Version 1.0
December 23, 2025

Title

Pilot Testing a Behavioral Intervention to Incorporate Advances in HIV Prevention for Black Young MSM in Alabama

Sponsored by

The National Institute of Mental Health

Protocol Chair

Henna Budhwani, PhD, MPH

ATTESTATION

I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

PRINCIPAL INVESTIGATOR

Henna Budhwani, PhD, MPH
Endowed Professor, College of Nursing
Florida State University (FSU)
Institute on Digital Health and Innovation
Innovation Park
Research Building B
2010 Levy Ave, RM B3400
Tallahassee, FL 32310
Email: hbudhwani@fsu.edu

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

AIDS: Acquired Immunodeficiency Syndrome
HIV: Human Immunodeficiency Virus

ABSTRACT

The overall goal of this 5-year Mentored Research Scientist Development K01-Award is to support Henna Budhwani, PhD, MPH become an independent investigator in the field of HIV prevention. The proposed project seeks to address the HIV crisis in Alabama, where rates of undiagnosed HIV in Black young men who have sex with men (18-29 years) exceed 20%. This project will adapt and test a behavioral intervention to promote HIV rapid testing in the community, deliver culturally appropriate prevention education, offer sociostructural supports, and refer eligible participants for pre-exposure prophylaxis. The proposed research study is to conduct a hybrid type 1 effectiveness-implementation pilot study of the adapted intervention in which the candidate will assess acceptability and feasibility of Kings (the adapted intervention). This rigorous project includes intensive training at the candidate's home university and from other prominent institutions; engagement within the Adolescent Medicine Trials Network for HIV/AIDS Interventions; comprehensive mentoring from senior HIV researchers with expertise in minority, youth, and men who have sex with men health; and a thoughtful research strategy that addresses significant threats, high rates of undiagnosed HIV and insufficient engagement with HIV prevention services, including pre-exposure prophylaxis, in Black young men who have sex with men in Alabama.

PROTOCOL

The purpose of this study is to adapt and test Brothers Saving Brothers, a brief two-part intervention that has been shown to increase rates of HIV testing and acceptance of prevention education in Midwest Black young men who have sex with men but has not been adapted for the South. This will be accomplished by updating it for rapid testing, pre-exposure prophylaxis education, and to include structural supports. We will pilot-test the adapted intervention to estimate intervention effects.

Community Based Organization staff will facilitate the enrollment process. Potential participants will directly enter data into a virtual screener via Qualtrics. Data will be directly uploaded and stored on a secure, encrypted server. Inclusion criteria include age, identifying as Black, English speaking, resident of Alabama, being sexually active with men, identifying as male, and has not taken an HIV test in the prior 6 months. If eligible, the participant will be asked to provide informed consent. Informed consent will include the request to access medical records related to HIV re-testing and pre-exposure prophylaxis. Limited data on rates of pre-exposure prophylaxis exist, but since this study is with high-risk for HIV young men who have sex with men, we anticipate most participants will be eligible for pre-exposure prophylaxis per guidelines. After informed consent is collected, pre-study survey data will be self-reported. The system will then randomize participants to Kings or the standard control condition in a 2:1 allocation. Participants will be followed by 6-months post-enrollment.

DURATION

This protocol will last about three years; each participant will be enrolled for six months after their enrollment.

SAMPLE SIZE

The original target sample size was N=60; however, this study ultimately enrolled N=59.

INCLUSION OR POPULATION

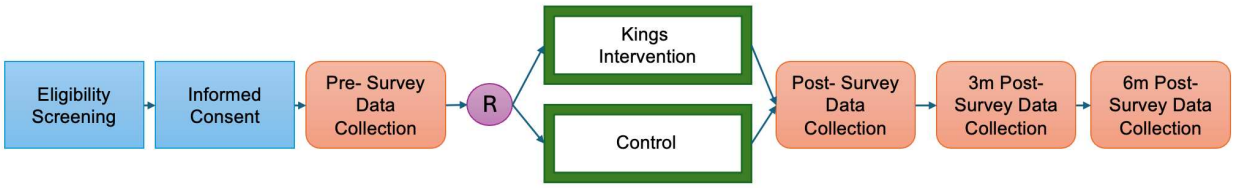
Age 18-29 years at the time of enrollment, identifying as Black, English speaking, resident of Alabama, sexually active with men, identifying as having sex = male, and has not taken an HIV test in the prior 6 months.

DATA COLLECTION

All data collection will occur via secure digital link to online surveys that will be linked by unique, anonymized participant identification numbers. Data collection, via this process will occur in the (1) screener, (2) pre-randomization, pre-intervention or control data collection, (3) post- data

collection, (4) 3 months post-data collection, and (5) 6 months post data collection, Please see the trial's schema below.

SCHEMA, RANDOMIZED CONTROLLED PILOT TRIAL



STATISTICAL POWER

As a pilot study, this project is not statistically powered.

STATISTICAL ANALYSIS PLAN

Descriptive statistics will be used to identify the characteristics of the sample. Baseline differences between the intervention group and control group will be examined using student's t tests (for continuous variables) or chi-square tests (for categorical variables). Second, the feasibility / acceptability / satisfaction will be evaluation through multiple indicators, with focus on the simple question, "I like this app."

Preliminary efficacy of the intervention will be assessed using both bivariate statistics (e.g., t test, chi-square test, and fisher exact test) and multivariate statistics adjusting for demographic factors and baseline differences. To examine the preliminary effect of the intervention, we compared changes over time in HIV knowledge, pre-exposure prophylaxis knowledge, internalized homophobia, everyday discrimination, and medical mistrust within each group, as well as the increase from baseline to 6-month between the two groups. We also will assess the differences in willingness to take HIV test, self-reported HIV testing rates, and interest in learning more about pre-exposure prophylaxis and pre-exposure prophylaxis consultation with prescription between the two groups using Chi-square and Fisher's exact test. The effect of the intervention will be further examined using a generalized estimating equation controlling for potential confounders including education, income and social support. All statistical analyses will be performed using the SAS 9.4 statistical software package.

UAB SCHOOL OF PUBLIC HEALTH

Institutional Review Board
Protocol Oversight Review Form

Date Submitted to IRB: **August 15, 2018**

Title of Project: **Adapting and Pilot Testing a Behavioral Intervention to Incorporate Advances in HIV Prevention for Black Young MSM in Alabama**

Name of Principal Investigator: **Henna Budhwani**

Signature of Principal Investigator: Hbudhwani

School: **Public Health**
Department: **Health Care Organization and Policy**
Division: **NA**

Review Process (as determined by Department Chair):

- ☒ Departmental Review
- ☐ Divisional Review (Division Director or Designate)
- ☐ Center or Departmental Protocol Review Committee Review
- ☐ Project Review Panel (PRP)—Appointed by the Department Chairman or Division Director (PRP report attached)

I have reviewed the proposed research and concluded that the following apply:

- The research is scientifically valid and is likely to answer the scientific question;
- The researcher and the study team are qualified and/or credentialed to conduct the procedures proposed;
- The researcher has identified sufficient resources in terms of experienced research personnel, facilities, and availability of medical or psychological services that may be necessary as a consequence of participation in the research to protect the research participants.

Name of Official: **Martha Wingate, DrPH** Title: **Interim Chair**

Signature: Martha S Wingate Date: 8/16/18

Health Care Organization & Policy
330 Ryals Public Health Building
1665 University Boulevard
205.934.3748
Fax 205.934.3347

The University of Alabama at Birmingham
Mailing Address:
RPHB 330
1530 3RD AVE S
BIRMINGHAM AL 35294-0022

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 |
irb@uab.edu

APPROVAL LETTER

TO: Budhwani, Henna M.

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 12-Oct-2018

RE: IRB-300002136
Adapting and Pilot Testing a Behavioral Intervention to Incorporate Advances in HIV Prevention for Black Young MSM in Alabama

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The IRB reviewed and approved the Initial Application submitted on 10-Oct-2018 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Expedited
Expedited Categories:	7
Determination:	Approved
Approval Date:	12-Oct-2018
Approval Period:	One Year
Expiration Date:	11-Oct-2019

The following apply to this project related to informed consent and/or assent:

- Waiver of 24 Hour Waiting Period
- Waiver of Consent Documentation

Documents Included in Review:

- hsp.clean.181010.
- waiverdocumentation.180824
- consent.youth.181004
- interview.180822
- consent.staff.181004
- focusgroup.180822

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
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APPROVAL LETTER

TO: Budhwani, Henna M.

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 30-Jan-2019

RE: IRB-300002136
Progressing to the 90-90-90 Goals in the Deep South by Pilot Testing a Behavioral HIV Prevention Intervention for Young Black MSM in Rural and Urban Alabama

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The IRB reviewed and approved the Revision/Amendment submitted on 28-Jan-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Expedited
Expedited Categories:	7
Determination:	Approved
Approval Date:	30-Jan-2019
Expiration Date:	11-Oct-2019

The following apply to this project related to informed consent and/or assent:

- Waiver of 24 Hour Waiting Period
- Waiver of Consent Documentation

Please note: OSP number has been updated to 000521819.

Documents Included in Review:

- praf.190128.doc

Human Subjects Protocol (HSP)

Form Version: February 1, 2017

- You are applying for IRB review of the research described in this form.
- To avoid delay, respond to all items in order and include all required approvals and documents. For more tips, see the UAB IRB website.
- To complete the form, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck.
- All responses should be Times New Roman, Bold, and Underlined.
- Submit all materials to AB 470, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review you are applying for:

☐ Convened (Full) IRB ***-OR-***

☐ Expedited - See the Expedited Category Review Sheet, and indicate the category(ies) here:

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☒7

1. IRB Protocol Title: Adapting and Pilot Testing a Behavioral Intervention to Incorporate Advances in HIV Prevention for Black Young MSM in Alabama

2. Investigator and Contact Person

a. Name of Principal Investigator: **Henna Budhwani**

Degree(s)/Title: **PhD, MPH** BlazerID: **bhenna**

Dept/Div: **Health Care Organization and Policy**

Mailing Address: **RPHB 330C** UAB ZIP: **35294**

Phone: **2059757613** Fax: _____ E-mail: **budhwani@uab.edu**

b. Name of Contact Person: **Same** Title: _____ Phone: _____

E-mail: _____ Fax: _____

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and all key personnel comply with reporting requirements of the UAB Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed on the protocol have completed initial IRB training and will complete continuing IRB training as required;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;
- Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;
- Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: _____ **Date: 10/10/2018**

3. Protocol Personnel

Including the PI, list all key personnel (each individual involved in the design and conduct of this protocol). See the Key Personnel Flowchart.

Complete the UAB (3.a.) and non-UAB (3.b) tables, as applicable. Use the checkboxes to show each individual's role, whether the individual has financial interests as defined by the UAB CIRB, and briefly describe the individual's protocol responsibilities and qualifications to perform those responsibilities. **Insert additional rows as needed.**

FDA: For studies involving investigational drugs, list all investigators who will be listed on FDA Form 1572 and include a copy of the 1572. Send the IRB a copy of Form 1572 any time you update the form with the FDA.

a. UAB Personnel (includes UAB affiliates and Children's of Alabama personnel)

Name, Degree, and Dept.	Blazer ID	Role	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: **Henna Budhwani** Degree: **PhD, MPH** Department: **Public Health**	**bhenna**	Principal Investigator	☒No ☐Yes	**K01 Candidate; will obtain consent.**

b. Non-UAB Personnel Relying on UAB IRB - If you are requesting that the UAB IRB serve as the IRB of record for anyone not affiliated with UAB, list these individuals below.

Name and Degree	From Institution with or without own IRB?	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: Degree: Institution: Email:	☐Has own IRB but requests that UAB IRB serve as IRB of record?-***OR***- ☐Does not have own IRB and needs to rely on UAB IRB.	☐No ☐Yes	
Name: Degree: Institution: Email:	☐Has own IRB but requests that UAB IRB serve as IRB of record?-***OR***- ☐Does not have own IRB and needs to rely on UAB IRB.	☐No ☐Yes	

***Financial Interest** – for each individual listed above, answer **Yes** or **No** as to whether the individual or an immediate family member has any of the following:

- An ownership interest, stock options, or other equity interest related to the investigator's institutional responsibilities of any value.
- Compensation greater than $5,000 in the previous two years when aggregated for the immediate family
- Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship, regardless of compensation.
- Any other Financial Interest as defined by the UAB CIRB.

UAB Personnel: If the individual or his/her spouse or dependent child has a Financial Interest, a disclosure has to be made to the UAB CIRB. A completed CIRB evaluation has to be available before the IRB can complete its review.

Non-UAB Personnel: If the individual has a Financial Interest, ***include a copy of the report from his/her own institution's conflict of interest review with this submission to the UAB IRB.***

c. Do the investigators listed above include any students using this research for their thesis or dissertation?

☒ No, continue with Item 3.d.
☐ Yes, complete the following

Student Name	Thesis/Dissertation Title

d. Is the principal investigator a student, fellow, or resident? ☐Yes ☒No

If Yes, complete items below and obtain signature of faculty advisor or supervisor:

Supervisor's Name: _____
Degree(s) / Job Title: _____
Additional Qualifications pertinent to the protocol: _____

Telephone: _____
E-Mail: _____
Signature: _____

e. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol: **This IRB request is related to an NIMH funded K01-application (career development mentored scientist award) that will cover 77.5% of the PI's (Dr. Budhwani's) professional effort and time. As a K01, Dr. Budhwani will first participate in a series of trainings funded from this award, then she will apply her learning to conduct a hybrid type 1 effectiveness-implementation randomized control trial of the adapter intervention.**

f. Is medical supervision required for this research? ☐Yes ☒No

If Yes, who will provide the medical supervision?

☐ PI will provide ***-OR-***

☐ Other:

Name: _____ Telephone: _____

If other than PI, obtain signature of person providing medical supervision:

Signature _____

g. Describe your process for ensuring all key personnel are adequately informed about the protocol and their research-related duties and functions: **As part of the K01-commitment, the PI will be required to provide bi-weekly updates related to this application to all the key personnel. Additionally, those identified as mentors will participate on a monthly Skype call with me to discuss the progress on the goals defined in this K01-applicationl only mentors and the PI will attend these Skype calls – study participants will not be involved. Mentors are senior researchers at the rank of full Professor or Distinguished Professor. All mentors are current in the Human Subjects training, as required by the National Institutes of Health. Mentors will not have any direct engagement with study participants.**

4. Funding

Is this protocol funded? ☒Yes ☐No

If No, specify that costs of the protocol will be covered by funds from the UAB department or other source named: _____

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.

a. Title of Grant, Contract, or Agreement: **Adapting and Pilot Testing a Behavioral Intervention to Incorporate Advances in HIV Prevention for Black Young MSM in Alabama**

b. UAB PI of Grant, Contract, or Agreement: **Henna Budhwani**

c. Office of Sponsored Programs (OSP) Assigned Number: **OSP #520558**
(If not yet available, enter "Pending" and provide upon receipt from OSP.)

d. Sponsor, Funding Route:
(Check and describe all that apply)
(If subaward, list both the funding source and the institution receiving the direct award)

☒ Gov't Agency or Agencies—Agency name(s): National Institute of Mental Health (**NIMH)**
- ☐ Department of Defense (DoD): Identify DoD component: _____
- ☐ Department of Energy (DOE)
- ☐ Department of Justice (DOJ)
- ☐ Department of Education

☐ NIH Cooperative Group Trial - Group name: _____
☐ Private Nonprofit (e.g., Foundation) - Name: _____
☐ Industry, investigator-initiated - Name: _____

Describe the funding arrangement: _____

NOTE: The UAB IRB typically only reviews industry-sponsored protocols that are investigator initiated or when the protocol qualifies for expedited review or involves gene therapy.

☐ UAB Departmental/Division Funds—Specify: _____

5. Locations Involved

a. Indicate all performance sites that will provide space, services, or facilities for the conduct of this protocol.

☐ UAB Hospital
☐ UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital
☐ The Kirklin Clinic at Acton Road
☐ UAB Callahan Eye Hospital
☐ UAB Clinical Research Unit
☐ Children's of Alabama
☐ Birmingham Veterans Affairs Medical Center
☐ Jefferson County Department of Health
☒ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol) - Describe: **University of Alabama at Birmingham (UAB) School of Public Health, Birmingham AIDS Outreach (BAO), and Selma AIR (staff will be recruited for Aim 3; PRAF will be submitted).**

NOTE: Documentation of IRB approvals from sites receiving subawards must be received by the UAB OIRB before funding will be released for that subaward.

b. Describe the space, service, or facilities available for the conduct of the research in the performance sites listed in Item 5.a (For research on UAB campus, include building names): **Both organizations have office meeting rooms and private rooms to conduct qualitative data collection.**

c. Is this protocol a clinical trial requiring clinical services at one of the performance sites listed in Item 5.a above? ☐Yes ☒No

If Yes, will any of the services be billed to either participants/their insurance or to the study account through the Hospital Billing Office (PFS) or the HSF Billing Office (MSO)? ☐Yes ☐No

If Yes, submit a Full Fiscal Approval Process (FAP)-designated unit submission to s complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP requirements, go to FAP - SiteMinder Processes.

d. Is this a field study? ☐Yes ☒No

If Yes, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors:

e. Has this protocol been rejected or disapproved by another review board (another IRB, similar review board, or departmental review committee(s)) that authorizes the use of its patient populations? ☐Yes ☒No

If Yes, provide name(s) of the review board(s) and reason(s) not approved: _____

Attach copies of the disapprovals.

NOTE: If this protocol is subsequently rejected or disapproved by another review board, promptly notify UAB IRB.

f. Will the protocol be conducted at or recruit participants from the Birmingham Veterans Affairs Medical Center (BVAMC)? ☐Yes ☒No

If Yes, describe the involvement of the BVAMC: _____

Attach the VA IRB approval and VA IRB-stamped consent form(s), if applicable.
NOTE: See the BVAMC section of the IRB Guidebook for more information.

g. Will the protocol be conducted at or recruit participants from the Jefferson County Department of Health (JCDH)? ☐Yes ☒No
If Yes, describe the involvement of the JCDH and list the JCDH clinics being used: _____
Attach the JCDH Research Review Panel approval, if applicable.
NOTE: Human subjects research conducted at certain JCDH clinics requires review by the JCDH Research Review Panel. See the JCDH section of the IRB Guidebook for more information.

6. Clinical Trial

Does this protocol meet the following definition of a clinical trial? ☒Yes ☐No
**A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information, see the full definition of clinical trial here.*
If Yes, you will need to fulfill the following requirements (regardless of funding):

a. All key personnel must complete the Good Clinical Practices (GCP) training. For information on this requirement, visit the IRB website here.

b. This protocol must be registered on ClinicalTrials.gov. Provide the National Clinical Trial (NCT) identifier number: **NCT03680729**
If you have any questions regarding registering a study on ClinicalTrials.gov, email the UAB Center for Clinical and Translational Science at ccts@uab.edu.

7. Multi-Site Studies

a. Is this a multi-site study with the UAB investigator as the lead investigator? ☐Yes ☒No

b. Is this a multi-site study with UAB as a coordinating site? ☐Yes ☒No

c. If Yes to a or b, describe the management of information obtained in multi-site research that might be relevant to the protection of participants. Include, at a minimum, how the following items are managed:
- IRB approvals from other sites
- Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)
- Interim results
- Protocol modifications

_____

8. Drugs

Will any drugs or supplements be *used or studied* in this protocol? ☐Yes ☒No
If Yes, attach the completed Drug Review Sheet.

9. Devices

a. Will any devices be *studied* in this protocol? ☐Yes ☒No

b. Will any *not FDA-approved* devices be *used or studied* in this protocol? ☐Yes ☒No
If Yes to a or b, attach the completed Device Review Sheet.

10. Special Approvals

a. Does this protocol involve the use of radioisotopes? ☐Yes ☒No
If Yes, attach documentation of approval from the Radiation Safety Division.

b. Does this protocol include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? ☐Yes ☒No
If Yes, attach documentation of approval from the Infection Control Committee of the appropriate facilities.

c. Does this protocol involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).

d. Does this protocol require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).

e. Does this protocol use stored (existing) specimens from a repository? ☐Yes ☒No
If Yes, attach documentation of approval for use of specimens, and describe how existing specimens are labeled: _____

11. Use of Specimens

Does this protocol involve the collection of specimens? ☐Yes ☒No
If Yes, complete 11.a-11.h.
If No, skip to Item 12.

a. How will specimens be obtained, processed, distributed, and stored? _____

b. How will specimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)? _____

c. How will clinical data associated with the specimens be collected and stored? _____

d. What participant-identifying information will be collected and linked to the specimens? _____

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens). _____

f. Is genetic testing planned as part of this protocol? ☐Yes ☐No
If Yes, describe the planned genetic testing here. _____

g. Will specimens be stored for future use? ☐Yes ☐No
If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases. _____

h. Will specimens be shared with other investigators in the future? ☐Yes ☐No
If Yes, answer i. and ii.
i. What identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? _____
ii. Outline your procedure for assuring IRB approval for release and use prior to release of specimens.

_____

NOTE: Investigators who receive and/or use these specimens must document approval from the appropriate IRB(s) before the specimens may be released.

12. Gene Therapy

Does this protocol involve gene therapy or administering recombinant materials to humans? ☐Yes ☒No

If Yes, submit the Gene Therapy Project Review Panel Report ***-OR-*** the Protocol Oversight Review Form For Clinical Vaccine Trials, as applicable.

13. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)? ☒Yes ☐No

If Yes, complete Items 13.a-13.f.

If No, skip to 14.

a. Will the data/information be stored or managed electronically (on a computer)? ☒Yes ☐No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)? ☐Yes ☒No

If Yes, attach copies of the privacy notices from each institution/entity, and provide the name of each institution/entity: _____

c. Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.

☐ UAB Hospital or UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
☐ UAB Callahan Eye Hospital
☐ Children's of Alabama
☐ Jefferson County Department of Health
☐ School of Dentistry
☐ School of Health Professions
☐ School of Medicine
☐ School of Nursing
☐ School of Optometry
☐ University of Alabama Health Services Foundation
☐ UAB Health Centers
☐ Viva Health
☐ Ophthalmology Services Foundation
☐ Valley Foundation
☐ Medical West - UAB Health System Affiliate
☐ None - **If None, skip to Item 14.**

d. Indicate any information systems that will be the sources of information used for the protocol.

☐ A system maintained centrally by UAB Health System (these include the following: HealthQuest for registration, billing, and patient administration; PowerInsight (clinical data warehouse); Cerner IMPACT for PowerNotes for meds, Lab, Radiology, UED, Surgery

NOTE: If a researcher needs information in a specified format or a specified time, the researcher must confirm with the unit who can supply the information/service that the request can be met before writing the information/service into the research protocol. In addition, the researcher must be aware that these services may have a cost attached that should be considered in the research budget.

To request access to clinical systems for research purposes, visit https://www.oneuabmedicine.org/web/hsis/technical-support, click "Accounts Request" and complete the form indicating access for research purposed.

☐ Another system on a UAB server - Describe: _____

e. Indicate which of the listed identifiers will be accessed, associated and/or linked with the protected health information (PHI) used for this protocol.

☒ Names
☒ Geographic subdivisions smaller than a state
☒ Elements of dates (except year) related to an individual
☒ Telephone numbers
☐ Fax numbers
☒ Email addresses
☐ Social security numbers
☐ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers
☐ Device identifiers and serial numbers
☐ Biometric identifiers
☐ Web universal resource locators (URLs)
☐ Internet protocol address numbers
☐ Full-face photographic images
☐ Any other unique identifying number - Describe: _____
NOTE: Codes are not identifying as long as the researcher cannot link the data to an individual
☐ None - **If None, skip to Item 14.**

f. Choose one plan to describe your use of the personal health information:

☐ The data collected meet the specifications for a "limited data set" (LDS)
-If the LDS will leave the covered entity or will be received from another covered entity you will need a Data Use Agreement

☒ Research staff will obtain authorization from each participant to use the information
-Include the HIPAA Authorization form, complete except for participant name and IRB protocol number, as the final page of the consent form

☐ PI requests waiver of authorization to use the information
-Attach Waiver of Authorization and Informed Consent form

PROPOSED RESEARCH

- The IRB will not accept grant applications and/or sponsor's protocols in lieu of the items as outlined below.
- Do not separate responses from items. Instead, insert your response to each item below the item, keeping the information in the order of this form.

14. Purpose - in nontechnical, lay language

a. Summarize the purpose and objectives of this protocol in one short paragraph. **The purpose of this study is to adapt and test Brothers Saving Brothers (BSB), a brief two-part intervention that has been shown to increase rates of HIV testing and acceptance of prevention education in Midwest black YMSM, but has not been adapted for the South. IThis will be accomplished by updating it for rapid testing, PrEP education, and to include structural supports. I will pilot-test the adapted intervention to estimate intervention effects and document implementation contexts.**

b. Describe how outcomes will be measured for this protocol. **Community Based Organization (CBO) staff will facilitate the enrollment process. Potential participants will directly enter data into an iPad screener (via the iSurvey platform). For more information of the iSurvey platform, please visit https://www.harvestyourdata.com/. Data will be directly uploaded and stored on a secure, encrypted UAB server, that will be established through UAB Central IT with the assistance of the UAB School of Public Health IT team. The device will determine eligibility. Inclusion criteria include age, identifying as Black, English speaking, resident of AL, being sexually active with men, identifying as male (will include YTGW and those transitioning depending on Aim 1 results), and has not taken an HIV test in the prior 6-months. If eligible, the participant will be asked to provide informed consent. Informed consent will be written and require a physical signature. Informed consent will include the request to access medical records related to HIV re-testing and PrEP uptake. Limited data on rates of PrEP eligibility exist, but since this study is with high-risk for HIV YMSM, we anticipate most participants will be eligible for PrEP per guidelines. After informed consent is collected, pre-study survey data (see Table with tentative variables below; a full survey will be included via amendment in 2020, about 1 year before I begin to collect data from study participants)will be self-reported (the participant will enter his own responses on the device further ensuring confidentially) on the same device. The system will then randomize participants to aBSB (N=30) or control (N=30). Block randomization will ensure a balance across intervention and control groups. Data collection will occur for 18 months: 12-months of recruitment followed by 6-months of follow-up.**

Table 1: Study measures to be collected from participants

Construct	Measures	# Items	Collection Times
Prescreening	Age, gender, sex, race, orientation, English speaking, sexually active, prior HIV testing[32,114]	9	Pre-screening
Contamination	Familiarity with aBSB in social network and components experienced by the participant[126,127]	3	Pre, 3-, and 6-
Prevention Knowledge	Subset of HIV Knowledge Questionnaire (HIV-K-Q)[121] and PrEP knowledge in YMSM[122]	11	Pre-, post-, and 6-
Culture	Internalized Homophobia Scale Revised (IHP-R)[123], Sub-scale, Perceived Racism Scale (PRS),[124] Sub-scale, Medical Outcomes Study Social Support Survey (MOS)[125]	29	Pre-, post-, 3- and 6-

15. Background - in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the design of this protocol. Include any relevant past or current research by the PI. For drug and device studies, summarize the previous results (i.e., Phase I/II or III studies). **Because this is a K01-pilot study, no preliminary data is available other than the original intervention protocol which was conducted by an unrelated investigator in Detroit, Michigan.**

16. Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB (if other sites relying on UAB IRB, list the number for each site)? **100 (70 black YMSM and 30 CBO staff)**

If multi-site study, total number at all sites/institutions: _____

b. Describe the characteristics of anticipated or planned participants (if multiple groups, repeat list for each group).

Sex: **Male and maybe female**

Race/Ethnicity: **Black for YMSM; any race for staff members**

Age: **18-29 for YMSM; 18 and older for staff members**

Health status: **Preferred health status is "healthy"**

c. From what population(s) will the participants be derived? **African American youth in Alabama and staff members engaged in HIV prevention services at community based organizations (CBOs)**

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants: **Both community-based organization partners have a longstanding track record of being able to successfully recruit these participants.**

d. Describe the inclusion/exclusion criteria:

Inclusion Criteria for Staff:

- **Minimally 18 years and 0 months of age**
- **Interacts with youth routinely**
- **Conducts or supervises community outreach and community-based HIV testing**
- **English speaking**
- **Can read English text**
- **Able and willing to provide informed consent**

Inclusion Criteria for youth participants:

- **Youth aged 18 years, 0 months to 29 years, 11 months**
- **Identifies as Black (or African American)**
- **Identifies as biologically male**
- **Is sexually active with male partners (MSM)**
- **Hasn't taken an HIV test in 6-months**
- **Is not currently on PrEP**
- **English speaking**
- **Able and willing to provide informed consent**

e. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group. **Data will be collected from black YMSM and outreach staff. For purposes of this study, black YMSM are 18-29 years, identify as black, and have sex with men (n=70). Staff include any CBO staff that engages with YMSM and conducts community-based HIV testing (n=30).**

f. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.

☐ Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Prisoners: Attach SPRF—Prisoners
☐ Minors (<18 years old): Attach SPRF—Minors
☒ Employees or students at institution where research conducted
☐ Persons who are temporarily decisionally impaired
☐ Persons who are permanently decisionally impaired
☐ Non-English Speakers

For each box checked, describe why the group is included **and** the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion: **Staff will inform the development and adaptation of the intervention, because of their personal experiences working with the local community. Staff are under no obligation to participate.**

g. List any persons other than those directly involved in the protocol who will be at risk. If none, enter "None": **None**

h. Describe the recruitment process (e.g., medical record review, referrals, letter of invitation, existing patients) that will be used to seek potential participants (e.g., individuals, records, specimens).

Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of Authorization for Recruitment/Screening. **Study recruitment will occur in Alabama, specifically in Birmingham, Selma, and surrounding areas of both Birmingham and Selma (up to 10 miles outside city limits). Recruitment will occur in the community. Community locations may include: wellness programs, junior colleges, housing complexes (specifically federally subsidized housing complexes), vocational training sites, LGBTQ events that may or may not be sponsored by my CBO partners, community resource centers, and festivals. We have discussed recruiting at predominantly African American churches, and the UAB Center for AIDS Research (CFAR) Spiritually Core has expressed significant interest in supporting this; however, until our Aim 1 data collection is complete, we will not know if this is feasible and appropriate. We will only recruit from community locations where my research mentors such as Dr. Naar (named previously), CBO staff from Selma AIR and BAO, and I -- all feel we can maintain confidentiality.**

i. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., IRB Protocol Number for approved databases) from which you will recruit participants. **We will; however, these materials will be developed collaboratively with potential study participants during Aims 1 and 2. Once a draft is developed, these materials will be provided to UAB's IRB in the form of an amendment for evaluation. As a Just In Time IRB review request, these materials are not yet available.**

j. Describe the screening process/procedures for potential participants. **No further screening will take place.**

17. Protocol Procedures, Methods, and Duration - in nontechnical, lay language

a. Describe the procedures for all aspects of your protocol. Tell us what you are doing.

The overall goal of this 5-year Mentored Research Scientist Development K01-Award is to support Henna Budhwani, PhD, MPH become an independent investigator in the field of HIV prevention. The proposed project seeks to address the HIV crisis in Alabama, where rates of undiagnosed HIV in black young men who have sex with men (YMSM, 18-29 years) exceed 20%. This project will adapt and test a behavioral intervention to promote HIV rapid testing in the community, deliver culturally appropriate prevention education, offer sociostructural supports, and refer eligible participants for pre-exposure prophylaxis (PrEP). Three specific aims are proposed as part of the pilot study.

Aim 1 is to elucidate experiences, beliefs, and predictors related to delivery and utilization of HIV testing and prevention services by black YMSM using qualitative research methods to inform the adaptation of the Brothers Saving Brothers (BSB) intervention. Aim 2 is to adapt the BSB intervention to include two HIV prevention tools (rapid testing and PrEP), to address structural barriers, and to be acceptable to black YMSM in Alabama. Aim 3 is to conduct a hybrid type 1 effectiveness-implementation pilot study of the adapted intervention

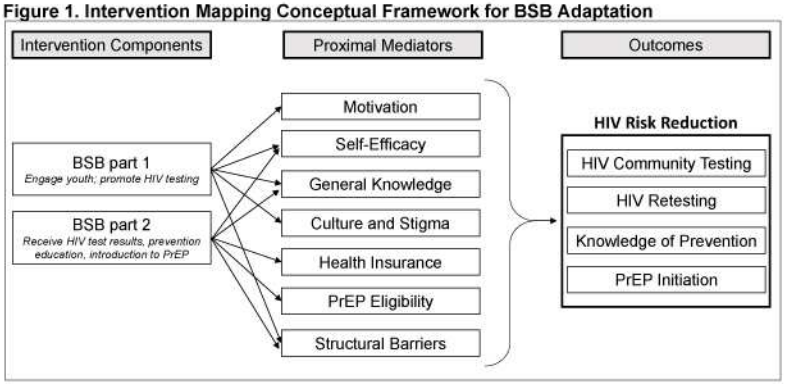
PROCEDURES FOR AIM 1

I intend to conduct focus groups and interview with racial gender and sexual minorities. My prompts will focus on elucidating specific ways to adapt BSB to navigate the sociocultural (southern) environment of these youth. In-depth interviews with community based organization (CBO) staff will be conducted. Topics will include: 1) Views on how youth-friendly their services are, 2) Thoughts on how minority-friendly their services are, 3) What language they use to explain PrEP and prevention to clients, 4) Opinions on how to increase rates of prevention services by minority youth and YMSM, and 5) Sociostructural support services available.

PROCEDURES FOR AIM 2

After the conclusion of Aim 1, I will use the 4-step intervention mapping model (for HIV) to adapt BSB (see Figure 1). I anticipate having to adapt the intervention 2-4 times. Each version of the adapted intervention will be demonstrated to YMSM and CBO staff using face-to-face roleplays. If I find traits of a prior version were better received, I will revert to those in the next cycle. After the intervention is finalized, select CBO staff will be trained in the intervention. I will conduct this face-to-face training to bring CBO staff to solid fidelity.

Figure 1. Intervention Mapping Conceptual Framework for BSB Adaptation



PROCEDURES FOR AIM 3

After Aim 2 is concluded, and I have a testable version of the BSB intervention, I will work with CBO staff recruit and enroll black YMSM. Potential study participants will directly enter data into an iPad screener (iSurvey). The device will determine eligibility. Inclusion criteria include age, identifying as Black, English speaking, resident of Alabama, being sexually active with men, identifying as male, and has not taken an HIV test in the prior 6-months. If eligible, the participant will be asked to provide informed consent. The system will then randomize participants to BSB or control. Block randomization will ensure a balance across intervention and control groups. See table below for characteristics of both. We will collect data on if the participant was willing to take an HIV test, if the participant started PrEP within 6-months, and if the participant re-tested for HIV within 6-months. We will collect self-report data on the participant's behaviors related to HIV prevention and personal characteristics from the participant before the intervention, after it, 3-months later, and 6-months later. These questionnaires have not yet been developed and are scheduled to be developed in Year 3 on the grant (2021-2022). Once developed, these questionnaires will be shared with the UAB IRB via amendment for approval. All interviews and intervention activities will be conducted in a private space. All HIV test results will be shared in a private space. Regardless of test reactivity, the way test results are shared will be standard, so that an onlooker cannot discern a test result by how the study participant was "treated." For those with a reactive test, the outreach worker will actively navigate the study participant to care for a confirmatory test. If the results show that the participant is positive for HIV, the study staff will tell the participant the results. The study staff will be required to give the participant's name to the Alabama Department of Public Health, because this is the law. If the participant is entered and completes the entire study, the participant will be in the study for 6 months. Selma AIR staff will be part of this Aim and will not be recruited until 2021-2022. At that time, an amendment will be submitted to the OIRB via PRAF indicating additional personnel.

BSB Intervention Specification and Unique Features

Characteristic	Standard Street Outreach	Brothers Saving Brothers (BSB)
Presentation	Presents as expert providing information and services	Communicates respect for clients as experts on their own behavior and emphasizes personal choice and responsibility
Assessment	Focuses on brief risk assessment	Focuses on assessment of readiness to learn HIV status in addition to brief risk assessment
Education	Focuses on providing standardized HIV education	Focuses on exploring ambivalence about learning HIV status with tailored education as needed
Support for Self-Efficacy	No specific component	Verbally affirms specific strengths to boost confidence for behavior change

Overall Communication	Training involves presenting information in a non-judgmental, respectful manner	Training involves specific client-centered micro-skills and strategies to elicit and reinforce motivational statements

b. What is the probable length of time required for the entire protocol (i.e., recruitment through data analysis to study closure)? **4 years**

c. What is the total amount of time each participant will be involved? **Maximum 4 years (staff). If CBO staff are engaged at the onset of the study and are still available at the conclusion, they could be participatory for the full 4-years. Black YMSM who participant in focus groups or in-depth interviews will be engaged for 1 day. Black YMSM who enroll in the effectiveness-implementation study will be active for 6 months.**

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "None." **None**

e. List the procedures, the length of time the procedure takes, the total # of times the procedure is performed, and indicate whether each is performed solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population.
-Insert additional table rows as needed.
-If procedure is sometimes research and sometimes routine care, include on separate lines with number of times as each.

Procedure	Length of Time Required of Participants	Total # of Times the Procedure is Performed	Research (Res) –OR- Routine Care
Focus Group	**1 hour**	**1**	☒Res ☐Routine
Interview	**1 hour**	**1**	☒Res ☐Routine
Intervention adaptation	**2 hours**	**1-2**	☒Res ☐Routine
Intervention	**1 hour**	**1**	☒Res ☐Routine
HIV Test	**10 minutes**	**1**	☒Res ☒Routine
PrEP Initiation	**30 minutes**	**1**	☒Res ☒Routine
HIV Retesting	**10 minutes**	**1**	☒Res ☒Routine
Survey	**15 minutes**	**4**	☒Res ☐Routine

f. Will an interview script or questionnaire be used? ☒Yes ☐No
If Yes, attach a copy.

g. Will participants incur any costs as a result of their participation? ☐Yes ☒No
If Yes, describe the reason for and amount of each foreseeable cost. _____

h. Will participants be compensated? ☒Yes ☐No
If Yes, complete i-v.
i. Type: (e.g., cash, check, gift card, merchandise): Direct Deposit, **Cash, or Gift Card**
ii. Amount or Value: **CBO staff will be eligible for incentives of $35 for participation in an in-depth interview. Young adults (YMSM participants) will be eligible for incentives of $35 for participation in a focus group, in-depth interview, or study questionnaire.**
iii. Method (e.g., mail, at visit): **Visit**
iv. Timing of Payments: (e.g., every visit, each month): **At each data collection point**
v. Maximum Amount of Compensation per Participant: **$175**

18. Benefits

Describe the potential benefits of the research. **Primary benfit of this study, if successful, is the development of a low-cost method to promote HIV testing and PrEP uptake in this community.**

19. Risks - in nontechnical, lay language

a. List the known risks for participants as a result of participation in the research. This should not include the minimal risk of loss of confidentiality. However, it should include any physical, psychological, social, economic, and/or legal risks. If there is a greater than minimal risk of loss of confidentiality describe why this is so. Do not list risks associated with the standard-of-care procedures.
NOTE: Risks included here should be included in the consent form or information sheet, as applicable.
Minimal risks may include the possibility of temporary increased stress for participants during the intervention interactions. If psychological distress occurs, participants will be informed that they may stop the study at any time if they feel uncomfortable. Staff in-depth interviews, however, will not focus on sensitive or personal aspects of their own behaviors, so for the staff many of these risks are of very low probability.

b. Estimate the frequency, severity, and reversibility of each risk listed. **Psychological stress and discomfort, minutes – minor – quickly reversed.**

c. Is this a therapeutic study or intervention? ☒Yes ☐No

If Yes, complete i.-iii.

i. Describe the standard of care in the setting where the research will be conducted: **There is not a systematic way in which to deliver community-based HIV testing; thus standard of care is variable from person to person.**

ii. Describe any other alternative treatments or interventions: **None**

iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using: **None**

d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? ☐Yes ☒No

If Yes, describe the provisions that have been made to make these resources available. _____

e. Do the benefits or knowledge to be gained outweigh the risks to participants? ☒Yes ☐No

If No, provide justification for performing the research: _____

20. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks. **My mentoring team and I will have taken additional measures to protect participants from study-related risks, including creating a Data and Safety Monitoring Board (DSMB), to review study procedures and any adverse events. Considering reviewer feedback around protections of human subjects and the vulnerability of YMSM of color in the Deep South (Alabama), my mentors and I determined that a DSMB is both warranted and prudent to convene in an effort to protect study participants. The DSMB will address adverse events (AE) and severe adverse events (SAE). Members of the DSMB have not been identified yet; however, in the proposal to the NIH, potential DSMB members were described as "Members of this DSMB will have experience with conducting research with young minority populations that are at high-risk for contracting HIV, HIV-infected persons, including those who are new to HIV care, and young gender and sexual minorities in high-stigma settings." Potential members of the DSMB will be experienced in the ethics of conducting research with high-risk for contracting HIV populations.**

If the protocol involves drugs or devices skip Items 20.b. and 20.c. and go to Item 21. Instead include this information in the Drug Review Sheet or Device Review Sheet, as applicable.

b. If hazards occur to an individual participant, describe (i) the criteria that will be used to decide whether that participant should be removed from the protocol; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants.

If an HIV test is reactive, outreach workers are trained to navigate the participant to care (for confirmatory test). Those with a reactive test will not receive the second part of aBSB. Their data collected prior to the first part of aBSB will be included in the analyses. If a participant appears to be in emotional distress, study staff will inquire as to the participant's well-being and whether they wish to stop the study visit. Participants who opt to stop the study visit, or who disclose potentially harmful information (e.g., suicidality) will be immediately referred for an assessment by a clinic social worker, psychologist, or counselor. We will enact the CBO's emergency protocol for persons who need immediate attention for escort to the local emergency department.

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire protocol and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants. **There are no foreseeable potential hazards that would outweigh the benefits for all persons.**

21. Informed Consent

a. Do you plan to obtain informed consent for this protocol? ☒Yes ☐No
If Yes, complete the items below.
If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

b. Do you plan to document informed consent (obtain signatures) for this protocol? ☒Yes ☐No
If Yes, complete the items below.
If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

c. How will consent be obtained? **Written**

d. Who will conduct the consent interview? **CBO partners or I will conduct the consenting process.**

e. Who are the persons who will provide consent, permission, and/or assent? **CBO staff and young African American sexual and gender minorities**

f. What steps will be taken to minimize the possibility of coercion or undue influence? **We will utilize an English-language consent form that explains that no special privileges or considerations will be conferred as a result of study participation, and that access to services or employment will not be affected by the potential participant's decision to enroll in the study. For those eligible for any part of the study, informed consent will be obtained prior to participation in study-related procedures following prescreening; no data collection will take place before informed consent is provided. Informed consent procedures for both youth and staff participants will take place in a private space. CBO study partners will be trained to communicate all Aims of the informed consent clearly, so that potential participants understand that their consent is voluntary and to avoid coercion. Consent will be written, and a physical signature will be required to offer consent by both youth and staff participants. Consent will use clear language that explains that the participant's relationship with the CBO will not be affected by his decision to participate or not participate in this study. The informed consent forms will be developed at no greater than a 5th grade reading level and may be read aloud to the potential participant, if deemed necessary.**

g. What language will the prospective participant and the legally authorized representative understand? **English**

h. What language will be used to obtain consent? **English**

i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "None." **None. This person will not be enrolled in the study, because they cannot legally provide "informed consent."**

j. If any protocol-specific instruments will be used in the consenting process, such as supplemental handouts, videos, or websites, describe these here and provide a copy of each. If not, enter "None."
None

k. How long will participants have between the time they are told about the protocol and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical. **Because this is primarily a community-based testing intervention study, we must consent and administer the condition immediately. There is no possible way to track down a participant to "test in the community," 24-hours after consent is provided, because then this would become a testing not a community-based testing intervention study. We are requesting a waiver of the 24-hour minimum.**

22. Procedures to Protect Privacy

Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed. **We will organize private rooms at the CBO partners' offices, namely Selma AIR and BAO,for this purpose; we will do similar at each community recruitment venue. Community recruitment venues have yet to be finalized as this is part of the research study. Prior studies have used sites such as parks and on or near university campuses. If a private room is unavailable, we will identify a private space where we can conduct informed consent and study procedures out of visible line sight and earshot of other people.**

23. Procedures to Maintain Confidentiality

a. Describe how you will store research data to maintain confidentiality (both paper records and electronic data), including how access is limited. If data will be stored electronically anywhere other than a server maintained centrally by UAB, identify the department and all computer systems used to store protocol-related data. **We will also employ storage and encryption techniques in compliance with UAB Data Security standards to safeguard all electronic data, as well as the protections outlined in Subpart C of title 45, part 46 of Code of Federal Regulations. Encrypted data will be saved on a UAB server, with password protection. The iSurvey database and associated data structures will be developed in year 3 and will not be adjusted during the protocol.**

b. Will any data from this protocol be given to any person, including the subject, or any group, including coordinating centers and sponsors? ☐Yes ☒No

If Yes, complete i-iii.

i. Who will receive the data? _____

ii. What data will be shared? _____

iii. How will the data be identified, coded, etc.? _____

24. Genomic Data Sharing (GDS)

Researchers who collect genomic data as part of a NIH grant funded after January 25, 2008 may be required to submit those data to a NIH database for broad scientific sharing. See Genomic Data Sharing in the IRB Guidebook for more information.

a. Does this protocol involve the proposed submission of genetic data into genomic repositories created to share genetic information for research purposes? ☐Yes ☒No

b. Will UAB be uploading the final genomic data to the central repository (e.g., dbGaP)? ☐Yes ☐No

If Yes to both a and b, submit a Detailed Data Sharing Plan to the IRB for review. This plan should include any known data use limitations and indicate whether aggregate-level data are appropriate for general research use. For guidance see the NIH Genomic Data Sharing Policy.

c. Submit a copy of the NIH Institutional Certification Form.

To determine which certification form to include, answer i-ii.

i. Was this protocol funded prior to January 25, 2015? ☐Yes ☐No

- **If yes,** and consent will be obtained, submit the Extramural Institutional Certification - Before January 25 - With Consent.
- **If yes,** and consent will not be obtained, submit the Extramural Institutional Certification - Before January 25 - Without Consent.

ii. Was this protocol funded after January 25, 2015? ☐Yes ☐No

- **If yes,** submit the Extramural Institutional Certification - After January 25.

25. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None." **None.**