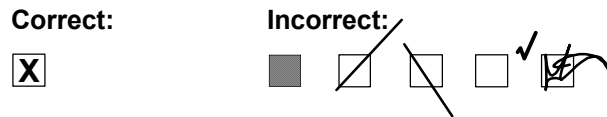


- Because some CRFs are source documents, the site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.
- Fax forms as soon as possible after they have been completed and reviewed (generally within 24 to 48 hours of the participant’s visit).

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.

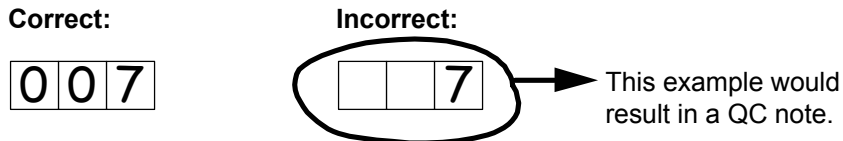


Mark only one response box for each item unless the “Mark all that apply” instruction is present.

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:

Correct:

4

Incorrect:

4

- 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
January	JAN
February	FEB
March	MAR
April	APR
May	MAY
June	JUN

Month	Abbreviation
July	JUL
August	AUG
September	SEP
October	OCT
November	NOV
December	DEC

For example, June 1, 2003 would be recorded as follows:

01 JUN 03
 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 2002 would be recorded as follows:

O	C	T	0	2
MMM			yy	

11.2.5 How to Record Time

Time is recorded on DataFax CRFs using the 24-hour clock, 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	

Note: 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

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.

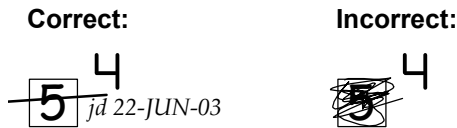
It is important to make these changes to the original CRF—*never* copy data onto a new form. After making the change, the CRF *must* be refaxed to SCHARP DataFax.

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 below when changing, clarifying, or amending data.

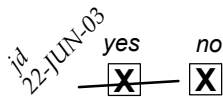
Whenever an entry on a DataFax CRF is changed, do the following:

- 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:



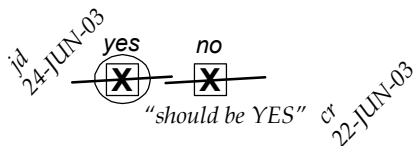
If an **X** is marked in the wrong response box, correct it by doing the following:

- 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:



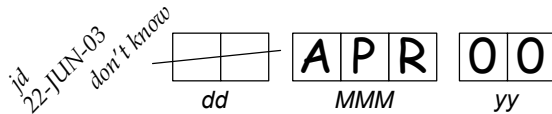
Note: The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

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.

Note: A skip pattern is the only valid reason to leave a response blank.

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:



If a required lab specimen is not collected and/or a test was not conducted, mark the Not done/Not collected box and record why it was not done or not collected on the comments lines or in the white space beside the item.

11.3 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 has been skipped as instructed by a skip pattern.
- 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, and/or

- missing data for items beginning a series of skip patterns.

While CRFs are waiting to be reviewed and faxed to SCHARP DataFax, 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.

Important: Use only the back of the CRF for a date stamp, never the front. Be sure to date stamp the back of the CRF each time it is faxed, including refaxes.

11.4 Faxing DataFax Forms

Only Datafax forms (forms with a barcode at the top of the page) should be faxed to SCHARP Datafax.

The SCHARP DataFax e-mail address is: **datafax@SCHARP.org**

The SCHARP DataFax number is: **1-206-667-4805**

After thorough review, forms should be faxed to SCHARP DataFax as soon as possible following the participant's visit. Keep in mind that the sooner a form is faxed, the sooner the data will enter the study database.

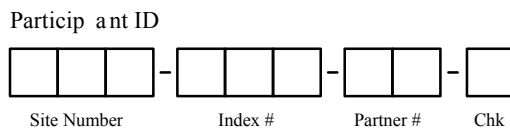
11.5 HPTN 052 Data Collection

11.5.1 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 randomization envelopes prior to study start-up. Each randomization envelope will include one index PTID and a list of ten linked partner PTIDs. When randomized, the index receives the index PTID found in the envelope and the partner receives the partner PTID listed on the upper portion of the form.

PTID boxes are located near the upper left corner of each DataFax CRF. On multiple page CRFs, the PTID must be filled in on each page.

The PTIDs used for HPTN052 are nine digits and consist of four parts: site number, index number, partner number, and a numeric check digit. The check digit is a number generated by SCHARP with the index number to help ensure that the correct PTID is recorded. Below is an example of the PTID structure used in HPTN052.



We are able to identify two participants as a couple because they share the same site number and index number.

Each index participant ID will have “00” in the partner section of the ID number. Each partner of the index will have the index participant’s index number and a unique *partner* number, with the first partner receiving 01, the second receiving 02 and so on

For example:

- Index A receives ID 050-021-00-7.
- The first partner of index A receives ID 050-021-01-2.
- If the relationship with the first partner ends, and a second partner joins the study, the new partner’s ID is the next ID on the list and would be 050-001-02-9.

11.5.2 Target and Allowable Visit Windows

A *target* visit window is the window within which a required visit **should** be completed. The target window for the Week 2 visit is -3 or +3 days from the target visit date. The target window for the monthly, quarterly, and yearly visits is -7 or +7 days from the target visit date.

An *allowable* window is a wider window to allow for situations where required visits cannot be done within the target window. As a result of LOA #3, the allowable windows for required visits have been revised as follows: Week 2 allowable window is -3/+3 days from the target visit date; monthly allowable window is -7 /+22 days from the target visit date; quarterly and yearly target window is -7/+59 days from the target visit date.

Following is a table illustrating the first year’s target and allowable windows for those on the *immediate arm*:

Visit Type	Target Day	Target Window	Allowable window
Enrollment	Day 0	none	Day 0 – Day 7
Week 2	Day 14	Day 11 – Day 17	Day 11 – Day 17
Month 1	Day 30	Day 23 – Day 37	Day 23 – Day 52
Month2	Day 60	Day 53 – Day 67	Day 53 – Day 82
Month 3 (Quarterly)	Day 90	Day 83 – Day 97	Day 83 – Day 149

Month 6 (Quarterly)	Day 180	Day 173 – Day 202	Day 173 – Day 239
Month 9 (Quarterly)	Day 270	Day 263 – Day 292	Day 263 – Day 329
Month 12 (Yearly)	Day 360	Day 353 – Day 382	Day 353 – Day 419

Following is a table illustrating the first year’s target and allowable windows for a *delay arm* participant. In this example, the participant initiates ART at the month 6 visit, but this can occur at any time during follow-up.

Visit Type	Target Day	Target Window	Allowable window
Enrollment	Day 0	none	None
Month 1	Day 30	Day 23 – Day 37	Day 23 – Day 52
Month 2	Day 60	Day 53 – Day 67	Day 53 – Day 82
Month 3 (Quarterly)	Day 90	Day 83 – Day 97	Day 83 – Day 149
Month 6 (Quarterly) (<i>ART initiation visit</i>)	Day 180	Day 173 – Day 202	Day 173 – Day 239*
Week 2	Day 194	Day 191 – Day 197	Day 191 – Day 197*
Month 7	Day 210	Day 203 – Day 217	Day 203 – Day 232*
Month 8	Day 240	Day 233 – Day 247	Day 233 – Day 262
Month 9 (Quarterly)	Day 270	Day 263 – Day 292	Day 263 – Day 329
Month 12 (Yearly)	Day 360	Day 353 – Day 382	Day 353 – Day 419

* Because the allowable window for quarterly and yearly visits is wide, you will encounter some overlap of allowable windows when a participant initiates ART. If the actual visit date for ART initiation occurs near the end of the allowable window, contact SCHARP to ensure the correct visit codes are used for the week 2 and monthly follow-up visits.

11.5.3 Missed Visits

A protocol-required follow-up visit is considered missed when neither the index nor the partner complete any procedures within the allowable visit window. A missed visit is documented with a Couples Missed Visit form. If either the index or the partner completes some procedures for the visit within the visit window, the visit is not considered a missed visit.

11.5.4 Interim Visits

A visit is considered an Interim Visit when the index or partner completes a protocol-required visit within the allowable window, and then returns within the same window for another visit where data is collected. If data is not collected, no CRFs are completed.

- For example, the couple's month 3 target visit date is October 15. The couple completes their month 3 visit on October 12. On October 20 the partner returns to the clinic for treatment of new STI symptoms. Because all procedures were already completed for the month 3 visit and October 20 is still within the month 3 allowable visit window, this is an Interim Visit.

11.5.5 Visit Codes

Each study visit is identified using a *visit code*. DataFax uses a three-digit visit code (##.#) to identify which data collection forms are completed at which study visits. Site staff are responsible for entering the visit code in the boxes provided at the top right corner of each page for all study follow-up forms. For some index Enrollment forms, SCHARP has internally recorded the visit codes so visit code boxes do not appear on the forms.

Visit code boxes are needed for all partner enrollment forms because new partners may enroll at any time during the study. Each partner Enrollment form has instructions on how to record the correct visit code.

A couple is expected to complete required visits together. However, if the index and partner complete the visit procedures separately within the visit window, their CRFs will receive the same visit code for that required visit - even though the index and partner CRFs will have different visit dates.

It is possible that more than one day may be needed to complete the procedures for a protocol-required visit. If the procedures are completed within the visit window, all CRFs receive the same visit code for the required visit - even though the CRFs will have different visit dates.

NOTE: *Any procedures for a required visit that are done within the allowable window receive the .0 visit code. If a visit occurs after the allowable window has closed but before the target window for the next visit has opened, contact Leslie Cottle at SCHARP (leslie@scharp.org) for instructions on how to code this visit.*

VISIT CODING CHANGES DUE TO LOA #3 to Protocol Version 3.0

Quarterly and yearly visits maintain the original visit code numbering (e.g., Month 9 visit code is still 10.0, Month 12 visit code is still 13.0)). ***Monthly visit codes are now used only for monthly visits required by the protocol and LOA #3.*** For example, the visit codes 02.0 (month 1) and 03.0 (month 2) are the only monthly visit codes used for a newly enrolled couple when the Index is randomized to the immediate arm. Those in the delay arm will use visit codes 02.0 and 03.0, and the two monthly visit codes immediately following ART initiation. (Note that one of the three one-month visits would occur at a quarterly or yearly visit).

Those participants already in follow-up will start following the quarterly visit schedule immediately after IRB approval of LOA #3 and after re-consenting. For example, a delay arm participant recently seen for his month 7 visit will not be scheduled again until month 9, the next quarterly visit. However, some monthly visits may have already been scheduled prior to your site's receipt of LOA approval. It is up to the site's discretion whether to cancel a monthly visit or to keep the monthly visit and give it an interim visit code (see below for interim visit details). For example, the site may want to bring in an immediate arm participant for a monthly visit to dispense additional ART, since without the monthly visit the participant may not have enough ART to make it to the next quarterly visit.

The following table is a partial list of required visits and their DataFax visit codes.

REQUIRED VISITS AND DATAFAX CODES

Visit	Required visits for Immediate Arm	Required Visits for Delay Arm
Enrollment	01.0	01.0
Week 2	01.x (interim visit)	---
Month 1	02.0	02.0
Month 2	03.0	03.0
Month 3 (quarterly visit)	04.0	04.0
Month 4	---	---
Month 5	---	---
Month 6 * (quarterly visit)	07.0	07.0
Week 2 (Delay arm only)*		07.1 (interim visit)
Month 7 **	---	08.0
Month 8 **	---	09.0
Month 9 (quarterly visit)	10.0	10.0
Month 12 (yearly visit)	13.0	13.0
Month 15 (quarterly visit)	16.0	16.0

* ART initiation can occur at any time for a delay arm participant. In this example, ART was initiated at the Month 6 visit. The Week 2 visit receives an interim visit code based on the previous *required* visit code.

**NOTE: Only required for the first three months after ART initiation (delay arm only) or after a new partner has enrolled (either arm).

Interim Visit Codes

In addition to the scheduled, protocol-required visits, interim visits may occur after the participant is enrolled in the study. When data is collected at an interim visit, the following guidelines should be used to assign visit codes.

- Record the two-digit whole number (to the left of the decimal point) visit code for the previous protocol-required visit. For example, if the most recent previously scheduled visit was 05.0, record “05” to the left of the decimal point in the visit code field.
- Use the guide below to complete the third box (to the right of the decimal point):
 - protocol-required visit. ##.1 = First Interim Visit after the most recent previously scheduled
 - ##.2 = Second Interim Visit after the most recent previously scheduled protocol-required visit.

Example #1: If an Index participant returns to the site two days after her Month 4 Visit (Visit Code = 05.0), record the following

Visit Code for this Interim Visit

0 5 . 1

visit code:

Example #2: If the Index participant or her partner returns 2 days after the 05.1 interim visit, record the following visit code:

Visit Code for this Interim Visit

0 5 . 2

If a participant comes in to the clinic between required visits, but no data is collected, the visit does not receive a visit code and is not documented in DataFax. If a participant comes to the clinic between required visits and *minor* data is collected that is not time-sensitive, such as concomitant medications dispensing, this information can be recorded on the appropriate log form and faxed as needed and does not need to be documented in DataFax as an interim visit.

Each interim visit, regardless of whether one or both people in a couple are present, must receive a new interim visit code. Example:

Visit Date	Visit Code	Present at Visit
04 JUN 05	02.0	Index, Partner
06 JUN 05	02.1	Index
08 JUN 05	02.2	Partner
10 JUN 05	02.3	Index, Partner

Any visit where data is collected that is not protocol-required receives an interim visit code based on the previous *required* visit's code. This means that an interim visit that occurs during follow-up for an immediate arm participant after month 3 will receive an interim visit code based on the previous quarterly or yearly visit, *regardless of whether it falls in a monthly visit window*.

IMMEDIATE ARM EXAMPLE: The participant comes in six weeks after his month 6 visit (code 07.0) to discuss STI symptoms. This visit receives interim visit code 07.1.

DELAY ARM EXAMPLE: The participant initiates ART at his Month 6 visit (code 07.0). His next required visits are two monthly (codes 08.0 and 09.0) and a quarterly (10.0). An interim visit occurs a week after the 08.0 monthly visit and receives code 08.1.

Post-ART (Week 2) visits still receive an interim visit code based on the previous required visit code.

VISIT CODING EXAMPLES

NEWLY ENROLLED PARTICIPANT IN IMMEDIATE ARM:

Visit	Visit Date	Visit code
Enrollment	01 September 2008	01.0
Week 2 visit	15 September 2008	01.1
Month 1	01 October 2008	02.0
Month 2	31 October 2008	03.0
Month 3 (Quarterly)	30 November 2008	04.0
<i>Interim visit</i>	<i>22 January 2009</i>	<i>04.1</i>

NEWLY ENROLLED PARTICIPANT IN DELAY ARM:

Visit	Visit Date	Visit code
Enrollment	01 September 2008	01.0
Month 1	01 October 2008	02.0
Month 2	31 October 2008	03.0
Month 3 (Quarterly)	30 November 2008	04.0
Month 6 (Quarterly)	28 February 2009	07.0
Month 9 (Quarterly)	29 May 2009	10.0
Month 10 (ART Initiation visit)	28 June 2009	11.0
Week 2 visit	12 July 2009	11.1
Month 11	28 July 2009	12.0
Month 12 (Yearly)	27 August 2009	13.0
Month 13	26 September 2009	14.0
<i>Interim visit</i>	<i>24 October 2009</i>	<i>14.1</i>
Month 15 (Quarterly)	25 November 2009	16.0
Month 18 (Quarterly)	23 February 2010	19.0

Visit schedule for a new partner

If a partner terminates and a new partner enrolls, the new partner's enrollment visit must take place on a quarterly visit or a date a monthly visit would normally occur and the index participant must be present. CRFs for both the partner and the index will receive the same ".0" visit code. The next three monthly visits following enrollment of the new partner will receive scheduled or required visit codes as well.

The following table outlines how to assign these visit codes to the index and partner CRFs for a new partner if the new partner enrolled at either visit 8.0, 9.0, or 10.0, as an example:

Visit	New partner enrolled at visit 8.0	New partner enrolled at visit 9.0	New partner enrolled at visit 10.0
Month 7	8.0 (enrollment visit)	---	---
Month 8	9.0	09.0 (enrollment visit)	
Month 9 (quarterly visit)	10.0	10.0	10.0 (enrollment visit)
Month 10	11.0	11.0	11.0
Month 11	---	12.0	12.0
Month 12 (yearly visit)	13.0	13.0	13.0

11.5.6 Collecting Data on Couples

Data is collected on the couple as well as on each individual in the couple. Always consider the participants as individuals, except in the following situations:

- **At the enrollment visit.**

Both the index and partner must be present at the enrollment visit in order to enroll.

- **When assigning Participant IDs.**

Two individuals are identified as a couple because their ID numbers share the same *site* number and *index* number.

- **When a visit is missed.**

A protocol-required follow-up visit is considered missed when neither the index nor the partner complete any procedures within the allowable visit window.

- **When both the index and the partner terminate from the study.**

A Couples Termination CRF is completed; Index Termination and Partner Termination CRFs are completed.

Note: If only the partner terminates from the study, the index can remain enrolled. However, if the index terminates from the study, the partner must also be terminated, *unless* the sexual relationship between the index and partner remains intact. In this case the partner can stay in the study alone.

11.5.7 ART Initiation Visits

For those index participants in the immediate arm, the ART initiation visit procedures occur during enrollment. For those index participants in the delay arm, the ART initiation may begin at an interim visit, but only on a date when a monthly visit would occur in order to maintain the quarterly visit schedule. The ART initiation visit should receive an interim visit code, **unless** the ART initiation visit is combined with a protocol-required visit.

11.5.8 Post-ART Initiation Visits

Every index participant prescribed ART must have a visit two weeks after the start of his/her initial ART regimen. Because this visit can occur at any time during the study for those in the delay arm, it receives an interim visit code, **unless** the post-ART initiation visit is combined with a protocol-required visit. For participants in the immediate arm, their Post-ART Initiation visit will occur

two weeks after enrollment, and will receive the next available interim visit code.

11.5.9 Recording lab values on CRFs

When recording a lab value on a CRF, it may be necessary to round the result up or down, as appropriate, to the level of precision allowed on the CRF.

- **Example:** Lab-reported hemoglobin value = 11.06 g/dL.

The following appears on the CRF:

. g/dL

Round the lab-reported value up to the tenths place and record as:

. g/dL

If the lab value is reported in a unit other than that which appears on the CRF, *first* perform the conversion, *then* round the converted result.

- **Example:** Lab-reported creatinine value = 128 umol/L

The following appears on the CRF:

.

First, convert from umol/L to mg/dL using the conversion factor (88.4).
 $128 \div 88.4 = 1.4479638$.

Then round the converted value down to the tenths place and record as:

. g/dL

If the lab value is not reported to the level of precision allowed on the CRF, record zero(s) in the places to the right of the decimal.

- **Example:** Lab-reported Hematocrit value = 11%.

The following appears on the CRF:

.

Record as:

. g/dL

11.5.10 Assigning Severity Grades on CRFs

For some lab assays, the severity grade range is calculated using a value from the DAIDS Toxicity Table and a local normal range. For example, Grade 1 for total bilirubin is 1.1–1.5 times the site lab upper limit of normal (ULN). There will be times when the calculated severity range will have more significant digits than the reported lab value, which can lead to confusion regarding which severity grade to assign.

When working with calculated severity grade ranges, remember the following:

- Rounding is permitted only when recording lab values on a CRF in order to match the level of precision allowed on the CRF (see Rounding when recording lab values on CRFs above).
- When calculating a severity grade range, never round on interim steps.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- If the calculated severity grade range has more significant digits than the lab value, do not round the calculated range values. Instead, treat all missing digits in the lab value as zeros.

Example: Total bilirubin = 1.4 mg/dL, site ULN = 1.3 mg/dL

	DAIDS Toxicity Table Grade Range	Site-specific Grade Range
Grade 1	1.1–1.5 x ULN	1.43–1.95 mg/dL
Grade 2	1.6–2.5 x ULN	2.08–3.25 mg/dL

The site-specific grade range is accurate to the hundredths place. Treating the hundredths place of the total bilirubin value as a zero gives us a value of 1.40.

The lab value (1.40) falls below the minimum calculated value for Grade 1 (1.43). Do not assign a severity grade or report as an Adverse Experience.

If the lab value falls between two calculated severity grade ranges, assign it the higher grade as stated in the DAIDS Toxicity Table General Instructions (page 1).

Example: Total bilirubin = 2.0 mg/dL, site ULN = 1.3 mg/dL

As in the example above, the site-specific grade range is accurate to the hundredths place. The hundredths place of the total bilirubin value is treated as a zero, giving us a value of 2.00.

The lab value (2.00) falls between the maximum calculated value for Grade 1 (1.95) and the minimum for Grade 2 (2.08). Therefore, this value should be assigned the higher grade (Grade 2).

11.5.11 Overview of HPTN 052 Forms

The data collection 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). Non-DataFax forms are easily identifiable because there is no DataFax barcode along the top of the form. Each Index DataFax form includes the word Index in the title and the letter “I” in the form acronym. Each partner DataFax form includes the word Partner in the title and the letter “P” in the form acronym. There are also some forms that are considered Couples forms. These have the word Couple in the title and the letter “C” in the form acronym. For example: Index Demographics (IDM-1); Partner Demographics (PDM-1); Couples Missed Visit (CMV-1).

Some data collection forms are required at each visit, others only at one visit or only when specifically indicated. The following table lists the forms that are required at each study visit and those “as needed” forms that may be needed depending on what occurs at a visit.

HPTN052 SCHEDULE OF CASE REPORT FORMS REVISE

VISIT TYPE	INDEX	PARTNER
SCREENING	Required: NONE	Required: NONE
ENROLLMENT	<p>Required:</p> <p>Index Enrollment (IEN-1)</p> <p>Index Demographics (IDM-1)</p> <p>Index Site-Specific Demographics (IDU-1; IDZ-1; IDI-1; IDW-1; IDT-1; IDB-1)</p> <p>Index Screening and Enrollment CD4/Viral Load Results (IEV-1)</p> <p>Index Complete Hematology (ICH-1)</p> <p>Index Complete Chemistries (ICC-1)</p> <p>Index Enrollment Pregnancy Report and History (IPR-1-2) <i>female participants only</i></p> <p>Index Circumcision Assessment (ICA-1) <i>male participants only</i></p> <p>Index Pre-existing Conditions (IPRE-1)</p> <p>Index Sexually Transmitted Diseases (IST-1)</p> <p>Index Quality of Life (IQL-1-4)</p> <p>Index Sexual History Assessment (ISX-1)</p> <p>Index Specimen Collection (ISC-1)</p> <p>Required if on ART:</p> <p>Index Pill Count (IPC-1)</p> <p>Index Antiretroviral Treatment Regimen Log (ITX-1)</p> <p>As needed:</p> <p>Index Con Medications Log (ICM-1)</p> <p>Index Symptomatic Sexually Transmitted Diseases (ISS-1)</p> <p>Index When to Start (IWT-1-4)</p> <p>Index Adverse Event Log (IAE-1)</p> <p>Index Pregnancy Report (IP-1)</p>	<p>Required:</p> <p>Partner Enrollment (PEN-1)</p> <p>Partner Demographics (PDM-1)</p> <p>Partner Site-Specific Demographics (PDU-1; PDZ-1; PDI-1; PDW-1; PDT-1; PDB-1)</p> <p>Partner Circumcision Assessment (PCA-1) <i>male participants only</i></p> <p>Partner Sexually Transmitted Diseases (PST-1)</p> <p>Partner Sexual History Assessment (PSX-1)</p> <p>Partner Specimen Collection (PSC-1)</p> <p>As needed:</p> <p>Partner Symptomatic Sexually Transmitted Diseases (PSS-1)</p>

HPTN052 SCHEDULE OF CASE REPORT FORMS

VISIT TYPE	INDEX	PARTNER
<p>DELAY ARM ONLY</p> <p>ART INITIATION VISIT (Initiation of the first ART regimen, either the peripartum or initial/primary)</p> <p>Initiation of ART must occur on a protocol-required visit, not at an <i>interim</i> visit</p>	<p>Required:</p> <p>Complete all forms required for the type of protocol visit at which ART is initiated (e.g., monthly, quarterly). If this occurs at a monthly visit, also complete:</p> <p>Index Complete Hematology (ICH-1)</p> <p>Index Complete Chemistries (ICC-1)</p> <p>Index CD4/Viral Load Results (IFV-1)</p> <p>In addition, the following are required:</p> <p>Index Pill Count (IPC-1)</p> <p>Index Antiretroviral Treatment Regimen Log (ITX-1)</p> <p>As needed:</p> <p>Index Sexually Transmitted Diseases (IST-1)</p> <p>Index Symptomatic Sexually Transmitted Diseases (ISS-1)</p> <p>Index Concomitant Medications Log (ICM-1)</p> <p>Index When to Start (IWT-1-4)</p> <p>Index Adverse Event Log (IAE-1)</p> <p>Index Pregnancy Outcome (IPO-1)</p> <p>Couples Status (CPS-1)</p>	<p>Required:</p> <p>Complete all forms required for the type of protocol visit at which ART is initiated (e.g., monthly, quarterly).</p> <p>As needed:</p> <p>Partner Sexually Transmitted Diseases (PST-1)</p> <p>Partner Symptomatic Sexually Transmitted Diseases (PSS-1)</p> <p>Partner HIV Test Results (PHT-1)</p>

HPTN052 SCHEDULE OF CASE REPORT FORMS

VISIT TYPE	INDEX	PARTNER
MONTHLY	<p>Required:</p> <p>Couples Status (CPS-1)*</p> <p>Index Follow-up Visit (IFU-1, -2)</p> <p>Required if on ART:</p> <p>Index Pill Count (IPC-1)</p> <p>Index Treatment Adherence (ITA-1. -3)</p> <p>As needed:</p> <p>Index CD4/Viral Load Results (IFV-1)</p> <p>Index Sexually Transmitted Diseases (IST-1)</p> <p>Index Symptomatic Sexually Transmitted Diseases (ISS-1)</p> <p>Index Complete Chemistries (ICC-1)</p> <p>Index Complete Hematology (ICH-1)</p> <p>Index Concomitant Medications Log (ICM-1)</p> <p>Index Antiretroviral Treatment Regimen Log (ITX-1)</p> <p>Index When to Start (IWT-1-4)</p> <p>Index Adverse Event Log (IAE-1)</p> <p>Index Pregnancy Report (IP-1)</p> <p>Index Pregnancy Outcome (IPO-1)</p> <p>Immunologic/Virologic Assessment Failure (IVA-1)</p>	<p>Required:</p> <p>Couples Status (CPS-1)*</p> <p>Partner Follow-up Visit (PFU-1)</p> <p>As needed:</p> <p>Partner Sexually Transmitted Diseases (PST-1)</p> <p>Partner Symptomatic Sexually Transmitted Diseases (PSS-1)</p> <p>Partner HIV Test Results (PHT-1)</p> <p>Index Pill Count (IPC-1)</p>

** Note: The Couples Status form is required if either the index or partner is present for a protocol-required visit.*

HPTN052 SCHEDULE OF CASE REPORT FORMS

VISIT TYPE	INDEX	PARTNER
QUARTERLY	<p>Required:</p> <p>Couples Status (CPS-1)*</p> <p>Index Follow-up Visit (IFU-1-2)</p> <p>Index Complete Hematology (ICH-1)</p> <p>Index Complete Chemistries (ICC-1)</p> <p>Index CD4/Viral Load Results (IFV-1)</p> <p>Index Quality of Life (IQL-1-4)</p> <p>Index Sexual History Assessment (ISX-1)</p> <p>Index Specimen Collection (ISC-1)</p> <p>Required if on ART:</p> <p>Index Pill Count (IPC-1)</p> <p>Index Treatment Adherence (ITA-1-3)</p> <p>As needed:</p> <p>Index Sexually Transmitted Diseases (IST-1)</p> <p>Index Symptomatic Sexually Transmitted Diseases (ISS-1)</p> <p>Index Concomitant Medications Log (ICM-1)</p> <p>Index Antiretroviral Treatment Regimen Log (ITX-1)</p> <p>Index When to Start (IWT-1-4)</p> <p>Index Adverse Event Log (IAE-1)</p> <p>Index Pregnancy Report (IP-1)</p> <p>Index Pregnancy Outcome (IPO-1)</p> <p>Immunologic/Virologic Assessment Failure (IVA-1)</p>	<p>Required:</p> <p>Couples Status (CPS-1)*</p> <p>Partner Follow-up Visit (PFU-1)</p> <p>Partner HIV Test Results (PHT-1)</p> <p>Partner Sexual History Assessment (PSX-1)</p> <p>Partner Specimen Collection (PSC-1)</p> <p>As needed:</p> <p>Partner Sexually Transmitted Diseases (PST-1)</p> <p>Partner Symptomatic Sexually Transmitted Diseases (PSS-1)</p> <p>Index Pill Count (IPC-1)</p>

** Note: The Couples Status form is required if either the index or partner is present for a protocol-required visit.*

HPTN052 SCHEDULE OF CASE REPORT FORMS

VISIT TYPE	INDEX	PARTNER
PARTNER SEROCONVERTS	<p>Required: Index CD4/Viral Load Results (IFV-1) Index Specimen Collection (ISC-1)</p> <p>As needed: Index Sexually Transmitted Diseases (IST-1) Index Symptomatic Sexually Transmitted Diseases (ISS-1)</p>	<p>Required: Partner CD4/Viral Load Results (PVL-1) Partner Complete Hematology (PCH-1) Partner Complete Chemistries (PCC-1) Partner Specimen Collection (PSC-1) Partner Termination (PTM-1)</p> <p>As needed: Partner Sexually Transmitted Diseases (PST1) Partner Symptomatic Sexually Transmitted Diseases (PSS-1)</p>
CONFIRMED VIROLOGIC FAILURE	<p>Required: Index CD4/Viral Load Results (IFV-1) Index Treatment Adherence (ITA-1-3) Index Specimen Collection (ISC-1) Index Antiretroviral Treatment Regimen Log (ITX-1)</p> <p>As Needed: Index Sexually Transmitted Diseases (IST-1) Index Symptomatic Sexually Transmitted Diseases (ISS-1)</p>	<p>Required: NONE</p> <p>As needed: Partner Sexually Transmitted Diseases (PST1) Partner Symptomatic Sexually Transmitted Diseases (PSS-1)</p>
TERMINATION VISIT	<p>Required: Index Follow-up Visit (IFU-1-2) Index Specimen Collection (ISC-1) Index Termination (ITM-1)</p> <p>Couples Termination (CTM-1) <i>note: complete only if Index and partner terminates.</i></p> <p>Complete all other required Yearly CRFs and other CRFs as needed, unless a quarterly visit was done within the previous 60 days. If a quarterly visit was done, only complete the Index Sexually</p>	<p>Required: Partner Follow-up Visit (PFU-1) Partner Specimen Collection (ISC-1) Partner Termination (PTM-1)</p> <p>Couples Termination (CTM-1) <i>note: complete only if Index and partner terminates.</i></p> <p>Complete all other required Yearly CRFs and other CRFs as needed, unless a quarterly visit was done within the previous 60 days. If a quarterly visit was done, only complete the Index Sexually</p>

11.6 How to Complete 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 in a non-biased, non-judgmental manner.

Interviewing Techniques

An interviewer uses both verbal and non-verbal techniques to obtain the most honest, accurate, and thorough responses from participants.

Some techniques to remember:

- Always remain neutral
- Ask all questions in the order presented in the questionnaire
- Ask all questions exactly as worded
- Discourage unrelated conversation while asking questions

These techniques are discussed in the sections below.

Welcoming the Participant

- Introduce yourself, and try to create rapport (connection) between yourself and the participant to help him/her feel comfortable during the interview.
- Some DataFax forms include introduction statements before certain items to help prepare the participant for sensitive questions. Read each of these introductions as they appear on the forms.

Asking Sensitive Questions

This study is about a very sensitive subject: HIV. Gaining an understanding of participants' quality of life, ability to adhere to their prescribed treatment, and sexual behavior patterns can affect the transmission of HIV and the development of prevention methods.

Many of the interview questions ask about attitudes and behaviors related to the partner with whom the participant enrolled in the study. In order for participants to answer honestly, it is important that the questionnaires are administered to each member of the couple privately. It is also important to emphasize that all responses to the questionnaires will be kept confidential, even from their partner.

Your level of comfort with asking sensitive questions will affect the participant's comfort and answers. 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 them know you are listening and are aware that s/he is being asked difficult questions. Avoid apologizing for questions or making facial gestures that might show you feel any way but neutral about a question or the participant's response.

It is important to begin with interview with the questionnaire containing the least sensitive material and then move on to more sensitive information as the participant becomes more comfortable with the interviewer and responding to personal questions. Administer the questionnaires in the same order each time as follows: Index and Partner Demographics forms, Index Quality of Life, Index Treatment Adherence, Index and Partner Sexual History Assessment.

Recording Participants' Responses Verbatim

Interviewer-administered questions usually have a list of response categories provided to capture the participant's response. Sometimes an "other, specify" box is included as one of the response categories in order to capture participant responses that do not fit into one of the categories listed. When a participant's response does not match or fit into one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "local language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, translate the text recorded on the "local language" line into English, and record the English translation of the response on the "English" line. If the participant's response was originally in English, leave the "English" line blank.

Pacing the Interview

You need to be attentive to both the needs of the participant and the constraints of your schedule. It is important that the participant not feel rushed. Pace your reading of the questions according to the assessment of the participant's ability to comprehend. Let the participant finish thinking before you record his/her response and go on to the next item.

Reading Items Aloud

Read all items to the participant exactly as worded, and speak clearly. Do not rephrase an item because this can change its meaning, making it inconsistent with another participant's interview. Provide explanation or interpretation if necessary only after reading the item word-for-word. Discourage unrelated conversation during data collection. When applicable, acknowledge questions and concerns raised by the participant during the interview, and state that the subject can be discussed at the end of the interview.

Instructions to the Interviewer

In addition to the questions that are read to the participant, the questionnaire contains interviewer instructions. All interviewer instructions are in *italic letters*. These instructions are not read to the participant.

Show Cards

Laminated “show cards” are provided for questions containing multiple responses or sub-items to aid questionnaire administration. Before reading the question to the participant, hand the corresponding card to the participant or place it on a table in front of the participant. Remove the card after the question is answered.

Probing

One of the major goals of the interviews is to obtain accurate information on many HIV related behaviors. These interviews ask participants to recall many aspects of personal behaviors. However, participants may not remember or know the answer to every question. 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 her response enough for the item to be adequately recorded.

- **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, s/he may need to hear the question more than once to provide an answer. If you notice the participant is confused, repeat the item as it is written rather than rephrasing the question. 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 him/her be more precise. The echo should always be repeated in a neutral, non-judgmental style.
- **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/her answer and may need some extra

11.7 Examples of ART Treatment Regimen and Pill Count CRF Completion

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) Index Antiretroviral Treatment Regimen Log (ITX-1)

SAMPLE: DO NOT FAX TO DATAFAX  Note: Number pages sequentially (01, 02, 03) for each regimen. Page **01**

HPTN 052 (096) ITX-1 (400)

Index ID: ----

Site Number Index Number Partner Ctk Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B					
1. Regimen Start Date: dd MMM yy 28 APR 06				6. Regimen Stop/Modification Date: dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>					
2. Visit Code at which regimen was started: 031				7. Visit Code at which regimen was stopped or modified: <input type="text"/> <input type="text"/> <input type="text"/>					
3. This regimen is: <input type="checkbox"/> peripartum <input checked="" type="checkbox"/> initial/primary <input type="checkbox"/> secondary <input type="checkbox"/> salvage									
4. REGIMEN MEDICATIONS: Record codes for all medications in the regimen.				Medication Status					
Med Code	Dose (mg)	Frequency		no change	dose / freq. change	stopped	held	primary	secondary
4a. 05	<input type="text"/>	<input type="checkbox"/> qd <input checked="" type="checkbox"/> bld <input type="checkbox"/> tid <input type="checkbox"/> qid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
4b. 09	<input type="text"/>	<input type="checkbox"/> qd <input checked="" type="checkbox"/> bld <input type="checkbox"/> tid <input type="checkbox"/> qid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
4c.	<input type="text"/>	<input type="checkbox"/> qd <input type="checkbox"/> bld <input type="checkbox"/> tid <input type="checkbox"/> qid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
4d.	<input type="text"/>	<input type="checkbox"/> qd <input type="checkbox"/> bld <input type="checkbox"/> tid <input type="checkbox"/> qid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
4e.	<input type="text"/>	<input type="checkbox"/> qd <input type="checkbox"/> bld <input type="checkbox"/> tid <input type="checkbox"/> qid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
5. Initials and date of staff member completing Part A: LC 29-APR-06 Staff Initials / Date				8. Were any of the above stop/ modification codes reported as an AE?..... <input type="checkbox"/> yes <input checked="" type="checkbox"/> no → If no, go to item 9.					
				8a. Record AE Log page(s). <input type="text"/> <input type="text"/> <input type="text"/>					
				9. Initials and date of staff member completing Part B: _____ Staff Initials / Date					

07-MAR-07

Language **01**

/networks/hivnet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

Index ART Log

Here is an example of a participant's ART being held temporarily by the clinician.

Complete Part A of the form with the initial regimen information and fax to DataFax.

SAMPLE: DO NOT FAX TO DATAFAX



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

HPTN 052 (096) ITX-1 (400)

Index ID
 [] [] [] - [] [] [] - 00 - [] []
Site Number Index Number Partner Chk
Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B					
1. Regimen Start Date: <u>15 MAY 06</u>				6. Regimen Stop/Modification Date: [] [] [] [] [] []					
2. Visit Code at which regimen was started: <u>03 1</u>				7. Visit Code at which regimen was stopped or modified: [] [] []					
3. This regimen is: <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>									
4. REGIMEN MEDICATIONS: <small>Record codes for all medications in the regimen.</small>									
Med Code	Dose (mg)	Frequency		Medication Status			Stop/Mod Codes		
		qd bid tid qid		no change	dose / freq. change	stopped	held	primary	secondary
4a.	<u>05 0000</u>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	[] []	[] []
4b.	<u>09 0000</u>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	[] []	[] []
4c.	[] [] [] []	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	[] []	[] []
4d.	[] [] [] []	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	[] []	[] []
4e.	[] [] [] []	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	[] []	[] []
5. Initials and date of staff member completing Part A: <u>LC 17-May-06</u>				8. Were any of the above stop/modification codes reported as an AE? <input type="checkbox"/> <input type="checkbox"/>					
<small>Staff Initials / Date</small>				<small>yes no</small>					
				8a. Record AE Log page(s). [] [] [] []					
				9. Initials and date of staff member completing Part B: _____					
<small>Staff Initials / Date</small>				<small>Staff Initials / Date</small>					

07-MAR-07

01
Language

inetworkshinet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

Index ART Log

Also complete Part A of a second page indicating the medications are held and fax to DataFax.

Item 1 on page 02, 'regimen start date', must be the same as the regimen stop date, item 6, on page 01.

SAMPLE: DO NOT FAX TO DATAFAX



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

HPTN 052 (096) ITX-1 (400)

Index ID
 [] [] [] - [] [] [] - 00 - [] []
Site Number Index Number Partner Chk
Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B					
1. Regimen Start Date: <small>dd MMM yy</small> 15 MAY 06				6. Regimen Stop/Modification Date: <small>dd MMM yy</small> [] [] [] [] [] []					
2. Visit Code at which regimen was started: <small>peripartum initial/primary secondary salvage</small> 03 1 <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				7. Visit Code at which regimen was stopped or modified: [] [] []					
3. This regimen is:									
4. REGIMEN MEDICATIONS: <small>Record codes for all medications in the regimen.</small>									
Med Code	Dose (mg)	Frequency		Medication Status	Stop/Mod Codes				
				<small>no change</small>	<small>dose / freq. change</small>	<small>stopped</small>	<small>held</small>	<small>primary</small>	<small>secondary</small>
4a. 05	0000	qd	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4b. 09	0000	bid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4c. []	[]	tid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4d. []	[]	qid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4e. []	[]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Initials and date of staff member completing Part A: <u>LC 17-May-06</u> <small>Staff Initials / Date</small>				8. Were any of the above stop/modification codes reported as an AE? <small>yes no</small> <input type="checkbox"/> <input checked="" type="checkbox"/> If no, go to item 9.					
				8a. Record AE Log page(s). [] [] [] [] [] []					
				9. Initials and date of staff member completing Part B: _____ <small>Staff Initials / Date</small>					

07-MAR-07

01
Language

inetworkshinet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

Index ART Log

Also complete Part A of a second page indicating the medications are held and fax to DataFax.

Item 1 on page 02, 'regimen start date', must be the same as the regimen stop date, item 6, on page 01.

Record '0000' in the dose fields to indicate the medications are held.

SAMPLE: DO NOT FAX TO DATAFAX



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

HPTN 052 (096) ITX-1 (400)

Index ID
 [] [] [] - [] [] [] - 00 - []
Site Number Index Number Partner Chk
Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B				
1. Regimen Start Date: <small>dd MMM yy</small> 15 MAY 06				6. Regimen Stop/Modification Date: <small>dd MMM yy</small> [] [] [] [] [] []				
2. Visit Code at which regimen was started: <small>peripartum initial/primary secondary salvage</small> 03 1 <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				7. Visit Code at which regimen was stopped or modified: [] [] []				
3. This regimen is:								
4. REGIMEN MEDICATIONS: <small>Record codes for all medications in the regimen.</small>								
Med Code	Dose (mg)	Frequency		Medication Status			Stop/Mod Codes	
		<small>qd bid tid qid</small>		<small>no change</small>	<small>dose / freq. change</small>	<small>stopped</small>	<small>held</small>	<small>primary secondary</small>
4a. 05	0000	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
4b. 09	0000	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
4c. []	[]	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
4d. []	[]	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
4e. []	[]	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
5. Initials and date of staff member completing Part A: <u>LC 17-May-06</u> <small>Staff Initials / Date</small>				8. Were any of the above stop/modification codes reported as an AE? <small>yes no</small> <input type="checkbox"/> <input type="checkbox"/> If no, go to item 9.				
				8a. Record AE Log page(s). [] [] [] []				
				9. Initials and date of staff member completing Part B: _____ <small>Staff Initials / Date</small>				

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inetworkshinet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

01
Language

Index ART Log

Also complete Part A of a second page indicating the medications are held and fax to DataFax.

Item 1 on page 02, 'regimen start date', must be the same as the regimen stop date, item 6, on page 01.

Record '0000' in the dose fields to indicate the medications are held.

NOTE: DataFax needs a Treatment log with only Part A completed indicating the *current* treatment status, even if the current status is 'held'.

SAMPLE: DO NOT FAX TO DATAFAX



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

HPTN 052 (096) ITX-1 (400)

Index ID
 [] [] [] - [] [] [] - 00 - [] []
Site Number Index Number Partner Chk
Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B					
1. Regimen Start Date: <small>dd MMM yy</small> 15 MAY 06				6. Regimen Stop/Modification Date: <small>dd MMM yy</small> 30 MAY 06					
2. Visit Code at which regimen was started: <small>peripartum initial/primary secondary salvage</small> 03.1				7. Visit Code at which regimen was stopped or modified: 04.0					
3. This regimen is: <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>									
4. REGIMEN MEDICATIONS: <small>Record codes for all medications in the regimen.</small>									
Med Code	Dose (mg)	Frequency		Medication Status		Stop/Mod Codes			
		<small>qd bid tid qid</small>		<small>no change</small>	<small>dose / freq. change</small>	<small>stopped</small>	<small>held</small>	<small>primary</small>	<small>secondary</small>
4a. 05	0000			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	53	
4b. 09	0000			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	99	
4c.				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4d.				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4e.				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5. Initials and date of staff member completing Part A: <u>LC 17-May-06</u> <small>Staff Initials / Date</small>				8. Were any of the above stop/ modification codes reported as an AE? <small>yes no</small> <input checked="" type="checkbox"/> <input type="checkbox"/> If no, go to item 9.					
				8a. Record AE Log page(s). 001 [] [] [] []					
				9. Initials and date of staff member completing Part B: <u>LC 1-Jun-06</u> <small>Staff Initials / Date</small>					

07-MAR-07

01
Language

inetworkshinet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

Index ART Log

If the participant starts taking the same or some other medications, complete Part B of page 02 and fax to Datafax.

SAMPLE: DO NOT FAX TO DATAFAX



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

HPTN 052 (096) ITX-1 (400)

Index ID
 [] [] [] - [] [] [] - **00** - []
Site Number Index Number Partner Chk
Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B					
1. Regimen Start Date: 15 MAY 06				6. Regimen Stop/Modification Date: 30 MAY 06					
2. Visit Code at which regimen was started: 03.1				7. Visit Code at which regimen was stopped or modified: 04.0					
3. This regimen is: <input type="checkbox"/> peripartum <input checked="" type="checkbox"/> initial/primary <input type="checkbox"/> secondary <input type="checkbox"/> salvage									
4. REGIMEN MEDICATIONS: Record codes for all medications in the regimen.									
Med Code	Dose (mg)	Frequency		Medication Status			Stop/Mod Codes		
		qd bid tid qid		no change	dose / freq. change	stopped	held	primary	secondary
4a. 05	0000	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	53	
4b. 09	0000	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	99	
4c.		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4d.		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4e.		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5. Initials and date of staff member completing Part A: LC 17-May-06				8. Were any of the above stop/modification codes reported as an AE? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no If no, go to item 9.					
				8a. Record AE Log page(s): 001					
				9. Initials and date of staff member completing Part B: LC 1-Jun-06					

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01
Language

inetworkshivnet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

Index ART Log

If the participant starts taking the same or some other medications, complete Part B of page 02 and fax to Datafax.

In this example, Combivir is being permanently stopped but the participant will start taking Efavirenz again.

SAMPLE: DO NOT FAX TO DATAFAX



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

HPTN 052 (096) ITX-1 (400)

Index ID
 [] [] [] - [] [] [] - 00 - [] []
Site Number Index Number Partner Chk
Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B					
1. Regimen Start Date: <small>dd MMM yy</small> 15 MAY 06				6. Regimen Stop/Modification Date: <small>dd MMM yy</small> 30 MAY 06					
2. Visit Code at which regimen was started: <small>peripartum initial/primary secondary salvage</small> 03.1 <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				7. Visit Code at which regimen was stopped or modified: 04.0					
3. This regimen is: <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>									
4. REGIMEN MEDICATIONS: <small>Record codes for all medications in the regimen.</small>									
Med Code	Dose (mg)	Frequency		Medication Status		Stop/Mod Codes			
		<small>qd bid tid qid</small>		<small>no change</small>	<small>dose / freq. change</small>	<small>stopped</small>	<small>held</small>	<small>primary</small>	<small>secondary</small>
4a. 05	0000	qd	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	53	
4b. 09	0000	qd	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	99	
4c.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4d.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4e.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5. Initials and date of staff member completing Part A: <u>LC 17-May-06</u> <small>Staff Initials / Date</small>				8. Were any of the above stop/modification codes reported as an AE? <small>yes no</small> <input checked="" type="checkbox"/> <input type="checkbox"/> <small>If no, go to item 9.</small>					
				8a. Record AE Log page(s). 001 [] [] []					
				9. Initials and date of staff member completing Part B: <u>LC 1-Jun-06</u> <small>Staff Initials / Date</small>					

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networkshinet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

01
Language

Index ART Log

If the participant starts taking the same or some other medications, complete Part B of page 02 and fax to Datafax.

In this example, Combivir is being permanently stopped but the participant will start taking Efavirenz again.

Because the Efavirenz was held for a period of time (dose = 0000), the 'dose/freq change' box must be checked and the stop/mod code should be '99'/Other.

SAMPLE: DO NOT FAX TO DATAFAX



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

HPTN 052 (096) ITX-1 (400)

Index ID

 Site Number Index Number Partner Chk **Index Antiretroviral Treatment Regimen Log**

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A				PART B			
1. Regimen Start Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>				6. Regimen Stop/Modification Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
2. Visit Code at which regimen was started: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>				7. Visit Code at which regimen was stopped or modified: <input type="text"/> <input type="text"/> <input type="text"/>			
3. This regimen is: <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>							
4. REGIMEN MEDICATIONS: Record codes for all medications in the regimen.							
Med Code	Dose (mg)	Frequency		Medication Status		Stop/Mod Codes	
		qd bid tid qid		no change	dose / freq. change stopped held	primary secondary	
4a. 09	0600	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4b. 23	0040	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4c. 15	0300	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4d.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4e.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Initials and date of staff member completing Part A: <u>LC 01-Jun-06</u>				8. Were any of the above stop/modification codes reported as an AE? <input type="checkbox"/> <input checked="" type="checkbox"/> If no, go to item 9.			
				8a. Record AE Log page(s). <input type="text"/> <input type="text"/> <input type="text"/>			
				9. Initials and date of staff member completing Part B: <u>LC 1-Jun-06</u>			

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Language

inetworkshinet/forms/PTN_052/forms/index_forms/p052_index_antiretroviral_treatment.fm

Index ART Log

Complete Part A of a new page 03 indicating the medications the participant is on and fax to Datafax.

In this example, the participant has been prescribed Efavirenz, Stavudine, and Lamivudine.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code **040**

1

HPTN 052 (096)

IPC-1 (175)

Page 1 of 1

Index ID

123-456-00-9
Site Number Index Number Partner Chk

Index Pill Count

Visit Date

01 JUN 06
dd MMM yy

Instructions: Complete this form with the index or the partner each time study medications are returned and dispensed.

Med Code	# of pills brought in at this visit	Mark if pills not brought in	# of pills remaining at this visit <small>NO LONGER APPLICABLE FOR THIS PROTOCOL</small>	# of pills remaining at this visit <small>NO LONGER APPLICABLE FOR THIS PROTOCOL</small>	Total # of pills dispensed at this visit
05	009	<input checked="" type="checkbox"/>			039
04	003	<input checked="" type="checkbox"/>			033
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			

Comments: Participant did not bring in 1 unopened bottle of Combivir and 1 unopened bottle of Atazanavir

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/network/ahivnet/forms/PTN_052/forms/index_forms/p052_index_pill_count.fm

01
Language

LC 03-Jun-06
Staff Initials / Date

Index Pill Count

Here is an example of a participant bringing in open bottles of pills and leaving at home the unopened bottles.

The participant brought in one bottle of Combivir containing 9 pills and one bottle of Efavirenz containing 3 pills.

Because the participant stated he left unopened bottles of each medication at home, this item is checked and a comment is written.