Section 10. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-012/IPM 010 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact Corey Miller (corey@scharp.org).

For this study, the SDMC (Statistical and Data Management Center) is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, WA, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-012/IPM 010 team members, along with their job roles and e-mail addresses, are listed below.

Role on MTN-012/IPM 010	Name	E-mail address
Protocol Statistician	Liza Noonan	liza@scharp.org
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Reporting Programmer	Cathy Kirkwood	ckirkwoo@scharp.org
Laboratory Programmer	Della Wilson	della@scharp.org
CASI Programmer	Lynda McVarish	lmcv@scharp.org
Data Coordinator	Suzanne Cullers	scullers@scharp.org
Document Specialist	Lori Filipcic	lorif@scharp.org

10.1 DataFax Overview

DataFax is the data management system used by SCHARP to receive and manage data collected at study sites. The site faxes an electronic image of each case report form (CRF) to SCHARP DataFax, and the original hard copy CRF is retained by the site.

CRF Transmission

Case report forms can be transmitted to SCHARP in one of two ways: faxed using a fax machine connected to the internet (fax to e-mail <datafax@scharp.org>), or if needed a fax machine connected to a land phone line (fax to phone number 206.667.4805).

SCHARP's Information Systems Technology (IST) group is available to consult with the site to determine the best method for data transmission. The SCHARP IST group can be contacted via e-mail at support@scharp.org. The SCHARP IST group should also be contacted anytime the site has technical questions or problems with their fax equipment.

Data Entry/Quality Control

Once a CRF image is received by SCHARP DataFax, the following occurs:

- DataFax identifies the study to which each CRF belongs using the barcode at the top of the form. It reads and enters the data into the study database and stores each CRF on a computer disk.

- Each CRF is then reviewed by at least two members of SCHARP's Data Operations Group. Problems such as missing or potentially incorrect data are identified and marked with Quality Control notes (QCs).

- QCs are compiled into QC reports that are sent via e-mail to the study site on a regular basis. Sites are asked to correct or clarify any problems identified on the QC reports and refax the corrected CRFs to SCHARP DataFax.

- When the re-faxed pages are received, SCHARP staff review the corrected pages and resolve the QCs.

If a change is made to a CRF but the updated page is not re-faxed to SCHARP DataFax, the change will **not** be entered and the study database will continue to contain incomplete or incorrect data. Additionally, if the change was prompted by a QC, the QC will continue to appear on subsequent QC reports until the modified CRF is received at SCHARP. Therefore, it is very important that the site refax updated CRF pages to SCHARP DataFax **any time** a change is made to a CRF, regardless of whether or not the change was made in response to a QC report.

## 10.2 DataFax Form Completion

10.2.1 Guidelines

Based on the use of fax technology and Good Clinical Practices (GCPs), the following guidelines should be used for completing DataFax CRFs:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.

- Press firmly when recording data or writing comments.

- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.

- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.

- Write numbers as large as possible while staying within the boundaries of the boxes.

- Record data on the front of CRFs only. DataFax cannot read the back of CRFs.

- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.

- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).

- Mark only one answer except when given the instruction "Mark all that apply."

- A response is required for every item unless instructed otherwise by a skip pattern.

- **Never** obscure, mark over, or punch holes through the barcode at the top of each CRF. DataFax requires the barcode to identify the CRF.

- **Never** use correction fluid ("white-out") or correction tape on CRFs.

- Remove any paper clips, staples, or other attachments before faxing CRFs.

- The site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.

- Fax forms as soon as possible after they have been completed and reviewed. Ideally, completed forms will be faxed to SCHARP within 1–2 days of completing the visit, though up to 5 days is allowed.

10.2.2   How to Mark Response Boxes

Many items on DataFax CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash or other character.

Correct: **Incorrect:**
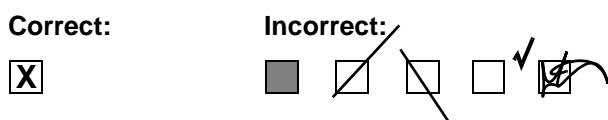
Mark only one response box for each item unless the "Mark all that apply" instruction is present.

10.2.3   How to Record Numbers

Some questions on DataFax CRFs include boxes for recording a numeric response. DataFax can only read the numbers in these boxes if they are recorded clearly. The following instructions should be followed when recording numeric responses:

- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

  The following example shows how a value of 7 is recorded when three response boxes are provided:

  Correct: **Incorrect:**

  This example would result in a QC note.
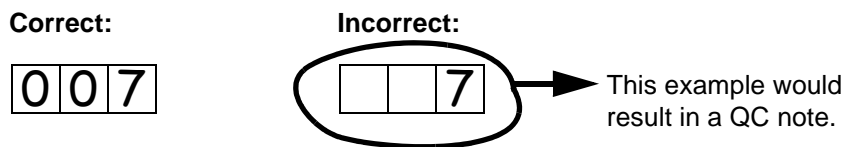
- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

  In the following example, the 4 could be misinterpreted as a 7 or a 1 because DataFax can only read what is *inside* the box:

  Correct: **Incorrect:**

- Write the number(s) simply, with few loops.

The following example shows the format in which numbers will be most easily read by DataFax. Also included are some commonly used formats that may be difficult for DataFax to identify.

Easily Identified:

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

Difficult to Identify:

| Ø | 1 | 2 | 3 | 4 | | 7 |

10.2.4   How to Record Dates

Dates are recorded using the "dd MMM yy" format, where "dd" represents the two-digit day, "MMM" represents the three-letter abbreviation of the month (in capital letters), and "yy" represents the last two digits of the year.

The month field must be filled in with the three-letter abbreviation *in English* for the date to be read in DataFax. Abbreviations are shown below:

Month	Abbreviation	Month	Abbreviation
January	**JAN**	July	**JUL**
February	**FEB**	August	**AUG**
March	**MAR**	September	**SEP**
April	**APR**	October	**OCT**
May	**MAY**	November	**NOV**
June	**JUN**	December	**DEC**

For example, June 6, 2011 is recorded as:

| 0 6 | J U N | 1 1 |
| *dd* | *MMM* | *yy* |

Sometimes, only a month and a year are required (e.g., diagnosis date for a pre-existing condition), in which case the response boxes will look like this:

| | | | | | |
| *MMM* | | *yy* |

A diagnosis date of October, 2010 would be recorded as follows:

| O C T | 1 0 |
| *MMM* | *yy* |

10.2.5   How to Record Time

Time is recorded on DataFax CRFs using the 24-hour clock (00:00-23:59), in which hours are designated from 0–23. For example, in the 24-hour clock 2:25 p.m. translates to 14:25 (2 p.m. = 14), which would be recorded as follows:

$$1\ 4 : 2\ 5$$

hr   min

Midnight is recorded as 00:00, not 24:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
Midnight	00:00	Noon	12:00
1:00 a.m.	01:00	1:00 p.m.	13:00
2:00 a.m.	02:00	2:00 p.m.	14:00
3:00 a.m.	03:00	3:00 p.m.	15:00
4:00 a.m.	04:00	4:00 p.m.	16:00
5:00 a.m.	05:00	5:00 p.m.	17:00
6:00 a.m.	06:00	6:00 p.m.	18:00
7:00 a.m.	07:00	7:00 p.m.	19:00
8:00 a.m.	08:00	8:00 p.m.	20:00
9:00 a.m.	09:00	9:00 p.m.	21:00
10:00 a.m.	10:00	10:00 p.m.	22:00
11:00 a.m.	11:00	11:00 p.m.	23:00

10.2.6   Data Corrections and Additions

Sometimes, data on a DataFax CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a QC report or as a result of site review of the CRF before faxing.

It is important to make these changes to the original CRF—***never*** copy data onto a new form. After making the change, the CRF *must* be re-faxed to SCHARP DataFax.

Note: If a correction or addition is made to one page of a multiple-page CRF, only refax the page that was changed.

Note: Never write over an entry once it is recorded. Use the standards outlined in the following paragraphs when changing, clarifying, or amending data.

Whenever an entry on a DataFax CRF is changed, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),

- place the correct or clarified answer near the box, and

- initial and date the correction as shown below:

**Correct:**   **Incorrect:**

jd 22-DEC-11

- If an **X** is marked in the wrong response box, correct it by doing the following:

- draw a single horizontal line through the incorrectly marked box,

- mark the correct box, and

- initial and date the correction as shown below:

jd 22-DEC-11 yes no
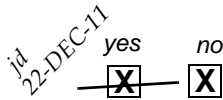
If the correct answer has previously been crossed out, do the following:

- circle the correct item,

- write an explanation in the white space near the item, and

- initial and date all corrections as shown below:

*jd 22-DEC-11* yes no "should be YES" *cr 24-DEC-11*
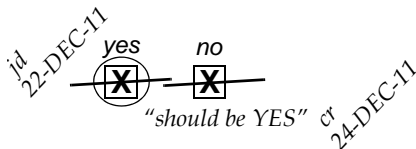
The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

10.2.7   How to Handle Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer, draw a single horizontal line through the blank boxes and initial and date the item. It is helpful to write "don't know," "refuses to answer," "UNK" (unknown), "N/A" (not applicable), or "REF" (refused) near the blank boxes.

For example, when recording a date, if the exact day is not known, draw a single horizontal line through the "dd" boxes and write "don't know" next to the response boxes, as shown below:

jd 22-DEC-11 *don't know* | A | P | R | | 1 | 1 |
                   dd   *MMM*   *yy*
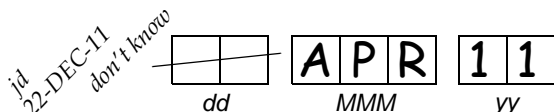
A skip pattern is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion, or as an update to the form.

10.3 MTN-012/IPM 010 Study-Specific Data Collection Information

10.3.1   Participant IDs (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provides each site with a list of PTIDs prior to study start-up. The site should assign one PTID to each participant enrolled in the study. The PTIDs are assigned in sequential order as participants enroll in the study. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, he maintains that same PTID throughout the entire study.

PTID boxes are located near the upper left corner of each CRF page.

Site staff are responsible for maintaining a log linking PTIDs to participant names (PTID-Name Link log) in accordance with Section 4 of this manual.

The PTIDs used for this study are nine digits and formatted as "XXX-YYYYY-Z." The PTID consists of three parts: the DataFax site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in MTN-012/IPM 010.

Participant ID

Site Number   Participant Number   Chk
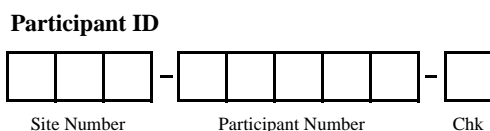
10.3.2   Study Visit Timing

Screening and Enrollment

The initial screening visit is defined as the day the participant provided written informed consent to be screened for the study. The enrollment visit will be scheduled to take place within 30 days of the initial screening visit.

A participant is considered enrolled once the participant has been assigned the appropriate MTN-012/IPM 010 Randomization Envelope (circumcised or uncircumcised). Assignment of MTN-012/IPM 010 Randomization Envelopes will be documented using the appropriate MTN-012/IPM 010 Randomization Envelope Tracking Record provided to each site by SCHARP.

Multiple Screening Attempts (Re-screens)

If a participant's first screening attempt is unsuccessful, he may re-screen for the study if he chooses. If he does re-screen, ALL screening procedures (except PTID assignment), evaluations, and forms must be repeated, including provision of written informed consent. Once a PTID is assigned to a participant, that PTID is used for that participant for all re-screening attempts. If a participant re-screens, only case report forms from the successful screening and

enrollment visit are faxed to SCHARP.

Follow-Up Visits

There is 1 required follow-up visit for MTN-012/IPM 010. The visit type, visit code, target visit day, and visit window are listed in Table 10-1. The target days and windows are listed in days, with the day of Enrollment Day 0.

Table 10-1: MTN-012/IPM 010 List of Visits, Visit Codes, Target Visit Dates, and Target Visit Windows

All visit windows are in days; Enrollment = Day 0

Visit	Visit Code	Day Target Window Opens	Target Date	Day Target Window Closes
Screening	01.0	Day -30	**N/A**	Day 0
Enrollment	02.0	N/A	**Day 0**	n/a
Final Clinic Visit	03.0	within 24 hours after last study product application	**Day 7**	Day 14

Target Dates and Visit Windows

All attempts must be made to schedule and complete visits on the target date for the visit. Visit target dates are set based on the enrollment date (Day 0) and do not change if subsequent actual visits take place before or after the target date. Visits completed within the target window will appear on the MTN-012/IPM 010 Retention Reports as being completed "on-time."

The Final Clinic visit should be targeted to occur within 24 hours of the final study product application. However, there may be cases where it is not possible to complete the visit on the target date. Therefore, the follow up visit may be completed within a visit window around the target date. The visit window for the Final Clinic Visit is +7 days from the target date. For example, if a participant enrolls into MTN-012/IPM 010 on 16 May 2011, his Final Clinic Visit target date is 23 May 2011. However, if he is unable to come to the clinic that day, the Final Clinic Visit can be completed between 23 May 2011 and 30 May 2011. For participants who do not complete scheduled visits within the target window, the visit will be considered "missed" and relevant CRFs will be completed to document the missed visit.

SCHARP will provide sites with an Excel spreadsheet tool that may be used to generate individual participant follow-up visit calendars. The spreadsheet requires that the participant's enrollment date be entered. Once the enrollment date is entered, the target date and visit window for the follow-up visit will appear in the spreadsheet, which can then be printed and added to the participant's study notebook.

Missed Visits

In those cases where a participant is not able to complete any part of a required follow-up visit within the visit window, the visit is considered missed. For example, a participant who enrolls into MTN-012/IPM 010 on 22 April 2011 cannot be reached for his Final Clinic Visit within the acceptable visit window (29 April 2011 - 6 May 2011). In this case, since the visit window for that

participant's Final Clinic Visit has "closed," the visit is considered missed, and is documented by completing a Missed Visit form.

Interim Visits

A study visit is considered an interim visit when a participant completes a phone call or presents at the site for additional clinical/laboratory assessments and/or procedures *outside* of the required evaluations for a scheduled study visit. Interim visits may be performed at any time during the study for any reason such as: administrative reasons (a participant has study-related questions for the staff), product-related (a participant needs replacement study product), lab-related (a participant needs a lab test repeated for confirmation), or clinical follow-up (a participant needs additional clinical follow-up for an Adverse Experience). If any data are required to be reported on a DataFax CRF as a result of an interim contact/visit, an Interim Visit form must be completed and faxed to SCHARP DataFax. If no DataFax forms are required for the interim visit (for example, the participant does not report any new AEs during the follow-up phone call), the interim visit may be documented by a chart note only (no CRFs required).

An example of when an Interim visit form would be needed follows:

- a participant completes the follow-up phone call as scheduled. During the phone call he reports that he notices slight redness without irritation on his penis where he has been applying the study product. In this case data will be recorded on a DataFax form (i.e. Adverse Experience Log form), This is considered an interim visit and an Interim Visit form is completed to document the visit. Visit code assignment for interim visits is covered in Section 10.3.3. In this case additional interim visits may occur as a result of clinical follow-up.

For questions about phone contacts and assignment of visit codes to such contacts, please contact the SCHARP MTN-012/IPM 010 Project Manager.

10.3.3   Visit Codes, and Page Numbers

Visit Codes

Some DataFax CRFs will include boxes in the upper right corner for a visit code and have the following visit code structure:

$$\boxed{}\boxed{}.\boxed{} \qquad \boxed{\textbf{1}}$$

Visit Code

DataFax uses the visit code to identify the visit at which a CRF is completed. However, not all DataFax CRFs include boxes for visit codes. If a form is only completed once during a study (for example, the Enrollment form or the Termination form), the visit code will be automatically assigned in DataFax.

When visit code boxes are provided, site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page. For multiple-paged CRFs, site staff need to make sure that all the pages of the CRF are marked with the same visit code for given participant and visit. Please see Table 10-1 for specific visit codes used for the study visits.

Visit Codes for Interim Visits

In addition to the scheduled, protocol-required visits listed in Table 10-1, interim visits may occur once the participant is enrolled (see Section 10.2.9 for a definition and examples of unscheduled/ interim visits). Interim visit codes are assigned using the following guidelines:

- In the box to the left of the decimal point, record the one-digit visit code for the most recent scheduled visit (whether that visit was completed or missed).

- Use the guide below to complete the box to the right of the decimal point:

  - ##.1 = the first interim visit after the most recent scheduled visit,

  - ##.2 = the second interim visit after the most recent scheduled visit, and so on.

Example: A participant returns to the site clinic on Day 4 to report new symptoms which require a new AE Log form to be completed. This current visit is considered and interim visit and is assigned the following interim visit code:

Visit Code for this Interim Visit:

Visit Code $\boxed{0}\boxed{4}.\boxed{1}$

NOTE: <u>Not</u> all interim visits are assigned visit codes. An interim visit should be assigned an interim visit code only if data collected at the visit warrants completion of a new DataFax form, such as an AE Log form or Product Hold/Discontinuation Log form. An Interim Visit form must be completed for each and every visit that is assigned an interim visit code.

Page numbers

Other CRFs, such as log forms (i.e., Adverse Experience Log form, Concomitant Medications Log form, Product Hold./Discontinuation Log form), include boxes in the upper-right corner for recording page numbers, as shown below:

Page $\boxed{}$

Assign page numbers in sequential order, starting with 01 (or 001 for Adverse Experience Log forms). For example, the second Concomitant Medications Log page would be assigned page number 02, the third page would be assigned 03, and so on throughout study participation.

10.3.4   Staff Initials/Date

Most CRFs include a line in the lower-right corner for a staff member's initials and the date on which the form was completed. When more than one staff member records data on a CRF, the site should designate the staff member who has primary responsibility for the form. This individual completes the staff initials/date field. The individual not identified in the staff initials/ date field writes his/her initials and date next to each data element for which he/she is responsible.

10.3.5   Case Report Form Completion Schedule

The SCHARP-provided case report forms for this study include DataFax forms (forms that are completed and faxed to SCHARP DataFax) and non-DataFax forms (forms that are completed but **not** faxed to SCHARP DataFax).

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following tables (Table 10-2)

lists the DataFax and non-DataFax forms that are **required** to be completed at each MTN-012/ IPM 010 study visit.

Table 10-2: Case Report Form Completion Schedule

Screening Visit (within 28 days prior to Enrollment)		Visit Code: 01.0
Form Acronym	**Form Name**	**Plate #**
Required		
DEM-1	Demographics	001
Non-DataFax	Behavioral Eligibility	n/a
Non-DataFax	Enrollment Eligibility	n/a
Non-DataFax	Baseline Medical History (from website)	n/a
Non-DataFax	Physical Exam	n/a
GE-1, GE-2	Genital Exam	201, 202
STI-1	STI Laboratory Results	131
LR-1, LR-2	Laboratory Results	135, 136
CM-1	Concomitant Medications Log	423
Enrollment Visit (Day 0)		**Visit Code: 02.0**
Form Acronym	**Form Name**	**Plate #**
Required		
ENR-1, ENR-2	Enrollment	070, 071
PRE-1	Pre-existing Conditions	012
Non-DataFax	Behavioral Eligibility	n/a
Non-DataFax	Physical Exam	n/a
GE-1, GE-2	Genital Exam	201, 202
Non-DataFax	MTN-012/IPM 010 LDMS Specimen Tracking Sheet	n/a
As Needed		
CM-1	Concomitant Medications Log	423
Non-DataFax	Baseline Medical History (from website)	n/a
HTR-1	HIV Test Results	351
Final Clinic Visit		**Visit Code: 03.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FCV-1	Final Clinic Visit	210
Non-DataFax	Follow-up Medical History Log	n/a
Non-DataFax	Physical Exam	n/a
GE-1, GE-2	Genital Exam	201, 202
LR-1, LR-2	Laboratory Results	135, 136
Non-DataFax	MTN-012/IPM 010 LDMS Specimen Tracking Sheet	n/a
SPR-1	Study Product Returns	415
ESI-1	End of Study Inventory	489
TM-1	Termination	490
As Needed		
CM-1	Concomitant Medications Log	423
AE-1	Adverse Experience Log	460
HTR-1	HIV Test Results	351
MV-1	Missed Visit	463

10.3.6   Site Review of DataFax Forms

Each form must be reviewed for completeness and legibility before being faxed to SCHARP DataFax. As part of the review, the site should check the following:

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., name, phone number, national identification number, or any other personal identifiers).

- A response has been recorded for each item, unless the item was skipped as instructed by a skip pattern or the item was marked as missing or unknown as described in 10.2.7.

- All text responses are clearly recorded.

- There are no marks on or above the DataFax barcode at the top of each DataFax page.

- There are no:
  - missing dates,
  - missing visit codes,
  - incorrect PTIDs,
  - incorrect visit codes,
  - missing data for items beginning a series of skip patterns, and/or
  - inconsistent or discrepant data.

While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is also necessary to have a system to identify whether a CRF has been faxed to SCHARP DataFax. Such a system may include using a stamp to date the back of the CRF, or utilizing the SCHARP CRF Tracking System (see SSP Section 10.3.7 for more information).

Important: If a date stamp is used to document when the form is faxed, *only* stamp the back of the CRF, *never* the front. Be sure to date stamp the back of the CRF each time it is faxed, including re-faxes.

10.3.7   Faxing DataFax Forms

To streamline the submission of DataFax forms, the site should identify which staff members will be responsible for faxing forms to SCHARP DataFax and receiving and responding to QC reports.

It is important that the sites fax completed DataFax CRFs to SCHARP within the time period specified in the site's MTN-012/IPM 010 Data Management SOP, and that they respond promptly to requests for clarifications and corrections included in QC reports. Early detection of recurrent problems provides an opportunity to reduce errors and improve data quality.

For sites wishing to confirm the receipt of faxed forms at SCHARP, the CRF Tracking System (CTS) is available. This system generates two types of e-mails listings: 1) the number of form pages received at SCHARP; and 2) which specific forms were received at SCHARP for a given PTID and visit. Please contact the MTN-012/IPM 010 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

10.3.8   Non-DataFax Forms

MTN-012/IPM 010 sites will receive non-DataFax forms from SCHARP. These forms will be easily identifiable because there will not be a DataFax barcode along the top of the CRF. In place of the barcode, the following text will appear: "NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX."

These forms should **not** be faxed to SCHARP DataFax. Instead, they should be kept in the participant's file as a record of the activities recorded on the form. The form completion guidelines described in sections 10.2.8 through 10.2.11 should be applied when completing non-DataFax CRFs.

10.4 Form Supply and Storage

10.4.1   Form and Specimen Label Supply

An initial supply of case report forms needed for the study will be supplied by SCHARP using form visit packets, where the packet contains all of the required CRFs for the visit. For example, the Screening Visit packet will include all of the CRFs listed as required for this visit in the Case Report Form Completion Schedule table (Table 10-2). In addition to form packets for each visit listed in Table 10-2, bulk supplies of "as needed" CRFs will be provided to the site (for example, Adverse Experience Log forms, Concomitant Medications Log forms, etc.). Subsequent supplies of forms will be available for download and printing at each site as needed via the ATLAS website.

SCHARP will also ensure sites have access to specimen labels (printed on-site). Specimen labels should be used for all primary specimen collection containers. Please refer to the Laboratory section of the manual for more information on laboratory specimen collection and labeling.

10.4.2   Form Storage

Specifications for form storage will be detailed in the site's MTN-012/IPM 010 Data Management SOP. It is recommended that for each participant, study CRFs be stored in a hard-cover notebook. SCHARP can provide a template for use in creating notebook cover labels and spine labels. SCHARP can also provide a template that can be used to create tab dividers.

It is suggested that Concomitant Medications Log forms, Adverse Experience Log forms, and Product Hold/Discontinuation Log forms be kept in their own tabbed sections within the participant study notebook. This makes page numbering and updating of these forms easier than if these forms are stored by visit within the participant's study notebook.

10.5 Completing Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize data quality, it is critical that site staff 1) complete interviewer-administered forms in a consistent manner from participant to participant 2) do not influence a participant's answer, and 3) help a participant feel

comfortable enough to share personal information and opinions. By doing so, site staff ensure that the data they collect is honest, accurate, and unbiased.

In MTN-012/IPM010 there are two interviewer-administered forms; meaning CRFs containing questions which must be read aloud word-for-word to the participant as printed on the CRF. The CRFs are the non-DataFax Behavioral Eligibility form and the Demographics form. Other forms, such as the non-DataFax Baseline Medical History form, are completed by obtaining information from the participant, but you are not required to read the questions on these forms aloud word-for-word to the participant. Completion of these forms can instead consist of more of a "discussion" with the participant rather than a structured, verbatim administration of the items.

Below are some guidelines and techniques that may be useful when completing both interviewer-administered forms as well as medical history forms.

Welcoming the Participant

- When a new participant arrives at the clinic, always make the participant feel comfortable. Perhaps offer him a glass of water or other beverage.

- Introduce yourself, and try to create a rapport (connection) between yourself and the participant to help him feel comfortable during the interview.

- Let the participant know what you will be talking to him about personal and sensitive topics as part of the visit.

Asking Sensitive Questions

All microbicide studies involve asking sensitive questions (such as questions about sexual behaviors). Your level of comfort with asking sensitive questions will affect the participant's level of comfort with answering the questions. If you ask the questions in a confident and supportive manner, the participant will feel more confident and comfortable answering the questions. Make eye contact with the participant to let him know that you are listening and are aware that you are asking him difficult questions. Avoid apologizing for questions or making facial gestures that may show you feel any way but neutral about a question or the participant's response. If the participant feels judged for his behavior, he will be less likely to share honestly with you.

Pacing the Interview

Every participant is different. Some will know or say the answer to questions very quickly. Others may have to think longer to come up with answers, or may change their answers after giving more thought to the subject. Always account for this variety when doing an interview. Read items slowly. Let the participant finish thinking before you record his response and proceed to the next item on a form.

Reading Items Aloud

Read all items to the participant **word-for-word**, and speak clearly. Avoid re-phrasing items because this can change the meaning of the item, making it inconsistent with other participants' interviews. Provide explanation or interpretation, if necessary, only after reading the item word-for-word. Avoid tangential—though related—counseling and educational discussions during data collection. When applicable, acknowledge questions and concerns raised by the participant during the interview, and state that the subject can be discussed after the end of the interview.

For items with multiple sub-items, read all sub-items to the participant and record the appropriate response for each, based on participant report.

Vary your tone of voice so that you don't sound automated. Emphasize the important words in a given item, so that the participant understands the meaning of the question asked. When given the option, choose "clinical" versus "street" or "vernacular" language based on participant's preferences/cues.

Probing

Participants may not remember or know the answer to every question they are asked. The technique for helping a participant remember an answer, clarify a response, decide between two similar but different answers, or report something more precisely is called "probing."

Effective probing helps a participant think more about a question or refine an answer that is too general. However, probing must not bias or otherwise direct participant responses. As the interviewer, you cannot offer the participant an answer. Therefore, all probes must be neutral.

The following are some probing strategies to use when a participant initially answers "don't know" to an item, or cannot refine his response enough to allow for adequate documentation.

- **Repeat Probe:** The repeat probe is used by repeating the item or response categories (if the response categories are part of the question). Although the participant might hear you the first time you ask a question, he may need to hear the question more than once to provide an answer. Instead of rephrasing a question if you notice the participant is confused, first repeat the item as it is written. Sometimes hearing the question a second time is all that is needed.

- **Echo Probe:** The echo probe involves repeating the participant's exact response. Sometimes hearing the answer with a different voice will help the participant respond more precisely. Always repeat the participant's response in a neutral, non-judgmental way.

- **Silent Probe:** The silent probe is used by pausing briefly after a participant gives what seems to be an uncertain answer. Although silence can feel awkward, sometimes it is helpful when a participant is trying to determine the most accurate answer to a question. Use a silent probe when the participant sounds unsure of his answer and may need some extra time to think more carefully about the question.

- **Non-verbal Probe:** The non-verbal probe is used by giving hand or facial gestures that may help the participant to come up with an answer. Remember that all such gestures must be neutral and nonjudgmental.

- **Specification Probe:** The specification probe is used by asking the participant to give a more precise answer. Although a participant may give an answer that he considers accurate, it may not be specific enough for purposes of form completion. For example, an item asks for the exact number of times the participant did something and he answers with a range ("5 to 10"). In this case, the probe, "Can you be more specific?" is often enough to help the participant give the most accurate response.

- **Historical Probe:** The historical probe is used by asking whether the event in question occurred anytime around major holidays or personal events such as a birthday or other life event. Some items require the participant to recall dates, and initially he may be unable to recall a specific date. Referencing a calendar can also help the participant remember dates.

Watching for Non-verbal Cues

A participant may give you one answer verbally, but express something else using body language or facial expressions. Although you should not question a participant so as to make him feel like you don't trust his answers, be aware of whether he is giving you non-verbal cues that indicate he is not feeling comfortable, not taking the interview seriously, or not answering honestly.

Checking Your Work

During the interview it is important to use the forms instructions (those on the front and back of each page) to guide the interview. Make sure the participant understands what you are asking and responds accordingly. Record all reported information on the forms. **After the interview and while**

the participant is still there, review the forms for accuracy and completeness so you can complete an item that may have accidentally been missed. **Once the participant has left the interview, any items identified as missing responses must remain as is and will be considered "missing data."** Because all interviewer-administered CRFs are source documents (with the participant being the source of the data), missing items cannot be completed once the participant has left the site clinic. For items identified as "missing," please line through the response boxes, write "missing" in the white space next to the item, and initial and date.

10.6 Form Completion Instructions

Detailed form completion instructions for each form are provided on the back of each form page. These instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, not all form items are listed in the forms instructions, and will only see instructions for those items requiring detailed explanation.

Below are some additional instructions for the Pre-existing Conditions, Concomitant Medications Log, Adverse Experience Log, and Laboratory Results forms.

Pre-existing Conditions and Concomitant Medication Log forms:

- For the Pre-existing Conditions and Concomitant Medication Log forms, note that each page must be faxed to SCHARP any time a new entry is added or modified, even if the page is not complete. Do NOT wait to fax to SCHARP until all entries on a page are completed.

Adverse Experience Log (AE Log) form:

- For the Adverse Experience Log form, do not wait until the AE resolves before faxing the form to SCHARP.

- Always make changes, corrections, and updates to the originally-completed Adverse Experience Log form page. Once an AE Log form page has been started and faxed to SCHARP, the data from that page should never be transcribed onto another AE Log form page.

For item 1, note that planned procedures or surgeries are not AEs. For example, a tonsillectomy is not an AE; rather, it is a treatment that will be collected in item 7 of the form. Any adverse experiences associated with the planned procedure or surgery are AEs.

Laboratory Results form:

- Depending on a site's normal reference ranges, it is possible that a participant can have a value that falls within the normal range, but is still gradable per the DAIDS Toxicity Table. Always refer to the DAIDS Toxicity Table when determining whether or not a lab value is gradable and should be reported as an AE.

10.7 Case Report Forms

This section contains each MTN-012/IPM 010 case report form developed for the study. They are presented in alphabetical order, with the DataFax forms first, followed by the non-DataFax forms. Detailed form completion instructions for each form are provided on the back of each form page.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 012/IPM 010 (187)   DEM-1   (001)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ]

Site Number   Participant Number   Chk

Demographics

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd   *MMM*   *yy*

1.   What is your date of birth?........................   [ ][ ] [ ][ ][ ] [ ][ ] ➔ If unknown, record age: [ ][ ]

dd   *MMM*   *yy*   *years*

2.   What is your gender? ....   *male* [X]   ~~*female*~~ **NOT APPLICABLE FOR THIS PROTOCOL.** [ ]

yes   *no*

3.   Do you consider yourself to be Latino or of Hispanic origin?   [ ]   [ ]

4.   What is your race? *Mark all that apply.*

[ ]   4a.   American Indian or Alaskan Native

[ ]   4b.   Asian

[ ]   4c.   Black or African American

[ ]   4d.   Native Hawaiian or other Pacific Islander

[ ]   4e.   White

[ ]   4f.   other, specify: _____

[ ] [ ] [ ] [X]   16-FEB-11

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[0][1]
Language   Staff Initials / Date

Demographics (DEM-1)

Purpose: This form is used to document participant demographic information.

General Information/Instructions: This form is completed only once for each study participant, at the Screening Visit.

- **Visit Code:** There is no visit code field on this form since this form is only completed once at the Screening Visit.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of his age. Do not complete both answers.

- **Item 2:** This item does not require a response. This item (gender) has been hard-coded as "male" for all study participants.

- **Item 4:** Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background.

SAMPLE: *DO NOT FAX TO DATAFAX*

▮ ▮ ▇ ▮ ▮ ▮ ▇ ▇ ▮

MTN 012/IPM 010 (187)   ENR-1   (070)

Participant ID

[ ][ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]   **Enrollment**

Site Number   Participant Number   Chk

1. Was the participant, based on all inclusion and exclusion criteria, eligible for the study? ....
   yes [ ]   *no* [ ] ➝ *If no, end of form.*

2. Date the informed consent form for enrollment was marked or signed: ....
   [ ][ ] [ ][ ][ ] [ ][ ]
   dd   *MMM*   *yy*

3. Was the participant able and willing to provide written informed consent for specimen storage and future research?..................
   yes [ ]   *no* [ ] ➝ *If no, go to item 4.*

   3a. Date the informed consent form for specimen storage and future research was marked or signed: ....
   [ ][ ] [ ][ ][ ] [ ][ ]
   dd   *MMM*   *yy*

4. Randomization envelope number: ....
   [ ][ ][ ]

   4a. Date assigned: ....
   [ ][ ] [ ][ ][ ] [ ][ ]
   dd   *MMM*   *yy*

   4b. Time assigned: ....
   [ ][ ] : [ ][ ]   *24-hour clock*
   hr   *min*

   4c. Randomization code: ....
   [ ][ ][ ]

5. Date product dispensed by pharmacy: ....
   [ ][ ] [ ][ ][ ] [ ][ ]
   dd   *MMM*   *yy*

6. Is this participant circumcised or uncircumcised? ....
   circumcised [ ]   *uncircumcised* [ ]

Comments**:** _____

_____

[ ] [ ] [ ] [x]   16-FEB-11

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[0][1]
Language   Staff Initials / Date

Enrollment (ENR-1)

Purpose: This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, he is assigned a randomization envelope), and only after completion of the Enrollment Visit.

- **Visit Code:** There is no visit code field on this form since this form is only completed once at the Enrollment Visit.

Item-specific Instructions:

- **Item 1:** If response to this item is "no" (the participant was not eligible for this study), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

- **Item 2:** Record a complete date.

- **Item 3:** Mark "yes" only if the participant gave consent to have his lab specimens stored for future research testing.

- **Item 3a:** Record a complete date.

- **Item 4:** Record the 3-digit envelope number present on the randomization envelope assigned to this participant.

- **Item 4a:** Record the date the randomization envelope was assigned to the participant. This date should match the "date assigned" recorded for this envelope on the MTN-012/IPM 010 Randomization Envelope Tracking Record.

- **Item 4b:** Record the time the randomization envelope was assigned to the participant. Use a 24-hour clock to record time. For example, if the randomization envelope was opened at 2:24 p.m., record 14:24. This time should match the "time assigned" recorded for this envelope on the MTN-012/IPM 010 Randomization Envelope Tracking Record.

- **Item 4c:** Record the participant's randomization code present on the prescription.

- **Item 5:** Record the exact day, month, and year study product was dispensed to this participant.

- **Item 6:** This item is based on results from the Genital Exam. It is not based on participant self-report.

SAMPLE: *DO NOT FAX TO DATAFAX*

▌ ▌ █ ▌ ▌ ▌ █ █ █

MTN 012/IPM 010 (187)   ENR-2   (071)

Participant ID

				-						-		

Site Number   Participant Number   Chk

Enrollment

7.   Did the participant complete the CASI Baseline Behavioral Questionnaire at this visit? ....

yes ☐   *no* ☐ ➔ ***If no, specify in Comments, and go to item 8.***

7a.   Date CASI Baseline Behavioral Questionnaire was completed: ....

dd   MMM   yy

SPECIMEN STORAGE

Specimen Collection Date

dd   MMM   yy

8.   Plasma ....

stored ☐   *not stored* ☐ ➔   *Reason:* _____

Comments: _____

_____

☐ ☐ ☐ ☒   16-FEB-11

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Language   Staff Initials / Date

Enrollment (ENR-2)

Item-specific Instructions:

- **Item 7:** Completion of the CASI Baseline Behavioral Questionnaire is required for all participants at the Enrollment Visit. If the required questionnaire was not done, specify the reason on the Comments lines.

- **Item 8:** Record the date that the specimen was *collected* for this visit. A complete date is required.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 012/IPM 010 (187)   PRE-1   (012)

Note: Number pages sequentially (01, 02, 03) for each participant.   **Page** ☐☐

Participant ID

☐☐☐ – ☐☐☐☐ – ☐

Site Number   Participant Number   Chk

Pre-existing Conditions

☐ **No pre-existing conditions reported or observed.**

_____
Staff Initials / Date

→ ***End of form. Fax to SCHARP DataFax.***

---

1. | **Description** | | *MMM* *yy* |
| | **Date of Diagnosis/ Surgery** | ☐☐☐ ☐☐ |

| **Comments** | **Severity Grade** ☐ ☐ *not gradable* | **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date |

2. | **Description** | | *MMM* *yy* |
| | **Date of Diagnosis/ Surgery** | ☐☐☐ ☐☐ |

| **Comments** | **Severity Grade** ☐ ☐ *not gradable* | **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date |

3. | **Description** | | *MMM* *yy* |
| | **Date of Diagnosis/ Surgery** | ☐☐☐ ☐☐ |

| **Comments** | **Severity Grade** ☐ ☐ *not gradable* | **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date |

4. | **Description** | | *MMM* *yy* |
| | **Date of Diagnosis/ Surgery** | ☐☐☐ ☐☐ |

| **Comments** | **Severity Grade** ☐ ☐ *not gradable* | **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date |

5. | **Description** | | *MMM* *yy* |
| | **Date of Diagnosis/ Surgery** | ☐☐☐ ☐☐ |

| **Comments** | **Severity Grade** ☐ ☐ *not gradable* | **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date |

6. | **Description** | | *MMM* *yy* |
| | **Date of Diagnosis/ Surgery** | ☐☐☐ ☐☐ |

| **Comments** | **Severity Grade** ☐ ☐ *not gradable* | **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date |

☐ ☐ ☐ ☒   16-FEB-11

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Language

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Pre-existing Conditions (PRE-1)

Purpose: This form is used to document the participant's pre-existing medical conditions.

General Information/Instructions: Only medical conditions experienced up to study product initiation should be recorded unless otherwise specified in the protocol or Study Specific Procedures (SSPs). Include current medical conditions and any ongoing conditions such as mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.

- **Description:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."

- **Date of Diagnosis/Surgery:** If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.

- **Comments:** This field is optional. Use it to record any additional relevant information about the condition.

- **Severity Grade:** For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *Male Genital Toxicity Table*. If a condition is not gradable, mark the "not gradable" box.

- **Is condition ongoing?:** Mark "yes" if condition is ongoing at enrollment.

- **Pre-existing Conditions Revisions and Updates:** If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s).

SAMPLE: *DO NOT FAX TO DATAFAX*

| | | | | | | | | **Visit Code** | ☐☐ . ☐ | 1 |

MTN 012/IPM 010 (187)   RPD-1   (082)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number   Participant Number   Chk

Replacement Product Dispensation

1. Replacement envelope number: .... ☐☐☐

  1a. Date opened: .... ☐☐ ☐☐☐ ☐☐
        dd   MMM   yy

  1b. Time opened: .... ☐☐ : ☐☐ *24-hour clock*
        hr   min

2. Date replacement product dispensed by pharmacy: .... ☐☐ ☐☐☐ ☐☐
        dd   MMM   yy

3. Replacement randomization code dispensed: .... ☐☐☐

Form completed by: _____   Form verified by: _____
  Staff Initials / Date   Staff Initials / Date

Comments: _____

☐ ☐ ☐ ☒ 16-FEB-11

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0 1
Language   Staff Initials / Date

Replacement Product Dispensation (RPD-1)

Purpose: This form is used to document when replacement study product is dispensed.

General Information/Instructions: This form is faxed to SCHARP DataFax only if replacement product is dispensed to an enrolled participant.

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1:** Record the 3-digit envelope number present on the replacement envelope assigned to this participant.

- **Item 1a:** Record the date the replacement envelope was opened. This date should match the "date assigned" recorded for this envelope on the MTN-012/IPM 010 Replacement Envelope Tracking Record

- **Item 1b:** Record the time the replacement envelope was opened. Use a 24-hour clock to record time. For example, if the randomization envelope was opened at 2:24 p.m., record 14:24. This time should match the "time assigned" recorded for this envelope on the MTN-012/IPM 010 Replacement Envelope Tracking Record.

- **Item 2:** Record the exact day, month, and year replacement study product was dispensed to this participant.

- **Item 3:** Record the participant's replacement randomization code present on the prescription.

SAMPLE: *DO NOT FAX TO DATAFAX*

Visit Code ☐☐.☐

1

MTN 012/IPM 010 (187)   SPR-1   (083)

Page 1 of 1

Participant ID

☐☐☐-☐☐☐☐-☐

Site Number   Participant Number   Chk

Study Product Returns

		yes	no, specify: _____
1.	Was study product returned?	☐	☐ → **End of form.**

2. Date product was returned by participant: .... ☐☐ ☐☐☐ ☐☐
    dd   *MMM*   *yy*

3. Number of **used** applicators returned: .... ☐ **used** *applicators returned*

4. Number of **unused** applicators returned: .... ☐☐ **unused** *applicators returned*

Comments**:** _____

☐ ☐ ☐ ☒ 16-FEB-11

0 1

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Language   Staff Initials / Date

Study Product Returns (SPR-1)

Purpose: This form is used to document study product returns.

General Information/Instructions: This form should be completed once for each participant after he has completed study treatment or has been permanently discontinued from study product use.

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1:** If study product was not returned, record the reason on the line provided.

- **Item 2:** Record the exact day, month, and year study product was returned by the participant.

SAMPLE: *DO NOT FAX TO DATAFAX*

Visit Code ☐☐.☐   1

MTN 012/IPM 010 (187)   GE-1   (201)   Page 1 of 2

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number   Participant Number   Chk

Genital Exam

Examination Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

	EXAM	FINDINGS
1.	Foreskin (internal and external)	*N/A (circumcised)* ☐ *normal* ☐ *abnormal* ☐ ⟶ **If abnormal, specify type of finding.** *Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____
2.	Penile Shaft	*normal* ☐ *abnormal* ☐ ⟶ **If abnormal, specify type of finding.** *Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____
3.	Glans	*normal* ☐ *abnormal* ☐ ⟶ **If abnormal, specify type of finding.** *Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____
4.	Urethral Meatus	*normal* ☐ *abnormal* ☐ ⟶ **If abnormal, specify type of finding.** *Mark all that apply.* ☐ ulceration ☐ erythema (with induration) ☐ edema ☐ erythema (without induration) ☐ discharge ☐ other, specify: _____

☐ ☐ ☐ ☒ 16-FEB-11

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☐0☐1

Language   Staff Initials / Date

Genital Exam (GE-1)

Purpose: This form is used to document the genital exams conducted during Screening, Enrollment, and follow-up.

General Information/Instructions: For abnormal findings identified after enrollment, complete or update an Adverse Experience Log form when applicable.

- **Visit Code:** Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Items 1–4:** If an abnormal finding is observed, mark the appropriate finding(s) in the space provided.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 012/IPM 010 (187)　　　GE-2　　(202)

Visit Code ☐☐.☐　　　　1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐

Site Number　　Participant Number　　Chk

Genital Exam

	EXAM	FINDINGS
5.	Scrotum	normal ☐　abnormal ☐ ⟶ **If abnormal, specify type of finding.** *Mark all that apply.* ☐ vesiculation　　☐ peeling ☐ bullous reaction　☐ erythema (with induration) ☐ ulceration　　　☐ erythema (without induration) ☐ bruising, petechiae　☐ other, specify: 　 or ecchymoses　　＿＿＿＿＿＿＿＿＿
6.	Inguinal Lymph Nodes	normal　enlarged and painless　enlarged and painful 6a. Right　☐　　☐　　☐ 6b. Left　☐　　☐　　☐

Items 7 and 8 are only completed for visits AFTER Enrollment.

7. During this genital exam, was any dried product observed on the penile shaft, glans, urethral meatus, scrotum, or foreskin? *Mark "none observed" or all that apply.*

　☐ none observed

　☐ penile shaft

　☐ glans

　☐ urethral meatus

　☐ scrotum

　☐ foreskin

8. Were any **new** AE Log pages completed for this visit? ....　*yes* ☐　*no* ☐ ⟶ **If no, end of form.**

　8a. Record AE Log page number(s):

　　AE Log page #　　*AE Log page #*　　*AE Log page #*

　　☐☐☐　　☐☐☐　　☐☐☐

Comments: ＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

☐ ☐ ☐ ☒　16-FEB-11

0 1
Language　　Staff Initials / Date

Genital Exam (GE-2)

Item-specific Instructions:

- **Item 5:** If an abnormal finding is observed, mark the appropriate finding(s) in the space provided.

- **Items 7–8:** These items are only completed at follow-up visits. Leave these items blank at Screening and Enrollment.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 012/IPM 010 (187)　　　FCV-1　(210)

Visit Code ☐☐ . ☐0

☐1

Page 1 of 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number　　Participant Number　　Chk

Final Clinic Visit

Visit Date

☐☐ ☐☐☐ ☐☐
dd　　MMM　　yy

1. Date of final study product application:　☐☐ ☐☐☐ ☐☐
　　dd　　MMM　　yy

2. Time of final study product application:　☐☐ : ☐☐　*24-hour clock*
　　hr　　min

not done

3. Date of PK blood draw: .... ☐☐ ☐☐☐ ☐☐　**OR**　☐ → *If not done, record reason(s) on Comments line and go to item 5.*
　　dd　　MMM　　yy

4. Time of PK blood draw: .... ☐☐ : ☐☐　*24-hour clock*
　　hr　　min

5. Did the participant complete the CASI Product Acceptability and Adherence Questionnaire? ....
　　yes　　*no*
　　☐　　☐ → ***If no, end of form.***

　5a. Date CASI Product Acceptability and Adherence was completed: ..... ☐☐ ☐☐☐ ☐☐
　　　dd　　MMM　　yy

Comments**:** _____

☐ ☐ ☐ ☒　16-FEB-11

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0 1
Language　　Staff Initials / Date

Final Clinic Visit (FCV-1)

Purpose: This form is used to document the required follow-up visit. It is completed at the Final Clinic Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1:** Record a complete date.

- **Item 2:** Use a 24-hour clock to record time. For example, if the time of final study product application was at 9:24 p.m., record 21:24.

- **Item 3:** Record a complete date or mark the "not done" box.

- **Item 4:** Use a 24-hour clock to record time.

- **Item 5:** Completion of the CASI Product Acceptability and Adherence Questionnaire is required for all participants at the Final Clinic Visit. If the required questionnaire was not done, specify the reason on the Comments lines.

SAMPLE: *DO NOT FAX TO DATAFAX*

Visit Code ☐☐.☐

☐ 1

MTN 012/IPM 010 (187)   STI-1   (131)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number   Participant Number   Chk

STI Laboratory Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

Not done/ Not collected

Alternate Collection Date
dd   *MMM*   *yy*

☐   ☐☐ ☐☐☐ ☐☐

1. HIV

negative   positive   indeterminate

1a. HIV EIA ....   ☐   ☐   ☐
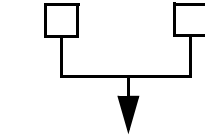
If positive or indeterminate, complete HIV Test Results.

Not done/ Not collected

Alternate Collection Date
dd   *MMM*   *yy*

☐   ☐☐ ☐☐☐ ☐☐

2. SYPHILIS

non-reactive   reactive

2a. Syphilis screening test ......   ☐   ☐

If non-reactive, go to item 3.

2a1. Syphilis titer..............   **1:** ☐☐☐☐

negative   positive   indeterminate

2b. Syphilis confirmatory test   ☐   ☐   ☐

Not done/ Not collected

Alternate Collection Date
dd   *MMM*   *yy*

3. Gonorrhea and Chlamydia

negative   positive

☐   ☐☐ ☐☐☐ ☐☐   3a. *N. gonorrhea* (urine) ....   ☐   ☐

☐   ☐☐ ☐☐☐ ☐☐   3b. *C. trachomatis* (urine) ....   ☐   ☐

Comments**:** _____

_____

☐ ☐ ☐ ☒   16-FEB-11

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Language   Staff Initials / Date

STI Laboratory Results (STI-1)

Purpose: This form is used to document STI laboratory results as required or clinically indicated during Screening, Enrollment, and follow-up.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Results Reporting:**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and provide an explanation on the Comments line.

- **Repeat Local Laboratory Tests:** Sometimes it is necessary to repeat a local lab test.
  - For a repeat test of the *same* **sample**, record only the results considered the most accurate. If a first result was already recorded and faxed to SCHARP DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to SCHARP DataFax.
  - For a repeat test using a ***different sample*** (e.g., a blood re-draw for a repeat CBC), at Screening or Enrollment, record the repeat test results on the original form by updating the item. Amend the original form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to SCHARP DataFax.
  - For a repeat test using a ***different sample*** (e.g., a blood re-draw for a repeat CBC), at follow-up, record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax the new form to SCHARP DataFax.

Item-specific instructions:

- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.

- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

- **Not done/Not collected:** If the "Not done/Not collected" box is marked, provide an explanation on the Comments lines.

- **Item 1a:** If the HIV EIA result is positive or indeterminate at screening, enrollment, or follow-up, follow the protocol HIV testing algorithm and record the associated test results on the HIV Test Results form.

- **Item 2a1:** Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:32 would be recorded on the form as "1:0032."

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 012/IPM 010 (187)   LR-1   (135)

Visit Code ☐☐.☐   ☐ 1

Page 1 of 2

Participant ID

☐☐☐ - ☐☐☐☐ - ☐

Site Number   Participant Number   Chk

Laboratory Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

Not done/ Not collected ☐

Alternate Collection Date

dd   *MMM*   *yy*

☐☐ ☐☐☐ ☐☐

1. HEMOGRAM

	Not reported		**Severity Grade** *If applicable*	**AE Log Page #**	**Not reportable as an AE**
1a. Hemoglobin	☐	☐☐.☐ g/dL	☐	☐☐☐	OR ☐
1b. Hematocrit	☐	☐☐.☐ %			
1c. MCV	☐	☐☐☐.☐ fL	**Severity Grade** *If applicable*	**AE Log Page #**	**Not reportable as an AE**
1d. Platelets	☐	☐☐☐☐.☐ x10³/mm³	☐	☐☐☐	OR ☐
1e. WBC	☐	☐☐☐.☐ x10³/mm³	☐	☐☐☐	OR ☐

Not done

DIFFERENTIAL ☐ ➡ *If not done, go to item 2.*

	Not reported	**Absolute Count** *cells/mm3*	**Severity Grade** *If applicable*	**AE Log Page #**	**Not reportable as an AE**
1f. Neutrophils	☐	☐☐☐☐☐	☐	☐☐☐	OR ☐
1g. Lymphocytes ...	☐	☐☐☐☐	☐	☐☐☐	OR ☐
1h. Monocytes	☐	☐☐☐☐			
1i. Eosinophils	☐	☐☐☐☐			
1j. Basophils	☐	☐☐☐☐			

Comments: _____

☐☐☐☐ X 16-FEB-11

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Language   Staff Initials / Date

Laboratory Results (LR-1)

Purpose: To document safety laboratory results as required or clinically indicated during screening, enrollment, and follow-up.

Initial Specimen Collection Date: Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

Alternate Collection Date: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. A complete date is required.

Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments lines.

- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.

- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.

- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.

    - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.

- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).

- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.

    - Treat all missing digits in the lab value as zeros.

    - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.

- There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.

AE Log Page #: If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

Not Reportable as an AE: Only mark this box if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

SAMPLE: *DO NOT FAX TO DATAFAX*

Visit Code ☐☐.☐

1

MTN 012/IPM 010 (187)   LR-2   (136)

Page 2 of 2

Participant ID

☐☐☐☐-☐☐☐☐☐-☐

Site Number   Participant Number   Chk

Laboratory Results

Not done/ Not collected	Alternate Collection Date			2. CHEMISTRIES		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
	dd	*MMM*	*yy*		*U/L*			
☐	☐☐	☐☐☐	☐☐	2a. AST (SGOT)	☐☐☐☐	☐	☐☐☐	OR ☐
☐	☐☐	☐☐☐	☐☐	2b. ALT (SGPT)	☐☐☐☐	☐	☐☐☐	OR ☐
☐	☐☐	☐☐☐	☐☐	2c. Creatinine ..... *mg/dL* ☐☐.☐		☐	☐☐☐	OR ☐

2c1. Calculated creatinine clearance: ..... ☐☐☐ *mL/mm*

2d. Weight .... ☐☐☐ *kg*

Not done/ Not collected	Alternate Collection Date			3. URINE TESTS
	dd	*MMM*	*yy*	
☐	☐☐	☐☐☐	☐☐	

Not done			*negative or trace*	*1+*	*2+*	*3+*	*4+*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
☐	3a.	Protein	☐	☐	☐	☐	☐	☐	☐☐☐	OR ☐

Not done			*negative*	*positive*
☐	3b.	Glucose	☐	☐
☐	3c.	Blood	☐	☐
☐	3d.	Leukocyte esterase (LE)	☐	☐
☐	3e.	Nitrites	☐	☐
☐	3f.	Culture	☐	☐

Comments**:** _____

☐☐☐ ☒ 16-FEB-11

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Language

_____
Staff Initials / Date

Laboratory Results (LR-2)
Item-specific Instructions:

Alternate Collection Date: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. A complete date is required.

Results Reporting
- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments lines.

- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.

- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.

- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.

  - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.

- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).

- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.

  - Treat all missing digits in the lab value as zeros.

  - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.

- There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.

AE Log Page #: If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

Not Reportable as an AE: Only mark this box if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

- **Item 2c1:** When calculating the participant's creatinine clearance, use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when the blood specimen was drawn, but was weighed at a previous visit (within the allowable window for creatinine clearance per the SSP Manual), record the weight from the previous visit. Also, record in the "Alternative Collection Date" boxes the date of the previous visit when the participant was weighed. If the participant has a creatinine value but cannot have his creatinine clearance calculated (due to missing weight data), line through the response boxes and initial and date.

SAMPLE: *DO NOT FAX TO DATAFAX*

■ ■ ■ ■ ■ ■ ■ ■   **Visit Code** ☐☐.☐   1

MTN 012/IPM 010 (187)   IV-1   (350)   Page 1 of 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number   Participant Number   Chk

Interim Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

1. What is the reason for this interim visit? *Mark all that apply.*

   ☐ 1a. in-person visit to report new symptoms

   ☐ 1b. phone call with participant to report new symptoms ➤ *Complete/Update Adverse Experience Log if applicable.*

   ☐ 1c. follow-up of symptoms and/or AE(s)

   ☐ 1d. participant needs replacement product ➤ *Complete Replacement Product Dispensation.*

   ☐ 1e. participant is returning used or unused applicators ➤ *Complete/Update Study Product Returns.*

   ☐ 1f. other, specify: _____

2. Besides this Interim Visit form, what other DataFax study forms were completed at this visit? *Mark all that apply.*

   ☐ 2a. none ➤ *End of form.*

   ☐ 2b. Genital Exam

   ☐ 2c. Adverse Experience Log (new)

   # of pages

   2c1. How many **new** AE Log pages have been completed for this visit? ☐☐

   ☐ 2d. Laboratory Results

   ☐ 2e. STI Laboratory Results

   ☐ 2f. Study Product Returns

   ☐ 2g. Product Hold/Discontinuation Log (new)

   ☐ 2h. other, specify: _____

Comments: _____

☐☐☐☐ x   16-FEB-11

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Language   Staff Initials / Date

Interim Visit (IV-1)

Purpose: Complete this form when an interim visit occurs during study follow-up. See the Study-specific Procedures Manual for a definition and examples of interim visits that require an Interim Visit form to be completed.

General Information/Instructions: Any other forms completed for this visit must have the same Visit Code as this Interim Visit form.

Item-specific Instructions:

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:

  - Record the one-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was Enrollment (Visit Code = 02.0), record "02" to the left of the decimal point in the visit code field.

  - Record the number that corresponds to the Interim Visit in the third box (the box to the right of the decimal point):

    - 0X.1 = First Interim Visit after the most recent scheduled regular visit.

    - 0X.2 = Second Interim Visit after the most recent scheduled regular visit.

- **Item 2:** Note that marking a box indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.

- **Item 2a:** Mark the "none" box if the Interim Visit form is the only DataFax form completed for this visit.

- **Item 2c:** Mark this box if a new (previously unreported) AE is reported or observed at this visit. If the box to the left of "Adverse Experience Log (new)" is marked, record how many new AE Log pages were completed for this visit in item 2d1. For example, if two new AEs were reported, record "02." Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.

- **Item 2g:** Mark this box if a new (previously unreported) product hold or discontinuation is reported at this visit.

SAMPLE: *DO NOT FAX TO DATAFAX*

■ ▌ ▌ ▌ ▌ ▌ ▌ ▌ ■ **Visit Code** ☐☐.☐   ☐1

MTN 012/IPM 010 (187)   HTR-1 (351)   Page 1 of 1

Participant ID

☐☐☐☐ – ☐☐☐☐☐ – ☐   **HIV Test Results**

Site Number   Participant Number   Chk

Sample 1

1.   HIV Western Blot or IFA

Not done/ Not collected   **Specimen Collection Date**   *negative*   *positive*   *indeterminate*

☐   ☐☐ ☐☐☐ ☐☐   ☐   ☐   ☐
     dd   MMM   yy

➤ *If positive at Screening, go to item 4.*

➤ *If negative or indeterminate, contact MTN Network Lab.*

Sample 2

2.   HIV EIA

Not done/ Not collected   **Specimen Collection Date**   *negative*   *positive*   *indeterminate*

☐   ☐☐ ☐☐☐ ☐☐   ☐   ☐   ☐
     dd   MMM   yy

➤ *If negative, contact MTN Network Lab.*

3.   HIV Western Blot or IFA

Not done/ Not collected   **Specimen Collection Date**   *negative*   *positive*   *indeterminate*

☐   ☐☐ ☐☐☐ ☐☐   ☐   ☐   ☐
     dd   MMM   yy

➤ *If negative or indeterminate, contact MTN Network Lab.*

---

negative   *positive*   *other, specify:* _____

4.   Final HIV status: ....   ☐   ☐   ☐

➤ *If positive at Screening, participant is ineligible.*

Comments**:** _____

☐ ☐ ☐ ☒   16-FEB-11   ☐0☐1   _____

Language   Staff Initials / Date

HIV Test Results (HTR-1)

Purpose: This form documents confirmatory HIV test results and final HIV status. This form is completed each time a participant has a positive or indeterminate HIV EIA test result during study follow-up.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** required specimens are available and recorded and item 4 has been completed.

- **Visit Code:** The visit code recorded on this form should be the same visit code recorded on the STI Laboratory Results form documenting the positive HIV test result.

- **Specimen Collection Date:** Record the date the specimen was collected (NOT the date results were reported or recorded on the form). For Sample 1, the Specimen Collection Date should be the same date as the collection date of the HIV EIA positive specimen.

- **Not done/Not collected:** Mark this box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines at the bottom of the form.

Item-specific Instructions:

- **Item 4:** Once a participant's HIV status has been determined, record the final HIV status. If the final HIV status is not clearly negative or clearly positive, mark the "other, specify" box and provide a reason(s) on the line provided.

- **Comments:** Document any problems or reasons why expected results are not available (for example, if the sample was lost or damaged), on the lines provided.

SAMPLE: *DO NOT FAX TO DATAFAX*

■■■ | ■ ■■ ■

Note: Number pages sequentially (01, 02, 03) for each participant.　**Page** ☐☐

MTN 012/IPM 010 (187)　　PH-1　(410)

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number　　Participant Number　　Chk

Product Hold/Discontinuation Log

1. Date and visit code when study product hold was initiated:　☐☐ ☐☐☐ ☐☐　*visit code* ☐☐.☐

   dd　MMM　yy

2. Why is study product being held? *Mark all that apply.*

   ☐　2a.　participant unable or unwilling to comply with required study procedures

   ☐　2b.　participant may be put at undue risk

   ☐　2c.　participant reports the use of PEP for possible HIV-1 exposure.

   　　　　　　　　　　　　　　　　AE Log page #　*AE Log page #*　*AE Log page #*

   ☐　2d.　adverse experience　————▶　☐☐☐　☐☐☐　☐☐☐

   ☐　2e.　other, specify: _____

3. Date of last study product use: ....　☐☐ ☐☐☐ ☐☐

   dd　MMM　yy

4. Was the participant instructed to resume study product use? ....

   yes　*no (permanently discontinued)*

   ☐　　☐

   4a. Date and visit code when participant was instructed to resume or permanently discontinue study product use:　☐☐ ☐☐☐ ☐☐　*visit code* ☐☐.☐

   dd　MMM　yy

Comments: _____

☐ ☐ ☐ ☒　16-FEB-11

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Language　Staff Initials / Date

Product Hold/Discontinuation Log (PH-1)

Purpose: This form is used to document temporary holds and early permanent discontinuations of study product use for participants.

General Information/Instructions: This form is completed each time a participant is instructed to temporarily stop (hold) or permanently discontinue study product use prior to his Day 6 Visit. If, at the same study visit, a product hold/discontinuation is initiated for more than one reason, complete a single Product Hold/Discontinuation Log page and mark all applicable reasons.

In the case of temporary product holds, do not wait for information about product resumption to fax the form— fax this form to SCHARP DataFax as soon as items 1–3 have been completed. Refax the page once item 4 has been completed.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Product Hold/Discontinuation Log pages after faxing, unless instructed by SCHARP.

- **Item 2:** Mark the box to the left of the reason why the participant is being instructed to hold or permanently discontinue study product use. If product is being held or discontinued due to an adverse experience, record the page number of the AE Log documenting the product hold or permanent discontinuation. If the product hold/discontinuation is due to a reason other than the ones listed, mark the "other, specify" box and record the reason for the hold/discontinuation on the line provided.

- **Item 3:** Record the date the participant last used study product. Use a best estimate if the actual date cannot be determined.

- **Item 4:** Complete this item once study staff have determined that the participant can resume study product use or have determined that he is permanently discontinued from study product use. Mark the "yes" box if study staff instructed the participant that he can resume use of study product. If the participant was permanently discontinued from study product use, mark the "no (permanently discontinued)" box.

- **Item 4a:** Record the date and visit code on which the participant was told by a study staff member that he could resume or that he should permanently discontinue study product use.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 012/IPM 010 (187)　　　CM-1　(423)

Note: Number pages sequentially (01, 02, 03) for each participant　**Page** ☐☐

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number　　Participant Number　　Chk

Concomitant Medications Log

☐ **No medications taken at Screening/Enrollment.**
　　　Staff Initials/Date
　➤ *Fax to SCHARP DataFax.*

☐ **No medications taken throughout study.**
　　　Staff Initials/Date
　➤ *End of form. Fax to SCHARP DataFax.*

1.

Medication *(generic name)*

Staff Initials/Log Entry Date

Indication

Taken for a reported AE?
☐ *yes*　☐ *no*

Date Started
☐☐ ☐☐☐ ☐☐
dd　*MMM*　*yy*

Date Stopped
☐☐ ☐☐☐ ☐☐　**OR** ☐ Continuing at end of study
dd　*MMM*　*yy*

➤ *Record AE Log page(s):*
☐☐☐ ☐☐☐
☐☐☐ ☐☐☐

Frequency *Mark only one.*
☐ *prn*　☐ *qd*　☐ *tid*　☐ *qhs*
☐ *once*　☐ *bid*　☐ *qid*　☐ *other, specify:* _____

Dose/Units

Route *Mark only one.*　PO ☐　IM ☐　IV ☐　TOP ☐　IHL ☐　VAG ☐　REC ☐　*other, specify:* _____

2.

Medication *(generic name)*

Staff Initials/Log Entry Date

Indication

Taken for a reported AE?
☐ *yes*　☐ *no*

Date Started
☐☐ ☐☐☐ ☐☐
dd　*MMM*　*yy*

Date Stopped
☐☐ ☐☐☐ ☐☐　**OR** ☐ Continuing at end of study
dd　*MMM*　*yy*

➤ *Record AE Log page(s):*
☐☐☐ ☐☐☐
☐☐☐ ☐☐☐

Frequency *Mark only one.*
☐ *prn*　☐ *qd*　☐ *tid*　☐ *qhs*
☐ *once*　☐ *bid*　☐ *qid*　☐ *other, specify:* _____

Dose/Units

Route *Mark only one.*　PO ☐　IM ☐　IV ☐　TOP ☐　IHL ☐　VAG ☐　REC ☐　*other, specify:* _____

3.

Medication *(generic name)*

Staff Initials/Log Entry Date

Indication

Taken for a reported AE?
☐ *yes*　☐ *no*

Date Started
☐☐ ☐☐☐ ☐☐
dd　*MMM*　*yy*

Date Stopped
☐☐ ☐☐☐ ☐☐　**OR** ☐ Continuing at end of study
dd　*MMM*　*yy*

➤ *Record AE Log page(s):*
☐☐☐ ☐☐☐
☐☐☐ ☐☐☐

Frequency *Mark only one.*
☐ *prn*　☐ *qd*　☐ *tid*　☐ *qhs*
☐ *once*　☐ *bid*　☐ *qid*　☐ *other, specify:* _____

Dose/Units

Route *Mark only one.*　PO ☐　IM ☐　IV ☐　TOP ☐　IHL ☐　VAG ☐　REC ☐　*other, specify:* _____

☐ ☐ ☐ ☒ 　16-FEB-11

☐0☐1
Language

Concomitant Medications Log (CM-1)

Purpose: All medication(s) that are used by the participant during the study (including the protocol-defined screening period), other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

General Information/Instructions: When to fax this form:

- once the participant has enrolled in the study;

- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);

- when the participant has completed study participation; and/or

- when instructed by SCHARP.

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.

- **No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01.

- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.

- **Medication:** For combination medications, record the first three main active ingredients.

- **Indication:** For health supplements, such as multivitamins, record "general health." For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). For recreational drugs, record "recreation."

- **Date Started:** If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, the year is required.

- **Date Stopped:** At the participant's Termination visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required.

- **Frequency:** Below is a list of common frequency abbreviations:

prn as needed	**qd** every day	**tid** three times daily	**qhs** at bedtime
once one time	**bid** twice daily	**qid** four times daily	

- Use "other, specify" for alternate dosing schedules.

- **Route:** Below is a list of common route abbreviations:

PO oral	**IM** intramuscular	**IV** intravenous	**TOP** topical	**IHL** inhaled	**VAG** vaginal	**REC** rectal

- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).

MTN 012/IPM 010 (187)   AE-1   (460)

Note: Number pages sequentially (001, 002, 003) for each participant. **Page** ☐☐☐

Participant ID

☐☐☐ – ☐☐☐☐ – ☐

Site Number   Participant Number   Chk

Adverse Experience Log

Date Reported to Site

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

---

1. Adverse Experience (AE)

_____

Record diagnosis (in English) if available. Include anatomical location, if applicable.

2. Onset Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

---

3. Severity

☐ Grade 1 – Mild

☐ Grade 2 – Moderate

☐ Grade 3 – Severe

☐ Grade 4 – Potentially life-threatening

☐ Grade 5 – Death

4. Relationship to Study Product

☐ Related

☐ Not related
Record rationale or alternative etiology in Comments.

5. Study Product Administration

☐ No change

☐ Held

☐ Permanently discontinued

☐ N/A

---

6. Status/Outcome

☐ Continuing

☐ Resolved

☐ Death

☐ Severity/frequency increased
Report as a new AE.

☐ Continuing at end of study participation

6a. **Status/Outcome Date**
Leave blank if Status/Outcome is "Continuing."

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

7. Treatment *Mark "None" or all that apply.*

☐ None

☐ Medication(s)
Report on Concomitant Medications Log.

☐ New/Prolonged hospitalization
Comment below.

☐ Procedure/Surgery
Comment below.

☐ Other
Comment below.

---

8. Is this an SAE according to ICH guidelines? ....   *yes* ☐   *no* ☐

9. Has/will this AE be reported as an EAE? ....   *yes* ☐   *no* ☐

10. At which visit was this AE first reported? .... ☐☐.☐
Visit code required (regular or interim).

11. Was this a worsening of a pre-existing condition? ....   *yes* ☐   *no* ☐

Comments**:** _____

_____

_____

☐☐☐ ☒ 16-FEB-11

0 1
Language   Staff Initials / Date

Adverse Experience Log (AE-1)

Purpose: To document any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol.

General Information/Instructions: Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE page #" (specify page number of diagnosis AE).

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.
- **Item 1:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
- **Item 2:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
- **Item 3:** To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *Male Genital Toxicity Table*.
- **Item 4:** Mark the assessment of the relationship between the AE and the study agent. Mark "Related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "Not related" if there is not a reasonable possibility that the AE is related to the study agent. If "Not related," record an alternative etiology, diagnosis, or explanation in the "Comments" field. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 5:**
  - *No change*: Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation.
  - *Held:* Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark "Held" for the AE(s) that contributed to the product hold.
  - *Permanently discontinued:* Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, only mark "Permanently discontinued" for the AE that contributed to the permanent discontinuation.
  - *N/A (not applicable):* Mark if the AE occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
  - *Continuing:* AE is continuing at the time it is reported.
  - *Resolved:* Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
  - *Death:* Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation."
  - *Severity/frequency increased:* If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "Continuing" box previously marked and mark "Severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs.
  - *Continuing at end of study participation:* Mark this box whenever an AE is continuing at the time of participant study termination.
- **Item 6a:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant no longer experienced the AE; or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
- **Item 7:** Indicate if treatment was clinically indicated for the AE, regardless of whether the treatment was actually used. Also mark this item if the participant self-treated.
- **Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 012/IPM 010 (187)   MV-1   (463)

Visit Code ☐☐ . 0   1

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number   Participant Number   Chk

Missed Visit

Form Completion Date

☐☐ ☐☐☐ ☐☐
dd   *MMM*   *yy*

	dd	*MMM*	*yy*
1. Target Visit Date:	☐☐	☐☐☐	☐☐

Comments: _____

_____

_____

☐ ☐ ☐ ☒   16-FEB-11

0 1
Language

_____
Staff Initials / Date

Missed Visit (MV-1)

Purpose: Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study Specific Procedures (SSP).

General Information/Instructions: If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the date of the missed visit. A complete date is required.

Item-specific Instructions:

- **Item 1:** Record the target date of the visit. A complete date is required.

SAMPLE: *DO NOT FAX TO DATAFAX*

▐ █ █ ▌█ █ ▌ ▌ █

MTN 012/IPM 010 (187)   ESI-1   (489)

Participant ID

| | | | – | | | | | | – | | |

Site Number   Participant Number   Chk

End of Study Inventory

Form Completion Date

| | | | | | | | |

dd   *MMM*   *yy*

1. What is the **highest** visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax?...

   visit code

   | | | . | |

2. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?..........

   # of interim visits

   | | | |

3. Indicate the **highest** page number submitted for this participant for each of the following forms:

   page #   *no pages submitted*

   3a. Adverse Experience Log (AE-1) .... | | | | **OR**   ☐

   page #

   3b. Concomitant Medications Log (CM-1) | | |

   page #

   3c. Pre-existing Conditions (PRE-1) .... | | |

   page #   *no pages submitted*

   3d. Product Hold/Discontinuation Log (PH-1) | | | **OR**   ☐

Comments: _____

☐ ☐ ☐ ☒   16-FEB-11

| 0 | 1 |

Language   Staff Initials / Date

End of Study Inventory (ESI-1)

Purpose: This form is used to confirm that SCHARP has received all study data for a given participant.

General Information/Instructions: Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form).

Item-specific instructions:

- **Form Completion Date:** A complete date is required.

- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.

- **Item 2:** Record the total number of Interim Visit DataFax forms submitted for this participant. If no Interim Visit forms were submitted for the participant, record "000" in the boxes.

- **Item 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.

- **Item 3d:** Record the highest page number of the Product Hold/Discontinuation Log submitted for this participant, even if that page was marked for deletion.

SAMPLE: *DO NOT FAX TO DATAFAX*

■■■■▮ ▮ ▮▮

MTN 012/IPM 010 (187)   TM-1   (490)

Participant ID

| | | | | – | | | | | | | – | | |

Site Number   Participant Number   Chk

Termination

1. Termination Date: *dd* *MMM* *yy* | | | | | | | | | | *Date the site determined that the participant was no longer in the study.*

2. Reason for termination. *Mark only one.*

☐ 2a. scheduled exit visit/end of study ⟶ ***End of form.***

☐ 2b. death, *indicate date and cause if known*

    dd *MMM* *yy*

    2b1. date of death | | | | | | | | | | **OR** ☐ date unknown

    2b2. cause of death _____   **OR** ☐ cause unknown

Complete or update Adverse Experience Log.

☐ 2c. participant refused further participation, specify: _____

    2d. **NOT APPLICABLE FOR THIS PROTOCOL.**

☐ 2e. participant relocated, no follow-up planned

☐ 2f. investigator decision, specify: _____

☐ 2g. unable to contact participant

    2h. **NOT APPLICABLE FOR THIS PROTOCOL.**

☐ 2i. inappropriate enrollment ⟶ ***End of form.***

☐ 2j. invalid ID due to duplicate screening/enrollment ⟶ ***End of form.***

☐ 2k. other, specify: _____

☐ 2l. early study closure ⟶ ***End of form.***

3. Was termination associated with an adverse experience? ....

    yes *no* *don't know*

    ☐ ☐—☐ ⟶ ***If no or don't know, end of form.***

    3a. Record AE Log page: | | | **OR** Specify: _____

Comments: _____

| | | |☐| |x| 16-FEB-11

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Language   Staff Initials / Date

Termination (TM-1)

Purpose: This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Item-specific Instructions:

- **Item 1:** A complete date is required.

- **Item 2:** Mark only the primary reason for termination.

  - **Item 2a:** Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.

  - **Item 2b1:** At a minimum, the month and year are required.

  - **Item 2l:** Early study closure: Only mark 2l when instructed by SCHARP.

- **Item 3a:** Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the "specify" line.

SAMPLE: *DO NOT FAX TO DATAFAX*   **Not a DataFax form. Do not fax to DataFax.**

MTN 012/IPM 010 (187)

Page 1 of 2

Participant ID

☐☐☐☐–☐☐☐☐☐–☐

Site Number   Participant Number   Chk

Enrollment Eligibility

Visit Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

		yes	*no*
1.	At Screening, is the participant at least 18 years of age?	☐	☐
2.	Is the participant able and willing to provide written informed consent to be screened for and take part in the study?	☐	☐
3.	At Screening, is the participant able and willing to provide adequate locator information, as defined in site SOP?	☐	☐
4.	Is the participant able and willing to communicate in written and spoken English?	☐	☐
5.	At Screening, is the participant HIV-uninfected per HIV Testing Algorithm in Appendix II?	☐	☐
6.	Is the participant in general good health, according to clinical judgment of the Investigator of Record or designee?	☐	☐

If any items 1–6 are marked "no," participant is ineligible. ◄

☐ ☐ ☐ ☒   16-FEB-11

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Language   Staff Initials / Date

Enrollment Eligibility (non-DataFax) Page 1 of 2

Purpose: This form is used to document the participant's administrative, clinical, and laboratory eligibility for the study at screening and enrollment. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: If a participant is being re-screened, a new Enrollment Eligibility form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.

SAMPLE: *DO NOT FAX TO DATAFAX*   **Not a DataFax form. Do not fax to DataFax.**

MTN 012/IPM 010 (187)

Participant ID

[ ][ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number   Participant Number   Chk

Enrollment Eligibility

7. Does the participant have any of the following laboratory abnormalities at Screening:

		yes	*no*
7a.	hemoglobin < 10.0 g/dL?	☐	☐
7b.	platelet count < 100,000/mm^3?	☐	☐
7c.	white blood cell count < 2,000 cells/mm^3?	☐	☐
7d.	alanine transaminase (ALT) and/or aspartate aminotransferase (AST) > 2.5x the site laboratory upper limit of normal (ULN)?	☐	☐
7e.	serum creatinine > 1.3 x the site laboratory ULN?	☐	☐
7f.	calculated creatinine clearance less than 80 mL/min by the Cockcroft-Gault formula for males?	☐	☐

Note: Otherwise eligible participants with any of the above exclusionary laboratory results may be re-tested. If a participant is re-tested and a non-exclusionary result is documented within 30 days of providing informed consent for Screening, the participant may be enrolled.

8. At Screening or Enrollment, is the participant diagnosed with an STI or reproductive tract infection (RTI) requiring treatment, per current Centers for Disease Control and Prevention (CDC) guidelines? ....

yes *no*
☐ ☐

9. At Screening or Enrollment, does the participant have a clinically apparent Grade 1 or higher genital exam finding (observed by study staff)? ....
☐ ☐

10. At Screening or Enrollment, does the participant have any Grade 1 or higher genital or urinary symptoms? ....
☐ ☐

11. At Screening or Enrollment, is the participant diagnosed with phimosis or hypospadias?
☐ ☐

12. At Screening or Enrollment, are penile, scrotal piercing or penile tattoos observed during genital examination? ....
☐ ☐

13. Does the participant have 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 the study objectives? ....
☐ ☐

If any items 7–13 are marked "yes," participant is ineligible. ◄——

[ ] [ ] [ ] [x] 16-FEB-11

[0][1]

Language   Staff Initials / Date

Enrollment Eligibility (non-DataFax) Page 2 of 2

No additional instructions.

SAMPLE: *DO NOT FAX TO DATAFAX*   **Not a DataFax form. Do not fax to DataFax.**

MTN 012/IPM 010 (187)

Page 1 of 2

Participant ID

☐☐☐ – ☐☐☐☐ – ☐

Site Number   Participant Number   Chk

Behavioral Eligibility

Visit Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

To confirm your eligibility for the study, I need to ask you a few more questions.

1. Are you willing to abstain from the following during study participation:

                                                                                           yes   *no*

   1a.   vaginal intercourse, even with a condom? ....   ☐   ☐

   1b.   oral intercourse, even with a condom? ....   ☐   ☐

   1c.   anal intercourse (including receptive anal intercourse), even with a condom? ....   ☐   ☐

   1d.   masturbation and other activities that may cause irritation or injury to the penis? .....   ☐   ☐

   1e.   using genitally-applied preparations (except use of usual cleansing products for
          genital hygiene) other than the study product? ....   ☐   ☐

   1f.   non-urgent surgical procedures of the penis/GU area? ....   ☐   ☐

2. Do you agree not to participate in other research studies involving drugs, medical devices,
    or genital products for the duration of study participation (until all follow-up visits are
    complete)? ....   *yes*   *no*
                                                                                                    ☐   ☐

                    If any items 1–2 are marked "no," participant is ineligible. ◄──────┘
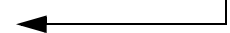
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Language   Staff Initials / Date

Behavioral Eligibility (non-DataFax) Page 1 of 2

Purpose: This form is used to document the participant's behavioral eligibility for the study at screening and enrollment. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: If a participant is being re-screened, a new Behavioral Eligibility form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.

General Information/Instructions: If the participant provides a response indicating he is ineligible, continue to administer this form until all items are completed. Refrain from indicating to the participant the reason why he is ineligible.

SAMPLE: *DO NOT FAX TO DATAFAX* **Not a DataFax form. Do not fax to DataFax.**

MTN 012/IPM 010 (187)

Participant ID

				–						–		

Site Number   Participant Number   Chk

Behavioral Eligibility

3.   Do any of the following apply to you:

		yes	no
3a.	known adverse reaction to any of the study products or components of the study products (ever)?	☐	☐
3b.	post-exposure prophylaxis (PEP) for HIV exposure within 6 months prior to Enrollment?	☐	☐
3c.	penile procedures (e.g., biopsy, circumcision) within 42 days or less prior to Enrollment?	☐	☐
3d.	participation in any other research studies involving drugs, medical devices, or genital products within 30 days prior to Enrollment?	☐	☐
3e.	within 3 months prior to Enrollment, history of a non-gonococcal urethritis and/or sexually transmitted infection (STI), including outbreak of genital herpes or condylomata?	☐	☐

		yes	no	N/A
3f.	for uncircumcised men, the treatment of candidal balanoposthitis/balanitis within 30 days prior to Enrollment?	☐	☐	☐
3g.	history of recurrent dermatosis (e.g., eczema)?	☐	☐	
3h.	non-therapeutic injection drug use within 12 months or less prior to Screening?	☐	☐	
3i.	currently using an immunosuppressant (with the exception of local non-genital use of low potency products e.g., inhaled corticosteroid for asthma)?	☐	☐	

If "yes," participant is ineligible. ◄

☐	☐	☐	☒	16-FEB-11

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Language   Staff Initials / Date

Behavioral Eligibility (non-DataFax) Page 2 of 2

No additional instructions.

SAMPLE: *DO NOT FAX TO DATAFAX*　**Not a DataFax form. Do not fax to DataFax.**

MTN 012/IPM 010 (187)

Participant ID

☐☐☐ – ☐☐☐☐ – ☐	**Follow-up Medical History Log**	**Page** ☐☐☐

Site Number　　Participant Number　　Chk

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**	**Is this condition reportable as an AE?** *yes* ☐ *no* ☐
	Outcome Date (dd-MMM-yy)	**Severity Grade**	*AE Log Page #* ☐☐☐ ←

Comments	**Medication taken?** *yes* ☐ *no* ☐
	Report on Concomitant Medications Log. ←

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**	**Is this condition reportable as an AE?** *yes* ☐ *no* ☐
	Outcome Date (dd-MMM-yy)	**Severity Grade**	*AE Log Page #* ☐☐☐ ←

Comments	**Medication taken?** *yes* ☐ *no* ☐
	Report on Concomitant Medications Log. ←

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**	**Is this condition reportable as an AE?** *yes* ☐ *no* ☐
	Outcome Date (dd-MMM-yy)	**Severity Grade**	*AE Log Page #* ☐☐☐ ←

Comments	**Medication taken?** *yes* ☐ *no* ☐
	Report on Concomitant Medications Log. ←

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**	**Is this condition reportable as an AE?** *yes* ☐ *no* ☐
	Outcome Date (dd-MMM-yy)	**Severity Grade**	*AE Log Page #* ☐☐☐ ←

Comments	**Medication taken?** *yes* ☐ *no* ☐
	Report on Concomitant Medications Log. ←

☐ ☐ ☐ ☒　16-FEB-11

0 1

Language

Follow-up Medical History Log

This form is used to document and track **all** medical conditions observed in or reported by the study participant during follow-up. This includes all signs, symptoms, and laboratory-based medical conditions. This form is reviewed and updated at each study visit and participant contact (e.g., telephone contacts), including interim visits/contacts, unless stated otherwise by the protocol.

Item-specific Instructions

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers.

- **Medical Condition:** Whenever possible, provide a diagnosis. Include anatomical location when applicable. Record only one diagnosis, sign, or symptom per entry.

- **Onset Date:** Record complete dates whenever possible. At a minimum, month and year are required. If the "day" portion is not known, record zeros for the day (example "00-JAN-11").

- **Outcome Date:** Record a complete date whenever possible. At a minimum, month and year are required. Record the date on which the participant no longer experiences the medical condition or the date of the study visit or specimen collection at which the resolution/status outcome is first noted. If the outcome is not able to be obtained (for example, a participant is lost to follow-up), record "unknown".

- **Severity:** Consult the appropriate *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* as specified by the protocol.

- **Is this condition reportable as an AE?:** Mark "yes" if the condition has been reported on an AE Log case report form. Refer to the protocol for a listing of which conditions are required to be reported on an AE Log form.

Review Documentation

For every follow-up visit, document that this log page was reviewed (and updated, as applicable) by recording a staff initials and date in one of the spaces below. Note that the page does not need to be reviewed once **all** conditions on the page have a recorded outcome date.

Staff Initials/Date	*Staff Initials/Date*	*Staff Initials/Date*	*Staff Initials/Date*
Staff Initials/Date	*Staff Initials/Date*	*Staff Initials/Date*	*Staff Initials/Date*
Staff Initials/Date	*Staff Initials/Date*	*Staff Initials/Date*	*Staff Initials/Date*
Staff Initials/Date	*Staff Initials/Date*	*Staff Initials/Date*	*Staff Initials/Date*

SAMPLE: *DO NOT FAX TO DATAFAX* **Not a DataFax form. Do not fax to DataFax.**

MTN 012/IPM 010 (187)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐

Site Number   Participant Number   Chk

Physical Exam

Exam Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

VITAL SIGNS

                                    yes   *no*

1. Were vital signs done?   ☐   ☐ → **If no, specify reason, then go to item 2.**   *Reason:* _____

   1a. Oral Temp .... ☐☐ . ☐ *°C*

   1b. BP ...... ☐☐☐ / ☐☐☐ *mmHg*

   1c. Pulse .... ☐☐☐ *per minute*

   _____
   Vital Signs: Staff Initials / Date

                                              not done
2. Height: .... ☐☐☐ *cm* **OR** ☐

FINDINGS

not evaluated   *normal*   *abnormal* → **If abnormal, please specify.**

☐ ☐ ☐ 3. General appearance _____

☐ ☐ ☐ 4. Abdomen _____

☐ ☐ ☐ 5. HEENT _____

_____

☐ ☐ ☐ 6. Oral Mucosa _____

☐ ☐ ☐ 7. Neck _____

☐ ☐ ☐ 8. Lymph Nodes _____

☐ ☐ ☐ 9. Heart _____

☐ ☐ ☐ 10. Lungs _____

☐ ☐ ☐ 11. Extremities _____

☐ ☐ ☐ 12. Neurological _____

☐ ☐ ☐ 13. Skin _____

→ **If any are abnormal and ongoing at Enrollment, record findings on Pre-existing Conditions form.**
If abnormal during follow-up, update or complete Adverse Experience Log when applicable.

_____
Findings: Staff Initials / Date

Comments**:** _____

☐ ☐ ☐ ☒ 16-FEB-11

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☐0☐1

Language   Staff Initials / Date

Physical Exam

Purpose: This form is used to document the participant's vital signs and physical exam findings.

General Information/Instructions: This form is completed each time a physical exam is performed. Because this is a non-DataFax form, do NOT fax to SCHARP DataFax.

Item-specific Instructions:

- **Vital Signs:** Use leading zeros when needed. The staff member who completes these items should initial and date in the space provided.

- **Findings:** The staff member who completes these items should initial and date in the space provided.