Purpose

The purpose of this SOP is to describe maintaining participant confidentiality in MTN-032.

Scope

This SOP applies to all staff involved in conducting and/or overseeing participant recruitment, eligibility confirmation, administering informed consents, and administering the interviews (IDI or FGD) for MTN-032.

Responsibilities

*[MTN-032 staff members delegated by the Investigator of Record to conduct MTN-032 recruitment, eligibility confirmation, administering informed consent, and administering the interviews (IDI or FGD)]* are responsible for understanding and following this SOP.

*[MTN-032 Study Coordinator, Recruitment Coordinator or other designee]* is responsible for training study staff to conduct MTN-032 procedures in accordance with this SOP, and for day-to-day oversight of staff.

MTN-032 Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-020 staff members follow this SOP.

**Procedures**

1. Participant Records
   1. Participants must be informed, through the informed consent process, of the extent to which confidentiality of records identifying them will be maintained. See protocol section 13 for more information on confidentiality of research records. *[Sites to reference to relevant site SOPs regarding securing participant records.]*
   2. *[Sites to insert description of maintaining the audio recordings as source documents, including only using PTID on audio CD, and how the recordings will be kept secured and confidential. Reference to other site SOPs may also be included here, such as Informed Consent, securing participant records, Data Management SOP, etc.]*
   3. *[Sites may choose to add further language regarding securing participant files, and agencies/ authorities allowed to review participant records for monitoring reasons, etc.]*
2. Confidentiality during In-Depth Interview
   1. *[Sites to describe how privacy of the interview will be maintained, such as conducting the interview in a counseling room, etc. To also include any procedures or approaches staff may use to help the participant feel comfortable and to ensure confidentiality of what is discussed during the interview.]*
3. Confidentiality during Focus Group Discussions
   1. *[Sites to describe how privacy of the focus group discussion will be maintained, such as conducting the FGD in a private setting, etc. To also include any procedures or approaches staff may use to help participants feel comfortable and to help ensure confidentiality of what is discussed during the interview. Description of using fake names during the discussion may also be included here.]*
   2. Confidentiality considerations regarding the involvement of male partners of HOPE participants
      1. *[Sites to describe how the privacy of female HOPE and AHA participants will be maintained while current and/or former male partners are on site for AHA-related activities.]*

**List of Abbreviations and Acronyms**

EC Ethics Committee

ICF Informed Consent Form

IRB Institutional Review Board

MTN Microbicide Trial Network

PTID Participant Identification

SOP Standard Operating Procedure

SSP Study-Specific Procedures

*[Insert additional as applicable]*

**Attachments**

*[List any additional as needed]*

**References**

*[List any additional as needed]*

**History**

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| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
| 1.0 | *Xx Mon YR* | NA | *Xx Mon YR* | Initial Release |

Approval

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|  | Author, Author’s Title |  |  | Date |
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|  | Reviewer, Reviewer’s Title |  |  | Date |