

Attachment B: IRB Approval Letter

MINUTES
NOVA RESEARCH COMPANY
INSTITUTIONAL REVIEW BOARD (IRB)
NIAID HIV Vaccine Research Education Initiative (NHVREI)
Contract No. HHSN266200600024T
Highly Impacted Population (HIP) Survey
Bethesda, Maryland
September 25, 2009
9:00 a.m. to 12:00 Noon

Meeting Agenda

- Introductions: Elliott Bovelle, IRB Chair & Paul Young, Principal Investigator
- Overview of NHVREI: Caroline McLeod, Project Director
- Review/Discussion/Vote: Elliott Bovelle

IRB Members in Attendance

Elliott Bovelle, PhD
Annette B. Ramirez de Arellano, DrPH
Flora Terrell Hamilton, DSW, LICSW, LCSW-C
Joyce Hamilton Berry, PhD
Frederick Snyder, PhD (ABD)
Dana Young, JD

Others in Attendance

Paul Young, MBA, MPH
Caroline McLeod, PhD
Natalie Gay, MS, Recorder and Research Associate

Dr. Bovelle called the meeting to order.

Introductions

Mr. Young and Dr. Bovelle welcomed the Board and introductions were provided by Board members and NOVA Research Company (hereafter, NOVA) staff.

Dr. McLeod: Brief Summary of NHVREI

Dr. McLeod began by stating that the purpose of NHVREI is to increase knowledge about and support for HIV vaccine research among U.S. populations most heavily affected by HIV/AIDS—African Americans, Hispanics/Latinos, and Men Who Have Sex With Men (MSMs). NOVA is conducting a program evaluation that includes a process and outcome evaluation of the NHVREI program implementation and its impact. For the evaluation, data will be collected from program sites, key influencers, and target populations [via Highly Impacted Population (HIP) Survey].

The HIP survey is a survey of the general population with oversampling of the highly impacted populations to measure knowledge, attitudes, and beliefs related to development of biomedical HIV prevention strategies—vaccine, microbicides, and PrEP. Survey data will be collected via telephone interviews and online survey administration. NOVA is subcontracting with Field Research Corporation, located in California, for the surveys.

Dr. McLeod briefly reviewed domains of the HIP survey: awareness; HIV salience; knowledge, attitudes, along with attitudes towards support for HIV vaccines, microbicides, and PrEP; support for clinical trials for HIV vaccines, microbicides, and PrEP; projected use of HIV vaccines, microbicides, and PrEP; respondent demographics; and respondent attitudes after completing the survey.

Dr. McLeod explained that the survey contains three questions that are sensitive. The first question is related to sexual orientation. It is important to identify the responses of MSMs in the general population as MSMs are one of the highly impacted populations targeted by NHVREI now and in the future. The second question is related to HIV testing and status. This question is an important covariate in attitudes toward prevention. Lastly, the survey contains a question on whether the respondent is transgendered. This is an important subgroup highly impacted by HIV/AIDS.

Survey respondents will be provided with an informed consent and will have the option to opt-out of the survey (i.e., survey is voluntary). Procedures are in place to protect the confidentiality of individuals who provide sensitive information.

Board Review/Discussion

- The use of the words “African American” and “Black” is inconsistent. The Board recommends the terminology “African American or Black” as a grouped response choice because members from these groups are not unified in the use of the individual terms and it will also help to minimize offense in this group.
- There was some discussion about the \$20 incentive being too small given the nature of the information being asked. During Dr. McLeod’s presentation, she explained that nine cognitive interviews have been conducted to date and NOVA did not receive any push back from participants on providing sensitive information. In addition, Dr. McLeod explained that it has been shown that people are more willing to participate when identified as part of an NIH study.
- There were several questions related to the transgendered survey item:
 - (1) Board asked whether the transgendered question would be broken down by ethnicity;
 - (2) Board wanted to know what definition of transgendered was being used for the survey; however, Dr. McLeod had previously explained that it was self-defined. The Board indicated that many transgendered advocates want to be identified as a gender and suggested that some studies have added transgendered as a gender category;
 - (3) Board asked why the transgendered question was at the end of the survey while the gender question was at the beginning. They recommended that persons be able to select transgender as a gender for the first question.

Dr. McLeod explained that at the beginning of the survey, if the respondent provided a “transgender” response to a question about gender, the interviewer would prompt for information about male to female, or female to male. Transgender is thus a response option for the telephone survey, as recommended by the IRB, but is not read by the interviewer.

However, a specific transgender question (Do you identify as transgendered?) is asked at the end of the telephone survey because an early presentation of the question may cause general and/or older population to think that the HIP survey is a sex survey and cause an immediate hang-up. The younger population probably would not think this way.

The issue identified by the Board is that an option for “transgendered” will need to be added to the gender question on the online survey in order to make it parallel to the telephone survey. The Board suggested that the gender question may need to be with the transgendered question at the end of the survey. However, this creates problems for flow of the survey, since the consent statement is long, and it is better to ask some questions before launching into an explanation of terminology. NOVA will make the two surveys parallel, will include transgender as an option for the “gender” question, and will decide what order is best for survey flow.

- The IRB discussed how certain parts of the population may be excluded using the current sampling method. The IRB was concerned that many people who are infected with HIV don’t have an address, telephone, or e-mail and questioned whether a more robust outreach methodology should be considered to reach persons at highest risk for HIV infection.

Dr. McLeod explained that with HIP, NIAID is seeking national estimates of knowledge, attitudes and behavior related to HIV/AIDS biomedical interventions for (1) the general population, (2) all African Americans, (3) all Hispanic/Latinos, and (4) all MSMs in the U.S. National estimates require a sampling frame (i.e., an address-based frame listing all people that are part of population to be surveyed). Statistical sampling techniques will allow NIAID to generalize findings to all the people in the frame with precision that can be quantified. In contrast, findings from convenience samples (such as an intercept survey of persons at-risk for HIV) are impossible to generalize with known precision to the larger U.S. population. Oversampling of the Highly Impacted Populations is required because a survey limited to the general population will not include enough people from HIP groups to create estimates with the desired precision.

A national estimate of the attitudes of persons within HIP populations is important because clinical trials for HIV prevention methods require broad support from the HIP communities. NIAID needs to know about their overall opinions regardless of persons’ risk level, because persons who consider volunteering for clinical trials are influenced by their family, their friends, and their community, and these individuals may or may not engage in high-risk behaviors.

Tens of thousands of volunteers will be needed in the next several years for clinical trials to develop biomedical methods for preventing HIV. To date, the level of support for HIV research among the HIP communities has been relatively low. While NHVREI activities have identified some perceptions and concerns related to this lack of support, the extent and strength of these concerns across social class and geographic area are unknown. Information provided from the HIP survey will allow NHVREI to address concerns from HIP communities as a first step to building support for the development of biomedical HIV prevention strategies.

To summarize, it is true that the HIP survey may not reach people from certain at-risk populations; NIAID feels that their views will be represented through information collected from other NHVREI activities. The final report and all publications from the HIP survey data will document the limitations related to the survey frame, (including the fact that people without addresses were not well represented in the survey), and findings will be interpreted with this in mind.

- There was some discussion on the order (i.e., negative to positive) of response values—Strongly Disagree...Strongly Agree—for survey questions; however, the Board decided that the order of response values is not the Board’s focus for review; the order of response values for scales is the researcher’s priority for analytical purposes. Additionally, the Board suggested that responses should be repeated for each question.
- The reading level of the HIP survey raised some concern among IRB members. The Board agreed that the survey should be “scaled down” to a lower reading level. For example, the survey

contains phrases, such as, “Vaccines trigger the immune system to fight HIV”. The Board suggested using the phrase “helps body to fight” instead of “trigger the immune system”. The Board suggested that terms similar to this phrase be clearly defined whenever possible. Additionally, prompts were suggested by the Board for survey conducted via phone due to the length of survey questions. NOVA is in the process of revising survey items to lower the reading level and reduce the length of the survey. IRB members will provide further consultation on items as soon as the revised survey becomes available.

- Specific changes were requested for the Consent Form.
 - On page 7 of the HIP survey, the Board recommended adding a bullet, which says, “Your identity will be protected.”
 - On page 7 of the HIP survey, more details (e.g., limited access and storage) need to be provided on how participants’ answers and contact information will be stored according to best practices for data security.
 - In addition, a statement regarding the Privacy Act and how it provides additional protection for responses should be added.
 - The consent form for the online survey needs to have a Continue button that reads, “I agree to continue” in lieu of a signature. As for the telephone survey, the Board agreed that if people do not want to participate, they would opt out.

- The following comments about materials were made, and these will be incorporated in accordance with feedback from NOVA’s subcontractor and cognitive interview data:

Pre-Notification Cards/Letters/Script

Response Card for Unmatched Households - boxes for the categories of gender, ethnicity, and race need to be added.

1st Invitation Letter for Unmatched Households - the phrase “call us to set up a telephone interview...” should be re-worded to: “call us at (insert number) to set up an interview.”

Reminder Card for All Households - the sentence, “Your thoughts and opinions are important to us, needs to be added after “We still haven’t heard from you!”

First Voicemail Message for Matched Households script – add statement “We would really like you to participate in this study.”

Unfinished Survey E-mail to Knowledge Panel and Opt-In Panel Members - the word “for” should be deleted from the phrase, “We need for you to complete the entire survey” within the follow-up script. Additionally, a comma should be added after “Additionally you will get [KN panelist incentive] when you complete the survey.”

HIP Survey

A brief description of microbicide is needed (refer to page 8 of HIP survey). For example, microbicides keep the virus from spreading.

Where possible, simplify language in survey by operationalizing concepts, e.g., instead of “trigger the immune system” use “helps body to fight”. NOVA is working to simplify language while retaining the meaning that NIAID wants to investigate.

The Board recommended that male to female and female to male responses for transgender should be subcategories. The Board recommended that a box should be added under Gender for transgendered for the online survey format.

The Board requested an explanation on why survey question #5, part c (page 9), "for one of more of your friends and/or people you know...", is structured into one question as opposed to two; the Board felt that friends and people you know are two different groups and suggested two separate questions. Similarly, the Board asked for the rationale for stating the "concern for one or more of your family" as opposed to a member of your family for question #5, part b (page 9).

All Forms

Racial categories: The heading on page 3 of the HIP Screener, African American needs to be reworded to Black or African American. The Board also recommended that Hispanic/Latino, Asian/Pacific Islander, American Indian/Native American be added for racial categories on the Response Card for Unmatched Households. The Board recommended these changes be consistent throughout the survey, screener, and other materials. Additionally, racial categories need to be consistent with OMB stipulations.

Vote/Decisions

Regarding the NHVREI HIP Survey: the Board provided provisional approval for collection of HIP survey data. Full approval will be granted pending the following:

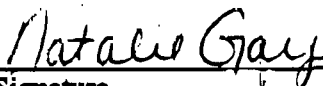
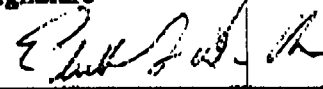
- ✓ 1. Modifications to the consent form consistent with issues previously discussed;
- ✓ 2. Consistent use of the term "African American or Black" throughout all study materials;
- ✓ 3. Use of a "transgender" category as an option for gender for both versions of the survey.
- ✓ 4. Documentation of limitations of address-based sample frames in final publications, including undercoverage of homeless persons and others that might be at very high risk for HIV/AIDS.
- ✓ 5. Review of all final forms of the survey, screener, and pre-notification letters and postcards. All final documents should be sent to the Board as soon as they are completed. The Board requested the opportunity to review the online survey. An e-mail will be sent to the Board when the online survey is available. A follow-up call may be requested.
- ✓ 6. Review of Spanish language versions of the survey, consent form, and notification materials by Board member, Dr. Ramirez. They should be sent as soon as they are all available.
- ✓ 7. The Board requested a prior notice to review materials that involve substantive changes. In the event that major changes are made to survey materials, the Board would reconvene via teleconference.

Dr. Bovelle adjourned the meeting.

Minutes Prepared by: Natalie A. Gay
Recorder/Research Associate

Minutes Approved by: Elliott Bovelle, PhD
NOVA IRB Chair

Minutes, IRB Meeting, September 23, 2009

 Signature	
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