Section 2. Decliner Population

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2.1 Introduction

This section provides information on requirements for study procedures in MTN-025 for the Decliner Population, including screening, enrollment and visit(s) procedures. Note that sites participating in the qualitative component may conduct in-depth interviews (IDIs) on a subset of participants who decline participation in HOPE. Procedures for the decliner IDIs are covered in detail in SSP Section 17: Qualitative Component.

2.2 Documentation Requirements

Essential documents pertaining to the Decliner Population, e.g. Decliner Screening and Enrollment Logs, should be filed in accordance with site specific procedures for other HOPE Essential Documents. Record retention requirements for the Decliner Population are the same as those for the main HOPE study population. No documents may be destroyed without written permission from DAIDS. Study sites must maintain adequate and accurate participant file records containing all information pertinent to participation in the HOPE Decliner Population for each study participant.

2.2.1 Participant File Contents and Source Documentation

Files for those participating in the Decliner Population should contain:

- Documentation that the participant met the eligibility criteria to participate in the Decliner Population
- Documentation that the participant provided written consent to participate in the Decliner Population prior to the conduct of any study procedures
- A record of all contacts, and attempted contacts, with the participant
- A record of all procedures performed by study staff during the study (e.g. on decliner visit checklists and/or other site-specific procedural flow sheets or chart notes)

- Case report forms (CRFs) applicable to decliners and other forms (e.g. Decliner Behavioral Eligibility Worksheet and Decliner Eligibility Checklist) provided by the MTN Statistical and Data Management Center (SDMC) or MTN LOC
- If applicable (for sites participating in the qualitative component, and for those participants selected for a decliner IDI): interview transcripts, notes recorded on interview guides, separate sheets, and/or additional materials used for IDIs
- Referrals made as a result of information gathered during decliner visit procedures

2.3 Decliner Participant Accrual

Former ASPIRE participants who decline or express no interest in joining the main HOPE study will be offered participation as part of the Decliner Population subset. It is anticipated that many participants who decline participation will be identified at the point of first recruitment contact (e.g. phone contact). As such, sites should be prepared to offer education on the decliner population subset at the point of prescreening/recruitment contact (see SSP 4.3.2 for information on pre-screening/recruitment).

Participants may also decide to decline enrollment into HOPE at any point during the MTN-025 screening period (i.e. up to the point the participant is determined to be eligible and enrolled in HOPE). Note that being found ineligible for MTN-025 enrollment (screen failure) does not equate to declining participation in the study. Only participants who actively decline study participation (i.e. express disinterest in enrollment) should be considered for decliner group enrollment. For example, if a participant was ineligible due to positive HIV or pregnancy testing, they should not be considered for decliner population enrollment.

Site-specific procedures for recruitment into the decliner population should be covered within MTN-025 Accrual SOPs.

2.4 Decliner Visits

2.4.1 Visit Scheduling

If a potential HOPE participant is not interested in taking part of HOPE, she will be offered participation as part of the Decliner Population subset. If the participant is already at the clinic, the informed consent for Decliner Population can be administered and visit procedures conducted on the same day. If the participant is not at the clinic, and she is interested in participating in the Decliner Population subset, she can be scheduled for screening and enrollment procedures. The study visit can be conducted at a single visit or multiple visits may be conducted to complete all required study procedures, if necessary.

2.4.2 Visit Locations

Study visits can be conducted at either the study clinic, participant's home, or designated neutral location, depending on participant's preference and staff availability. When scheduling visits at an off-site location, staff must ensure that participant confidentiality is maintained and study records will be safely maintained.

Should a participant express interest in joining the decliner population, but wish to have this visit done off-site, staff should explain confidentiality/safety issues and confirm over the phone that the participant is agreeable to completing the visit at a location outside of the clinic. Study staff should discuss any issues that may jeopardize participant confidentiality and/or safety, such as living situation (e.g., persons living with participant, availability of private space at participant's home). Also, in an effort to minimize the risk of social harm to participants and to study staff who will conduct home visits, discuss with participants whether they have disclosed participation in the study to family, neighbors, or others that may learn of

these visits. Additionally, study staff should discuss with participants how they will identify themselves so as to protect participant confidentiality and their own safety. This conversation should be fully documented in the participant's chart before any off-site visit is conducted.

The site-specific SOP for off-site visits should include specification of routine data management procedures that must be followed for conducting off-site visits, including details of which procedures will be put in place to help ensure that documents (e.g. Demographics form, visit checklist, chart notes) and audio recordings (if applicable, for qualitative sites and participants selected for a decliner IDI), are not lost, stolen, or mixed up across participants.

2.4.3 Informed Consent

Informed consent for the Decliner Population should follow site-specific SOPs and information outlined in Section 5 of this manual for administering and documenting informed consent. Participants must provide informed consent for screening and enrollment into the decliner group prior to completing any decliner group procedures.

The participant must not be asked to agree to take part in the Decliner Population, or to sign the informed consent form, until she fully understands the screening and enrollment process and the study. The MTN-025 Decliner Population Screening and Enrollment Informed Consent Comprehension Checklist, which is available in the Study Implementation Materials section of the MTN-025 web page, will assist staff in assessing participant comprehension and targeting follow-up educational efforts to ensure that participants understand all information required to make an informed decision. Note that use of the comprehension checklist is required. The checklist will be administered to each potential participant after she has completed the informed consent discussions and before she is asked to sign or mark the informed consent form. The checklist should not be presented to participants as a "test," but rather as a way of double-checking that study staff have fulfilled their responsibility to provide all information needed for the participant to make an informed decision about enrolling in the study. If any misinformation is reported back, study staff should explain the correct information before proceeding to another question.

2.4.4 Decliner Screening and Enrollment Logs

The DAIDS policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* requires study sites to document screening and enrollment activity on screening and enrollment logs. These logs may be maintained electronically but must be 21 CFR Part 11 compliant if the log is considered a source document. Decliner Screening and enrollment logs should be updated in real time and completed once a participant provides informed consent for decliner screening and enrollment. Participants who are approached, but do not provide informed consent for decliner screening and enrollment should not be included on this log. A sample decliner screening and enrollment log suitable for use in MTN-025 is available on the MTN-025/HOPE Website (http://www.mtnstopshiv.org/node/7330). Study sites are encouraged to reference the eligibility criteria item numbers in protocol Sections 5.2 and 5.3 when recording the reason for screening failure/discontinuation on the screening and enrollment logs.

2.4.5 PTID Assignment

PTID assignment for the Decliner Population will follow the same guidance as HOPE. Please refer to section 4.3.5 for information about this process.

2.4.6 Eligibility Criteria and Definition of Enrollment

Decliner Population participants must meet all the following criteria, which are outlined in sections 5.4 and 5.5 of the protocol, to be eligible for inclusion in the decliner population component of the study:

- Inclusion:
  - Able and willing to provide informed consent
  - Participated in MTN-020 (ASPIRE)
  - Declines participation in the main HOPE study
  - Able and willing to perform the Decliner Population study procedures
- Exclusion:
  - Has any other 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 study objectives.

Eligibility criteria which are based on self-report will be evaluated by administration of the Decliner Behavioral Eligibility Worksheet (available on the MTN-025 Website: http://www.mtnstopshiv.org/node/7330).

Designated staff will document the status of each eligibility criteria by checking "Yes" or "No" on the MTN-025 Decliner Eligibility Checklist (available on the MTN-025 Website: http://www.mtnstopshiv.org/node/7330). If the participant is confirmed to be eligible based on procedures listed above, the IoR or designee should complete final sign-off of eligibility on the Decliner Eligibility Checklist, and have this verified by a second staff member who will also sign-off on the Decliner Eligibility Criteria Checklist. If the Screening & Enrollment visit is being conducted off-site, confirmation of eligibility by designated staff can occur over the phone through discussion with site staff conducting the visit off-site, to be verified upon return to the clinic. **At this point the participant is considered enrolled in the decliner population subset.** All staff members who are responsible for signing off on the Decliner Eligibility Checklist should be clearly delegated per the Delegation of Authorities Log and listed as sub-investigators on the FDA Form 1572.

Eligibility procedures for the decliner population should be outlined within site-specific Eligibility SOPs.

2.4.7 Ineligible Participants

For all participants determined to be ineligible for the decliner population, the following documentation should be in place:

- Completed Decliner Screening and Enrollment ICF
- Specific, per protocol, reason(s) for ineligibility, with date of determination, as per the completed Decliner Eligibility Checklist. Documentation in chart notes, by designated staff, can be substituted if preferred.
- Completed Pre-screening Outcome CRF
- Completed Eligibility Criteria – Decliner Population CRF, updated with screen failure reason(s) and entered into Medidata Rave
- Necessary referrals on file (as appropriate)
- All source documentation completed up until the time that ineligibility was determined
- Chart notes complete up until the time ineligibility was determined
- Indication of what visit procedures were conducted (on visit checklists)

In addition, the Decliner Screening and Enrollment Log should be updated with date of discontinuation of screening and reason(s) for screen failure (list item number as appropriate from the Decliner Eligibility Checklist).

2.4.8 Decliner Visit Procedures

It is expected that procedures involved with the HOPE Decliner Population will be completed in one visit; however, multiple visits may be scheduled to complete these procedures. Once participants sign the informed consent and have met eligibility criteria, the following procedures will be conducted:

- Collection of demographic data
- Administration of behavioral assessment
- If applicable, conduct of in-depth interview (at sites participating in the qualitative component and if the participant is selected for a decliner IDI)
- Provide reimbursement

A sample visit checklist for Decliner Population can be found on the MTN Website (http://www.mtnstopshiv.org/node/7330). The sample checklist includes all requirements/activities for the study visit(s) and sites are encouraged to adapt this template to fit site needs. Participant checklists should be filed with the participant files. Every item in the left column of each checklist should be initialed or marked 'NA'. If the visit procedures deviate from what is outlined in the checklist, documentation of this should be in the comments section at the bottom of the checklist or in chart notes.

2.4.9 Data Collection Procedures

The following CRFs will be completed for all enrolled decliner participants:

- Eligibility Criteria – Decliner Population
- Enrollment – Decliner Population
- Demographics
- Baseline Behavior Assessment

All interviewer-administered CRFs (Baseline Behavioral Assessment CRF) should be administered in the preferred language of the participant. This may be different than the language she provided informed consent in, as long as fluency is confirmed/documented in both languages (e.g. on the IC coversheet and/or chart notes). Any deviation from this should be documented in the participant chart notes. In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that participant interviews be conducted with a non-biased, non-judgmental approach. Study staff should help the participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

Relevant CRFs required for the Decliner Population will be associated with the visit titled "Decliner Population Screening/Enrollment".