Adapting the Finding Respect and Ending Stigma Around HIV (FRESH) Intervention for the Dominican Republic

Identifier: NCT04491539

Unique Protocol ID: 526497

Document Date: August 24, 2022

This page has intentionally been left blank; no participant names have been included in this document developed for public release.

Human Subjects Protocol (HSP, Original)

Form Version: July 29, 2019

- 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; click checkboxes to check/uncheck.
- All responses should be Times New Roman, Bold, and Underlined.
- NOTES REGARDING VA RESEARCH: BVAMC research cannot be reviewed by an external IRB (only UAB IRB). Ensure you complete this form for any BVAMC research. BVAMC Research must be signed off by the BVAMC supervisor for scientific/scholarly review via PORF prior to submission of this form.

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 the Finding Respect and Ending Stigma around HIV (FRESH) Intervention for the Dominican Republic

2. Investigator and Contact Person

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

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

Dept/Div: **Health Care Organization and Policy** Mailing Address: **RPHB 330C** UAB ZIP: **0022**

Phone: **(205) 975-7613** E-mail: **budhwani@uab.edu**

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

E-mail:

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 submission 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.

3. Protocol Personnel

a. Complete the **IRB PERSONNEL FORM to list all key personnel (each individual involved in the design and conduct of this protocol).**

b. Non-UAB Personnel Relying on UAB IRB - If you are requesting that the UAB IRB serve as the IRB of record for any non-UAB personnel, list these individuals below. Add additional rows as necessary.

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	_____

***** 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.***

VA Personnel: The VA Financial Conflict of Interest (fCOI) form must be submitted to the VA fCOI Committee Chair. Include in 3.a above any financial conflict of interest as submitted on that VA fCOI form. If there is a conflict, submit a copy of the management plan with this submission.

c. Are any of the investigators listed on the IRB PERSONNEL FORM students using this research for their thesis or dissertation? ☐Yes ☒No

If No, continue with Item 3d.

If Yes, provide the name of the student and the 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: _____

Supervisor's Signature:_____

e. 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 _____

f. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol:

The PI will devote her effort to this project. She will be responsible for all administrative and financial aspects of the project and will oversee all scientific aspects of the project. She will work closely with the team in the Dominican Republic (DR) to oversee human subjects research activities performed there and ensure that all activities are in compliance with the local IRB approval.

g. Describe your process for ensuring all key personnel are adequately informed about the protocol and their research-related duties and functions:

At the beginning of the study, the team will meet (virtually) weekly and will correspond by email almost daily. As the study gets underway, the team will meet (virtually) weekly or more often if needed. UAB personnel, including the PI, will be responsible for training the DR team who will directly interact and intervene with participants. This training will occur on-site in the DR as well as electronically.

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 the Finding Respect and Ending Stigma around HIV (FRESH) Intervention for the Dominican Republic**

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

c. Office of Sponsored Programs (OSP) Assigned Number: **OSP #000526497**
(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): **NIH/FIC**
- ☐ 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-sponsored, industry-initiated - Name: _____
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.
☐ Industry-sponsored, 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: _____
☐ VA Funding —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 NOTE: *Research may only be conducted by investigators who have a BVAMC appointment*
- ☐ Jefferson County Department of Health
- ☒ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol) - Describe:
  UAB School of Public Health and government HIV clinics in Santo Domingo and Santiago, Dominican Republic: Hospital Cabral y Baez, Hospital Periferico Juan XXIII, and Hospital Calventi.
  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):
At UAB, the research will take place in the Ryals Public Health Building, in the private offices of the investigators. The primary academic research site in the Dominican Republic is the Universidad Iberoamericana (UNIBE), a Higher Education Center that emerged in 1982 as a result of the initiative expressed by the Ibero-American Cooperation Institute and by a Management Committee in the Dominican Republic. UNIBE's mission is to promote academic excellence, research and training of highly qualified professionals, capable of generating and leading changes, with ethical values necessary to contribute to the development of local and global society. Our vision includes commitment to the integral development of society and academic excellence, which is characterized by forging responsible leaders and by its permanent innovative vocation.

c. Does this protocol require clinical services at one of the 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 Fiscal Approval Process (FAP)-designated unit 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 BVAMC consent form(s), if applicable. Attach any other applicable BVAMC forms (such as the Privacy and Information Security Checklist and The BVAMC FCOI forms).
NOTE: Investigators conducting research at BVAMC **must** have a BVAMC appointment.
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: **We will register as soon as the official Notice of Award is received**
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? ☐Yes ☒No
b. Is the UAB Investigator the lead investigator? ☒Yes ☐No
c. Is this a multi-site study with a coordinating site? ☐Yes ☒No
d. Is this a multi-site study with UAB as a coordinating site? ☐Yes ☒No

If Yes to a, b, c, or d, describe the management of information obtained in multi-site research that might be relevant to the protection of participants:
UAB will have an IRB approval and the primary DR site will have an IRB approval. All DR sites will rely on the IRB approval given in the DR. Unanticipated problems will be addressed as described in 20b and 20c. UAB is responsible for all reports to the sponsor and for alerting the UAB IRB to all protocol modifications throughout the project.

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 result; & 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.
If BVAMC, attached the completed BVAMC 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 biospecimens, 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) biospecimens from a repository? ☐Yes ☒No
If Yes, attach documentation of approval for use of biospecimens, and describe how existing biospecimens are labeled: _____

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

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

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

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

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

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" biospecimens). _____

f. Is genetic testing planned as part of this protocol? ☐Yes ☐No
If Yes, describe the planned genetic testing here. _____
i. Does this include whole genome sequencing? ☐Yes ☐No
ii. Will participants be informed of the results of any DNA testing? ☐Yes ☐No

g. Will biospecimens 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. In addition, indicate where the biospecimens will be banked _____
- If above is a BVAMC location, what IRB is responsible for overseeing the operations of the biospecimens bank (i.e., local IRB or other multi-site or central IRB?) _____

h. Will biospecimens be shared with other investigators in the future? ☐Yes ☐No
i. What identifiers, clinical information and demographic information will be shared; or will the biospecimens be stripped of identifiers (i.e., anonymized)? _____
NOTE: *Coding data is not considered anonymous.*
ii. Outline your procedure for assuring IRB approval for release and use prior to release of biospecimens. _____
NOTE: *Investigators who receive and/or use these biospecimens must document approval from the appropriate IRB(s) before the biospecimens may be released.*

i. Will specimens be destroyed after the project-specific use is completed? ☐Yes ☐No
j. Will specimens be used and/or shared for commercial profit? ☐Yes ☐No
k. Will specimens be destroyed after the project-specific use is completed? ☐Yes ☐No
l. Will participants be informed of the results of the specimen testing? ☐Yes ☐No

m. Are there any implications for family members based on specimen testing results? ☐Yes ☐No
(If yes, the family members may be participants.)

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
☐ Birmingham Veterans Affairs Medical Center
☒ 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 or BVAMC 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

NOTE: For BVAMC research, the BVAMC HIPAA authorization form or UAB HIPAA waiver form must be completed and submitted with the HSP.

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 research is to adapt an educational intervention (Finding Respect and Ending Stigma around HIV) that has been proven to be effective in Africa and the US to meet the needs of HIV clinics in the Dominican Republic. Health outcomes, as well as perceptions/attitudes/beliefs, will be measured before and after the intervention.

b. Describe how outcomes will be measured for this protocol.

Outcomes related to changes in stigma, perceptions, beliefs, etc. will be collected before and after the educational workshop (intervention). Data

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).

There are high levels of stigma against sexual and gender minorities (SGMs) in the Caribbean. Many Caribbean nations have a dominant conservative ideology that criminalizes MSM sexual behaviors and shames young SGM, particularly those who are living with HIV. In the DR, stigmatizing views are commonplace, and policies that perpetuate stigma towards PLWH and SGMs are embedded in DR laws. Stigmatizing attitudes toward PLWH and SGMs are often reflected in the behaviors of health workers, and thus stigmas may become embedded in HIV clinics, leading PLWH to be reluctant to engage in care. In the DR, PLWH routinely experience intersectional stigma for being a PLWH and for identifying as an SGM. This intersectional stigma may increase the amount and intensity of stigma experienced by SGMs who are living with HIV, with synergistic effects on health outcomes. Research shows that these stigmas are significant barriers to HIV treatment services and contribute to the DR's low 16% viral suppression rate.

HIV and intersectional stigmas in healthcare settings are significant barriers to care in the DR. Consejo Nacional para el VIH y el SIDA (CONAVIHSIDA) recently released results from its national study on HIV stigma. This study found that over a third of HWs had no stigma training; a third of HWs were afraid to draw blood from PLWH, and 56% of HWs did not want to provide services to SGMs living with HIV, because they felt SGMs deserved to be HIV-infected. Findings from the THS further validate the notion that stigma is a significant barrier to HIV services in the DR. In fact, it was only after advocates took their demands to the Inter-American Human Rights Commission that antiretroviral therapy (ART) was approved as a covered medical expense in the DR, and it wasn't until 2009 that PLWH were allowed to enroll in the DR National Health Insurance System. Stigmatizing attitudes from HWs push the epidemic underground and promote the spread of HIV, because PLWH and SGMs may avoid engaging in care due to fears of stigma from HWs. Thus, it is imperative that tailored interventions to reduce stigmas in clinics be developed and tested. If stigmas are not addressed, the DR will likely see a rise in new infections and worsening of HIV outcomes in PLWH.

There are surprisingly few intersectional stigma reduction interventions for healthcare settings. Clinic-based stigma-reduction interventions have primarily been developed for Asian and African settings, making the adaptation of FRESH for the Caribbean unique. In assessing interventions for appropriateness, we applied Nyblade's key criteria for stigma-reduction efforts. Evidence-based strategies include selecting interventions that involve PLWH and HWs, use of participatory methods, address actionable drivers of stigma in the short term, put PLWH at the core of the response, and create partnerships between PLWH experiencing stigma and HWs to model non-stigmatizing behaviors. Considering the lack of HIV-stigma research in the DR and that FRESH is one of the few interventions that meets these criteria, the DR is a

priority setting for the cultural adaptation and testing of the FRESH intervention that involves both PLWH and HWs.

The Finding Respect and Ending Stigma around HIV (FRESH) intervention is ideal to adapt and test. The FRESH intervention was originally developed in a study in five African nations,30 then was adapted for the United States. Since we have data showing that FRESH is adaptable, revising it for Latinx and Hispanic populations could yield scientific evidence leading FRESH to become a validated multi-region stigma-reduction intervention. The FRESH intervention brings together HWs of all types and PLWH to collaborate in a workshop to increase understanding of HIV-related and intersectional stigmas. FRESH facilitates conversations on effects of stigma on health and well-being and guides participants to better recognize and understand stigmas. FRESH includes didactic content and interactive activities. Each topic includes contact-theory informed activities designed to bring HWs and PLWH together to change perceptions of each other while enhancing empowerment and empathy. Facilitators use a standard manual for consistent content delivery. FRESH was efficacious in reducing stigmas in Africa, and the United States pilot had promising results (Preliminary Studies). We are confident that FRESH is an excellent intervention to adapt for the DR because, 1) FRESH is sustainable. Facilitators can train other trainers. 2) FRESH is low-cost. As a socio-structural intervention, there are no clinical costs. 3) FRESH is extensible. We have shown that FRESH was adapted from African contexts to the United States, and 4) FRESH is flexible. FRESH was adapted to address a spectrum of relevant intersectional stigmas in the US Deep South, among other modifications.

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)? **0**

If multi-site study, total number at all sites/institutions:
40 in intervention workshops; half providers and hald PLWH clients.

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

PLWH participants

Sex: **all**
Race/Ethnicity: **all**
Age: **16+**
Health status: **HIV positive**

healthcare workers

Sex: **all**
Race/Ethnicity: **all**
Age: **18+**
Health status: **not applicable**

c. From what population(s) will the participants be derived?
Healthcare workers and patients from the clinics in the DR

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants:
We will collaborate with multiple organizations in the Dominican Republic that have an established track record of recruiting and retaining our target population.

d. Describe the inclusion/exclusion criteria:

Inclusion Criteria for Healthcare worker (HW) participants:

- **Minimally 18 years and 0 months of age**
- **Works at one of the three study sites**
- **Interacts with PLWH**
- **Spanish speaking**
- **Can read Spanish text**
- **Able and willing to provide informed consent**

Inclusion Criteria for PLWH participants:

- **Minimally 16 years and 0 months of age**
- **Is HIV-positive**
- **Spanish speaking**
- **Receives treatment at one of the three study sites**
- **Identifies as a Sexual or Gender Minority person (SGM)**
- **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.

Adaptation Site: At Site 1, we will engage 44 PLWH patients (men and women) and 12 HW to participate in focus groups and in-depth interviews. This feedback will inform how the FRESH intervention is adapted and then implemented at Sites 2 and 3.

Site 2: 10 PLWH and 10 HW will participate in the educational workshop; it is expected that the workshop will benefit all patient-provider interactions and not just those of workshop participants.

Site 3: 10 PLWH and 10 HW will participate in the educational workshop; it is expected that the workshop will benefit all patient-provider interactions and not just those of workshop participants. This will be a delayed-start site.

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 **NOTE**: For BVAMC Research <19 years old
☐ 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:

For youth living with HIV participants (aged 16-17), we will take written or verbal informed consent from both the youth and his or her legal guardian. In cases where these youth have been legally emancipated; we will attach a copy of the participant's emancipation record (often kept clinic) with his/her informed consent. This human subjects research will be delivered to a Spanish-speaking population by native Spanish speakers who are local DR residents. This protocol will also be reviewed by a local DR IRB as to make sure that the research complies with local cultural norms and regulations.

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.
Leadership at sites have agreed to participate and PLWH will be recruited during events hosted by clinics or during their clinical visits.

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.
These need to be developed with DR collaborators; when ready, pre-recruitment, we will share via an amendment to UAB's IRB.

j. Describe the screening process/procedures for potential participants.
Potential participants will complete a pre-workshop assessment on paper or via an ipad survey to assess eligibility.

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 DR sites will be randomly assigned. Site 2 will be the site randomized to receive the adapted FRESH intervention first. Site 3 will receive the FRESH intervention at a later date. 10 sexual and gender minority PLWH and 10 HW will participate in the workshop at each site (total n from both sites=40). From workshop participants, we will collect pre- (N=40) and post- (N=40) surveys to assess satisfaction, feasibility, acceptability. We will collect outcome information on demographics, stigma-related measures, and HIV-related behavioral outcomes by asking all HWs and PLWH in Site 2 and 3 clinics.

UAB specific research activities include: traveling to DR sites to provide training on FRESH and the adapted FRESH, overseeing FRESH workshop implementation, possibly interacting with study participants participating in workshops and surveys, receiving all study data, data analysis, manuscript writing, presentations.

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? **12 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
Site 1: focus group	**1 hour**	**1**	☒Res ☐Routine
Site 1: in-depth interviews	**1 hour**	**1**	☒Res ☐Routine
Site 1: feedback on adapted intervention	**1 hour**	**2**	☒Res ☐Routine
Site 2: pre-workshop stigma surveys	**30 minutes**	**2**	☒Res ☐Routine
Site 2: workshop participation	**16 hours**	**1**	☒Res ☐Routine
Site 2: post-workshop stigma-related surveys	**30 minutes**	**2**	☒Res ☐Routine
Site 3: pre-workshop stigma surveys	**30 minutes**	**2**	☒Res ☐Routine
Site 3: workshop participation	**16 hours**	**1**	☒Res ☐Routine
Site 3: post-workshop stigma-related surveys	**30 minutes**	**2**	☒Res ☐Routine

f. Will an interview script or questionnaire be used? ☒Yes ☐No
If Yes, attach a copy. **All interviews/scripts will be submitted to UAB IRB via amendment once developed and approved by DR sites and IRB.**

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): **cash**
ii. Amount or Value: **$50 USD (distributed as DR currency)**
iii. Method (e.g., mail, at visit): **at visit**
iv. Timing of Payments: (e.g., every visit, each month): **each workshop day**
v. Maximum Amount of Compensation per Participant: **$100 USD**

18. Benefits

Describe the potential benefits of the research. **Participants in this study are HWs and PLWH. If successful, this project will yield a model for sustainable implementation of an intervention to reduce stigma and improve outcomes across the HIV cascade in resource-poor settings. Given the limited risks associated with this intervention study, the benefits outweigh the risks. PLWH are at particular risk of being stigmatized, yet few interventions exist that specifically reduce stigma in healthcare settings for the Caribbean. This study will ultimately benefit both PLWH and their healthcare providers by creating stigma-free healthcare environments and improving outcomes along the HIV continuum of care.**

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.

Psychological distress. Our team has significant experience conducting intervention studies and behavioral surveys in the field of HIV stigma-reduction, including in the proposed setting (Dominican Republic). It has been our experience that it is rare for a participant to find an interview upsetting. We have infrequently encountered episodes of mild embarrassment or awkwardness, which quickly dissipate.

Breaches of confidentiality. The main potential risk of this study is breach of confidentiality. This is one of the most common risks of participation in research studies on sensitive topics such as stigma and HIV, especially in socially conservative communities. We acknowledge that unwanted disclosure may result in adverse consequences for participants, including negative psychological and social consequences. PLWH participants are particularly vulnerable due to the likelihood of being members of highly stigmatized groups in DR society, including MSM, sex workers, and trans persons. Healthcare workers may also be vulnerable if they are HIV-infected, members of any of these groups, or if they face consequences for voicing stigmatizing attitudes. Accordingly, our team has designed a strategy to protect participant confidentiality, as detailed below.

b. Estimate the frequency, severity, and reversibility of each risk listed.
Psychological distress- rare, moderate, reversible
Breach of confidentiality- rare, sever, irreversible

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: _____
ii. Describe any other alternative treatments or interventions: _____
iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using: _____

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.
The team will make every effort to protect all participants' confidential and private information in order to minimize possible study-associated risks. We will inform all participants that their

participation is voluntary, and we will utilize study identification codes in place of personal identifiers on study materials. 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. All study personnel are required to renew Human Subjects trainings biannually. No data will be accepted from or distributed to investigators or study staff if regulatory training is not current.

Protections for participant discomfort. Participants will be informed that they may stop the study at any time if they feel uncomfortable. Additionally, 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 clinic's emergency protocol for persons who need immediate attention for escort to the local emergency department. Interviewers will be trained to minimize distress/discomfort to participants, to recognize any signs of symptoms of distress, and to make appropriate referrals to appropriate community-based services, if necessary. Experienced mental health counselors will be consulted or referred to should a participant exhibit severe symptom of mental distress. Should a participant experience distress after-hours or on weekends, a back-up system will be in place in the event a mental health or medical professional is needed for assessment or immediate referral. Through our prior work in the Dominican Republic, we have compiled a list of community-based resources for PLWH, including mental health counseling, general health services, substance use, and other issues. These lists will continue to be updated, and a copy will systematically be provided to participants during interviews, focus groups, and questionnaires. Providing them to all participants (both HWs and PLWH) will reduce the likelihood that any one participant would be identified as needing a particular service, and implying that they have a particular need for a type of service.

Protections for breaches of confidentiality. All participants will be informed of study procedures and gauged for understanding of study tasks. In addition, study personnel will follow regulatory guidelines for obtaining written or verbal informed consent. All interviews and intervention activities will be conducted in private spaces, in so far as possible. For all participants, research data will be stored using a code (sequence number based on entry to the study) instead of names or other personal identifiers. Consent forms with links to participant study numbers will be kept in a in a locked file in a locked room with the PI (Budhwani) if paper-based or in an encrypted, password-protected file at UAB if electronic. According to UAB regulatory policy, records relating to research, including informed consent documents, shall be securely retained for one year after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or sponsor agency at reasonable times and in a reasonable manner. All electronic study data are kept on UAB secure encrypted password protected servers, and will only be available to research personnel. All study personnel will complete HIPPA and human subjects training in accordance with UAB Institutional Review Board policy.

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.

Once the project has begun, all clinically significant AEs will immediately be brought to the attention of the MPIs. The event will be categorized as an SAE or non-SAE, as expected or unexpected, and as likely or unlikely to be related to the study. The DSMB will review all AE reports for concurrence regarding

relatedness to the intervention, seriousness, and appropriate resolution. The DSMB will track all SAEs until resolution has been achieved. All SAEs and AEs will be entered into the study database so that they may be tracked. If an SAE is determined to be related to the intervention, it will be reported within 48 hours of occurrence or identification to the UAB IRB in accordance with UAB reporting protocols.

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.
If the incidence of SAEs and/or AEs probably or definitely related to participation in the study is unexpectedly high (overall or at any site), or differs substantially by Site ($P < 0.001$), the study team will discuss with the DSMB whether the study should be stopped or modified in some way in order to reduce the risk of potential harms to study participants. The DSMB will be given quarterly reports of any AEs and SAEs that occur. The DSBM may recommend modifications to the study procedures to minimize potential harms to study participants. If there are no serious concerns raised by the DSBM, the Chair will approve the protocol to continue as planned immediately following a DSMB meeting. If significant concerns are raised by the DSMB, the concerns will be forwarded to the MPIs as well as recommendations made to the IRBs. Recommendations may include modifying, suspending, or terminating the protocol.

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.
*For research being conducted at the BVAMC, the UAB Consent waiver form must be completed and submitted with the HSP.

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?
Consent will be obtained by the research team located in the Dominican Republic (DR). We will utilize a written Spanish-language consent form that describes that no special privileges or considerations will be conferred as a result of study participation and that access to services will not be affected by the potential participant's decision to enroll in the study. A physical or electronic signature will be required on the written informed consent form, but verbal informed consent will not require this. For those eligible for any part of the study, informed consent will be obtained prior to participation in study-related procedures. Informed consent procedures for all participants will take place in a private space. DR study staff will be trained to communicate all components of the written or verbal informed consent clearly, so that potential participants understand that their consent is voluntary and to avoid coercion. Consent will use clear language that explains that the participant's relationship with the clinic will not be affected by his or her decision to participate or not participate in this study. The informed consent language will be developed at no greater than a 5th grade reading level and may be read aloud to the potential participant, if deemed necessary. During the creation of the informed consent document, research staff will embed a series of basic questions to gauge the potential participant's understanding of procedures, in order to assure that participants are able to comprehend the details of the study. If the potential participant fails to answer these questions appropriately, he or she will not be enrolled into the study.

d. Who will conduct the consent interview?
Only trained study personnel in the DR, who speak Spanish, will facilitate the written or verbal informed consent processes with potential participants.

e. Who are the persons who will provide consent, permission, and/or assent?

For the health care workers, they will provide consent for themselves. For the patients at each clinic, they will provide consent for themselves if they are 18 years of age or older (legal age of adulthood in DR is 18). If patients at each clinic are aged 16-17, we will take informed consent from both the youth and his or her legal guardian unless youth provides proof of emancipation, which will be collected and documented along with his/her consent.

f. What steps will be taken to minimize the possibility of coercion or undue influence?

Informed consent procedures for all participants will take place in a private space. DR study staff will be trained to communicate all components of the informed consent clearly, so that potential participants understand that their consent is voluntary and to avoid coercion. Consent will use clear language that explains that the participant's relationship with the clinic will not be affected by his or her decision to participate or not participate in this study. The informed consent language will be developed at no greater than a 5th grade reading level and may be read aloud to the potential participant, if deemed necessary. During the creation of the informed consent document, research staff will embed a series of basic questions to gauge the potential participant's understanding of procedures, in order to assure that participants are able to comprehend the details of the study. If the potential participant fails to answer these questions appropriately, he or she will not be enrolled into the study.

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

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

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**

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 these are clinical patients who are living with HIV, often with inconsistent circumstances, it is important that we are able to inform and enroll in a single session. There will be a delay between when they learn of the protocol and each Aim, so they will be able to change their mind.**

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.

Study personnel will follow regulatory guidelines for obtaining written or verbal informed consent. All interviews and intervention activities will be conducted in private spaces, in so far as possible.

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.

The team will make every effort to protect all participants' confidential and private information in order to minimize possible study-associated risks. For all participants, research data will be stored using a code (sequence number based on entry to the study) instead of names or other personal identifiers. Research team members analyzing the study-related data will not attempt link the participant to identifying information or learn of his/her identity. Only the designated site personnel (and MPIs) can track the use of participant or

patient identifiers. Consent forms with links to participant study numbers will be kept in a in a locked file in a locked room with the PI (Budhwani) if paper-based or in an encrypted, password-protected file at UAB if electronic. According to UAB regulatory policy, records relating to research, including informed consent documents, shall be securely retained for one year after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or sponsor agency at reasonable times and in a reasonable manner. All electronic study data are kept on UAB secure encrypted password protected servers, and will only be available to research personnel. All study personnel will complete HIPPA and human subjects training in accordance with UAB Institutional Review Board policy.

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?

Study participants and the larger scientific community

ii. What data will be shared?

Findings related to this research will be provided to study participants in dissemination meetings and materials. Study data will only be shared with the larger scientific community in coded fashion. No data will be accepted from or distributed to investigators if regulatory approval has lapsed. Requests for study-related datasets will be submitted to the MPIs. Copies of each of these regulatory documents will be kept on file at UAB.

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

Coded

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**

Secondary (Move from UAB to FSU) Protocol

PROTOCOL TITLE:

Adapting the Finding Respect and Ending Stigma around HIV (FRESH) Intervention for the Dominican Republic

PRINCIPAL INVESTIGATOR:

Henna Budhwani, PhD, MPH
College of Nursing
(205) 296-3330
hbudhwani@fsu.edu

VERSION NUMBER/DATE:

Version 1: 08/20/22

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

Table of Contents

1.0 Study Summary

Note: We are only applying for IRB approval for the remainder of the project. Most of the study has already been completed. (See UAB IRB protocol document for orientation.) We are only applying for the remainder of what was previously approved at UAB. We are not proposing any changes to the approval we had at UAB. All local personnel in the Dominican Republic are covered under the local reviewing IRB at UNIBE.

Study Title	Adapting the Finding Respect and Ending Stigma around HIV (FRESH) Intervention for the Dominican Republic
Study Design	Survey
Primary Objective	Analyze perceptions/attitudes/beliefs around HIV
Secondary Objective(s)	Health outcomes (per de-identified, anonymous clinical data)
Research Intervention(s)	N/A
Study Population	Clients and health workers
Sample Size	N=100 clients and N=20 health workers
Study Duration for individual participants	One time survey
Study Specific Abbreviations/ Definitions	PLWH: people living with HIV SGM: sexual and gender minorities MSM: men who have sex with men

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives.

The overall purpose of this research project is to adapt an educational intervention (Finding Respect and Ending Stigma around HIV) that has been proven to be effective in Africa and the US to meet the needs of HIV clinics in the Dominican Republic. Health outcomes, as well as perceptions/attitudes/beliefs, will be measured before and after the intervention.

The purpose of this IRB submission is to just collect the last round of in-clinic survey data and the last round of de-identified and anonymous clinical data.

2.2 State the hypotheses to be tested.

N/A

3.0 Background

3.1 Describe the relevant prior experience and gaps in current knowledge.

There are high levels of stigma against sexual and gender minorities (SGMs) in the Caribbean. Many Caribbean nations have a dominant conservative ideology that criminalizes MSM sexual behaviors and shames young SGM, particularly those who are living with HIV. In the DR, stigmatizing views are commonplace, and policies that perpetuate stigma towards PLWH and SGMs are embedded in DR laws. Stigmatizing attitudes toward PLWH and SGMs are often reflected in the behaviors of health workers, and thus stigmas may become embedded in HIV clinics, leading PLWH to be reluctant to engage in care. In the DR, PLWH routinely experience intersectional stigma for being a PLWH and for identifying as an SGM. This intersectional stigma may increase the amount and intensity of stigma experienced by SGMs who are living with HIV, with synergistic effects on health outcomes. Research shows that these stigmas are significant barriers to HIV treatment services and contribute to the DR's low 16% viral suppression rate.

HIV and intersectional stigmas in healthcare settings are significant barriers to care in the DR. Consejo Nacional para el VIH y el SIDA (CONAVIHSIDA) recently released results from its national study on HIV stigma. This study found that over a third of HWs had no stigma training; a third of HWs were afraid to draw blood from PLWH, and 56% of HWs did not want to provide services to SGMs living with HIV, because they felt SGMs deserved to be HIV-infected. Findings from the Transgender Health Study further validate the notion that stigma is a significant barrier to HIV services in the DR. In fact, it was only after advocates took their demands to the Inter-American Human Rights Commission that antiretroviral therapy (ART) was approved as a covered medical expense in the DR, and it wasn't

until 2009 that PLWH were allowed to enroll in the DR National Health Insurance System. Stigmatizing attitudes from HWs push the epidemic underground and promote the spread of HIV, because PLWH and SGMs may avoid engaging in care due to fears of stigma from HWs. Thus, it is imperative that tailored interventions to reduce stigmas in clinics be developed and tested. If stigmas are not addressed, the DR will likely see a rise in new infections and worsening of HIV outcomes in PLWH.

3.2 Describe any relevant preliminary data.

N/A

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

There are surprisingly few intersectional stigma reduction interventions for healthcare settings. Clinic-based stigma-reduction interventions have primarily been developed for Asian and African settings, making the adaptation of FRESH for the Caribbean unique. In assessing interventions for appropriateness, we applied Nyblade's key criteria for stigma-reduction efforts. Evidence-based strategies include selecting interventions that involve PLWH and HWs, use of participatory methods, address actionable drivers of stigma in the short term, put PLWH at the core of the response, and create partnerships between PLWH experiencing stigma and HWs to model non-stigmatizing behaviors. Considering the lack of HIV-stigma research in the DR and that FRESH is one of the few interventions that meets these criteria, the DR is a priority setting for the cultural adaptation and testing of the FRESH intervention that involves both PLWH and HWs.

The Finding Respect and Ending Stigma around HIV (FRESH) intervention is ideal to adapt and test. The FRESH intervention was originally developed in a study in five African nations, then was adapted for the United States. Since we have data showing that FRESH is adaptable, revising it for Latinx and Hispanic populations could yield scientific evidence leading FRESH to become a validated multi-region stigma-reduction intervention. The FRESH intervention brings together HWs of all types and PLWH to collaborate in a workshop to increase understanding of HIV-related and intersectional stigmas. FRESH facilitates conversations on effects of stigma on health and well-being and guides participants to better recognize and understand stigmas. FRESH includes didactic content and interactive activities. Each topic includes contact-theory informed activities designed to bring HWs and PLWH together to change perceptions of each other while enhancing empowerment and empathy. Facilitators use a standard manual for consistent content delivery. FRESH was efficacious in reducing stigmas in Africa, and the United States pilot had promising results

(Preliminary Studies). We are confident that FRESH is an excellent intervention to adapt for the DR because, 1) FRESH is sustainable. Facilitators can train other trainers. 2) FRESH is low-cost. As a socio-structural intervention, there are no clinical costs. 3) FRESH is extensible. We have shown that FRESH was adapted from African contexts to the United States, and 4) FRESH is flexible. FRESH was adapted to address a spectrum of relevant intersectional stigmas in the US Deep South, among other modifications.

4.0 Study Endpoints

4.1 Describe the primary and secondary study endpoints.

In-clinic data will be collected for one month. If approved in time, we expect to start in-clinic data collection September 1, 2022.

Retrospective clinic data will be collected after IRB approval for the months of July 1st-August 31st, 2022.

5.0 Study Intervention

1.1 Description: *Describe the study intervention that is being evaluated.*

N/A: The intervention has already been delivered to participants. They are no longer enrolled in the study.

6.0 Procedures Involved

6.1 Describe and explain the study design.

The remainder of the study is a one-time survey for participants.

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

We will collect outcome information on demographics, stigma-related measures, and HIV-related behavioral outcomes by asking all HWs and PLWH in Site 2 and 3 clinics to complete in-clinic anonymous surveys (we expect the effects of the workshop to impact stigma throughout the whole clinic, not just the workshop participants). In-clinic stigma surveys will be completed at 4 time points pre- and post- workshop (intervention). Time points 1-3 have already been completed.

Research personnel at FSU will not be collecting data. However, the surveys, attached to this submission, will be held through FSU's Qualtrics forum. Research personnel at FSU will not have any way to identify the individual participants (i.e. no names or identifiers are being collected). All data collection methods will be done by the local team in the Dominican Republic, who have separate IRB approval at UNIBE.

In addition, outcomes related to HIV care will be collected from the national HIV medical records system monthly. Data will include 1) Number of new-to-care PLWH, 2) ART initiation, and 3) Viral load

suppression rates. These data will be used to compare site-level HIV cascade outcomes pre- and post- FRESH. This data is de-identified and will be collected by the local team in the Dominican Republic. There is no way to trace data to individuals, as the data will be collected through the Ministry of Health. FSU personnel, if approved, will receive the anonymous data from the local Dominican Republic team.

6.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*
- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*

All data collection is anonymous. There is no way to trace data to back individuals. Contact with human subjects will not be done through FSU.

The surveys are in Spanish but will be attached to the submission. English translations of the surveys are also provided with a letter from the local Dominican Republic team verifying that the surveys are translated accurately and match.

6.4 Describe what data will be collected during the study and how that data will be obtained. Note that IF the data will include any health information that is subject to the HIPAA Privacy Rule, refer to the IRB's HIPAA requirements [link] and follow any applicable instruction accordingly, including describing how the HIPAA Privacy Rule requirement will specifically be implemented in sections 17 (Data Management and Confidentiality) and 19 (Provisions to Protect the Privacy Interests of Subjects) of this protocol.

Survey data (copies attached) will be collected by the Dominican Republic team. FSU study personnel will not collect data. The survey will be taken anonymously through FSU's Qualtrics forum.

The Dominican Republic team will collect the relevant clinical data from the Ministry of Health. They will share the anonymous data with FSU personnel for data analysis.

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

N/A

7.0 Data and Specimen Banking

7.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

N/A

7.2 List the data to be stored or associated with each specimen.

N/A

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

N/A

8.0 Sharing of Results with Subjects

8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.

Results will not be shared, as all remaining data is anonymous.

9.0 Study Timelines

9.1 Describe:

- *The duration of an individual subject's participation in the study.*
- *The duration anticipated to enroll all study subjects.*

Individuals will participate in a one-time survey. FSU study personnel will not be enrolling participants.

10.0 Subject Population

10.1 Describe generally the individuals that will be included in your study.

The study population for the surveys includes clients at the clinics and health workers at the clinics.

10.2 Describe any subject populations that will be specifically targeted, or specifically excluded from your sample.

N/A

10.3 Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of these populations as subjects in your research unless you include them in the description of your subject population.)

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

We will not include any of the above populations.

11.0 Vulnerable Populations

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

N/A

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally, if known.

In total, we estimate samples of N=400 PLWH client surveys; N=80 HW surveys. HIV care data, at the clinic-level and not the individual-level, will be obtained from the sites monthly for the full 24-months.

13.0 Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited. If recruitment will involve a non-FSU site, describe whether site approval for recruitment is required, and attach documentation of site approval.

We will not be recruiting participants at FSU.

13.2 Describe the source of subjects.

Survey participants are clients or health workers at the clinics.

13.3 Describe the methods that will be used to identify potential subjects.

See above.

13.4 Describe materials that will be used to recruit subjects. (Describe materials that will be used to recruit subjects. For advertisements and all other recruitment materials, attach the final copy of printed, web-based, online or other electronically conveyed materials in the Local Site Documents/Recruitment materials section of the RAMP IRB submission workspace for the study. When advertisements are taped for broadcast, attach the final audio/video tape; you may submit the wording of the advertisement prior to taping to preclude re-taping based upon required or suggested IRB revisions, provided the IRB reviews the final audio/video tape). Refer to "WORKSHEET: Advertisements & Other Recruitment Materials (HRP-315)" to ensure that recruitment procedures and recruitment materials will conform to requirements for IRB review and approval.

See above.

13.5 Describe as applicable whether and how subjects will be paid, earn course or other credits, reimbursed or provided with any financial or other incentive, token or gift for taking part in the research. Include a description and schedule of the total amount or value as well as the timing of any payments, credits, reimbursement or other incentive, token or gift. Indicate how if at all any amount is pro-rated for research visit or activity completion, and whether and how subjects' refusal to answer any question or subjects' withdrawal from or discontinuing taking part in the study or any study activity will reduce or preclude subjects from earning part or all of such any payment, credit, reimbursement or other incentive, token or gift.

Also describe the proposed method (how, by whom, form etc.) of payment/disbursement. While payment should not be contingent upon completion of the entire study, a proportion or progressive partial payment as an incentive for completion of the study is acceptable.

Refer to this FSU link regarding use of gift cards: https://procurement.fsu.edu/vendors/NationalGiftCard.

Refer to this FSU Controller link regarding use of cash payments for human subject incentive payments: https://controller.vpfa.fsu.edu/services/accounts-payable/unencumbered-payments/employee-cash-advance-requests.

Incentives will not be processed through FSU.

13.6 Describe as applicable whether and how student subjects will be provided with course or other academic credit for taking part in the study. Include a description about whether student subjects' refusal to answer any question or withdrawal from or discontinuing taking part in the study or any study activity will reduce or preclude student subjects from earning part or all of such credit.

N/A

14.0 Withdrawal of Subjects

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

N/A

14.2 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

N/A

15.0 Risks to Subjects

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a

description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. For each of these risks, describe in detail how the risks will be minimized.

There should not be any risks at Florida State University. Survey data will be collected via FSU Qualtrics, but there will be no interaction with participants at FSU. FSU personnel will only have access to the anonymous data.

Participants may experience temporary stress due to the nature of some of the survey questions. The local Dominican Republic team will inform the participant that they may stop the survey at any time if stress occurs.

15.2 *If information about the study's actual purpose will not be completely or accurately described to study subjects, or in any way be withheld, obscured, masked, or blinded from study subjects (e.g., you want to avoid participation bias or priming prospective subjects), you are required to describe here that you will: (a) as part of the consent process provide subjects with a statement to the effect that subjects may not be made aware of some features about the study, such as its exact purpose, study questions and materials, or subjects' responses that you would like to collect, and that subjects will be provided with additional information about the study at the end of their participation or at any time they withdraw, (b) debrief subjects at the end of their participation or at any time they withdraw, and (c) provide the IRB with a copy of all materials that will be used to debrief subjects.*

N/A

15.3 *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*

N/A

15.4 *If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*

N/A

15.5 *If applicable, describe risks to others who are not subjects (e.g., family members, colleagues, acquaintances or other persons) but about whom subjects will or may, as part of any study activity, identify, reference or provide identifiable, private information about these other individuals).*

N/A

15.6 *Special instructions if children (individuals less than 18 years of age) will be included as subjects: Federal law at 45 CFR 46, section 46.406 permits the involvement of children as human subjects in research for which there is no prospect of direct benefit to individual*

*child subjects, but ONLY IF the risks in the research represent only a **minor increase** over minimal risk to a child.*

Minimal risk *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of healthy children.*

If applicable (i.e., there is no prospect of direct benefit to individual child subjects), describe how the probability (e.g., likelihood) and magnitude (e.g., severity, duration, reversibility) of any harm or discomfort anticipated in the research involving children represents only a minor (i.e., slight, negligible) increment beyond minimal risk to healthy children as subjects.

N/A

16.0 Potential Benefits to Subjects

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

Participants in this study are HWs and PLWH. Overall, if successful, this project will yield a model for sustainable implementation of an intervention to reduce stigma and improve outcomes across the HIV cascade in resource-poor settings. Given the limited risks associated with this intervention study, the benefits outweigh the risks. PLWH are at particular risk of being stigmatized, yet few interventions exist that specifically reduce stigma in healthcare settings for the Caribbean. This study will ultimately benefit both PLWH and their healthcare providers by creating stigma-free healthcare environments and improving outcomes along the HIV continuum of care.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others. Also, payment to research subjects for participation in studies is not considered a benefit so do not list payment to research subjects in this section; if a recruitment incentive will be offered, described this in section 13 under Recruitment Methods.

There is no direct benefit to the specific participants taking the survey.

17.0 Data Management and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

Our analysis plan includes three steps: 1) Evaluate reliability of translated scales; 2) Assess acceptability of the adapted intervention;

3) Analyze stigma and related constructs pre- and post-intervention and between intervention sites. To ensure reliability of newly translated stigma scales, we will calculate Cronbach's alphas and compare the statistic for the Spanish version to the English version. To examine acceptability of the intervention, we will analyze post-FRESH questionnaire data on workshop satisfaction. We will use descriptive statistics for stigma outcomes and potential mediators and moderators of interest. We will compare changes from pre-FRESH to post-FRESH. Data from all time points will be used. Analyses will be performed for healthcare workers and people living with HIV separately and in aggregate. Analyses will include all participants who provide pre- and post-workshop data. Thus, final data will be presented as pre- and post-intervention changes in healthcare workers and people living with HIV. Estimates of correlations, intra-cluster correlation, within-period correlation, etc. will be calculated to inform future trial designs. Due to the small number of pilot participants, we will not conduct mediation analyses to examine pathways. We will conduct exploratory analyses of associations of potential mechanisms with outcome variables. HIV cascade outcomes will be compared pre- and post-intervention to provide guidance on the design of the future R01 trial. As a pilot study to develop preliminary estimates, this study is not powered to show efficacy. However, in preparation for the full-scale R01 trial, we conducted precision estimates for this study and a power analysis for the future R01.

17.2 *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.*

17.3 *Describe any procedures that will be used for quality control of collected data.*

We are requesting IRB approval for data analysis and the final two steps of data collection including collecting anonymous, de-identified post-visit survey data from patients and providers and anonymous, de-identified medical records data. 1) Password-protected clinical records data will be delivered from the Dominican Republic to the United States via encrypted and secure box.net folder; once the data has been delivered to the folder, the FSU research team will verify the data and share with the biostatistician at the University of Alabama at Birmingham (UAB) for analyses. The UAB biostatistician is covered under the UAB IRB. There are no patient identifiers in the data. 2) Qualtrics data will be collected via the FSU approved Qualtrics system. Data will be downloaded intermittently during the two week data collection window into a secure box.net folder dedicated to these anonymous, identifier-less data. Once downloaded. The data will be password protected with a strong password and only shared for analysis purposes, as detailed

in the original proposal. No additional steps will be taken for quality control. These procedures led to successful outcomes for the prior three rounds of data collection without any breeches.

17.4 Describe how data or specimens will be handled study-wide:

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have access to the data or specimens?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How data or specimens will be transported?*

N/A

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required for any study that may involve any harm or discomfort for which the probability or magnitude is greater than those that may be ordinarily encountered by healthy persons in daily life or during the performance of routine physical or psychological examinations or test.

A DSMB was not required by the NIH. Because data collection is anonymous and de-identified, there is no way to map back to individuals. The medical records data contain limited information, none of which would indicate and AE or SAE, since the data is purely administrative. However, in- clinic data is being collected from patients and providers. These data are also anonymous and therefore unidentifiable; these data primarily focus on experiences of stigma and discrimination in the clinic setting. Upon the completion of the study, findings will be reported to the clinics.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

FSU study personnel will not have contact with participants.

19.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

FSU study personnel will not have contact with participants.

19.3 Indicate how the research team is permitted to access any sources of information about the subjects.

All remaining data is anonymous.

20.0 Compensation for Research-Related Injury

This section is required for any study that may involve any harm or discomfort for which the probability or magnitude is greater than those that may be ordinarily encountered by healthy persons in daily life or during the performance of routine physical or psychological examinations or test.

20.1 Describe the available compensation in the event of research related injury.

N/A

20.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury.

N/A

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

N/A

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe:

FSU study personnel will not be consenting participants. All consenting will be done by the Dominican Republic team, who have IRB approval at UNIBE.

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

FSU study personnel will not be consenting participants. All consenting will be done by the Dominican Republic team, who have IRB approval at UNIBE.

24.0 Setting

24.1 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*

Lotes y Servicios and Centro Sanitario in the Dominican Republic

- *Identify where research procedures will be performed.*

  Lotes y Servicios and Centro Sanitario in the Dominican Republic

- *Describe the composition and involvement of any community advisory board.*

  N/A at FSU.

- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization.*

    None noted; any relevant considerations were addressed in the local IRB review by UNIBE.

  - *Local scientific and ethical review structure outside the organization.*

    IRB at UAB (Alabama) and UNIBE (Dominican Republic).

- *Describe non-FSU site approval to conduct research at any non-FSU site or location, and attach approval documentation. If no such approval was required, so state and be prepared to provide documentation. Studies involving non-FSU sites, institutions or agencies, such as TMH, CRMC, FAMU, state agencies and other organizations, may require those sites' IRB, research review or other approvals. Before submitting your studies for FSU IRB review, you must contact such sites to ascertain their review requirements and comply accordingly. The FSU IRB may require documentation of such site contact. Collaborations involving TMH are subject to specific requirements; click here for more information.*

  We have received IRB approvals from UAB (Alabama) and UNIBE (Dominican Republic). See letters.

25.0 Resources Available

25.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

N/A at FSU

Statistical Analysis Plan, Overall

Our analysis plan includes three steps: 1) Evaluate reliability of Spanish translated stigma scales; 2) Assess acceptability of the adapted intervention; 3) Analyze stigma and related constructs pre- and post-intervention and between intervention sites. To ensure reliability of newly translated stigma scales, we will calculate Cronbach's alphas and compare the statistic for the Spanish version to the English version. To examine acceptability of the intervention, we will analyze post-FRESH questionnaire data on workshop satisfaction. We will use descriptive statistics for stigma outcomes and potential mediators and moderators of interest. We will compare changes from pre-FRESH to post-FRESH. Data from all time points will be used. Analyses will be performed for healthcare workers and people living with HIV separately and in aggregate. Analyses will include all participants who provide pre- and post-workshop data. Thus, final data will be presented as pre- and post-intervention changes in healthcare workers and people living with HIV. Estimates of correlations, intra-cluster correlation, within-period correlation, etc. will be calculated to inform future trial designs. Due to the small number of pilot participants, we will not conduct mediation analyses to examine pathways. We will conduct exploratory analyses of associations of potential mechanisms with outcome variables. HIV cascade outcomes will be compared pre- and post-intervention to provide guidance on the design of the future R01 trial. As a pilot study to develop preliminary estimates, this study is not powered to show efficacy. However, in preparation for the full-scale R01 trial, we conducted precision estimates for this study and a power analysis for the future R01.

Statistical Analysis Plan, Primary Outcomes

While we will collect various forms of data, primary outcomes will be assessed from the pre-post workshop data. Cronbach's alphas will be calculated for each multi-item scale to examine for the internal consistency. Assumption of normality will be checked. Pre -and post- survey measures will then compare to assess the change after the workshop intervention using paired t-tests if the normality is confirmed, and Wilcoxon signed rank tests if the normality assumption was violated. The significance level will be $p<0.05$. All analyses will be performed with SAS (Version 9.4, Cray, North Carolina, USA), but SPSS can be used in its place if needed.