruited online will have the opportunity to complete an online screener (instead of an in person or phone screener). This will be done with a Confrimit questionnaire, which is accessible through the internet. The Confrimit questionnaire has similar language as the in-person/phone recruitment screener. The survey will track individual responses via IP address, which is specific and unique per device used to complete the tool. The survey tool will also incorporate skip logic and disqualification, so those who complete the survey electronically will be notified if they are eligible or not. Survey responses are stored electronically, in a secure account accessed only by the Senior Study Coordinator at APLA Health and Wellness. The Senior Study Coordinator will check for new responses on a daily basis. Based on the responses provided, the Seniors Study Coordinator and/or the Study Coordinator will determine if the individual is eligible for the study using the pre-determined eligibility criteria for inclusion in the program. For eligible clients, the survey will include an option for respondents to provide their name, contact number and email address so the Project Rise team can reach out to them. They will be notified of their eligibility status, and asked if they might be interested in participating in the study. Those who are interested will be scheduled for an appointment. All electronic responses will be transferred to a QDS warehouse for record keeping and data analysis. Once the entries have been reviewed, they will be deleted from the electronic record. This survey will be included in all electronically advertised media showcasing Project Rise. This includes social media websites, online periodicals, and organizational newsletters. It will also be available on the APLA website as well. The link will be a click-through, allowing people to complete the questionnaire from the convenience of an electronic device as an alternative to calling in. The link will be maintained and administrated by the Senior Study Coordinator.

Note that Project Rise is advertised as a Facebook Page that is managed by APLA Health project staff. Interested individuals interact through the page, not with specific staff. When receiving messages on Facebook, they are received through the Page, and all responses are done through the Page (rather than a staff-person's profile). There is also an option to "Like" the page, and show online support. We have set up security settings so no one can see or be notified that any individual has "Liked" the page. Only Project Rise staff administering the page will be able to see the full list of individuals who have chosen to "Like" the page; clients who like it, however, will not be able to see this list, protecting the identity and confidentiality of interested individuals who may not be out and open about HIV status, gender identity, sexual orientation, or other personal information.

Incentivized recruitment: We will also offer incentives for participants in the study to recruit others in their social networks. All participants who have registered for Project Rise will be able to receive recruitment incentives, including those who are already participating in the program. Participants will be given study palm cards and materials to distribute to communities and individuals they know. When interested clients call to screen, they will be asked how they heard about the program. If the interested client provides the name of a specific individual, study staff will make a note in the electronic participant database. Study staff will notify the participant that someone they referred to Project Rise screened for the study, but they will not be provided the specific name of who it was. For each person screened (up to 3 people) and referred, the referring participant will receive \$10, for a maximum of \$30. To ensure confidentiality, participants will not be told the names of the specific clients who screened. Screening history and participation data will not be shared outside of the study team. All electronic screening information is kept in a secure spreadsheet in a folder only accessible to study team staff, and on password-protected computers and accounts. Paper screeners are kept in locked drawers at APLA Health's office in Baldwin Hills, and not shared with people outside the study team.

Street Recruitment: SRG staff will screen participants can be screened at a variety of off-site locations (e.g., on Skid Row; in front of clinics, service organizations, and homeless shelters). Screening data will be collected using Samsung TAB A Tablets running the Android operating system using Open Data Kit (ODK) interviewing software. As interviews are conducted, data will be stored on the tablet and later uploaded to an ODK Aggregate server hosted at RAND. We will provide a \$2 cash incentive for individuals who are screened by street recruiters. Street recruiters may use the brief screener (that is used for the online screener) or the longer full screener (that is currently used when participants call in). They will ensure that anything confidential is discussed in a space where the conversation cannot be overheard by others, in which others are not in earshot, and they will stop the interview if other people enter the space and are able to overhear anything that should be confidential, consistent with SRG protocols for field interviewing.

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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5 - Procedures

Procedure	Answer questions by clicking on all	Status
https://rhino.rand.org/Rhino/ResourceAdministration/Project/PrintSmartForms?Project=com.webbridge.entity.Entity%5B0ID%5B93ADB21269EC9C4... 14/86		

ID: 2016-0940	active links below	
COVID-19 Survey Items	5C Procedures - Interactions with Participants	Completed
	5E Procedures - Risks	Completed
	5F Procedures - Benefits, Incentives, Costs	Completed
	5G Procedures - Confidentiality	Completed
Electronic Adherence Assessment (MEMS)	5C Procedures - Interactions with Participants	Completed
	5E Procedures - Risks	Completed
	5F Procedures - Benefits, Incentives, Costs	Completed
	5G Procedures - Confidentiality	Completed
Intervention	5A Procedures - Interventions: Overview	Completed
	5E Procedures - Risks	Completed
	5F Procedures - Benefits, Incentives, Costs	Completed
	5G Procedures - Confidentiality	Completed
Medical Records Assessment	5D Procedures - Secondary Data	Completed
	5E Procedures - Risks	Completed
	5G Procedures - Confidentiality	Completed
Surveys	5C Procedures - Interactions with Participants	Completed
	5E Procedures - Risks	Completed
	5F Procedures - Benefits, Incentives, Costs	Completed
	5G Procedures - Confidentiality	Completed
Viral Load Assessment	5A Procedures - Interventions: Overview	Completed
	5B Procedures - Interventions: Biologic Samples or Specimens	Completed
	5E Procedures - Risks	Completed
	5F Procedures - Benefits, Incentives, Costs	Completed
	5G Procedures - Confidentiality	Completed

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COVID-19 Survey Items

3C Research Overview - Procedures

Related Populations:

- *People Living with HIV*

3C1 Procedure Description

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 checked="" type="checkbox"/> B.	Interview	(e.g., phone interview)
<input checked="" 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 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:

- 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
- 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*

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repeated are covered in 5C4.

We will call all current study participants and offer them an extra \$10 to complete the COVID-19 items during their regularly scheduled study appointment, or at another convenient time of their choosing. In addition, during all study appointments, as we already do, we will ask participants if they need any resources and provide referrals. Study interviewers will refer patients to relevant COVID-19 resources in Los Angeles County (e.g., testing) as needed. We will store these new survey data securely using the same protocol as for the overall survey dataset, as described in the DSP. As we currently do for other resources, we will follow up with individuals to whom we provide COVID-19-related resources (in about a week, or sooner if needed) in order to determine if they were able to access the resources as needed. These additional procedures will continue until COVID-19-related public health issues are no longer impacting the study. The questions will be asked by phone during the COVID-19 crisis. If there is a return to some in person interviews in the future, but the COVID-19 crisis is not yet resolved, we may ask these questions in person (and allow participants to complete them as a survey rather than an interview, if they wish).

As with our current COVID-19 procedures, participants may wait to get the gift cards until they can come into APLA Health in person, or they may meet a study staff member at the APLA Health food bank to receive their gift cards sooner.

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

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.*

We anticipate that participants will answer the questions once. However, if the COVID-19 public health crisis lasts for over 6 months, we may check in again with participants who are still in the study in 6 months, to again determine how they are being affected and whether resources are needed.

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

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 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.
If an employer were to find out that a participant had COVID-19, they may not be able to get a job or may lose their job. As with all data in the study, we have strict data safeguarding procedures for keeping data secure and confidential, including using unique participant IDs rather than participant names for all survey data.

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?
no
- 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 may get distressed if others were to know their personal health information around COVID-19. As with all data in the study, we have strict data safeguarding procedures for keeping data secure and confidential, including using unique participant IDs rather than participant names for all survey data.

5F Procedures - Benefits, Incentives, and Costs

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?
Participants will receive an extra \$10 gift card for answering the COVID-19 questions.
- 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.
As with our current COVID-19 procedures, participants may wait to get the gift cards until they can come into APLA Health in person, or they may meet a study staff member at the APLA Health food bank to receive their gift cards sooner, if a staff

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member is available. Participants are all eligible to get food at the APLA food bank and many do so; thus, they are already going to the food bank and would not need to make an extra trip for the study.

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.*

- | | |
|---|--|
| <input checked="" type="checkbox"/> A. Substance use | including alcohol, drugs, and tobacco |
| <input checked="" type="checkbox"/> B. Physical health | including diagnosis, treatment, or any other private physical health information |
| <input checked="" 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 checked="" 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"/> A. Names | including names appearing on consent forms, payment receipts, medical records, and emergency contact lists |
| <input checked="" 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"/> C. Dates | including birth date, marriage date, and treatment or visit dates from medical records |
| <input type="checkbox"/> 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) |
| <input type="checkbox"/> E. Audio, video, or biometric indicators | including photographic or video images, audio recordings, and finger or voice prints |

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

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

Electronic Adherence Assessment (MEMS)

3C Research Overview - Procedures

Related Populations:

- *People Living with HIV (Full Committee - Approved)*

3C1 Procedure Description

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.	Other interaction research procedures	(e.g., obtaining information from individuals)

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.

3C1.5 * If "N" above, please describe the interaction procedure.

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.

For participants who are not leaving home due to COVID-19 risk, program staff will drive to the participant's address to pick up the electronic monitoring device and get a signed HIPAA form. The participant will be asked to put the device into a plastic/paper bag (which can be supplied by study staff if needed). The staff-person will confirm a time to pick up the device. Once they arrive, the staff-person will knock on the participant's door. They will step back from the door at least 6 feet, and the participant will give the device to the staff-person by putting it in a bag outside their door. The staff-person will collect the bag, and then provide the HIPAA form for the client to sign. The client will sign the form, put into a provided envelope, and then leave the envelope outside for the staff-person to collect. The staff-person will collect the envelope and provide gift cards to the participant. Once the signed HIPAA form and packaged device have been secured, the staff-person will wipe the device with antiseptic, download data onto their study laptop at home or in APLA's offices. If downloaded at home, the data will be

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immediately transferred to Kiteworks for data transfer and processing. HIPAA forms will be locked in APLA's offices for medical records data collection.

While in the field, program staff will be protected. APLA Health provides its staff with facemasks, gloves, antiseptic wipes and hand sanitizer for all client interactions. It is APLA Health policy for staff to wear PPE while in the office, in the field, and when interacting with participants. Program staff will maintain 6 feet of social distancing between themselves and the participant at all times, and will also enforce that the participant wear a facemask during the interaction as well. Participant and program staff will monitor themselves to see if they have any flu-like symptoms before the visit, and will postpone any scheduled interactions if there is any concern of coronavirus transmission. Participants and program staff will also monitor themselves after the visit to make sure their interaction did not facilitate coronavirus transmission. If there is any concern, program staff will follow agency and LACDPH protocols for contact tracing and reporting of possible exposures/positive diagnoses.

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.*

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.

Interviewers will use text to remind participants about appointments, using study cell phones that are not used for other purposes, outside of the study.

For participants who are not leaving home due to COVID-19 risk, program staff will drive to the participant's address to pick up the electronic monitoring device and get a signed HIPAA form. The participant will be asked to put the device into a plastic/paper bag (which can be supplied by study staff if needed). The staff-person will confirm a time to pick up the device. Once they arrive, the staff-person will knock on the participant's door. They will step back from the door at least 6 feet, and the participant will give the device to the staff-person by putting it in a bag outside their door. The staff-person will collect the bag, and then provide the HIPAA form for the client to sign. The client will sign the form, put into a provided envelope, and then leave the envelope outside for the staff-person to collect. The staff-person will collect the envelope and provide gift cards to the participant. Once the signed HIPAA form and packaged device have been secured, the staff-person will wipe the device with antiseptic, download data onto their study laptop at home or in APLA's offices. If downloaded at home, the data

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will be immediately transferred to Kiteworks for data transfer and processing. HIPAA forms will be locked in APLA's offices for medical records data collection.

While in the field, program staff will be protected. APLA Health provides its staff with facemasks, gloves, antiseptic wipes and hand sanitizer for all client interactions. It is APLA Health policy for staff to wear PPE while in the office, in the field, and when interacting with participants. Program staff will maintain 6 feet of social distancing between themselves and the participant at all times, and will also enforce that the participant wear a facemask during the interaction as well. Participant and program staff will monitor themselves to see if they have any flu-like symptoms before the visit, and will postpone any scheduled interactions if there is any concern of coronavirus transmission. Participants and program staff will also monitor themselves after the visit to make sure their interaction did not facilitate coronavirus transmission. If there is any concern, program staff will follow agency and LACDPH protocols for contact tracing and reporting of possible exposures/positive diagnoses.

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

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

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

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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 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

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

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

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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

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?

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

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

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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. None of the identifiers 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.
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

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[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

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

Intervention

3C Research Overview - Procedures

Related Populations:

- *People Living with HIV (Full Committee - Approved)*

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)

☐ B. Interview (e.g., phone interview)

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<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 checked="" 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 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

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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 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.

Intervention sessions take place at several APLA Health locations. If a client is unable to attend a session at APLA Health, the intervention counselor can travel to meet the participant in his/her home or a confidential location. In such instances, the counselor would find a confidential, private space in which the session cannot be overheard by others, in which others are not in earshot (e.g., in fast food restaurants, coffee shops, parks, people's homes), and would stop the session if other people enter the space and are able to overhear anything, consistent with SRG protocols for field interviewing.

In addition, due to the COVID-19 situation, APLA Health staff have been told to work at home. Thus, the intervention counselor will conduct intervention sessions by phone from home, using a dedicated study cell phone, and in a private space in which others cannot overhear (the counselor lives alone). We will modify the sessions to be done without the electronic adherence monitoring component, as that requires an in-person interaction.

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

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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 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)

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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 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.

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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 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

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.**

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.**

- | | |
|---|--|
| <input checked="" type="checkbox"/> A. Substance use | including alcohol, drugs, and tobacco |
| <input checked="" type="checkbox"/> B. Physical health | including diagnosis, treatment, or any other private physical health information |
| <input checked="" 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 checked="" 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 checked="" type="checkbox"/> L. Other | |
| <input type="checkbox"/> 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.**

- | | |
|--|---|
| <input checked="" type="checkbox"/> A. Names | including names appearing on consent forms, payment receipts, medical records, and emergency contact lists |
| <input checked="" 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 |

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<input checked="" type="checkbox"/>	C. Dates	including birth date, marriage date, and treatment or visit dates from medical records
<input type="checkbox"/>	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)
<input checked="" 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 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

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- ☐ 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

Medical Records Assessment

3C Research Overview - Procedures

Related Populations:

- *People Living with HIV (Full Committee - Approved)*

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)
- ☐ B. Interview (e.g., phone interview)

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- | | |
|---|---|
| <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 type="checkbox"/> 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.*

- | | |
|--|--|
| <input checked="" type="checkbox"/> A. Names | including names appearing on consent forms, payment receipts, medical records, and emergency contact lists |
| <input checked="" 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"/> C. Dates | including birth date, marriage date, and treatment or visit dates from medical records |
| <input checked="" type="checkbox"/> 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) |
| <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 |

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

- | |
|---|
| <input checked="" type="checkbox"/> A. Research team members (whether or not they are RAND associates) |
| <input checked="" type="checkbox"/> B. Person or organization providing the data (i.e., data provider) |
| <input checked="" type="checkbox"/> C. Subcontractors, vendors, or other service providers hired by RAND (other than the data provider) |
| <input type="checkbox"/> 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)?**

- | |
|-------------------------------------|
| <input type="radio"/> Yes |
| <input checked="" type="radio"/> No |
| <input type="radio"/> Don't know |

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

- 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.

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. Alternately, participants can go directly to a Quest lab (where Rise blood samples are sent for processing) to have their blood drawn for the study. Viral load suppression will be defined as <200 copies of virus per milliliter of blood plasma.

If participants wish to go to a Quest lab, we will offer ride assistance, specifically, the Circulation program (e.g., to transport clients from APLA Health & Wellness in Koreatown and Long Beach to Quest Diagnostics blood draw sites). For example, APLA Health in Koreatown is at 611 S. Kingsley Drive, Los Angeles, CA 90005, a half mile away from the closest Quest draw site at 500 S Virgil Ave Suite 202, Los Angeles, CA 90010. Prior to the appointment, APLA project staff will book a ride through the Circulation portal. The client will meet the APLA staff person at APLA Health's location. The Circulation ride will take the staff person and participant to the Quest draw site, and then back to APLA Health, where the remainder of the session will be completed.

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. Alternately, participants can go directly to a Quest lab (where Rise blood samples are sent for processing) to have their blood drawn for the study. Viral load suppression will be defined as <200 copies of virus per milliliter of blood plasma.

If participants wish to go to a Quest lab, we will offer ride assistance, specifically, the Circulation program (e.g., to transport clients from APLA Health & Wellness in Koreatown and Long Beach to Quest Diagnostics blood draw sites). For example, APLA Health in Koreatown is at 611 S. Kingsley Drive, Los Angeles, CA 90005, a half mile away from the closest Quest draw site at 500 S Virgil Ave Suite 202, Los Angeles, CA 90010. Prior to the appointment, APLA project staff will book a ride through the Circulation portal. The client will meet the APLA staff person at APLA Health's location. The Circulation ride will take the staff person and participant to the Quest draw site, and then back to APLA Health, where the remainder of the session will be completed.

In the event that participants do not want to get their blood drawn and see APLA Health staff in person due to COVID-19, they will be asked to send photos or screenshots of their most recent HIV viral load lab results to the study team cell phone using WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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

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* 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. Participants will receive \$50 for bringing their HIPAA form to their provider to obtain the data on their own, and then returning their data to the study team.

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 * 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

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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.

Photos of viral load levels will be sent to the study cell phone via WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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.

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.

Photos of viral load levels will be sent to the study cell phone via WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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 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.

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further protect confidentiality, the study will be covered by a federal Certificate of Confidentiality.

Photos of viral load levels will be sent to the study cell phone via WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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. Physical health | including diagnosis, treatment, or any other private physical health information |
| <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 | |

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.

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

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- ☐ 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

Recruitment Discussion Groups

3C Research Overview - Procedures

Related Populations:

- People Living with HIV (Does not involve human subjects)

3C1 Procedure Description

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 checked="" 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) |

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<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 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:

- 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
- 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.*

Section 3 – Discussion Groups

In order to introduce community members to the Project Rise study and boost recruitment numbers, we would like to host community discussion groups. Community discussion groups are useful for introducing community members to programs and initiatives. As such, we believe a discussion group would be helpful for us to discuss treatment adherence with clients, introduce Project Rise, and increase our client pool. Such an approach was used on a prior RAND study to increase recruitment for a similar population [Kanouse, D. E., Bluthenthal, R. N., Bogart, L. M., Iguchi, M. Y., Perry, S., Sand, K., & Shoptaw, S. (2005). Recruiting drug-using men who have sex with men into behavioral interventions: A two-stage approach. *Journal of Urban Health*, 82(1), i109-i119.].

Recruiting for the discussion groups will be separate from recruiting for the Project Rise study. We will utilize a simplified screener. To be eligible for participation, one must be 18 years or older, be living with HIV, be prescribed medications for at least 6 months, have self-described adherence issues, and identify as Black/African American. Interested participants will call members of our study team to screen for eligibility.

These discussion groups will not be considered research; we do not intend to publish any information gleaned from the discussion groups. The purpose of the discussion groups is to increase awareness about the study, knowledge of issues related to the study, and boost recruitment for Project Rise.

After screening and being invited to participate in the group discussion, members of the study team will notify eligible participants of a date for the group. Those who are available will be scheduled to attend.

The group will incorporate a series of questions and probes, moderated by Project Rise study team. The questions will focus on experiences with taking HIV medications and treatment, their views on treatment adherence, and the kinds of programs and services they believe would help them improve and stay adherent to their regimens. The discussion group will last about an hour and a half. The groups will also be used to introduce participants to Project Rise, and participants will be invited to register for the program at the conclusion of the session. Participants will be given incentives of \$40 in gift cards and

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provided with refreshments during the group.

All screening information will be tracked using paper forms. All screeners will be kept in locked drawers at APLA Health's location in Baldwin Hills that can only be accessed by the study team. No screening information is shared with anyone outside the study team. A list of attendees of each discussion group will be kept electronically, and stored in a secure folder and computer at APLA Health. Information on these rosters will be limited to name, phone number and email if available. These rosters will not be shared with any individuals outside the study team, and any paper copies printed will be shredded at the conclusion of each focus group discussion. Clients who decide to screen for the study will be treated like any other clients as per our approved IRB protocol.

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

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

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

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

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- 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?
no
- 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.
Section 3 – Discussion Groups
In order to introduce community members to the Project Rise study and boost recruitment numbers, we would like to host community discussion groups. Community discussion groups are useful for introducing community members to programs and initiatives. As such, we believe a discussion group would be helpful for us to discuss treatment adherence with clients, introduce Project Rise, and increase our client pool. Such an approach was used on a prior RAND study to increase recruitment for a similar population [Kanouse, D. E., Bluthenthal, R. N., Bogart, L. M., Iguchi, M. Y., Perry, S., Sand, K., & Shoptaw, S. (2005). Recruiting drug-using men who have sex with men into behavioral interventions: A two-stage approach. Journal of Urban Health, 82(1), i109-i119.].
Recruiting for the discussion groups will be separate from recruiting for the Project Rise study. We will utilize a simplified screener. To be eligible for participation, one must be 18 years or older, be living with HIV, be prescribed medications for at least 6 months, have self-described adherence issues, and identify as Black/African American. Interested participants will call members of our study team to screen for eligibility.
These discussion groups will not be considered research; we do not intend to publish any information gleaned from the discussion groups. The purpose of the discussion groups is to increase awareness about the study, knowledge of issues related to the study, and boost recruitment for Project Rise.
After screening and being invited to participate in the group discussion, members of the study team will notify eligible participants of a date for the group. Those who are available will be scheduled to attend.
The group will incorporate a series of questions and probes, moderated by Project Rise study team. The questions will focus on experiences with taking HIV medications and treatment, their views on treatment adherence, and the kinds of programs and services they believe would help them improve and stay adherent to their regimens. The discussion group will last about an hour and a half. The groups will also be used to introduce participants to Project Rise, and participants will be invited to register for the program at the conclusion of the session. Participants will be given incentives of \$40 in gift cards and provided with refreshments during the group.
All screening information will be tracked using paper forms. All screeners will be kept in locked drawers at APLA Health's location in Baldwin Hills that can only be accessed by the study team. No screening information is shared with anyone outside the study team. A list of attendees of each discussion group will be kept electronically, and stored in a secure folder and computer at APLA Health. Information on these rosters will be limited to name, phone number and email if available. These rosters will not be shared with any individuals outside the study team, and any paper copies printed will be shredded at the conclusion of each focus group discussion. Clients who decide to screen for the study will be treated like any other clients as per our approved IRB protocol.

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?
no
- 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.
Section 3 – Discussion Groups
In order to introduce community members to the Project Rise study and boost recruitment numbers, we would like to host community discussion groups. Community discussion groups are useful for introducing community members to programs

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and initiatives. As such, we believe a discussion group would be helpful for us to discuss treatment adherence with clients, introduce Project Rise, and increase our client pool. Such an approach was used on a prior RAND study to increase recruitment for a similar population [Kanouse, D. E., Bluthenthal, R. N., Bogart, L. M., Iguchi, M. Y., Perry, S., Sand, K., & Shoptaw, S. (2005). Recruiting drug-using men who have sex with men into behavioral interventions: A two-stage approach. *Journal of Urban Health*, 82(1), i109-i119].

Recruiting for the discussion groups will be separate from recruiting for the Project Rise study. We will utilize a simplified screener. To be eligible for participation, one must be 18 years or older, be living with HIV, be prescribed medications for at least 6 months, have self-described adherence issues, and identify as Black/African American. Interested participants will call members of our study team to screen for eligibility.

These discussion groups will not be considered research; we do not intend to publish any information gleaned from the discussion groups. The purpose of the discussion groups is to increase awareness about the study, knowledge of issues related to the study, and boost recruitment for Project Rise.

After screening and being invited to participate in the group discussion, members of the study team will notify eligible participants of a date for the group. Those who are available will be scheduled to attend.

The group will incorporate a series of questions and probes, moderated by Project Rise study team. The questions will focus on experiences with taking HIV medications and treatment, their views on treatment adherence, and the kinds of programs and services they believe would help them improve and stay adherent to their regimens. The discussion group will last about an hour and a half. The groups will also be used to introduce participants to Project Rise, and participants will be invited to register for the program at the conclusion of the session. Participants will be given incentives of \$40 in gift cards and provided with refreshments during the group.

All screening information will be tracked using paper forms. All screeners will be kept in locked drawers at APLA Health's location in Baldwin Hills that can only be accessed by the study team. No screening information is shared with anyone outside the study team. A list of attendees of each discussion group will be kept electronically, and stored in a secure folder and computer at APLA Health. Information on these rosters will be limited to name, phone number and email if available. These rosters will not be shared with any individuals outside the study team, and any paper copies printed will be shredded at the conclusion of each focus group discussion. Clients who decide to screen for the study will be treated like any other clients as per our approved IRB protocol.

5F Procedures - Benefits, Incentives, and Costs

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?
\$40 in gift cards and refreshments
- 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.
They will receive incentives after they participate in the discussion 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

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- ☐ 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
- ☐ 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 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

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- ☐ 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

Surveys

3C Research Overview - Procedures

Related Populations:

- *People Living with HIV (Full Committee - Approved)*

3C1 Procedure Description

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 checked="" 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) |

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<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 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:

- 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.

Interviews may also be conducted by phone on a dedicated study cellphone, from a private location (interviewers' homes) in which the interviewer cannot be heard by others. This last option has been added because APLA Health staff have been told to work at home during the COVID-19 situation. In this case, interviewers will upload all study data (from QDS, the ACASI program) from their study laptop onto the secure Kiteworks data sharing site; study staff at RAND will download the data as soon as it is received and tell APLA staff, so that it can be deleted from the study laptop. In addition, consent for the baseline interview would be done by phone (verbally) for baseline phone interviews, and then written informed consent will be obtained when the client next is seen in person (after the COVID-19 situation is resolved).

In some cases, we may also conduct study visits off-site, if a participant is screened as eligible and unable or unwilling to travel to the study locations. We would find a confidential, private space in which the interview cannot be overheard by others, in which others are not in earshot (e.g., in fast food restaurants, coffee shops, parks, people's homes), and would stop the interview if other people enter the space and are able to overhear the interview; the team will be trained on SRG's protocols for field interviewing.

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

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will text reminders to participants using the dedicated study cell phone. Only the Project Rise staff team would have access to the cell phone.

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

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 $\alpha = .74$), 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*

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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.**

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

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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 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, 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

- 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

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?

Assessments: 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).

Incentivized Recruitment: We will also offer incentives for participants in the study to recruit others in their social networks. All participants who have registered for Project Rise will be able to receive recruitment incentives, including those who are already participating in the program. Participants will be given study palm cards and materials to distribute to communities and individuals they know. When interested clients call to screen, they will be asked how they heard about the program. If the interested client provides the name of a specific individual, study staff will make a note in the electronic participant database. Study staff will notify the participant that someone they referred to Project Rise screened for the study, but they will not be provided the specific name of who it was. For each person screened (up to 3 people) and referred, the referring participant will receive \$10, for a maximum of \$30. To ensure confidentiality, participants will not be told the names of the specific clients who screened. Screening history and participation data will not be shared outside of the study team. All electronic screening information is kept in a secure spreadsheet in a folder only accessible to study team staff, and on password-protected computers and accounts. Paper screeners are kept in locked drawers at APLA Health's office in Baldwin Hills, and not shared with people outside the study team.

Circulation Ride Assistance: Transportation historically has been an issue for many individuals in Los Angeles County to attend appointments for medical and social service appointments. Some companies have begun using rideshare and assistance programs to help cover this. APLA Health currently utilizes a program called Circulation, which works with Lyft to provide transportation assistance to and from medical appointments, to government offices to receive required paperwork, and for emergent needs (not including emergency medical care). We will use this service for participants in our program as well. Administration of Circulation is done entirely by study staff. Participants will be offered the ability to use Circulation, and those who are interested will be registered on the Circulation platform by study staff. To register, the study staff person must provide the client's name, home address, and phone number on the portal for contact. The portal requires the client to electronically sign a consent form beforehand, which is done through the Circulation website. This form can be emailed by staff to the individual beforehand through an electronic link. If a client prefers to complete consent through this portal, Circulation will provide a safe and secure text/internet link for the client to complete prior to booking a ride. When the consent document is completed, study staff will be notified and they can proceed with booking rides on behalf of the client.

To schedule a ride, a study staff person uses the Circulation portal to book it on their behalf of the client. The client does not need to book rides through Circulation. When study staff members book the ride, the portal provides an estimated cost of the ride. The person booking the ride selects whether the trip is one-way or round trip, and a specific address for pick-up and drop-off. To ensure the client does not forget their ride, Circulation sends automated and secure text reminders when the ride is booked, the day before, when the car is dispatched, when it has arrived, and when the ride is complete. These text reminders just provide reminders about the ride, and do not list the address for drop-off, pick-up, or any details about the ride. For the return ride, Circulation provides a code for the client to activate in order to receive their return ride. Study staff can monitor ride progression as well. The portal also notifies staff when participants do not get into their ride, or if the ride is missed. Circulation provides monthly invoices through the portal. In order to pay for them, APLA Health's finances department determines the appropriate grants used to pay the invoice.

Circulation abides by strict confidentiality policies. Their agreement signed with APLA Health states that no information about the client is shared with anyone in their organization. Specific information such as name, address, phone number and/or email is kept completely through the app, and is not shared with anyone else. Additionally, Circulation riders and the portal follow specific requirements for patient confidentiality, in accordance to the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). Through these statutes, no information about clients utilizing circulation, such as the destination of rides, is shared with drivers. Additionally, no health information about clients is shared with Circulation or drivers enlisted by Circulation. As such, client health information is secure, as is their safety.

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 gift card 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

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

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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
- ☐ **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** 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

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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

- 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

Viral Load Assessment

3C Research Overview - Procedures

Related Populations:

- *People Living with HIV (Full Committee - Approved)*

3C1 Procedure Description

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"/> 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 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
- 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. Alternately, participants can go directly to a Qwest lab (where Rise blood samples are sent for processing) to have their blood drawn for the study. Viral load suppression will be defined as <200 copies of virus per milliliter of blood plasma.

If participants wish to go to a Quest lab, we will offer ride assistance, specifically, the Circulation program (e.g., to transport

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clients from APLA Health & Wellness in Koreatown and Long Beach to Quest Diagnostics blood draw sites). For example, APLA Health in Koreatown is at 611 S. Kingsley Drive, Los Angeles, CA 90005, a half mile away from the closest Quest draw site at 500 S Virgil Ave Suite 202, Los Angeles, CA 90010. Prior to the appointment, APLA project staff will book a ride through the Circulation portal. The client will meet the APLA staff person at APLA Health's location. The Circulation ride will take the staff person and participant to the Quest draw site, and then back to APLA Health, where the remainder of the session will be completed.

In the event that participants do not want to get their blood drawn and see APLA Health staff in person due to COVID-19, they will be asked to send photos or screenshots of their most recent HIV viral load lab results to the study team cell phone using WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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.

- ☒ 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

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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****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)**

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- ☐ 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.

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.

Photos of viral load levels will be sent to the study cell phone via WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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

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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.

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.

Photos of viral load levels will be sent to the study cell phone via WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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 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.

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.

Photos of viral load levels will be sent to the study cell phone via WhatsApp, which has end-to-end encryption. Study staff will tell participants to delete the photo from their phone immediately after they send it. APLA staff will transcribe the results from these photos to the medical records data collection spreadsheet (that has ID#s and not participant names), and will securely transmit the data to RAND via Kiteworks. Once the data has been securely transmitted, study staff will delete the photo from the study cell phone.

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

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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

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?
Participants will receive \$30 for the first venipuncture visit, \$40 at the 6-month follow-up and \$50 at 12-month followup. Participants who are asked to travel to Quest labs for blood draws (when the APLA Health clinic cannot be used due to restrictions in the time of COVID-19) will receive an extra \$10 gift card.
- 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 gift cards at these study visits. If they complete the venipuncture only, they will receive \$20. Participants who are asked to travel to Quest labs for blood draws (when the APLA Health clinic cannot be used due to restrictions in the time of COVID-19) will receive an extra \$10 gift card.

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

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.*

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<input checked="" 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"/> C. Dates	including birth date, marriage date, and treatment or visit dates from medical records
<input checked="" type="checkbox"/> 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)
<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 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.

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.

☐ Don't know

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?

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?

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

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Population

Procedure	Answer questions by clicking on all active links below	Name	Status
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Population	Procedure	Answer questions by clicking on all active links below	Name	Status
	Cost Data	Component does not require review		Not Required
	COVID-19 Survey Items	6A Informed Consent	Project Rise Consent Form edited 2020-01-17tc.docx 1/17/2020	Consent Will Be Performed - Document Uploaded
	Electronic Adherence Assessment (MEMS)	6A Informed Consent	Project Rise Consent Form edited 2020-01-17tc.docx 1/17/2020 (duplicate)	Consent Will Be Performed - Document Uploaded
	Intervention	6A Informed Consent	Project Rise Consent Form edited 2020-01-17tc.docx 1/17/2020 (duplicate)	Consent Will Be Performed - Document Uploaded
People Living with HIV	Medical Records Assessment	6A Informed Consent	Project Rise Consent Form edited 2020-01-17tc.docx 1/17/2020 (duplicate)	Consent Will Be Performed - Document Uploaded
	Recruitment Discussion Groups	Component does not require review		Not Required
	Surveys	6A Informed Consent	Project Rise Consent Form edited 2020-01-17tc.docx 1/17/2020 (duplicate)	Consent Will Be Performed - Document Uploaded
	Viral Load Assessment	6A Informed Consent	Project Rise Consent Form edited 2020-01-17tc.docx 1/17/2020 (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		

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 discussion group (in which we are not collecting data), participants will be told that the purpose of the discussion groups is to have an open forum and discussion about their experiences living with HIV, taking treatment, and perspectives on medications; that the discussion group will last about 1.5-2 hours; that all the information being collected in the screener will be kept completely private and confidential and is only used to schedule the groups.

6A3 Informed Consent Material Upload

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

B. No - I am requesting a waiver of consent in its entirety (partial waiver of elements is requested later when selecting either option A or C)

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6A8 Future Contract After Research Ends

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)?

No

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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

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.

Note that, during the COVID-19 situation only, we are requesting verbal informed consent for the few scheduled participants (3-5) left who have not yet completed the baseline appointment. These participants will complete phone interviews rather than in person interviews and thus we will obtain verbal informed consent from them prior to the baseline interview. We will ask them to sign the consent form at a later date, when we are able to have in person assessments again.

Update April 29 2020: For the added COVID-19 questions, the overall consent form covers the general study procedures. We will ask for verbal consent prior to asking the specific COVID-19 items for the survey.

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.

[Project Rise Consent Form edited 2020-01-17tc.docx\(0.02\)](#)

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.

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Note that the consent form was revised on 10/16/17 to reflect changes suggested by the reviewer as well as community stakeholder (to simplify the text), and new timing of study procedures (i.e., baseline survey will be given 1 month earlier).

Note that the consent form was again revised on 3/29/19 to reflect additions to the procedures regarding texting participants appointment reminders.

Note that the consent form was revised on Jan 17, 2020 to reflect an additional incentive of \$30 for participants obtaining medical record data directly from their provider.

Note that we are requested verbal informed consent during the COVID-19 situation, when all assessments will be done by phone. We will ask them to sign the consent form at a later date, when we are able to have in person assessments again. (Please see above explanation.)

6A4 Elements Included

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

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

6A8 Future Contract After Research Ends

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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7A - Main Documents to Upload

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		7A2 Recruitment Material	Internet Recruitment Scriptrev 10 4 18.docx 10/4/2018	Uploaded
		7A2 Recruitment Material	2018-10-24 Rise Recruitment Screener Bogart 10 26 18.docx 11/26/2018	Uploaded
		7A2 Recruitment Material	Rise Flyer6.pdf 1/18/2018	Uploaded
		7A2 Recruitment Material	Rise Card1b.pdf 11/8/2017	Uploaded
		7A2 Recruitment Material	Internet Recruitment Script 9-25-17.docx 9/26/2017	Uploaded
		7A2 Recruitment Material	IRB Phone and in-person recruitment Script 2018-04-24 IRB Modifications KT.docx 4/25/2018	Uploaded
Cost Data		7A2 Recruitment Material	Phone and in-person recruitment Script 2018-10-04 IRB Modifications.docx 10/4/2018	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 10.25.17.docx 10/25/2017	Uploaded
		7A6 Miscellaneous Documents	R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx 11/30/2016	Uploaded
		7A6 Miscellaneous Documents	CMH Request to Rely on External IRB has been Approved 2:14:17.pdf 2/14/2017	Uploaded
		7A6 Miscellaneous Documents	Patient Instructions for use of cap 09-25-17.doc 9/26/2017	Uploaded
		7A6 Miscellaneous Documents	CMH RAND HIV Adherence IAA Goggin Feb^17.pdf 2/14/2017	Uploaded
COVID-19 Survey Items		7A1 Participant Questions	COVID-19 Rise Survey 4 28 20.docx 4/29/2020	Uploaded
		7A2 Recruitment Material	Rise Flyer6.pdf 1/18/2018 (duplicate)	Uploaded

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Population	Procedure	Upload documents by clicking on all active links below	View Uploaded Documents	Document Status
Electronic Adherence Assessment (MEMS)		7A2 Recruitment Material	Rise Card1b.pdf 11/8/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	COVID-19RecruitmentScript.docx 4/29/2020	Uploaded
		7A5 Data Safeguarding Plan (DSP)	DSPforRiserev6 17 20.docx 6/17/2020	Uploaded
		7A6 Miscellaneous Documents		<u>Not Yet Uploaded</u>
		7A1 Participant Questions	Cost effectiveness.xlsx 10/16/2017	Uploaded
		7A2 Recruitment Material	Internet Recruitment Scriptrev 10 4 18.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	2018-10-24 Rise Recruitment Screener Bogart 10 26 18.docx 11/26/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Flyer6.pdf 1/18/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Card1b.pdf 11/8/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Internet Recruitment Script 9-25-17.docx 9/26/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 2018-10-04 IRB Modifications.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 10.25.17.docx 10/25/2017 (duplicate)	Uploaded
		7A5 Data Safeguarding Plan (DSP)	DSPforRiserev6 17 20.docx 6/17/2020 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx 11/30/2016 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17 edited 2019-05-10 kvt.docx 5/13/2019	Uploaded
		7A6 Miscellaneous Documents	CMH Request to Rely on External IRB has been Approved 2:14:17.pdf 2/14/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Patient Instructions for use of cap 09-25-17.doc 9/26/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CMH RAND HIV Adherence IAA Goggin Feb^17.pdf 2/14/2017 (duplicate)	Uploaded

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Population	Procedure	Upload documents by clicking on all active links below	View Uploaded Documents	Document Status
Intervention	7A6 Miscellaneous Documents	CheckinvisitsandRandomizationform10-16-17.docx	10/16/2017	Uploaded
		HIPPA Form 09-25-17.docx	9/26/2017	Uploaded
		Project Rise Retention LetterOct2020.docx	10/6/2020	Uploaded
		Project Rise Consent Form edited 2019-05-10.docx	5/13/2019	Uploaded
	7A2 Recruitment Material	Internet Recruitment Scriptrev 10 4 18.docx	10/4/2018 (duplicate)	Uploaded
		2018-10-24 Rise Recruitment Screener Bogart 10 26 18.docx	11/26/2018 (duplicate)	Uploaded
		Rise Flyer6.pdf	1/18/2018 (duplicate)	Uploaded
		Rise Card1b.pdf	11/8/2017 (duplicate)	Uploaded
	7A2 Recruitment Material	Internet Recruitment Script 9-25-17.docx	9/26/2017 (duplicate)	Uploaded
		Phone and in-person recruitment Script 2018-10-04 IRB Modifications.docx	10/4/2018 (duplicate)	Uploaded
		Phone and in-person recruitment Script 10.25.17.docx	10/25/2017 (duplicate)	Uploaded
		DSMPforRisetc 3 20 18.docx	3/20/2018	Uploaded
	7A5 Data Safeguarding Plan (DSP)	DSPforRiserev6 17 20.docx	6/17/2020 (duplicate)	Uploaded
		R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx	11/30/2016 (duplicate)	Uploaded
		HIPPA Form 09-25-17 edited 2019-05-10 kvt.docx	5/13/2019 (duplicate)	Uploaded
		CMH FWA letter exp 01-2019 RM.pdf	1/20/2017	Uploaded
	7A6 Miscellaneous Documents	CMH Request to Rely on External IRB has been Approved 2:14:17.pdf	2/14/2017 (duplicate)	Uploaded
		Patient Instructions for use of cap 09-25-17.doc	9/26/2017 (duplicate)	Uploaded
		CMH RAND HIV Adherence IAA Goggin Feb^17.pdf	2/14/2017	Uploaded

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Population	Procedure	Upload documents by clicking on all active links below	View Uploaded Documents	Document Status
		(duplicate)		
Medical Records Assessment		7A6 Miscellaneous Documents	HIPPA Form 09-25-17.docx 9/26/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Rise2.0InterventionManual 9 26 17.docx 9/26/2017	Uploaded
		7A6 Miscellaneous Documents	Project Rise Consent Form edited 2019-05-10.docx 5/13/2019 (duplicate)	Uploaded
	Medical Records Assessment	7A2 Recruitment Material	Internet Recruitment Scriptrev 10 4 18.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	2018-10-24 Rise Recruitment Screener Bogart 10 26 18.docx 11/26/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Flyer6.pdf 1/18/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Card1b.pdf 11/8/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Internet Recruitment Script 9-25-17.docx 9/26/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 2018-10-04 IRB Modifications.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 10.25.17.docx 10/25/2017 (duplicate)	Uploaded
		7A5 Data Safeguarding Plan (DSP)	DSPforRiserev6 17 20.docx 6/17/2020 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx 11/30/2016 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17 edited 2019-05-10 kvt.docx 5/13/2019 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CMH Request to Rely on External IRB has been Approved 2:14:17.pdf 2/14/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Patient Instructions for use of cap 09-25-17.doc 9/26/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CMH RAND HIV Adherence IAA Goggin Feb^17.pdf 2/14/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CheckinvisitsandRandomizationform10-16-17.docx 10/16/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17.docx 9/26/2017 (duplicate)	Uploaded

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Population	Procedure	Upload documents by clicking on all active links below	View Uploaded Documents	Document Status
Recruitment Discussion Groups		7A6 Miscellaneous Documents	Project Rise Consent Form edited 2019-05-10.docx 5/13/2019 (duplicate)	Uploaded
		7A2 Recruitment Material	2018-11-19 RISE Discussion Group Flyer.docx 11/28/2018	Uploaded
		7A6 Miscellaneous Documents	2018-11-27 Project Rise Focus Group Recruitment and Contact Form v2 KVT.docx 11/28/2018	Uploaded
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17 edited 2019-05-10 kvt.docx 5/13/2019 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Project Rise Consent Form edited 2019-05-10.docx 5/13/2019 (duplicate)	Uploaded
Surveys		7A1 Participant Questions	Pre-enrollment and baseline 10-09-2017.docx 10/16/2017	Uploaded
		7A1 Participant Questions	Pre-enrollment assessment 9 25 17Imb Submitted to HSPC.docx 9/26/2017	Uploaded
		7A1 Participant Questions	Participant Tracking and Locator Form 09-25-17.docx 9/26/2017	Uploaded
		7A1 Participant Questions	Rise 10 13 17 Follow-up.docx 10/16/2017	Uploaded
		7A2 Recruitment Material	Internet Recruitment Scriptrev 10 4 18.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	2018-10-24 Rise Recruitment Screener Bogart 10 26 18.docx 11/26/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Flyer6.pdf 1/18/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Card1b.pdf 11/8/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Internet Recruitment Script 9-25-17.docx 9/26/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 2018-10-04 IRB Modifications.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 10.25.17.docx 10/25/2017 (duplicate)	Uploaded
		7A5 Data Safeguarding Plan (DSP)	DSPforRiserev6 17 20.docx 6/17/2020 (duplicate)	Uploaded
		7A6 Miscellaneous	R01Rise 9 1 16 310pmFINAL	Uploaded

ID: 2016-0940

Population	Procedure	Upload documents by clicking on all active links below	View Uploaded Documents	Document Status
		Documents	UPDATEDFORHSPC.docx 11/30/2016 (duplicate)	
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17 edited 2019-05-10 kvt.docx 5/13/2019 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CMH Request to Rely on External IRB has been Approved 2:14:17.pdf 2/14/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Patient Instructions for use of cap 09-25-17.doc 9/26/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CMH RAND HIV Adherence IAA Goggin Feb^17.pdf 2/14/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CheckinvisitsandRandomizationform10-16-17.docx 10/16/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17.docx 9/26/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Project Rise Retention LetterOct2020.docx 10/6/2020 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Project Rise Consent Form edited 2019-05-10.docx 5/13/2019 (duplicate)	Uploaded
	Viral Load Assessment	7A2 Recruitment Material	Internet Recruitment Scriptrev 10 4 18.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	2018-10-24 Rise Recruitment Screener Bogart 10 26 18.docx 11/26/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Flyer6.pdf 1/18/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Rise Card1b.pdf 11/8/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Internet Recruitment Script 9-25-17.docx 9/26/2017 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 2018-10-04 IRB Modifications.docx 10/4/2018 (duplicate)	Uploaded
		7A2 Recruitment Material	Phone and in-person recruitment Script 10.25.17.docx 10/25/2017 (duplicate)	Uploaded
		7A3 Data and Safety Monitoring Plan (DSMP)	DSMPforRisetc 3 20 18.docx 3/20/2018 (duplicate)	Uploaded
		7A5 Data Safeguarding Plan (DSP)	DSPforRiserev6 17 20.docx 6/17/2020 (duplicate)	Uploaded
		7A6 Miscellaneous	QuestlettertoRAND - Sep 20.	Uploaded

ID: 2016-0940

Population	Procedure	Upload documents by clicking on all active links below	View Uploaded Documents	Document Status
		Documents	2019.pdf 9/24/2019	
		7A6 Miscellaneous Documents	R01Rise 9 1 16 310pmFINAL UPDATEDFORHSPC.docx 11/30/2016 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17 edited 2019-05-10 kvt.docx 5/13/2019 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CMH Request to Rely on External IRB has been Approved 2:14:17.pdf 2/14/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Patient Instructions for use of cap 09-25-17.doc 9/26/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	CMH RAND HIV Adherence IAA Goggin Feb^17.pdf 2/14/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	HIPPA Form 09-25-17.docx 9/26/2017 (duplicate)	Uploaded
		7A6 Miscellaneous Documents	Project Rise Consent Form edited 2019-05-10.docx 5/13/2019 (duplicate)	Uploaded

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		

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

ID: 2016-0940

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.[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		

7AX.2a ** Please upload the document.[2018-11-26 Project Rise Focus Group Discussion Guidelmb.docx\(0.01\)](#) | [History](#)**7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.**[Discussion Guide Questions](#)

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
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ID: 2016-0940

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

7AX.2a **** Please upload the document.**
[Pre-enrollment assessment 9 25 17mb 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

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		

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		

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.

ID: 2016-0940

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		

7AX.2a ** Please upload the document.
[COVID-19_Rise_Survey 4 28 20.docx\(0.01\)](#) | [History](#)

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

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		

7AX.2a ** Please upload the document.
[Internet Recruitment Scriptrev 10 4 18.docx\(0.01\)](#) | [History](#)

7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.
[Revised internet recruitment script to include instructions to click on a link to be screened.](#)

7A2 Recruitment Material

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

ID: 2016-0940

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

7AX.2a **** Please upload the document.**
[2018-10-24 Rise Recruitment Screener_Bogart_10 26 18.docx\(0.01\)](#) | [History](#)

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

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		

7AX.2a **** Please upload the document.**
[Rise Flyer6.pdf\(0.01\)](#) | [History](#)

7AX.3a **Please enter any comments that you wish to share with the reviewer regarding this document.**
[Revised flyer with APLA email address](#)

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		

7AX.2a **** Please upload the document.**
[Rise Card1b.pdf\(0.01\)](#) | [History](#)

7AX.3a **Please enter any comments that you wish to share with the reviewer regarding this document.**
[Updated flyer text and layout, with pictures](#)

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		

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.

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		

7AX.2a ** Please upload the document.

[2018-11-19 RISE Discussion Group Flyer.docx\(0.01\)](#) | [History](#)

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

[Recruitment Flyer](#)

7A2 Recruitment Material

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

ID: 2016-0940

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

7AX.2a **** Please upload the document.**
[IRB Phone and in-person recruitment Script 2018-04-24 IRB Modifications KT.docx\(0.01\)](#) | [History](#)

7AX.3a **Please enter any comments that you wish to share with the reviewer regarding this document.**
Revised recruitment script with added ineligibility criterion in track changes

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		

7AX.2a **** Please upload the document.**
[Phone and in-person recruitment Script 2018-10-04 IRB Modifications.docx\(0.01\)](#) | [History](#)

7AX.3a **Please enter any comments that you wish to share with the reviewer regarding this document.**
New screener that includes extra question for people who are recruited online (with an inclusion criterion of living in LA County or being willing to do in-person study assessments in LA County)

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		

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.**

ID: 2016-0940

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		

7AX.2a ** Please upload the document.
[COVID-19RecruitmentScript.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		

7AX.2a ** Please upload the document.
[DSMPforRisetc_3 20 18.docx\(0.01\)](#) | [History](#)

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

Submitting a revised DSMP, base don our recent reportable event:

- Added to protocol around study staff handling of reportable events, to state that study staff will add any relevant text to participant tracking form, so that all staff are aware of any necessary protocols specific to the participant (this was suggested by our independent data and safety monitor)
- Added an additional staff member at APLA to whom incidents involving clients would be reported, who could help to further protect the client as needed (APLA's Director of HIV Access and Community-Based Services and the site PI's supervisor)
- Deleted extraneous text at the end that duplicated text in the DSP

Note that the revised DSMP was approved by the study's independent data and safety monitor.

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		

7AX.2a ** Please upload the document.
[DSPforRiserev6 17 20.docx\(0.01\)](#) | [History](#)

7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.
[Revised DSP for transfer of HIV viral load photos via WhatsApp](#)

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.

ID: 2016-0940

[QuestlettertoRAND - Sep 20, 2019.pdf\(0.01\)](#) | [History](#)

- 7AX.3a** Please enter any comments that you wish to share with the reviewer regarding this document.
Final letter from Quest resolving inappropriate sharing of participant data from Quest to LA County Dept of Public Health

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.
[2018-11-27 Project Rise Focus Group Recruitment and Contact Form v2 KVT.docx\(0.01\)](#) | [History](#)

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

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.
[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

ID: 2016-0940

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.

[HIPPA Form 09-25-17 edited 2019-05-10 kvt.docx\(0.01\)](#) | [History](#)

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

Revised HIPAA form - only change is that APLA is not called "APLA Health & Wellness"

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

ID: 2016-0940

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

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.**
[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		

7AX.2a **** Please upload the document.**
[CMH_RANDOM_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

ID: 2016-0940

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.

[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)

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

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.

ID: 2016-0940

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
<hr/> People Living with HIV		

7AX.2a ** Please upload the document.
[Project Rise Retention LetterOct2020.docx\(0.01\)](#) | [History](#)

7AX.3a Please enter any comments that you wish to share with the reviewer regarding this document.
We have approval to send a letter to participants' home (if they consent to being contacted via mail). This is a draft of the letter that we will send.

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
<hr/> People Living with HIV		

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
<hr/> People Living with HIV		

ID: 2016-0940

7AX.2a **** Please upload the document.**[Project Rise Consent Form edited 2019-05-10.docx\(0.01\)](#) | [History](#)**7AX.3a** **Please enter any comments that you wish to share with the reviewer regarding this document.**

Revised consent form - only change is that APLA is not called "APLA Health & Wellness"

ID: 2016-0940

8A Conclusion

8A1 Other Ethical Issues

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