

Request for Sub-collection under the Generic ICR:
Formative Research and Tool Development
OMB 0920-0840, Expiration Date 01/31/2019

Developing Tools to Engage Adolescent Men Who Have Sex with Men (AMSM)

OMB No: 0920-0840
Exp. Date: 01/31/2019

**Supporting Statement
Part B**

September 7, 2017

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Supporting Statement

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondent Universe

This formative research study will enroll adolescents at high risk for HIV, living across the United States into online and in-person focus groups using multiple recruitment methods. Participants will be recruited to online focus group using the InsideHeads platform. In-person focus groups will involve recruitment through social media and broad based recruitment in the focus group cities (Boston and Philadelphia).

The 2015 Youth Risk Behavior Survey (YRBS), with data from 25 states and 19 cities, estimates that 2% of high school youth identify as gay or lesbian, 6% as bisexual, and 3.2% are unsure. Some 1.7% of youth report same-sex contact only, and 4.6% report sexual contact with both females and males.

Inclusion Criteria

Our intended recruitment is summarized below:

FG No.	Type of Focus Group	Sample/ Location	N	Type of Respondents	Age Range	Race/Ethnicity
1	Online	National (urban)	12	AMSM ¹	13-18 years ²	All
2	Online	National (rural)	12	AMSM ¹	13-18 years ²	All
3	In person	Philadelphia PA	12	AMSM ¹	14-17 years	Oversample Black
4	In person	Boston MA	12	AMSM ¹	14-17 years	All
5	Online	National	12	Transgender ³	13-17 years	All
6	Online	National	12	Transgender ³	18-24 years	All

¹ Cis-gender male attracted to other males, sexually active or inactive

² Breakout sessions for ages 13-15 and 16-18

³ Male assigned at birth or female assigned at birth (breakout sessions for each)

*The 14-17 year old age range for in-person focus groups is necessary because the CDC Division of Adolescent and School Health is particularly interested in this understudied

population to better understand the existing gaps in primary prevention of HIV. The project will develop tools and strategies for this population in order to address the striking disparities in HIV infection, particularly among Black and Latino, gay/bisexual young men and transgender youth (which the CDC defines as ages 13-24). In summary, it is critical to do research with this younger age range because:

- There is a dearth of prior research with sexual and gender minority youth, especially under age 18
- Primary prevention with adolescents is necessary to reduce new infections
- This population needs to be prioritized to address the shocking racial/ethnic, sexual orientation, and age disparities in new diagnosis data

Exclusion Criteria

Participants would be excluded from the focus group if they are unable to complete the screening and consent process.

Sample Size

For online and in-person focus groups collectively, the target sample size is a maximum of 72 participants.

Sample sizes for each component of the focus groups:

- Online focus groups – A maximum of 48 participants (24 transgender youth age 13-24, 24 AMSM age 13-18)
- In-person focus groups – A maximum of 24 participants (24 AMSM age 14-17)

Sampling Methods

Focus group sampling will involve broad based recruitment through a variety of methods. For in-person focus groups, we plan to collaborate with partner organizations in Philadelphia and Boston to recruit participants. In-person focus groups will take place at partner organizations in these cities that serve LGBT youth. These groups provide clinical services and community outreach for LGBT youth in their respective cities. If any of these organizations are unable to partner with us for whatever reason, we will seek out a similar organization that provides services and support to LGBT youth.

We will utilize recruitment ads to post in the partner organizations, on the social media accounts (Facebook, Instagram, Twitter) of partner organizations, and to be handed out at public events. The recruitment ads have been developed in partnership with our Youth Community Advisory Board (YCAB) to make culturally competent images that are attractive to youth.

For online focus groups, we will use similar recruitment ads. InsideHeads®, the online focus group platform, also provides recruitment services. InsideHeads is a marketing research company with over 17 years of experience recruiting participant panels and supporting platforms for online research.

Sampling Plan

A non-probability sample will be utilized for these focus groups in order to collect qualitative data from young individuals at high risk for HIV infection across the United States. A review of the literature and consultation with research advisors determined that a hybrid of online and in-person focus groups is preferred. The combination of online and in-person focus groups will allow for comparison between the two methods. We will also be able to use online focus groups to access youth who are unable to attend an in-person focus group.

For the in-person focus group:

- Entry will begin with a participant screener (**Attachment 3a**) conducted over the phone or in-person.
 - Eligible study participants must be residents of the United States and meet the criteria for one of the following groups: Male, attracted to/sexually active with men or identifies as sexual minority, lives in/around Philadelphia, 14-17 years, Black
 - Male, attracted to/sexually active with men or identifies as sexual minority, lives in/around Boston, 14-17, all races
- Eligible participants will arrive at the focus group site and be consented/assented (**Attachment 4a & 4b**).
- The focus group will be conducted using the focus group guide (**Attachments 3b & 3c**).

For the online focus group:

- Entry will begin with a participant screener (**Attachment 3a**) conducted through the InsideHeads platform.
 - Eligible study participants must be residents of the United States and meet the criteria for one of the following groups:
 - Male, attracted to/sexually active with men or identifies as sexual minority, national, urban/suburban, 13-18, all races
 - Male, attracted to/sexually active with men or identifies as sexual minority, national, rural, 13-18, all races
 - Transgender Youth – national, 13-17
 - Transgender Youth – national, 18-24
- Eligible participants will be consented/assented prior to focus group initiation (**Attachment 4a & 4b**).
- The focus group will be conducted using the focus group guide (**Attachment 3b or 3c**).

1. Procedures for the Collection of Information

Recruitment will take place in-person and online. For in-person focus groups, we will collaborate with partner organizations to recruit participants. We will utilize recruitment ads (**Attachment 5a**) to post in the partner organization, on the social media accounts (Facebook, Instagram, Twitter) of partner organizations, and to be handed out at public events. The recruitment ads have been developed in partnership with our youth community advisory board (YCAB) to make culturally competent images that are attractive to youth. Recruitment will also involve an approved set of recruitment language (**Attachment 5b**). Study staff will then determine

eligibility using a participant screener (**Attachment 3a**). If eligible, the participant will receive information about the date and time of the focus group. On the day of the focus group, participants will be consented/assented using an information sheet (**Attachment 4a & 4b**). For in-person focus groups, an audio recording of the focus group will be used to later transcribe the focus group conversations, which will be used for analysis along with the background survey data.

For online focus groups, we will use the same approved recruitment language (**Attachment 5b**) and recruitment ads (**Attachment 5a**). *InsideHeads*®, the online focus group platform, also provides recruitment services. *InsideHeads* is a marketing research company with over 17 years of experience recruiting participant panels and supporting platforms for online research. Potential participants recruited by *InsideHeads*, will be directed to a web page where they will be screened (**Attachment 3a**). If eligible, they will be directed to a page that explains the study purpose and procedures, and provides the electronic information sheet (**Attachment 4a & 4b**). Those consenting will be directed to procedural instructions of how to “attend” the online focus group (e.g. date, time, login instructions). During the designated days/times the online focus group will begin in a discussion board format, and be moderated by the study staff. Background survey data and typed transcripts from the online focus group on the *InsideHeads* platform will be used for analysis.

Data Management

- All personally identifying information (i.e., e-mail addresses and/or phone numbers collected for delivery of the token of appreciation) will be maintained in separate databases that are fully divorced from the focus group data.
- No PII will be delivered to CDC or used in future research or analysis.
- Focus group data will be organized in databases stored on secure local servers at TFI and will be backed-up regularly.
- Electronic equipment and files will be kept password-protected.
- Electronic devices will be kept locked when not in use.
- Individual records will be kept secure, accessible only to the study team.

For in-person focus groups, all de-identified data collected, including audio files and transcripts, will be stored on password-protected computer databases at The Fenway Institute. The online focus group will be conducted on a secure, password-protected, study-specific virtual focus facility, a computer-aided focus group platform supported by *InsideHeads*. Online focus group participants will be referred to by a pseudonym, and their name will not appear on written transcripts. There will be no way to link responses back to individual participants. *InsideHeads* IT support team monitors the system 24/7 to ensure the platform is always up to task, while industry-standard SSL encryption technology ensures discussions and attachments are

transmitted securely and archived safely. The anonymous, de-identified online focus group data (collected in a discussion board format—interactive real time typed questions and answers) will be downloaded from our password-protected virtual “classroom” on the virtual focus facility platform onto a TFI password-protected computer. Data shared between Fenway and NORC or CDC will be encrypted and shared via secure server, and any data will first be de-identified by Fenway prior to encrypted sharing.

2. Methods to Maximize Response Rates and Deal with Nonresponse

Study participation is voluntary, and study leads will make every effort to maximize the rate of response. The following procedures will be used to maximize cooperation and achieve the desired participation rates:

A \$50 token of appreciation for in-person focus groups and \$30 token of appreciation for online focus groups will be offered to participants.

The Fenway Institute (TFI) will provide contact information during the consent process for the Project Manager, Principal Investigator, and the TFI manager of research compliance in case of any concerns or questions related to their participation. All participants will also be provided with the Trevor Lifeline number that they may call if they experience distress.

If participants report any form of abuse, we will utilize our procedure for reporting child abuse (**Attachment 4f**) which also includes a list of resources that can be provided to the participant.

Main challenges to the success of the project include willingness of participants to share intimate information on sexual behavior. Proposed solutions are to ensure that responses will be safeguarded or maintained in a secure manner to protect privacy , as described in the information sheet used to consent participants (**Attachments 4a & 4b**), and to utilize accurate, unbiased language throughout the focus group to avoid insinuating a value judgment for any behaviors.

3. Test of Procedures or Methods to be Undertaken

The study team developed the focus group guide in partnership with the full study team, research advisors, and the Youth Community Advisory Board (YCAB). We obtained the input of researchers who have experience conducting online and in-person focus groups with adolescents and young adults who identify as sexual and gender minorities. We also received feedback from the YCAB, which is comprised of members of the target population for this study. Members of the study team have extensive experience conducting focus groups with adults and adolescents both online and in-person.

4. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Role	Name	Telephone Number	Email
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*Not Available (NA)