

11. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-024/IPM 031 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact the SCHARP Project Manager for the study as listed below.

The SDMC (Statistical and Data Management Center) for this study is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-024/IPM 031 team members, along with their job role and e-mail address, are listed below.

MTN-024/IPM 031 Statistical and Data Management Center (SDMC) Staff

Job Role	Name	Email Address
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11.1 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 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 DataFax support group is available to consult with the site to determine the best method for data transmission. The DataFax support group can be contacted via e-mail at <support@scharp.org>. This 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.
- Next, each CRF is 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 refaxed 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 refaxed 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.

11.2 DataFax Form Completion

11.2.1 General 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.

11.2.2 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.



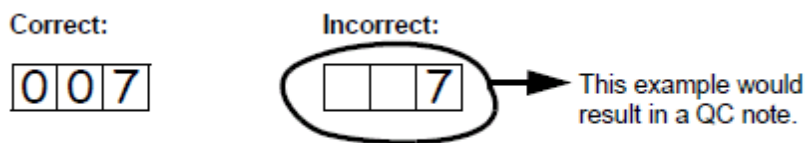
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

11.2.3 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:



- 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:



- 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

11.2.4 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, 2012 is recorded as:

06 JUN 12
 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:

<i>MMM</i>			<i>yy</i>		

A diagnosis date of October, 2011 would be recorded as follows:

O	C	T	1	1
<i>MMM</i>			<i>yy</i>	

11.2.5 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
<i>hr</i>			<i>min</i>	

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

12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
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

11.2.6 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. Initial and date all changes or additions.

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:

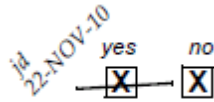
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and
- initial and date the correction as shown below:



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

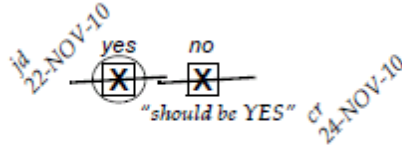
- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and

- 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:

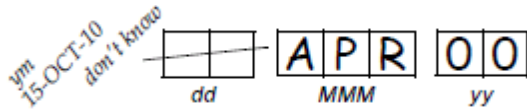


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

11.2.7 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.

11.2.8 Non-DataFax Forms

Non-DataFax forms are case report forms that are used for data documentation purposes, but are not faxed to SCHARP. These forms are created to ensure consistent and accurate data documentation across study sites for data that is not needed in the study database. Non-DataFax form is easily identifiable because there is no DataFax barcode along the top of the CRF. In place of the barcode, the following text appears: “NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.”

Non-DataFax forms are completed using the general guidelines presented above, and completed forms are stored similarly to DataFax forms in participant files/binders.

11.2.9 Faxing DataFax Forms

Each CRF with a bar code at the top is a DataFax form, and is faxed to SCHARP DataFax once completed and reviewed as described in the site's MTN Data Management SOP. Sites are encouraged to develop a system that identifies each time a form page is faxed so that re-faxing of unchanged forms can be avoided. A date stamp used on the back of the form page may be used for this purpose as long as the date stamp does not obscure data recorded on the front of the form page.

For sites wishing to confirm the receipt by SCHARP of faxed forms, 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 for each batch of forms faxed; and 2) which specific individual form pages were received at SCHARP for a given PTID and visit. Please contact the SCHARP DataFax Support Group (support@scharp.org) if you would like to use the CRF Tracking System or for more information about this fax confirmation system.

11.2.10 Form Storage

Specifications for form storage are described in the site's MTN Data Management SOP. It is recommended that for each participant, study CRFs be stored in a hard-cover notebook, with a tabbed section for CRFs completed at each study visit.

It is suggested that log forms (such as the Concomitant Medications Log, Adverse Experience Log, Clinical Product Hold/Discontinuation Log, and Protocol Deviations Log) 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.

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 divider labels.

11.2.11 MTN Data Management SOP

As a condition for study activation, each study site must have an SOP for MTN Data Management. This SOP should be reviewed and followed in combination with the information contained in the study protocol, this SSP Manual, and the site's Clinical Quality Management Plan (CQMP).

The MTN Data Management SOP contains information on and outlines site staff responsibilities for several data topics, including:

- Participant ID (PTID) assignment
- Participant study file organization
- Participant confidentiality
- Site data quality control (QC) processes
- Timing of DataFax form data transmission
- SCHARP data QC processes
- Electronically-captured study data
- Data storage

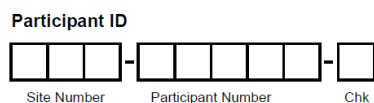
11.3 Study-Specific Data Collection Information

11.3.1 Participant ID numbers (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. Prior to study start, SCHARP provides each site with a list of PTIDs to be used for the study in the form of a study-specific MTN PTID Name-Linkage Log. The site assigns one PTID to each participant screened for the study. The PTIDs are assigned in sequential order as participants present for the screening visit. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, that same PTID is maintained for that participant for the duration of her study participation.

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

The PTIDs used for this study are nine digits and formatted as “WWW-XXXXX-Y.” The PTID consists of four parts: the DataFax site number (WWW), the participant number (XXXXX), and the numerical check digit (Y). The check digit (Y) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below are examples of the PTID structure used in MTN-024/IPM031.



11.3.2 Study Visit Timing

Screening and Enrollment

The initial screening visit is defined as the first day the participant provided written informed consent to be screened for the study. The enrollment visit will be scheduled to take place within 45 days of the initial screening visit. The date the participant is enrolled is Study Day 0.

Screening Attempts (Re-screens)

If a participant's first screening attempt is unsuccessful, the participant may re-screen a maximum of one time for the study if they choose. If they do re-screen, all screening procedures and forms must be repeated with the exception of PTID assignments. Once a PTID is assigned to a participant that PTID is used for the re-screen procedures and forms completed for that participant.

If a participant re-screens and enrolls in the study, only case report forms from the successful screening and enrollment visits are faxed to SCHARP.

Follow-Up Visits

For each follow-up visit, visit type, visit code, target visit day, and visit window are listed in Table 11-1. Target days and windows are listed in days, with the day of enrollment being Study Day 0.

Target Days and Visit Windows

Whenever possible, visits should be completed on the target day. If it is not possible to complete the visit on the target day, the visit should be completed within the visit window.

SCHARP will provide sites with a spreadsheet tool that may be used to generate 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 each required follow-up visit will appear. Please note that the final visit is dependent on the actual date of the previous visit. Therefore, the actual date of the 12-Week Final Clinic Visit must be manually entered in order to calculate the visit target date and windows for the 13-Week Follow-up Phone Call. The calendar can then be printed and added to the participant's study notebook.

Split Visits

Screening Visit may be split as long as all screening procedures are completed within the allowable 45 day window before enrollment.

Enrollment Visits may not be split. Refer to the Accrual section of this manual for more information regarding Enrollment Visit procedures and timing.

Whenever possible, all required follow-up visit evaluations should be completed on the same day. In those cases where this is not possible, the participant may come back and complete the remaining evaluations on another day, as long as that day is within the visit window. For example, a participant comes in on her 4-Week Study Visit target date and completes most of the required evaluations. She comes back 7 days later and completes the remaining required procedures. This is allowed, and is referred to as a "split" visit; as the participant completed all required visit evaluations on two separate days, both days being in the visit window.

Note that for split visits, only one Visit Summary CRF is completed, and all CRFs completed for the visit are assigned the same visit month/code. The "Visit Date" on the Follow-up Visit Summary CRF is the date of the first part of the split visit. See Section 11.3.3 for more information on assigning visit codes to split visits.

Table 11-1: Visit Timing Requirements

Visit Code	Visit Type	Visit Window Opens	Target Day/ Comments	Visit Window Closes
01.0	Screening	N/A	No more than 45 days prior to planned Enrollment day	N/A
02.0	Enrollment	Day after Screening Visit	Day 0	45 days after Screening Visit
03.0	1-Week Follow-up Phone Call	Day 1	Day 7	Day 13
04.0	4-Week Visit	Day 14	Day 28	Day 41
05.0	8-Week Visit	Day 42	Day 56	Day 69

06.0	12-Week/ Final Clinic Visit	Day 70	Day 84	Day 97
07.0	13-Week Follow-up Phone Call	1 day after the 12-Week/Final Clinic Visit	Varies	14 days after the 12-Week/Final Clinic Visit

* The Target Visit Date for the 13-Week Phone Call is based on the Actual Visit Date of the 12-Week Final Clinic Visit. Therefore, you must enter the Actual Visit Date for the 12-Week Final Clinic Visit in order to calculate the Target Date and Visit Windows for the 13-Week Phone Call.

Missed Visits

In 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, an enrolled participant does not report to the clinic for her 4-Week Visit until 42 days after enrollment. Per table 11-1, this visit has been missed. The missed visit is documented in the study database by completion of a Missed Visit CRF which is faxed to SCHARP.

Interim Visits

An interim visit occurs when there is a clinic visit with the participant, but required follow-up visit procedures are not done, either because the required follow-up visit has already been completed, or it is not within the visit window to complete the required visit. An interim visit may also occur via a non-required phone contact if the participant reports a new AE requiring reporting on an AE Log CRF, or the participant is instructed by study staff to hold or permanently discontinue study product use.

All interim visits/contacts with the participant should be documented in a chart note. Additionally, if the interim contact results in at least one newly-completed DataFax CRF, the interim visit is assigned an interim visit code (visit code ending in something other than “.0”). All phone contacts that meet interim visit criteria per paragraph above are also assigned interim visit codes. See section 11.3.3 for information on how to assign visit codes to interim visits.

Note that for MTN-024/IPM 031, there is no Interim Visit CRF. Instead, a Follow-up Visit Summary CRF is completed for interim visits/contacts as needed. The Visit Code of the Follow-up Visit Summary CRF will document whether the visit is a required (regular) visit or an interim visit.

11.3.3 Visit Codes and Page Numbers

Most CRFs will include boxes in the upper right corner for a visit code. DataFax uses the visit code to identify the visit at which a CRF is completed. For CRFs completed only once per participant (the Enrollment CRF, for example), there is no place to record a visit code, as the visit code has been automatically assigned by SCHARP.

The table below lists the visit codes assigned to each required follow-up visit.

Table 11-3: Visit Code Assignments for Required Follow-up Visits

Visit #	Visit	Visit Code
1	Screening	01.0
2	Enrollment	02.0
NA	1-Week Follow-up Phone Call	03.0
3	4-Week Visit	04.0
4	8-Week Visit	05.0
5	12-Week/Final Clinic Visit	06.0
NA	13-Week Follow-up Phone Call	07.0

Visit Codes for Interim Visits

Note that interim visit codes are not used for visits/contacts between the Screening Visit and Enrollment Visit, as CRFs completed for screening and enrollment have the visit code automatically-assigned.

For interim visits occurring after the Enrollment Visit, interim visit codes are assigned using the following guidelines:

- In the two boxes to the left of the decimal point, record the two-digit visit code for the most recently required follow-up visit, even if the visit was missed and/or if the participant is within the next visit's window.
- For the box to the right of the decimal point:
 - #.1 = the first interim visit after the most recently-required follow-up visit,
 - #.2 = the second interim visit after the most recently-required follow-up visit,
 - #.3 = the third interim visit after the most recently-required follow-up visit, and so on.

Example #1: A participant completes her 8-Week Visit (Visit Code = 05.0) on the target date. The participant returns to the site 2 days later to report a new genitourinary symptom. This interim visit is assigned a Visit Code of 05.1:

Visit Code for this Interim Visit

Visit Code

0	5
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Page numbers

Other CRFs, such as log forms (e.g., Adverse Experience Log, Concomitant Medications, or Protocol Deviations Log), may include boxes in the upper right corner for page numbers, as shown below:

Assign page numbers in sequential order, starting with 01 (or 001, for Adverse Experience Log CRFs). Continue to assign numbers in sequential order (for example, the second Concomitant Medications Log page would be assigned page number 02; the third page would be assigned 03, and so on).

11.3.4 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 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.

11.3.5 Form Supply

Sites are responsible for creating their own supplies of MTN-024/IPM 031 CRFs. Sites may either print CRFs (this is the preferred method) from PDF files provided by SCHARP (available on the MTN-024/IPM 031 Atlas web page), or via photocopy of hard-copy originals. CRF PDF files will include visit packets containing all of the CRFs required to be completed for the visit, as well as a file containing all of the CRFs created for the study.

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.

11.3.6 Case Report Form Completion Schedule

The SCHARP-provided 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. Table 11-4 lists the DataFax and non-DataFax forms that are required to be completed at each study visit.

Table 11-4: Schedule of Forms – CRFs Required to be Completed at Each Visit

Screening Visit: Visit Code 01.0	
DataFax forms	Non-DataFax forms
Eligibility Criteria Demographics Pelvic Exam Physical Exam Safety Laboratory Results STI Test Results HIV Results Pre-existing Conditions Concomitant Medications Log	Baseline Medical History Questions Sheet Pelvic Exam Diagrams Screening Menstrual History LDMS Specimen Tracking Sheet

Enrollment Visit: Visit Code 02.0	
DataFax forms	Non-DataFax forms
Enrollment Pelvic Exam Physical Exam Ring Collection and Insertion Specimen Storage Vaginal Practices	Pelvic Exam Diagrams Follow-up Medical History Log LDMS Specimen Tracking Sheet
1-Week Follow-up Phone Call: Visit Code 03.0	
DataFax forms	Non-DataFax forms
Follow-up Visit Summary	N/A
4-Week Visit: Visit Code 04.0	
DataFax forms	Non-DataFax forms
Follow-up Visit Summary Follow-up CASI Tracking Pelvic Exam Physical Exam Pharmacokinetics Ring Adherence Ring Collection and Insertion Specimen Storage Vaginal Practices	Pelvic Exam Diagrams Follow-up Medical History Log Study-approved Lubricant Use Log LDMS Specimen Tracking Sheet
8-Week Visit: Visit Code 05.0	
DataFax forms	Non-DataFax forms
Follow-up Visit Summary Follow-up CASI Tracking Pelvic Exam Physical Exam Pharmacokinetics Ring Adherence Ring Collection and Insertion Specimen Storage Vaginal Practices	Pelvic Exam Diagrams Follow-up Medical History Log Study-approved Lubricant Use Log LDMS Specimen Tracking Sheet
12-Week/Final Clinic Visit: Visit Code 06.0	
DataFax forms	Non-DataFax forms
Follow-Up Visit Summary Follow-Up CASI Tracking HIV Results Pelvic Exam Pharmacokinetics Physical Exam Ring Adherence Ring Collection and Insertion Safety Laboratory Results Specimen Storage Vaginal Practices	Pelvic Exam Diagrams Follow-up Medical History Log Study-approved Lubricant Use Log LDMS Specimen Tracking Sheet
13-Week Follow-up Phone Call: Visit Code 07.0	
DataFax forms	Non-DataFax forms
Follow-Up Visit Summary End of Study Inventory Termination	N/A

11.3.7 Completing Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that participant interviews be conducted with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

11.3.8 Site Review (Quality Control) of DataFax Forms

As described in the site's MTN Data Management SOP (and referenced in the site's Clinical Quality Management Plan, CQMP), each site must perform two Quality Control (QC) review steps prior to faxing DataFax forms to SCHARP. While DataFax CRFs are being reviewed, it is important that they are stored and tracked systematically.

Below are specific review guidelines that should be followed for these QC review steps.

11.3.9 MTN-024/IPM 031 QC Review Step #1

- Review CRFs based on participant responses to ensure completeness.
 - For the Screening Visit, Enrollment Visit, and all follow-up visits review all required and completed CRFs as listed in Tables 11-4 above. In addition, be sure to review any CRFs completed "as needed."

11.3.10 MTN-024/IPM 031 QC Review Step #2

This QC review step should occur before forms are faxed to SCHARP. Ideally, this review will happen once all lab results are available, so that all forms for a particular visit can be reviewed for consistency across documents. The goal, as outlined in the site's MTN Data Management SOP, is to correct data inconsistencies/errors prior to faxing forms to SCHARP so that QC notes are prevented.

General QC #2 procedures for all visits:

- Review visit checklist to ensure all required procedures were completed
- Ensure no participant identifiers other than the PTID are present on DataFax forms.
- Ensure the PTID is correct, and is the same on all forms/documents.
- Ensure the Visit Code assigned is correct, and is the same on all documents.
- Make sure a response has been recorded for each item, as required. Make sure skip patterns have been followed correctly.
- If a response box has a line for "other," "specify," or "describe," ensure text is recorded on the line.
- Make sure text responses are clearly recorded.

11.4 Form-Specific Completion Instructions

Detailed form completion instructions for each form are provided on the back of each form page. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all form items listed in the form-specific completion instructions, but rather, only those items needing detailed explanation.

Below are additional instructions for some of the CRFs used in this study. These instructions do not appear on the back of the form page due to lack of space.

Adverse Experience Log (AE-1)

- Do not wait until the AE resolves before faxing the form page to SCHARP.
- Always make changes, corrections, and updates to the originally-completed form page (do not complete a new form). 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.
- Note that AE Log page numbers do not need to be assigned in any special order with regard to AE onset date or date reported to site. For example, if it is discovered that for a participant, page 001 and 003 were assigned, but not 002, simply assign page # 002 to the next AE Log form you complete. It does not matter if the AE's onset date or date reported to site on page 002 is later than these dates reported on AE Log page 003 (a QC will not be generated).
- 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. Any adverse experiences associated with the planned procedure or surgery, are AEs.
- If an AE is marked as "related", please avoid putting additional detail regarding relatedness in the "Comments" section. Rather, provide as much relevant information as possible in item 1 (the text description of the AE). This will help avoid MedDRA coding queries during the study.
- For more details regarding how to report AEs please review SSP section 8.

11.5 Case Report Forms

The current version of the MTN-024/IPM 031 case report forms (not for actual data collection purposes use) can be found on the MTN-024/IPM 031 SSP web page on the MTN website (www.mtnstopshiv.org).