Section 9. Data Collection

This section provides information needed to successfully complete and submit MTN-009 case report forms (CRFs). It is important for sites to collect and record data carefully on CRFs; by doing so, the Statistical and Data Management Center (SDMC) can be confident that the data they are analyzing are accurate and complete. For questions about this section or about general data collection policies, procedures, or materials, please contact Karen Patterson (karen@scharp.org).

For this study, the SDMC 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-009 team members, along with their job roles and e-mail addresses, are listed below.

Role on MTN-009	Name	E-mail Address
Protocol Statisticians	Barbra Richardson	barbra@scharp.org
	Benôit Mâsse	bmasse@scharp.org
Project Manager	Karen Patterson	karen@scharp.org
Statistical Research Associate	Cliff Kelly	cwkelly@scharp.org
Protocol Programmer	Martha Doyle	mdoyle@scharp.org
ACASI Programmer	Lynda McVarish	lmcv@scharp.org
Reports Programmer	Kate Bader	kbader@scharp.org
Laboratory Programmer	Della Wilson	della@scharp.org
Data Coordinator	Debbie Lands	dlands@scharp.org
Document Specialist	Lori Filipcic	lorif@scharp.org

9.1 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 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 a land phone line (fax to phone number 206.667.4805) or faxed using a fax machine connected to the internet (fax to e-mail <datafax@scharp.org>).

SCHARP's Information Systems Technology (IST) group is available to consult with sites 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 a 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.

9.2   DataFax Form Completion

9.2.1   General Guidelines

Based on the use of fax technology and Good Clinical Practices (GCPs), follow the guidelines below when completing DataFax CRFs:

• Read carefully and follow all form instructions, which are printed on the back of each form

• 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 margins at the top, bottom, or sides of the CRF.

• Record written text responses on the lines provided. If additional space is needed, continue writing the response 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 the 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.

• Review completed CRFs, per local site SOP(s), for completeness and accuracy prior to faxing to SCHARP DataFax

• Fax CRFs 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.

9.2.2   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:**
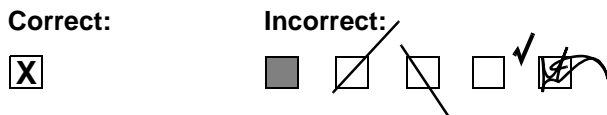
Mark only one response box for each item unless the "Mark all that apply" instruction is present.

9.2.3   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 boxes with leading 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.
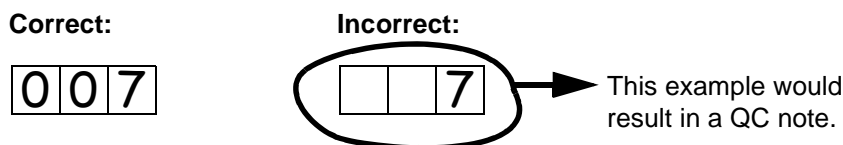
• Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

   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:

0 1 2 3 4   7

9.2.4   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, September 8, 2010 is recorded as:

0	8	S	E	P	1	0

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

9.2.5   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. Please note that 12:00am is often referred to as "midnight" and 12:00pm is often referred to as "noon".

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

9.2.6   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:
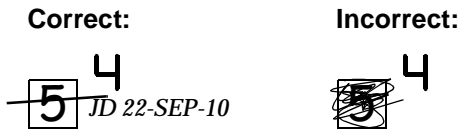
**Correct:**   **Incorrect:**

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:
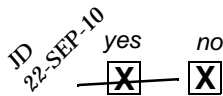
If the correct answer has previously been crossed out, do the following:

- circle the correct item,

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

- initial and date all corrections as shown below:
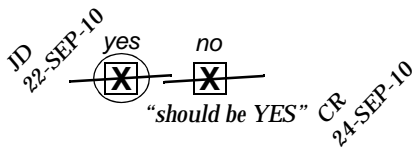
The standards above must *always* be followed whenever a CRF is changed, clarified, or amended, even if the change is made *before* the CRF is faxed to SCHARP for the first time.

9.2.7   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:
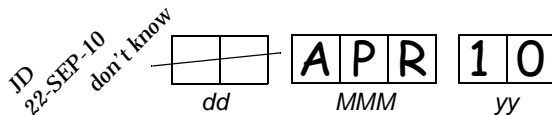
A skip pattern is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion, or as an update to the form.

## 9.3   MTN-009 Study-Specific Data Collection Information

9.3.1   Participant ID numbers (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, in the form of a PTID-Name Link Log. Once site staff determine that a woman is eligible to enroll in MTN-009, she may enroll in the study. In MTN-009, enrollment is considered the act of assigning a PTID. Ideally, site staff will assign PTIDs in sequential order to participants eligible and willing to enroll in MTN-009. Sites should ensure that each PTID is assigned only once, and that a given participant is assigned only one PTID. Once a participant has received a PTID, she will maintain that same PTID throughout the entire study.

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

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

The PTIDs used for this study are nine digits long and are formatted as "XXX-YYYYY-Z." The three parts of the PTID are: the 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-009.

Participant ID

Site Number	Participant Number	Chk
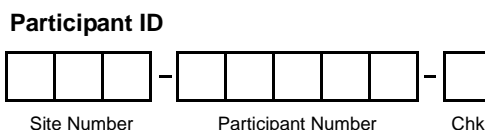
9.3.2   Study Visit Timing

Screening and Enrollment

The Screening and Enrollment Visit is the only visit in MTN-009 in which data is collected on CRFs for analysis purposes. Sites are encouraged to complete all Screening and Enrollment Visit procedures on the same calendar day, when possible. The ACASI questionnaire must be completed prior to HIV testing. If necessary, the blood draw may be done up to one week after completion of the ACASI questionnaire.

For MTN-009, a participant is considered enrolled in the study once the participant has been assigned a MTN-009 PTID.

Follow-Up Visits

The purpose of follow-up visits in MTN-009 is to provide participants with laboratory test results and counseling as needed. No data is collected for analysis purposes at follow-up visits. Thus, no CRFs are completed at follow-up visits. All follow-up visits should be documented in participant chart notes only.

Missed Visits

If a participant fails to show up for a visit to complete screening and enrollment procedures, or fails to show up for a follow-up visit, document the missed visit in the participant's chart notes only. No CRF documentation is completed for missed visits.

Interim Visits

Interim visits may occur during study follow-up to provide participants with additional test results, counseling, referrals, and services as needed. All interim visits should be documented in the participant chart notes only. No CRF documentation is completed for interim visits.

9.3.3   Visit Codes and Split Visits

DataFax uses the visit code to identify the visit at which a CRF is completed. The Screening and Enrollment Visit is assigned visit code 01.0. Since each MTN-009 CRF is completed only once in the study, as part of the Screening and Enrollment Visit, there is no Visit Code field on the CRFs. Rather, the visit code is embedded in the bar code at the top of each CRF and will be automatically assigned in DataFax. If screening and enrollment procedures are split across multiple visits (that is, blood is drawn up to one week after completion of the ACASI questionnaire), record on each CRF the Visit Date/Specimen Collection Date in which the procedures/questions listed on the form were completed. DataFax will allow for different dates to be recorded on the CRFs for a given participant, as long as the dates fall within the allowable one-week time period.

No visit codes are provided by the SDMC (SCHARP) for follow-up visits. However, sites may choose to develop local, site-specific visit codes in order to label and track follow-up visits in MTN-009.

9.3.4   Staff Initials/Date

Most forms 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 completing the form. This individual will complete 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.

9.3.5   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 to ensure that:

- 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 section 9.2.7.

- 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,

    - incorrect PTIDs,

    - 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 Section 9.3.6 below for more information).

Important: If a date stamp is used to document when a form is faxed to SCHARP DataFax, stamp *only* 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.

9.3.6   Faxing DataFax Forms

Only CRFs of enrolled participants should be faxed to SCHARP DataFax. For participants who screen more than once for the study and then enroll, only CRFs from the most recent Screening and Enrollment Visit should be faxed to SCHARP DataFax.

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-009 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-mail listings: 1) a listing of the number of form pages received at SCHARP; and 2) a listing of the specific forms that were received at SCHARP for a given PTID and visit. Please contact the MTN-009 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

9.4   Form Supply and Storage

9.4.1   Form and Specimen Label Supply

The case report forms will be supplied to sites in Screening and Enrollment visit packets. One packet contains all of the required CRFs for the Screening and Enrollment Visit. In addition, sites may order individual CRFs as needed.

SCHARP also will provide sites with blank specimen label stock and electronic label macro files for printing primary specimen labels on-site. These specimen labels should be used for all primary specimen collection containers in MTN-009. Please refer to the Laboratory section of this SSP Manual for more information on laboratory specimen collection and labeling.

Sites are asked to perform an inventory of form and primary specimen label supplies on a regular basis, and to order additional supplies, as needed, at least 3 weeks in advance of when the supplies will be needed.

9.4.2 Form Storage

Specifications for form storage will be detailed in the site's MTN-009 Data Management SOP. It is recommended that study staff store each participant's CRFs in a hard-cover notebook designated as the participant's study notebook. SCHARP will provide a template for site's optional use in creating notebook cover labels and spine labels.

9.5 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. Item-specific instructions are provided only for those items requiring additional clarification for purposes of form completion.

Below are some additional instructions for the case report forms.

- All case report forms in MTN-009 are DataFax forms and should be faxed to SCHARP for enrolled participants. If a participant screens more than once for the study, fax only the CRFs completed as part of the most recent MTN-009 Screening and Enrollment Visit that led to the participant's successful enrollment in the study.

- Only fax completed forms to SCHARP.

Eligibility Assessment form (EA)

- Complete this form for all women who consent to Screening and Enrollment in MTN-009, as evidenced by a signed MTN-009 informed consent form. It is used to assess a woman's eligibility for MTN-009 study participation.

- In MTN-009, assignment of a study participant identification number (PTID) to a woman is considered the effective act of enrollment in the study. Thus, when administering this form, site staff will not have a PTID to record on the form because the woman has not yet been enrolled and a PTID has not yet been assigned to her. Instead, record the woman's initials on the back of the first form page. Once the form is completed, if the woman is determined to be willing and eligible to enroll in the study, record the PTID on the form as soon as a PTID is assigned. If the woman is not eligible or willing to enroll in the study, record her initials on the form under the PTID field, and file the form in the woman's site records as part of the screening failure files.

Demographics form (DEM)

- Complete this form for enrolled participants only.

- This form includes interviewer-administered questions; that is, questions that site staff ask directly of participants in the context of a participant interview. The form serves as source documentation for all interviewer-administered questions.

- Each of the interviewer-administered questions on the MTN-009 Demographics form matches exactly (word-for-word) the interviewer-administered questions on the VOICE (MTN-003) Demographics form. For participants who enroll in MTN-009 then proceed to complete the VOICE Screening Part 1 Visit on the same day, the MTN-009 Demographics form will serve as source documentation for the interviewer-administered questions on the VOICE Demographics form. The responses to the interviewer-administered questions will be transcribed directly from the MTN-009 Demographics form onto the VOICE Demographics form.

CRF Table of Contents

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 009 (177)   EA-1   (005)   Page 1 of 1

Participant ID

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

Site Number   Participant Number   Chk

Eligibility Assessment

1. Did the participant present to the study site to pre-screen or screen for an HIV prevention trial?................................... *yes* ☐ *no* ☐ → **If no, participant is ineligible. End of form.**

   1a. For which trial does she plan to pre-screen or screen? .... *VOICE* ☐ *other, specify:* ☐ _____

2. Was the participant previously enrolled in MTN-009? .... *yes* ☐ *no* ☐ → **If yes, participant is ineligible. End of form.**

3. Is the participant between the ages of 18 and 40 years old, as verified per site SOPs? .... *yes* ☐ *no* ☐ → **If no, participant is ineligible. End of form.**

4. Was the participant able and willing to provide written informed consent for participation in MTN-009? .... *yes* ☐ *no* ☐ → **If no, participant is ineligible. End of form.**

   4a. When was the informed consent form for MTN-009 participation marked or signed?.............................. [ ][ ] [ ][ ][ ] [ ][ ] dd MMM yy

5. Was the participant able and willing to provide written informed consent for specimen storage and future research?...................... *yes* ☐ *no* ☐ → **If no, go to item 6.**

   5a. When was the informed consent form marked or signed to document participant consent for specimen storage and future research?... [ ][ ] [ ][ ][ ] [ ][ ] dd MMM yy

6. Does the participant have any condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achievement of the study objectives? .... *yes* ☐ *no* ☐ → **If yes, participant is ineligible. End of form.**

7. Did the participant enroll in MTN-009? .... *yes* ☐ *no* ☐ → **If no, end of form.**

   7a. Date of enrollment: .... [ ][ ] [ ][ ][ ] [ ][ ] dd MMM yy

Comments: _____

☐ ☐ ☐ [x]   17-FEB-10

N:\hivnet\forms\MTN_009\forms\m009_elig_assess.fm

[0][1] Language   Staff Initials / Date

9-13

Eligibility Assessment (EA-1)

Purpose: This form serves two purposes. It is used to document whether a woman is eligible for MTN-009, per the protocol inclusion and exclusion criteria. It is also used to document a woman's enrollment into MTN-009. This form must be completed for each participant who screens for MTN-009.

General Information/Instructions: This form is NOT interviewer-administered. It is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Screening and Enrollment Visit.

Note: There is no visit code field on this form, since this form is only completed at the Screening and Enrollment Visit.

Item-specific Instructions:

• **Item 2:** Review the Screening and Enrollment Log to verify whether the participant has previously enrolled in MTN-009.

• **Item 3:** Per protocol, a participant must be between the ages of 18 and 40 (inclusive) *at the time of screening* as verified according to site standard operating procedures (SOPs). Participants who are under 18 years or over 40 years of age should not be screened for the study.

• **Item 4a:** If the participant marks the informed consent form using her thumbprint, record the date the thumbprint was made.

• **Item 5:** Mark "yes" only if the participant gave optional consent to have her lab specimens stored for future research testing.

• **Item 7:** Per protocol, enrollment is the act of assigning an MTN-009 Participant ID (PTID) to a participant. Mark "yes" if the participant was assigned an MTN-009 PTID.

SAMPLE: *DO NOT FAX TO DATAFAX*

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number   Participant Number   Chk

Demographics

Visit Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

I will start by asking you some general questions about yourself.

1. What is your date of birth? .... ☐☐ ☐☐☐ ☐☐ → If unknown, record age: ☐☐ years

    dd   MMM   yy

2. What is your gender? ....   male ☐   female ☒

3. Are you currently married? ....   yes ☐   no ☐

    → *If yes, go to item 5.*

4. Do you currently have a primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis or who you consider to be your main partner.   ....   yes ☐   no ☐ → *If no, go to item 12 on page 2.*

5. How old is your husband/primary sex partner?......   ☐☐ years   don't know ☐

6. Are you currently living with him? ....   yes ☐   no ☐

7. Does he have any sex partners other than you?   yes ☐   no ☐   don't know ☐

8. Does he provide you with financial and/or material support? ....   yes ☐   no ☐

9. What is his average monthly income? *Record in local currency.* ....   ☐☐☐☐☐☐☐☐   don't know ☐   no income ☐

☐ ☐ ☐ ☒ 17-FEB-10

N:\hivnet\forms\MTN_009\forms\m009_DEM.fm

Language ⟦0⟧⟦1⟧   _____ Staff Initials / Date

9-15

Demographics (DEM-1)

Purpose: This form is used to collect participants' demographic and socioeconomic information.

General Information/Instructions: This form is a mixed form—some of the items are interviewer-administered (items 1–17), while other items are not (items 18–19a).

Note: There is no visit code field on this form, since this form is only completed at the Screening and Enrollment Visit.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. ***NOTE: participant must be between the ages of 18 and 40 years (inclusive) at the time of screening to be eligible for study participation.***

- **Item 4:** Record whether or not the participant **currently** has a primary sex partner.

- **Item 5:** Read aloud "husband" or "primary sex partner," depending on the participant's response to item 3 and item 4 (if not currently married). If the participant does not know her husband's or primary partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.

- **Item 8:** Record whether or not the participant's husband or primary partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.

- **Item 9:** Record the husband's or primary partner's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

    For example, if the income is 2,145 record:

0	0	0	0	0	2	1	4	5

    If the husband's or primary partner's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

SAMPLE: *DO NOT FAX TO DATAFAX*

Participant ID

				–						–	

Site Number   Participant Number   Chk

Demographics

10. What is his highest level of education?

☐ no schooling

☐ primary school, not complete

☐ primary school, complete

☐ secondary school, not complete

☐ secondary school, complete

☐ attended college or university

☐ don't know

11. Is he circumcised? By circumcised, I mean when the foreskin of the penis is removed. ....
Use visual aid.

yes ☐   no ☐   don't know ☐

12. Do you earn an income of your own?.............................

yes ☐   no ☐ ⟶ **If no, go to item 13.**

12a. What is your average monthly income?
Record in local currency. ....

12b. How do you earn your income?
Mark all that apply. ....

formal employment ☐   self-employed ☐   other, specify ☐

English: _____

Local Language: _____

13. What is your highest level of education?

☐ no schooling

☐ primary school, not complete

☐ primary school, complete

☐ secondary school, not complete

☐ secondary school, complete

☐ attended college or university

☐ ☐ ☐ ☐x 17-FEB-10

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Language   Staff Initials / Date

Demographics (DEM-2)

Item-specific Instructions:

- **Item 10:** If the participant does not know her husband or primary partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.

- **Item 11:** The intent of this item is to capture the circumcision status of the participant's husband/primary sex partner at the time this form is administered (Screening and Enrollment Visit). If the participant's husband/primary sex partner (as reported in items 3–4) is circumcised after the Screening and Enrollment Visit, do not update the response to item 11.

- **Item 12a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

  For example, if the income is 2,145 record:

0	0	0	0	0	2	1	4	5

  If the participant's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 12b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment. If "other, specify below" box is marked, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 009 (177)　　　　DEM-3　(003)

Participant ID

Site Number　　Participant Number　　Chk

Demographics

14.　How many children have you given birth to who were alive at birth?　　　 *# of children*

15.　Do you, or does someone in your family, own the house you are currently living in? ....　*yes*　*no*

16.　How many rooms are in the house you are currently living in? ....　*# of rooms*

17.　What is your ethnic group or tribe? ....　*ethnic/tribe code*
If other, specify:

English: _____

Local Language: _____

Interviewer: Complete the following items after the interview.

18.　*Where was the participant referred/recruited from? ....*　*recruitment code*

19.　*Did the participant complete the ACASI Questionnaire at this visit? ....*　*yes*　*no*　**If no, record reason(s) in Comments. End of form.**

19a.　*Date ACASI Questionnaire was completed: ....*　*dd*　*MMM*　*yy*

Comments: _____

_____

_____

_____

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Language　　Staff Initials / Date

Demographics (DEM-3)

Item-specific Instructions:

- **Item 14:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.

- **Item 15:** Record whether or not the participant (or someone in her extended family) owns the house she lives in.

- **Item 16:** Do not count bathrooms as rooms.

- **Item 17:** This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant's ethnic group or tribe. If the participant self-identifies with more than one ethnic group or tribe, record "90" (mixed) and document each group or tribe on the "Local Language" line. If the participant self-identifies with an ethnic group or tribe that is not included in the list of codes, record, "99" (other) and the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SOUTH AFRICA
07 - Zulu
08 - Xhosa
09 - Indian
10 - Colored
05 - Other African tribe
06 - White
90 - mixed
99 - other

- **Item 18:** This item asks where the participant was referred/recruited from to pre-screen or screen for an HIV prevention trial. It is not interviewer-administered. Refer to the code list developed and maintained at the site. Record the 2-digit site-specific code associated with the location (or person) from where this participant was referred or recruited.

SAMPLE: *DO NOT FAX TO DATAFAX*

▌ ▌ ▌ ▌ ▐ ▌ ▌ ▌ ▐ ▌

MTN 009 (177)   SEH-1   (034)

Page 1 of 1

Participant ID

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

Site Number   Participant Number   Chk

**Screening and Enrollment
HIV Test Results**

Specimen Collection Date

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

dd   *MMM*   *yy*

1.   HIV TEST RESULTS

	kit	*negative*	*positive*
1a. Rapid test 1	[ ][ ]	☐	☐
1b. Rapid test 2	[ ][ ]	☐	☐

➤ *If discordant, notify Network Lab and perform Western blot.*

Not done

☐

	negative	*positive*	*indeterminate*
1c. HIV Western Blot	☐	☐	☐

➤ *If negative or indeterminate, consult Network Lab.*

	negative	*positive*	*other, specify:*
2. Final HIV status	☐	☐	☐ _____

◄ *If negative, refer participant to HIV Prevention Trial.*

➤ *If positive, complete Laboratory Test Results form.*

Comments**:** _____

_____

☐ ☐ ☐ [x] 17-FEB-10

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[0][1]
Language   Staff Initials / Date

Screening and Enrollment HIV Test Results (SEH-1)

Purpose: This form is used to document local laboratory HIV test results of blood collected during the Screening and Enrollment Visit.

General Information/Instructions: Record specimen test results on this form as they become available. Fax this form to SCHARP DataFax once results for **all** collected specimens are recorded on this form.

Note: There is no visit code field on this form, since this form is only completed at the Screening and Enrollment Visit.

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

Item-specific Instructions:

- **Items 1a and 1b:** Record the assigned two-digit rapid test kit code. As of December, 2009, the rapid test kit codes are as follows. *Note: More test kit codes may be added to the list below as the study proceeds.*

Rapid Test	Kit Code
Abbott Determine	01
OraSure OraQuick	02
Uni-Gold Recombigen	03

- **Item 1c:** Mark *either* the "Not done" box *or* enter the test result.
- **Item 2:** 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 specify reason(s) on the line provided.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 009 (177)   LTR-1   (147)

Participant ID

[   ] [   ] [   ] – [   ] [   ] [   ] [   ] – [   ]

Site Number   Participant Number   Chk

Laboratory Test Results

Initial Specimen Collection Date

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

dd   *MMM*   *yy*

Alternate Collection Date

dd   *MMM*   *yy*

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

1.   T CELL SUBSETS   **Unable to analyze**   *cells/mm³*

1a.   Absolute CD4+ .....   [   ]   **OR**   [   ] [   ] [   ] [   ]

not available

1a1.   CD4+ % ....   [   ]   **OR**   [   ] [   ] . [   ]   %

Not done / Not collected   **Alternate Collection Date**

dd   *MMM*   *yy*

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

2.   HIV RNA   >   =   <   *viral copies/mL*

2a.   HIV RNA PCR   [   ] [   ] [   ]   [   ] [   ] [   ] [   ] [   ] [   ] [   ] [   ]

2b.   HIV RNA PCR
        kit lower limit   *50*   *400*   *viral copies/mL*
        of detection: ....   [   ]   [   ]   **OR**   [   ] [   ] [   ]

SPECIMEN STORAGE

Alternate Collection Date

dd   *MMM*   *yy*

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

3.   Plasma   ....   *stored*   *not stored*   *Reason:*

                              [   ]   [   ] ➡   _____

Comments**:** _____

_____

_____

[   ] [   ] [   ] [x]   17-FEB-10

[0] [1]

Language   Staff Initials / Date

Laboratory Test Results (LTR-1)

Purpose: This form is used to document local laboratory test results obtained during the study, as well as plasma storage.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when local laboratory results for all collected specimens are available and recorded.

Note: There is no visit code field on this form, since this form is only completed at the Screening and Enrollment Visit.

- **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 was collected on a different day than the Initial Specimen Collection Date. 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.

Item-specific Instructions:

- **Item 1a1:** If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 1a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.

- **Item 2:** Mark the "Not done/Not collected" box if HIV viral load testing is being conducted by the Network Lab only for this participant.

- **Item 2a:** Note that the ">" symbol is "greater than" and the "<" symbol is "less than." Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. For example, if a participant is tested with an assay that has 400 viral copies/mL as the lower limit of detection, and the lab reports her result as "238 viral copies/mL," mark the "=" box and record "00000238" viral copies/mL for item 2a.

- **Item 3**: Plasma storage is required at the Screening and Enrollment Visit for all enrolled participants. If, for some reason, it is not stored at this visit, mark "not stored" and record the reason why on the line provided.

SAMPLE: *DO NOT FAX TO DATAFAX*

▌▌▌▐▌▐▌▌▌

MTN 009 (177)   OTP-1   (040)

Participant ID

☐☐☐ – ☐☐☐☐ – ☐

Site Number   Participant Number   Chk

Other Trial Participation

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

1. Did this participant pre-screen for an HIV prevention trial? ....

yes ☐   *no* ☐ ➡ ***If no, go to item 2.***

   1a. For which trial did the participant pre-screen? ....

   VOICE ☐   *other, specify:* ☐ _____

   1b. Date of pre-screen: ....

   ☐☐ ☐☐☐ ☐☐
   dd   MMM   yy

2. Did the participant screen for an HIV prevention trial?....................

yes ☐   *no* ☐ ➡ ***If no, end of form.***

   2a. For which trial did the participant screen? ....

   VOICE ☐   *other, specify:* ☐ _____

   2b. Participant ID (PTID) of the trial: ....

   ☐☐☐ – ☐☐☐☐ – ☐   **OR**   *non-MTN trial* ☐

   Site Number   Participant Number   Chk

   2c. Date of screening: ....

   ☐☐ ☐☐☐ ☐☐
   dd   MMM   yy

   2d. Did the participant enroll in the trial? ....

   yes ☐   *no* ☐ ➡ ***If no, end of form.***

   2e. Date of enrollment: ....

   ☐☐ ☐☐☐ ☐☐
   dd   MMM   yy

Comments**:** _____

_____

_____

☐ ☐ ☐ ☒   17-FEB-10

☐0☐1☐ _____
Language   Staff Initials / Date

Other Trial Participation (OTP-1)

Purpose: This form is used to document participants' involvement in other HIV prevention trials.

General Information/Instructions: Complete this form once for each enrolled MTN-009 participant *who has been confirmed HIV-uninfected*. It is completed once the participant has completed her initial pre-screening or screening attempt for the other trial. For example, if a participant pre-screens for another HIV prevention trial, but does not complete a Screening Visit, complete this form once it is determined that the participant will not be screened. If a participant completes a Screening Visit for the other trial, complete this form once it is determined that she has screened out for the given screening attempt, or once she has enrolled in the other trial. If the participant has more than one screening attempt for the other trial, update this form as appropriate, initial/date the changes, and re-fax the form to SCHARP DataFax.

Note: There is no visit code field on this form, since this form is only completed once for each enrolled MTN-009 participant who has been confirmed HIV-**un**infected.

Item-specific Instructions:

- **Item 1a:** If the participant pre-screened for an HIV prevention trial other than VOICE, mark the "other, specify" box and write the trial name on the specify line. If the participant pre-screened for more than one HIV prevention trial, mark the box that corresponds to the trial she pre-screened for on or soonest after the date of MTN-009 enrollment. For example, a woman enrolls in MTN-009 on 05-JAN-10 and is confirmed HIV-uninfected. She pre-screens for VOICE that same day, and is found to be ineligible. She returns to the study clinic a month later to pre-screen for another HIV prevention trial. Mark the "VOICE" box, since the participant pre-screened for VOICE closer in time to the MTN-009 enrollment date.

- **Item 2a:** If the participant screened for an HIV prevention trial other than VOICE, mark the "other, specify" box and write the trial name on the specify line. If the participant screened for more than one HIV prevention trial, mark the box that corresponds to the trial she screened for on or soonest after the date of MTN-009 enrollment. For example, a woman enrolls in MTN-009 on 05-JAN-10 and is confirmed HIV-uninfected. She screens for VOICE that same day, and is found to be ineligible. She returns to the study clinic a month later to screen for another HIV prevention trial. Mark the "VOICE" box, since the participant screened for VOICE closer in time to the MTN-009 enrollment date.

- **Items 1b, 2c, and 2e:** A complete date is required (day, month, and year.)