

MTN-003C-01

PREMIS: Preventive Misconception in HIV Prevention Trials

Microbicide Trials Network

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Protocol Chairs:

Kevin P. Weinfurt, PhD, and Jeremy Sugarman, MD, MPH, MA

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MTN-003C-01

PREMIS

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PREMIS

LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|-------|--|
| BRWG | Behavioral Research Working Group |
| CAB | community advisory board |
| CI | cognitive interview |
| CORE | Coordinating and Operations Center |
| CRF | case report form |
| CRS | clinical research site |
| CWG | Community Working Group |
| DAIDS | Division of AIDS |
| FGD | Focus group discussion |
| GCP | Good Clinical Practices |
| HIV | human immunodeficiency virus |
| ICF | Informed Consent Form |
| IDI | In-depth interview |
| IND | investigational new drug |
| IoR | Investigator of Record |
| IRB | Institutional Review Board |
| MTN | Microbicide Trials Network |
| NIH | National Institutes of Health |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIMH | National Institute of Mental Health |
| OHRP | Office for Human Research Protections |
| PRO | Protocol Registration Office |
| QC | quality control |
| RE | regulatory entity |
| RSC | Regulatory Support Center |
| SMC | Study Monitoring Committee |
| SSP | study specific procedures |
| TDF | tenofovir disoproxil fumarate |
| VOICE | Vaginal and Oral Interventions to Control the Epidemic |

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PREMIS

PROTOCOL TEAM ROSTER

Protocol Chairs

Kevin P. Weinfurt, PhD

Protocol Chair

Duke University

Duke Clinical Research Institute

PO Box 17969

Durham, NC 27715 USA

Phone: 919-668-8101

Fax: 919-668-7124

Email: kevin.weinfurt@duke.edu

Jeremy Sugarman, MD, MPH, MA

Protocol Chair

Johns Hopkins Berman Institute of Bioethics

1809 Ashland Ave

Deering Hall, Room 203

Baltimore, MD 21205 USA

Phone: 410-614-5634

Fax: 410-614-5360

Email: jsugarman@jhu.edu

Site Investigator

Jonathan Stadler, MA

Senior Researcher

Wits Reproductive Health and HIV Institute

PO 18512, Hillbrow 2038 Johannesburg, South Africa

Phone: +27 (0) 11-358-5300

Fax: +27 (0)11-358-5400

Email: jstadler@wrhi.ac.za

US National Institutes of Health (NIH)

Roberta Black, PhD

Microbicide Research Branch Chief

National Institutes of Allergy and Infectious
Diseases (NIAID)/Division of AIDS
(DAIDS)

6700 B Rockledge Drive, Rm 5135

Bethesda, MD 20817 USA

Phone: 301-496-8199

Fax: 301-402-3684

Email: rblack@niaid.nih.gov

Lydia E. Soto-Torres, MD, MPH

DAIDS Medical Officer

NIAID/DAIDS

6700 B Rockledge Drive

Bethesda, MD 20892-7628 USA

Phone: 301-594-9705

Fax: 301-402-3684

Email: lsoto-torres@niaid.nih.gov

Dianne M. Rausch, PhD

Deputy Director

Center for Mental Health Research on
AIDS, National Institute of Mental Health
(NIMH)

6001 Executive Blvd, Rm 6218, MSC 9619

Bethesda, MD 20892 USA

Phone: 301-443-7281

Fax: 301-443-9719

Email: drausch@mail.nih.gov

MTN CORE

Katherine Bunge, MD
Protocol Safety Physician
Magee-Womens Hospital of UPMC
300 Halket Street
Pittsburgh, PA 15213 USA
Phone: 412-641-3464
Fax: 412-641-1133
Email: kbunge@mail.magee.edu

Beth Galaska Burzuk, MID
Protocol Development Manager
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-5579
Fax: 412-641-6170
Email: galaskaburzukb@upmc.edu

Sharon Hillier, PhD
Principal Investigator
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-8933
Fax: 412-641-6170
Email: shillier@mail.magee.edu

Ken Ho
Safety Physician
UPMC, Keystone Building, Suite 533
3520 Fifth Avenue
Pittsburgh, PA 15213 USA
Phone: 412-383-7178
Fax: 412-383-2900
Email: hok2@upmc.edu

Cindy Jacobson, PharmD
Director of Pharmacy Affairs
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-8913
Fax: 412-641-6170
Email: cjacobson@mail.magee.edu

Ian McGowan, MD, PhD, FRCP
Co-Principal Investigator
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-8999
Fax: 412-641-6170
Email: imcgowan@pitt.edu

Sharon A. Riddler, MD, MPH
Protocol Physician
UPMC, Keystone Building, Suite 510
3520 Fifth Avenue
Pittsburgh, PA 15213 USA
Phone: 412-383-1741 or 412-383-1675
Fax: 412-383-2900
Email: riddler@dom.pitt.edu

Devika Singh, MD, MPH
Protocol Safety Physician
Box 359927, Department of Global Health
ICRC, 325 Ninth Ave.
Seattle, WA 98104 USA
Phone: 206-744-8311
Fax: 206-520-3831
Email: dsingh@u.washington.edu

BRWG Representative

Ariane van der Straten, PhD, MPH
MTN BRWG Representative

RTI International

114 Sansome Street, Suite 500

San Francisco, CA 94104 USA

Phone: 415-848-1324

Fax: 415-848-1330

Email: ariane@rti.org

MTN CORE – FHI 360

Kat Richards, MPH

Prevention Research Specialist

FHI 360

Research Triangle Park, NC 27709 USA

Phone: 919-544-7040, Ext. 11306

Fax: 919-544-0207

Email: krichards@fhi360.org

Katie Schwartz, MPH

Senior Clinical Research Manager

FHI 360

PO Box 13950

Research Triangle Park, NC 27709 USA

Phone: 919-544-7040, Ext. 11224

Fax: 919-544-0207

Email: kschwartz@fhi360.com

Rhonda White, R. H. Ed.

Community Program Manager

FHI 360

PO Box 13950

Research Triangle Park, NC 27709 USA

Phone: 919-544-7040, Ext. 11515

Fax: 919-544-0207

Email: rwhite@fhi360.org

MTN Community Working Group (CWG) Representative

Nelisiwe Gusta Francisco
CWG Representative

PO Box 18512, Hillbrow 2038

Johannesburg, South Africa

Phone: +27(0)11 358 5424

Fax: +27(0)11 358 5545

Email: gfrancisco@wrhi.ac.za

MTN-003C-01

PREMIS

INVESTIGATOR SIGNATURE FORM

**Version 1.0
September 19, 2011**

A Study of the Microbicide Trials Network

**Sponsored by:
Division of AIDS, US National Institute of Allergy and Infectious Diseases
US National Institute of Mental Health
US National Institutes of Health**

I, the Investigator of Record (IoR), agree to conduct this study in full accordance with the provisions of this protocol. I agree to maintain all study documentation for a minimum of three years after submission of the site's final Financial Status Report to the US Division of Acquired Immunodeficiency Syndrome (DAIDS), unless otherwise specified by DAIDS or the Microbicide Trials Network (MTN) Coordinating and Operations Center. Publication of the results of this study will be governed by MTN policies. Any presentation, abstract, or manuscript will be submitted to the MTN Manuscript Review Committee, and made available to NIMH and DAIDS, for review prior to submission.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.

Name of Investigator of Record

Signature of Investigator of Record Date

MTN-003C-01

PREMIS

PROTOCOL SUMMARY

| | |
|---------------------------|---|
| Short Title: | PREMIS |
| Protocol Chairs: | Kevin P. Weinfurt, PhD, and Jeremy Sugarman, MD, MPH, MA |
| Sample Size: | ~30 |
| Study Population: | VOICE participants, specifically those enrolled in the VOICE-C substudy Group 1 who meet the eligibility criteria. |
| Study Site: | Wits Reproductive Health and HIV Institute (WRHI), Johannesburg |
| Study Design: | Qualitative interviews using cognitive interviewing methods |
| Study Duration: | 6 months |
| Study Regimen: | Each participant will be recruited for participation in one qualitative, cognitive interview. |
| Primary Objective: | To obtain qualitative information about how participants in an HIV prevention trial understand preliminary survey items developed for a measure of preventive misconception |

1 KEY ROLES

1.1 Protocol Identification

Protocol Title: PREMIS: Preventive Misconception in HIV Prevention Trials

Protocol Number: MTN-003C-01

Short Title: PREMIS

Date: September 19, 2011

1.2 Sponsor and Monitor Identification

Sponsor: DAIDS/NIAID/NIH
6700 B Rockledge Drive
Bethesda, MD 20892 USA

Sponsor: US NIMH
6001 Executive Boulevard
Rockville, MD 20852

1.3 Medical Officer

Medical Officer: Lydia E. Soto-Torres, MD, MPH
6700 B Rockledge Drive
Bethesda, MD 20892-7628 USA

1.4 Data Center

Data Center: Duke Clinical Research Institute (DCRI)
PO Box 17969
Durham, NC 27715 USA

1.5 Study Operations

DCRI: PO Box 17969
Durham, NC 27715 USA

FHI 360: PO Box 13950
Research Triangle Park, NC 27709 USA

2 BACKGROUND and INTRODUCTION

2.1 Preventive Misconception in HIV Prevention Trials

Some participants in HIV prevention trials engage in more risky behaviors after enrollment.¹⁻⁵ Such behaviors can compromise the health of the research participants as well as the scientific value of the prevention trial. Efforts to reduce these behaviors through counseling and education are not always successful. Risk behavior may be related to participants' false beliefs about the prevention trial and the investigational intervention being tested. In previous work, these beliefs have been termed the "preventive misconception".⁶ A better understanding of the relationship between the preventive misconception and risk behavior could inform efforts to reduce the negative effects of increased risk behavior in the context of HIV prevention clinical trials.

2.2 The MTN-003C (VOICE-C) Study and PREMIS

MTN-003, the Vaginal and Oral Interventions to Control the Epidemic (VOICE) Study is designed to assess the safety and efficacy of daily dose oral and vaginal formulations of tenofovir and oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) in preventing HIV acquisition. The VOICE study is a Phase 2B, five-arm, multi-site, randomized, placebo-controlled trial that is double-blinded within each mode of administration, but open-label with respect to the randomly assigned mode of administration (vaginal or oral). Approximately 5000 participants will be randomized to the five study arms in a 1:1:1:1:1 ratio. The VOICE study is being implemented in sub-Saharan Africa.

VOICE-C is an exploratory substudy of VOICE, using qualitative research methods, which will be conducted at site(s) selected by the MTN Executive Committee, with 4 groups of participants (see Table in Protocol Summary for details). VOICE female participants (Group 1) who have been in the trial for at least 12 weeks are offered participation in VOICE-C which involves one of the following three activities: a) a single visit during which they participate in a focus group discussion (FGD) (conducted at study exit, after completing their time in the trial) b) a single visit during which they participate in an in-depth interview IDI (conducted as the trial is unfolding) or c) long term (1 year for a total of approximately 4 visits) ethnographic research.

One aim of PREMIS is to develop and evaluate a measure of preventive misconception. Drawing on a conceptual model of the preventive misconception, PREMIS will evaluate participant understandability of draft survey items through cognitive interviews. Cognitive interviews are one-on-one interviews in which respondents complete the initial items and answer queries about how they understood and answered each item. In PREMIS, up to 30 people enrolled in VOICE-C will participate in an audio-recorded cognitive interview. Each interview will last approximately one hour and will be conducted by research staff at a single VOICE-C study site in Johannesburg.

2.3 Study Hypotheses and Rationale for Study Design

2.3.1 Study Hypothesis

PREMIS is an exploratory study that is not designed to test a hypothesis. However, the objectives of the study are based on the assumption that (1) research participants have varying

levels of understanding of the nature of the prevention trial which they are enrolled (for example, a participant may overestimate the probability or level of personal protection afforded by participating in the trial), and (2) that such misunderstanding may lead to behaviors that jeopardize the participant's welfare and the quality of the prevention study.

2.3.2 Rationale for Study Design

It is important that the preliminary survey items developed for the PREMIS tool are understood by respondents in the way they are intended to be understood. To evaluate understandability, the PREMIS team will use a survey research method known as cognitive interviewing. Cognitive interviews are one-on-one interviews in which respondents complete the initial items and answer queries about how they understood and answered each item. These interviews will provide valuable data to inform the development of a multi-item measure of preventive misconception in preparation for psychometric evaluation of the measure and subsequent validation of the measure in a larger sample of participants in future HIV prevention studies.

3 OBJECTIVES

3.1 Primary Objective

The primary objective of the PREMIS cognitive interviews is to obtain qualitative information about how participants in an HIV prevention trial understand preliminary survey items developed for a measure of the preventive misconception.

4 STUDY DESIGN

4.1 Identification of Study Design

Cognitive interviews are one-on-one interviews in which respondents complete the initial items and answer queries about how they understood and answered each item. PREMIS will use the Question Appraisal System to develop probes (ie, queries about items and responses) that test for likely sources of error in communication of the questions. Depending upon the item, probes will be used to assess understanding of key words and phrases, assumptions made by the item, how participants generate their responses, and the appropriateness of the response options given. All interviews will be audio-recorded and transcribed. Using the audio recordings and transcripts of the interviews, the study team will identify problems that arose with the items and consider revisions that might rectify the problems.

4.2 Description of Study Population

The PREMIS study population will consist of a convenience sample of up to 30 Group 1 VOICE-C study participants.

4.3 Time to Complete Accrual

The accrual period is targeted over approximately 24 weeks.

4.4 Expected Duration of Participation

PREMIS will involve a single in-person interview with an expected duration of 1 hour.

4.5 Sites

PREMIS participants will be recruited from VOICE-C study participants at the Wits Reproductive Health and HIV Institute in Johannesburg.

5 STUDY POPULATION

5.1 Selection of the Study Population and Recruitment

The inclusion and exclusion criteria in Sections 5.2 and 5.3 will be utilized to ensure the appropriate selection of study participants.

5.2 Inclusion Criteria

Potential participants must meet all of the following criteria to be eligible for inclusion in the study:

- 1) Age 18 – 45 years, inclusive at screening
- 2) Able and willing to perform the study procedures
- 3) Able and willing to provide informed consent in English for study participation
- 4) Has participated in an interview as a Group 1 participant of the VOICE-C substudy
- 5) Is currently using a VOICE study product

5.3 Exclusion Criteria

Potential participants who meet the following criteria will be excluded from the study:

- 1) Has any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

6 STUDY PRODUCT

PREMIS will not involve the administration of any study product.

7 STUDY PROCEDURES

Additional information on visit-specific study procedures are presented in this section. Detailed instructions to guide and standardize procedures across sites are provided in the MTN-003C-01 SSP Manual located at <http://www.mtnstopshiv.org>.

7.1 Screening and Enrollment

Screening for all data collection activities will include oral or written confirmation that participants meet the inclusion and exclusion criteria. Study staff will create checklists to ensure this is consistently documented.

Table 1: Screening and Enrollment

| Screening and Enrollment | |
|--------------------------------------|--|
| Component | Procedures |
| Administrative and Regulatory | <ul style="list-style-type: none">• Confirm eligibility• Obtain written informed consent for enrollment• Provide reimbursement for study visit |
| Behavioral | <ul style="list-style-type: none">• Conduct cognitive interview |

7.2 Cognitive Interview Procedures

The cognitive interviews (CI) will be conducted in private meeting rooms that are quiet enough for audio-recording and permit confidentiality of responses. The CIs should take place at the clinic, or another venue if requested by the participant and agreed upon by the study staff. Upon arrival for the CI, participants will be greeted and offered refreshments. The study staff member will then go through the informed consent document, allowing the participant an opportunity to ask questions. If and when written informed consent is completed, the CI will be conducted following a CI guide, which will allow for iteration, probing, and digression on relevant themes. The CIs will be audio-recorded and later transcribed. Ideally a note-taker will be present to take notes during the session, but only if a facilitator is available, the CI may still go on, and the facilitator will take brief notes as the interview is ongoing (these will be immediately expanded by the facilitator, after completing the CI). Following the CI, the participant will be thanked for her time and reimbursed for her travel and time.

Immediately following each CI, the facilitator will complete a one-page debriefing form that will list some basic statistics about the session (i.e. duration, mood of interview, people present, etc.) as well as a summary report of the interview, which will include their impressions of key issues (e.g., barriers and enabling factors, and the level at which they operate) related to the participant's understanding of the target questions. Each debriefing report will thus represent a summary and extraction of the full data that can be used in "real-time". This will allow access to pertinent findings while the data go through the longer process of transcription, coding, and more formal qualitative analysis.

8 ASSESSMENT OF SAFETY

PREMIS is minimum-risk research: it does not involve a study product and does not involve any clinical, laboratory or other procedures associated with significant risk to participants. Therefore, few safety concerns are expected as a result of study participation. The study site IoR is responsible for continuous monitoring of all study participants and for alerting the protocol team if unexpected concerns arise. Study sites will have written procedures for ensuring prompt reporting to the Institutional Review Board (IRB)/Ethics Committees (EC), of any unanticipated problem involving risks to subjects or others. No safety events will be captured in the study database.

8.1 Safety Monitoring

Site IoRs are responsible for continuous close safety monitoring of all study participants, and for alerting the Protocol Team if unexpected concerns arise. Since the safety risks are minimal in this study, if any such unexpected concerns arise, the team will notify an appropriate on-site staff member (Site Clinician, Counselor, Nurse) affiliated with the CRS for follow-up.

The Manual for Expedited Reporting of Adverse Events to Division of AIDS (DAIDS) will not be used for this study for the following reasons: 1) this study does not involve a study drug and is non-invasive; 2) adverse events are not primary or secondary objectives of the study. Untoward clinical or medical occurrences reported by study participants to have been experienced during study participation will be recorded in participant file notes.

9 CLINICAL MANAGEMENT

There are no additional clinical management considerations for participants enrolled in this study. Participants who express concerns with social, psychological or clinical issues will be referred for appropriate care to services available at the CRS, or at nearby partnering facilities.

10 ANALYTICAL CONSIDERATIONS

10.1 Overview and Summary of Design

PREMIS is an exploratory study using qualitative data collection methods. Cognitive interviews will be used to assess the understandability of a set of preliminary survey items. The cognitive interview guide will be designed using the Question Appraisal System to develop probes (i.e., queries about items and responses) that test for likely sources of error in communication of the questions.⁷ Depending upon the item, probes will be used to assess understanding of key words and phrases, assumptions made by the item, how participants generate their responses, and the appropriateness of the response options given.

10.2 Study Endpoints

The main outcome of interest in PREMIS is participants' understanding of a set of preliminary survey items. Participant responses to the cognitive interview; including how responses were generated, the appropriateness of the response options given, etc., will serve as the endpoint.

10.3 Primary Study Hypotheses

PREMIS is an exploratory study that is not designed to test a hypothesis. However, the objectives of the study are based on the assumption that (1) research participants have varying levels of understanding of the nature of the prevention trial which they are enrolled (for example, a participant may overestimate the probability or level of personal protection afforded by participating in the trial), and (2) that such misunderstanding may lead to behaviors that jeopardize the participant's welfare and the quality of the prevention study.

10.4 Number of Participants

PREMIS will include at least 15 and no more than 30 participants.

10.5 Data, Study Monitoring and Analysis

10.5.1 Study Monitoring Committee (SMC)

This is a brief study, and no SMC review will be performed for this study.

10.5.2 Data Analysis

The qualitative data from the study will be used to inform revision of survey items for subsequent psychometric evaluation and validation. Using the audio recordings and transcripts of the interviews, the study team will identify problems that arose with the items and consider revisions that might rectify the problems. Following a modified use of the Question Appraisal System (Willis 2005), content codes will be assigned to responses that (1) index the relevant part of the question (e.g., meaning of the term "reduce your risk") and (2) the interpretation or challenge associated with that part of the question (e.g., "Did not understand the meaning of 'reduce your risk'") or alternative wording offered by the participant. These codes will be reviewed by the study team to determine whether and how to modify the PREMIS measure items to more effectively query participants' attitudes and beliefs.

11 DATA HANDLING AND RECORDKEEPING

11.1 Data Management Responsibilities

A convention for file naming will be developed, and all data will be labeled according to this process. All files sent electronically will be password-protected. Duke will save all versions of all data files on a secure, password-protected server.

11.2 Source Documents and Access to Source Data/Documents

All study sites will maintain source data/documents in accordance with Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials. (<http://rsc.tech-res.com/policiesandregulations/>)

For PREMIS, source documentation may include recruitment logs, records of attendance, visit checklist, CRFs, interview data, participant file notes, and electronic audio files. Essential

documentation for the study also includes all versions of the protocol, informed consent forms, operating procedures and key communication with the protocol team. In accordance with U.S regulations, each IoR/designee will maintain, and store securely, complete, accurate and current study records throughout the study. Thereafter, instructions for record storage will be provided by DAIDS. No study records may be moved to an off-site location or destroyed prior to receiving approval from DAIDS.

11.3 Quality Control (QC) and Quality Assurance

All study sites will conduct quality control and quality assurance procedures in accordance with current DAIDS policies. (<http://rsc.tech-res.com/policiesandregulations/>)

12 CLINICAL SITE MONITORING

Duke and/or FHI 360 staff will review study records during the course of the study, however no formal clinical monitoring will be conducted.

13 HUMAN SUBJECTS PROTECTIONS

Site investigators will make efforts to minimize risks to participants. Participants and study staff members will take part in a thorough informed consent process. Before beginning the study, the IoR will have obtained IRB/EC approval. The IoR will permit audits by the NIH or any of their appointed agents, local authorities, site IRBs/ECs, representatives of the MTN, and OHRP.

13.1 Institutional Review Boards/Ethics Committees

Each participating institution is responsible for assuring that this protocol, the associated site-specific informed consent form, and study-related documents as required, are reviewed by an IRB/EC responsible for oversight of research conducted at the study site. Any amendments to the protocol must be approved by the responsible IRBs/ECs prior to implementation.

Each IoR/designee will make progress reports to the IRBs/ECs within three months after study termination or completion. These reports will include the total number of participants enrolled in the study, the number of participants who completed the study, all changes in the research activity, and all unanticipated problems involving risks to human subjects or others. Study sites will submit documentation of continuing review to the DAIDS Protocol Registration Office in accordance with the most current DAIDS policies at the time of registration.

13.2 Protocol Registration

Prior to implementation of this protocol, and any subsequent full version amendments, each site must have the protocol and the protocol consent forms approved, as appropriate, by their local IRB/EC and any other applicable regulatory entity (RE). Upon receiving final approval, sites will submit all required protocol registration documents to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). The DAIDS PRO will review the submitted protocol registration packet to ensure that all of the required documents have been received.

The site-specific informed consent form (ICF) *will not* be reviewed or approved by the DAIDS PRO, and the site will receive an Initial Registration Notification when the DAIDS PRO receives a complete registration packet. Receipt of an Initial Registration Notification indicates successful completion of the protocol registration process. Sites will not receive any additional notifications from the DAIDS PRO for the initial protocol registration. A copy of the Initial Registration Notification should be retained in the site's regulatory files.

Upon receiving final IRB/EC and any other applicable RE approval(s) for an amendment, sites should implement the amendment immediately. Sites are required to submit an amendment registration packet to the DAIDS PRO at the RSC. The DAIDS PRO will review the submitted protocol registration packet to ensure that all the required documents have been received. Site-specific ICF(s) *will not* be reviewed and approved by the DAIDS PRO and sites will receive an Amendment Registration Notification when the DAIDS PRO receives a complete registration packet. A copy of the Amendment Registration Notification should be retained in the site's regulatory files.

For additional information on the protocol registration process and specific documents required for initial and amendment registrations, refer to the current version of the DAIDS Protocol Registration Manual.

13.3 Study Coordination

Close coordination between protocol team members is necessary to track study progress, respond to queries about proper study implementation, and address other issues in a timely manner.

Study implementation will be directed by this protocol, which may not be amended without prior written approval from the Protocol Chair and DAIDS Medical Officer. Study implementation will also be guided by a common SSP manual that provides further instructions and operational guidance on conducting study procedures and associated data processing. Standardized study-specific training will be provided to all sites by Duke, or other designated members of the Protocol Team.

13.4 Risk Benefit Statement

13.4.1 Risks

Participation in research includes the risks of loss of confidentiality and discomfort with the personal nature of questions. Although the study site will make every effort to protect participant privacy and confidentiality, it is possible that participants' involvement in the study could become known to others, and that social harms may result.

13.4.2 Benefits

There are no direct benefits to participating in this study. However, the information that participants provide may help health professionals develop better ways to improve communication and understanding between researchers and participants in HIV prevention studies

13.5 Informed Consent Process

Written informed consent will be obtained from each study participant prior to completing any study procedures. In obtaining and documenting informed consent, the IoR and their designees will comply with applicable local and US regulatory requirements and will adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

Study staff must document the informed consent process in accordance with the Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (<http://rsc.tech-res.com/policiesandregulations/>). Participants will be provided with copies of the informed consent forms if they are willing to receive them.

13.6 Participant Confidentiality

All study procedures will be conducted in private, and every effort will be made to protect participant privacy and confidentiality to the extent possible. Each study site will implement confidentiality protections that reflect the local study implementation plan and the input of study staff and community representatives to identify potential confidentiality issues and strategies to address them. In addition to local considerations, the protections described below will be implemented at all sites.

All study-related information will be stored securely at the study site. All participant information will be stored in locked areas with access limited to study staff. All study data collection, and administrative forms will be identified by coded number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with password protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participants' ID numbers to identifying information will be stored in a separate, locked file in an area with limited access. Participants' study information will not be released without their written permission, except as necessary for review, monitoring, and/or auditing by the following:

- Study staff
- Site IRBs/ECs
- Representatives of the US OHRP, NIH, and/or contractors of the NIH, and other local or US regulatory authorities, and representatives of the MTN

13.7 Special Populations

13.7.1 Pregnant Women

Women who are pregnant cannot enroll in MTN-003C-01 in an effort to match participants to those in VOICE who are taking study product.

13.7.2 Children

The NIH has mandated that children be included in research trials when appropriate. This study meets "Justifications for Exclusion" criteria for younger children as set forth by the NIH. This study does not plan to enroll children under 18 years old.

13.8 Compensation

Pending IRB/EC approval, participants will be compensated for time and effort.

13.9 Study Discontinuation

This study may be discontinued at any time by National Institute of Allergy and Infectious Diseases (NIAID), the MTN, the Office for Human Research Protections (OHRP), other government or regulatory authorities, or site IRBs/ECs.

14 PUBLICATION POLICY

DAIDS/NIAID and MTN policies will govern publication of the results of this study. Any presentation, abstract, or manuscript will be submitted by the investigator to the MTN Manuscript Review Committee, DAIDS, and NIMH for review prior to submission.

APPENDIX I: Sample Informed Consent Document

SAMPLE INFORMED CONSENT FORM DIVISION OF AIDS, NIAID, NIH

MTN-003C-01

PREMIS: Preventive Misconception in HIV Prevention Trials

**Version 1.0
September 19, 2011**

PRINCIPAL INVESTIGATORS: Kevin P. Weinfurt and Jeremy Sugarman
PHONE: 1-919-668-8101
Short Title for the Study: PREMIS

INFORMED CONSENT

You are being asked to take part in this research study because you are a woman currently enrolled in VOICE, taking active study product and participating in VOICE-C. Approximately 30 women will participate in this study at this site. This Microbicide Trials Network (MTN) study is sponsored by the US National Institutes of Health (NIH). The person in charge of this study at this site is *[INSERT NAME OF PRINCIPAL INVESTIGATOR]*. Before you decide if you want to join this study, we want you to know about the study. This Screening/Enrollment consent form gives you information about this study. The study staff will talk with you about it and answer your questions about this study.

YOUR PARTICIPATION IS VOLUNTARY

Before you decide whether to be in the PREMIS, we would like to explain the purpose of the study. You may decide to withdraw from the study at any time.

PURPOSE OF THE STUDY

The main goal of this study is to help create a survey that will be used to better understand the thoughts and feelings of people during their participation in an HIV prevention study.

STUDY PROCEDURES

There are no medical procedures or drugs involved in this research study. If you agree to join this study, you will have an audio-recorded interview during which the interviewer may also take notes. We expect that the interview will take less than one hour and will be completed at the clinic or at a place agreed upon by you and the clinic staff. You will be asked some general descriptive questions, such as your age and gender, as well as some questions about your health, your HIV prevention study, and the thoughts and feelings you have experienced during your HIV prevention study.

To obtain information about your health and your participation in the HIV prevention studies VOICE and VOICE-C, a member of the study team may need to consult your research records. By signing this form, you are giving the study team permission to look up and record the needed information from your research record.

RISKS AND/OR DISCOMFORTS

During the interview we may ask you some questions that may cause you to feel embarrassed or uncomfortable. You can choose not to answer questions in the interview at any time. It is also possible that people or family members may find out that you are participating in this study and as a result, they may ask questions about the study, treat you unfairly, and you may encounter problems in being accepted by your family and/or community.

Another possible risk of this study is loss of confidentiality of the information you give. Every effort will be made to protect your confidential information, but this cannot be guaranteed. To reduce this risk, we will strictly protect the information recorded during your interview. If you agree to participate in this study, you agree also to the audio-recording of the interview. The audio recording, notes, and analyses from these materials will be kept confidential, which means that no one other than the study team will have access to your survey responses. The information that links you to the research materials will be kept in a secure location that will be accessed only by members of the study team for the purposes of this research. You will not be mentioned by name in any reports, articles, or presentations that result from this study.

NEW INFORMATION

You will be told about new information from this or other studies that may affect your health, welfare or willingness to stay in this study.

BENEFITS

There are no direct benefits to participating in this study. However, the information that you provide may help health professionals develop better ways to improve communication and understanding between researchers and participants in HIV prevention studies.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE SUBSTUDY WITHOUT YOUR CONSENT

You may be removed from this study without your consent for the following reasons:

- The study is stopped or canceled
- The study staff feels that staying in the study would be harmful to you
- Other administrative reasons

ALTERNATIVES TO PARTICIPATION

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about.

COSTS TO YOU

There is no cost to you for being in this study.

REIMBURSEMENT

[Sites to insert information about local reimbursement:]

You will receive [\$xx] for your time, effort, and travel for your PREMIS visit.

CONFIDENTIALITY

We will do our best to make sure that the personal information gathered for this study is kept private. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally.

Your records may be reviewed by any or all of the following:

- The study staff
- The Institutional Review Boards of the Duke University Health System and Johns Hopkins University
- [insert applicable local authorities, e.g., Ministry of Health, medicine control authority]
- Representatives of the US Federal Government, including the US Office for Human Research Protections (OHRP), National Institutes of Health (NIH), and/or contractors of the NIH, and other local and US regulatory authorities

PROBLEMS OR QUESTIONS

If you ever have any questions about this study, you should contact [insert name of the investigator or other study staff] at [insert telephone number and/or physical address].

If you have questions about your rights as a research participant, you should contact [insert name or title of person on the IRB/EC or other organization appropriate for the site] at [insert telephone number and/or physical address of above].

If you have questions about whom to contact at the research site, you should contact [insert name of the investigator or community educator or community advisory board (CAB) member [staff will decide which] at [insert telephone number and/or physical address].

SIGNATURES

[Insert signature blocks as required by the local IRB/EC:] If you have read this consent form, or had it read and explained to you, and you understand the information, and voluntarily agree to participate in the study, please sign your name or make your mark below.

| Participant Name (print) | Participant Signature or Mark | Date |
|-----------------------------|----------------------------------|------|
|-----------------------------|----------------------------------|------|

| Study Staff Conducting Consent Discussion (print) | Study Staff Signature | Date |
|--|-----------------------|------|
|--|-----------------------|------|

| Witness Name | Witness Signature | Date |
|--------------|-------------------|------|
|--------------|-------------------|------|

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