

Section 7. Data Collection and Data Management

For questions about this section or about general data collection procedures, please contact the HPTN 058 Project Manager at SCHARP, Huguette Redinger, redinger@scharp.org

For questions about QC reports, please contact the HPTN 058 Data Coordinator at SCHARP, Claire Chapdu, cchapdu@scharp.org.

7.1 DataFax Overview

What is DataFax?

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.

How are CRFs faxed to SCHARP DataFax?

SCHARP's Information Technology (IT) Group works with each site to determine the best solution for data transmission on a site-by-site basis.

What happens to CRFs once they have been faxed to SCHARP DataFax?

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 (QC) notes.
- QC notes 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 QC notes.

***Note:** 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 note, the note 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 data, regardless of whether or not the change was made in response to a QC report.*

7.2 DataFax Form Completion

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.
- 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.
- Record responses and comments in English.
- 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 barcodes 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, Post-it notes, or other attachments before faxing CRFs.
- 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).

How to Mark Response Boxes

Many items on DataFax CRFs have a box or series of boxes for recording a response.

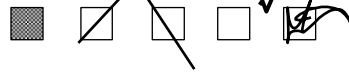
Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash

or other character.

Correct:



Incorrect:



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

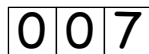
How to Record Numbers

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

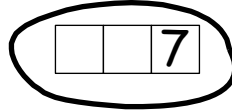
- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

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

Correct:



Incorrect:



This example would result in a QC note.

- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

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

Correct:



Incorrect:



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

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

Easily Identified:

0 1 2 3 4 5 6 7 8 9

Difficult to Identify:

Ø 1 2 3 4 7

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

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

0	1	J	U	N	0	3
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	

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

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.

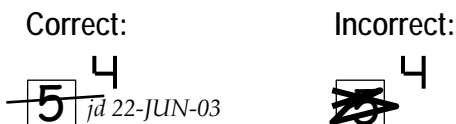
Note: If a correction or addition is made to one page of a multiple-page CRF, only refax the page that was changed.

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

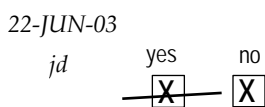
Whenever an entry on a DataFax CRF is changed, do the following:

- 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:

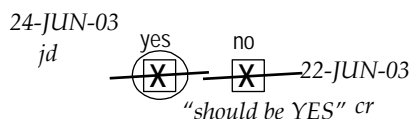


- If an **X** is marked in the wrong response box, correct it by doing the following:
 - draw a single horizontal line through the incorrectly marked box,
 - mark the correct box, and
 - initial and date the correction as shown below:



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.

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:

22-JUN-03
don't know
jd 

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/not collected on the comments lines or in the white space beside the item.

7.3 Rounding when recording lab values on CRFs

When recording a lab value on a case report form (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 µmol/L

The following appears on the CRF:

. mg/dL

First, convert from µmol/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:

. mg/dL

7.4 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:

1. 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).
2. When calculating a severity grade range, never round on interim steps.
3. Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
4. 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.

5. 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).

6. Greater Than/Equal To Symbols:

There is a one-digit gap between each grade for Blood Pressure on the Toxicity Table. We have confirmed with DAIDS that when there is a gap between values, as noted by a “greater than” (>) symbol, this should be interpreted as “greater than/or equal to” (≥).

7.5 Site Review of DataFAX Forms

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

7.6 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**

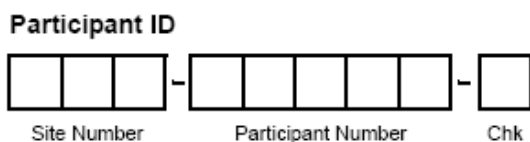
After thorough review, forms should be faxed to SCHARP DataFAX as soon as possible following the participant’s visit. Keep in mind that the sooner a form is faxed, the sooner the data will enter the study database.

7.7 Participant ID numbers (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database.

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. PTID formats will vary from study to study. SCHARP provides all study sites with a list of PTIDs prior to study activation.

The PTIDs used for HPTN058 are nine digits and consist of three parts: the site number, the participant number, and a numeric check digit. The check digit is a number generated by SCHARP to help ensure that the correct PTID is recorded. Below is an example of the PTID structure used in HPTN 058.



7.8 Visit Windows, Visit Codes, Missed and Interim Visits

7.8.1 Visit Windows

In HPTN 058 scheduled visits have defined target visit windows. Refer to Table 7-1: HPTN 058 visits by type and visit codes. For example, Visit 26.0 has a target visit window of 28 days before and 28 days after the visit target date. The target date is based on the enrollment date. For example, the target date for Visit 26.0 is 175 days from the date of enrollment (Day 0). A follow-up visit is considered “on-time” if completed within this window and before the next visit’s target window. It is highly recommended that all visits be completed within its target window.

7.8.2 Visit Codes

Most HPTN 058 DataFax CRFs require a visit code. The visit code tells DataFax at which visit the data was collected. The visit code is located on the right hand corner of these CRFs. HPTN 058 uses different visit codes depending on the visit type.

Site staff are responsible for entering the appropriate visit code on CRF pages that require a visit code. Refer to Table 7-1 for a list of the visit codes assigned to each visit type.

- **Screening Visits Code (all visits prior to enrollment).** CRFs that report data collected at any screening visit prior to enrollment use the special visit code **099.0**.
Exception: For female participants, the Urine Test Results (UTR-1) form is completed twice before enrollment. Once for screening and eligibility purposes and the second time for the pre-randomization urine pregnancy test. Because this second pregnancy test is performed on the same day as

enrollment (Visit 001.0), code **001.0** is used on the second UTR-1 CRF.

- **Induction Visit Code:** All participants will have at least one induction phase. Each induction phase takes 3 days and will be recorded on one Induction Record Form (IR-1). First induction code is Induction # **01**. Each subsequent induction will use sequential codes: Induction # 02, 03...
- **Suboxone Weekly Dosing Code.** The Weekly Dosing Record, (DR-1) and Missed or Discontinuation of Weekly Dosing (MDD-1) CRFs for these visits use a visit code equal to the corresponding week number. These forms are used from week 1 (code = Week # **01**) to week 52 (code = Week # **52**).
- **Safety Phase and Follow-up Visit Codes.** The visit code for these visit types is equal to the target visit number for that visit as long as it is within the target visit window and before the next scheduled visit's target window (examples: Visits 001.0; 002.0; 040.0, 156.0).
- **Using Visit Codes to report Adverse Experiences.** The Adverse Experience Log (AE-1) CRF does not require a visit code, however, item 10 on the form asks for the number of the visit at which the AE was first reported. Use Visit Codes for AEs as follows:
 - If the AE is first reported at any other visit use the target visit code number for that visit.
 - If the AE is reported at an interim visit between follow-up visits, use the visit code from the previous visit where data was collected, and add a number at the first decimal place to indicate if this is the first, second, third, etc, interim visit (e.g. use 002.1 for the first interim visit after Visit 2.0).
- **Interim Visit Codes.** If an interim visit occurs, the data is reported on DataFax CRFs, and the visit code used is the visit code from the previously completed visit, with a number at the first-decimal place, to indicate whether this is the first, second, third, etc. interim visit.

Example:

A participant completes Visit 26.0 on schedule. The visit code on the Local Laboratory Results (LLF-1) form is: **026.0**. One week later, the clinician is concerned about the ALT test results and asked that this lab test be repeated on a new sample. This is an interim visit, and the visit code becomes **026.1**. One week later, the study clinician orders a new Total Bilirubin test on a new sample. This is a second interim visit, and the visit code is **026.2**.

7.8.3 Interim Visits

Interim Visits are defined as visits that occur IN ADDITION to regularly scheduled study visits and which require data collected on DataFax CRFs. During interim visits, complete any require CRFs, plus an Interim Visit (**IV-1**) CRF.

Possible interim visits in HPTN 058 include:

- Additional HIV testing or laboratory assessments requested by the participant or ordered by site clinical staff.
- Additional visits to report an adverse experience or social harm.
- Additional visits to report pregnancy or pregnancy outcome.

NOTE: Extra Suboxone dosing and BDRC Counseling are NOT considered interim visits unless these visits result in additional data collection.

Example:

A BDRC counselor determines that a participant needs an extra weekly session at Week 9 to address a particular concern. The counselor also orders an additional urine drug screen at this visit. The test results will need to be reported on a Urine Test Results form (UTR-1), and this would require an interim visit code. In this case the interim visit code would be 008.1, because it follows previously scheduled visit 008.0. An Interim Visit (IV-1) CRF must be completed as well.

7.8.4 Missed Visits

A protocol-required follow-up visit is considered missed when none of the visit procedures are completed within the target visit window and before the next scheduled visit's target window. A missed visit is documented with a Missed Visit form (**MV-1**).

Example:

Visit 008.0 target window is from Day 42 to Day 56 and Visit 012.0 window is from Day 70 to Day 84.

A participant missed his Visit 008.0 window but comes to the clinic on Day 65, then the site can still complete that visit as Visit 008.0.

If the participant comes on Day 71 (within Visit 012.0 window) then Visit 008.0 is considered missed and a missed visit (**MV-1**) CRF must be completed and submitted to SCHARP.

Intervention-related visits (Suboxone weekly dosing and BDRC Counseling) do not have specified target visit windows, but are expected to be performed within the calendar week (Monday through Sunday).

NOTE: Suboxone weekly dosing and BDRC counseling visits do NOT require a Missed Visit (**MV-1**) CRF. However, if a full week of dosing is missed, a Weekly Dosing Record (**DR-1**) CRF must be submitted with the “*No dosing given this week*” box checked. In addition, a Missed or Discontinuation of Dosing (**MDD-1**) CRF must be completed and submitted to SCHARP.

Table 7-1: HPTN 058 Visits by Type and Visit Codes

Note 1: Make sure to read all footnotes and notes at the end of this table.

Note 2: Though Scheduled Visits are shown in parallel with the Weekly Dosing Visits , **they will NOT always coincide**, meaning they may not necessarily fall on the same week.

Screening, Enrollment, Induction and Scheduled Visits							Weekly Dosing Visits ¹			
Visit Description	Safety Phase (first 50)	Full Study	Visit Code on CRF (when applicable)	Target Day ²	Target Visit Window (in days)	Required DataFax CRFs ³	Substitution Group	Detox Group	Dosing Week # on CRF	Required CRF
Screening (28 days window)	X	X	099.0	-	-	RA-1 to 8, DEM-1, PRE-1, HTR-1, UTR-1, LLS-1, CM-1				
Enrollment/Randomization	X	X	-	-	-	DSM-1, ICQ-1-3, ENR-1				
	X	X	001.0	0	-	CM-1, UTR-1 (<i>female participants, pregnancy test only</i>)				
Induction #1	X	X	01	0	-	IR-1 (for Days 0,1, 2)				
Scheduled	X	X	001.0	0	4	UTR-1, LLF-1, SIA-1 (<i>Safety Phase only</i>)	X	X	01 ⁴	DR-1
Scheduled	X	-	002.0	7	+/-3	LLF-1, SIA-1, UTR-1 (<i>opiates/drugs test only</i>)	X	X	02	DR-1
Scheduled	X	-	003.0	14	+/-3	LLF-1, SIA-1, UTR-1 (<i>opiates/drugs test only</i>)	X	X	03	DR-1
Scheduled	X	X	004.0	21	+/-3	UTR-1, AA-1 (<i>Safety Phase only</i>), LLF-1 (<i>Safety Phase only</i>), SIA-1 (<i>Safety Phase only</i>)	X		04	DR-1
							X		05	DR-1
							X		06	DR-1
							X		07	DR-1
Scheduled	X	X	008.0	49	+/-7	UTR-1	X		08	DR-1

¹ One dosing week is from Monday to Sunday

² Target Days are based on the randomization/induction date (use Visit Scheduler Tool accessible through the HPTN 058 website to calculate target dates).

³ Refer to Table 7-2 for complete list of DataFax and Non-DataFax CRFs used at each visit.

⁴ Depending on what day of the week the first induction begins, Weekly Dosing 1 may start on the same OR the following week. Example 1: Induction begins on Wednesday and is completed on Friday, then Dosing Week 1 begins on the next day, Saturday, and must end on Sunday. – Example 2: Induction begins Friday and ends on Sunday, then dosing Week 1 begins on the next day, Monday, and must be completed within that same week and no later that Sunday.

Screening, Enrollment, Induction and Scheduled Visits							Weekly Dosing Visits ¹			
Visit Description	Safety Phase (first 50)	Full Study	Visit Code on CRF (when applicable)	Target Day ²	Target Visit Window (in days)	Required DataFax CRFs ³	Substitution Group	Detox Group	Dosing Week # on CRF	Required CRF
							X		09	DR-1
							X		10	DR-1
							X		11	DR-1
Scheduled	X	X	012.0	77	+/-7	LLF-1, UTR, CAW-1 ⁵	X		12	DR-1
							X		13	DR-1
							X		14	DR-1
							X		15	DR-1
Scheduled	X	X	016.0	105	+/-7	UTR-1	X		16	DR-1
							X		17	DR-1
							X		18	DR-1
							X		19	DR-1
Scheduled	X	X	020.0	133	+/-7	UTR-1	X		20	DR-1
							X		21	DR-1
							X		22	DR-1
							X		23	DR-1
Scheduled	X	X	024.0 *	161	+/-7	<i>* Any procedure done at visit 24.0 must be coded 026.0. Perform UTR-1 & SIA-1 once for these 2 visits unless clinically indicated..</i>	X		24	DR-1
							X		25	DR-1
Scheduled	X	X	026.0	175	+/- 28	AA-1, HTR-1, LLF-1, RA 1-8, SIA-1, UTR-1 [IR-1 may be repeated for the detox. group]	X	X ⁶	26	DR-1
							X	X ⁶	27	DR-1
Scheduled	X	X	028.0	189	+/-7	UTR-1	X	X ⁶	28	DR-1
							X		29	DR-1
							X		30	DR-1
							X		31	DR-1
Scheduled	X	X	032.0	217	+/-7	UTR-1	X		32	DR-1
							X		33	DR-1

⁵ Weekly counseling CRF (CAW-1) is completed from weeks 1-12. Completed form is **faxed only once** after week 12 counseling is done.

⁶ Participants in Detoxification Arm may be re-induced if determined to be eligible for second detoxification.

Screening, Enrollment, Induction and Scheduled Visits							Weekly Dosing Visits ¹			
Visit Description	Safety Phase (first 50)	Full Study	Visit Code on CRF (when applicable)	Target Day ²	Target Visit Window (in days)	Required DataFax CRFs ³	Substitution Group	Detox Group	Dosing Week # on CRF	Required CRF
							X		34	DR-1
							X		35	DR-1
Scheduled	X	X	036.0	245	+/-7	UTR-1	X		36	DR-1
							X		37	DR-1
							X		38	DR-1
							X		39	DR-1
Scheduled	X	X	040.0	273	+/-7	UTR-1, LLF-1	X		40	DR-1
							X		41	DR-1
							X		42	DR-1
							X		43	DR-1
Scheduled	X	X	044.0	301	+/-7	UTR-1	X		44	DR-1
							X		45	DR-1
							X		46	DR-1
							X		47	DR-1
Scheduled	X	X	048.0	329	+/-7	UTR-1	X		48	DR-1
							X		49	DR-1
							X		50	DR-1
							X		51	DR-1
Scheduled	X	X	052.0	357	-14/+28	AA-1, HTR-1, LLF-1, RA 1-8, SIA-1, UTR-1, CM-1, CAM-1 ⁷	X		52	DR-1
Scheduled	X	X	078.0	539	-14/+28	HTR-1, RA 1-8, SIA-1, UTR-1				
Scheduled	X	X	104.0	721	-14/+28	HTR-1, RA 1-8, SIA-1, UTR-1				
Scheduled	X	X	130.0	903	-14/+28	HTR-1, RA 1-8, SIA-1, UTR-1				
Scheduled	X	X	156.0	1085	-14/+28	HTR-1, RA 1-8, SIA-1, UTR-1, TM-1				

⁷ Monthly counseling CRF (CAM-1) is completed monthly during weeks 16-52, but is **faxed only once** after the last monthly counseling is completed (i.e. after week 52).

IMPORTANT CRF REMINDERS:

CM-1: complete at Screening and Enrollment and at any visit when new con. meds are reported or existing ones are stopped, up to week 52. Fax when week 52 is completed or when requested by SCHARP.

UTR-1: For female participants perform Pregnancy Test, in both arms, at screening, enrollment and week 4 only. Then, approximately every four weeks through week 52 in the Substitution Treatment Arm only. In the Detoxification Arm, pregnancy test should be repeated at week 26, for female participants who are eligible for a second detoxification.

MV-1: use only when a regular scheduled visit is missed altogether. DO NOT use for missed intervention visits.

MDD-1: use only when a full week of dosing is missed.

IV-1: use when additional data-collection is required at visits other than scheduled study visits.

TM-1: use at end of study or only when participant is confirmed to be no longer enrolled in the study.

As needed at any visit: SIL-1, PR-1, PO-1, AE-1 (AE log must be updated as necessary)

Table 7-2: HPTN 058 DataFax and non-DataFax Forms and Instructions

HPTN058 Schedule of Forms by Visit Type

The table below lists scheduled study visits by visit type, and forms completed at those visits. The table indicates the required visit codes for each type of visit when applicable.

LEGEND:

Non-DF = Not a DataFax form. Complete but do not submit to DataFax

R = Required

S = For site use. Do not submit to DataFax. Site may substitute with locally-developed form

X = Conditional or administrative form

<i>Visit type:</i>		Screening	Randomization/ Enrollment	Induction	Safety Phase	Suboxone Dosing	BDRC Counseling	Follow-up Visit #				
<i>Visit Code (if required):</i>		099.0	001.0	01 for IR-1 (02, 03... for add'l inductions) <u>use</u> <u>corresponding</u> <u>visit code for</u> <u>all other CRFs</u>	Visit # (001.0- 004.0)	Week # (01-03 for Detox Arm and, 01-52 for Substitution arm)	Week # (001.0-052.0)	004.0, 008.0, 012.0, 016.0, 020.0,	024.0/ 026.0	028.0, 032.0, 036.0, 040.0, 044.0, 048.0	052.0	078.0, 104.0, 130.0, 156.0
Screening Assessment	Non-DF	S										
Informed Consent Quiz for Screening	Non-DF	S										
Demographics	DEM-1	R										
Pre-existing Conditions	PRE-1	R										
Physical Exam	Non-DF	S										

Visit type:	Screening	Randomization/ Enrollment	Induction	Safety Phase	Suboxone Dosing	BDRC Counseling	Follow-up Visit #					
							004.0, 008.0, 012.0, 016.0, 020.0,	024.0/ 026.0	028.0, 032.0, 036.0, 040.0, 044.0, 048.0	052.0	078.0, 104.0, 130.0, 156.0	
Visit Code (if required):	099.0	001.0	01 for IR-1 (02, 03... for add'l inductions) use corresponding visit code for all other CRFs	Visit # (001.0- 004.0)	Week # (01-03 for Detox Arm and, 01-52 for Substitution arm)	Week # (001.0-052.0)						
Screening Local Laboratory Results	LLS-1	R										
DSM-IV Diagnostic Worksheet	DSM 1-3	R						R ¹				
Medical History	Non-DF	S										
Eligibility Checklist	Non-DF	S						S ²				
Informed Consent Quiz for Enrollment	ICQ 1-3		R									
Informed Consent Evaluation Survey	ICS-1		X									
Enrollment/Randomization	ENR-1		R									
Risk Assessment	RA 1-8	R						R		R	R	
HIV Test Results ³	HTR-1	R	X	X	X	X	X	X	R	X	R	R
Local Laboratory Results ³	LLF-1				R			R (visit 012.0 only)	R	R (week 040.0 only)	R	
Urine Test Results ³	UTR-1	R	R	X ⁴	R			R	R	R	R	R

¹ DSM-IV is repeated if needed for Detoxification Treatment Arm participants if they are determine to be eligible for 2nd detoxification.

² Complete Eligibility Checklist for Detoxification Treatment Arm participants who may be eligible for 2nd detoxification.

³ These CRFs can be used anytime, as determined by clinician, outside regular scheduled visits.

<i>Visit type:</i>		Screening	Randomization/ Enrollment	Induction	Safety Phase	Suboxone Dosing	BDRC Counseling	Follow-up Visit #				
<i>Visit Code (if required):</i>		<i>099.0</i>	<i>001.0</i>	<i>01 for IR-1 (02, 03... for add'l inductions) use corresponding visit code for all other CRFs</i>	<i>Visit # (001.0- 004.0)</i>	<i>Week # (01-03 for Detox Arm and, 01-52 for Substitution arm)</i>	<i>Week # (001.0-052.0)</i>	<i>004.0, 008.0, 012.0, 016.0, 020.0,</i>	<i>024.0/ 026.0</i>	<i>028.0, 032.0, 036.0, 040.0, 044.0, 048.0</i>	<i>052.0</i>	<i>078.0, 104.0, 130.0, 156.0</i>
Social Impact Assessment	SIA-1				R				R		R	R
Social Impact Log ⁵	SIL-1			X	X	X	X	X	X	X	X	X
Clinical Opiate Withdrawal Scale (COWS)	Non-DF			S								
Induction Record	IR-1			R					R ⁶			
Weekly Dosing Record	DR-1					R						
Missed or Discontinuation of Dosing	MDD-1					X						
Weekly Counseling Session Attendance	CAW-1						R (weeks 1-12)					
Monthly Counseling Session Attendance	CAM-1						R (weeks 13-52)					
Interim Visit	IV-1				X	X	X	X	X	X	X	X

⁴ Urine test must be performed at subsequent Inductions and use the corresponding scheduled visit code.

⁵ SIL-1 is completed for each social impact reported whenever social harms are assessed, whether during or between regular visits. At the end of the study, all unresolved SILs must be re-submitted with the status marked "Unresolved at end of study".

⁶ Induction is repeated for Detoxification Treatment Arm participants who are determined to be eligible for a 2nd detoxification if needed.

Visit type:		Screening	Randomization/ Enrollment	Induction	Safety Phase	Suboxone Dosing	BDRC Counseling	Follow-up Visit #				
Visit Code (if required):		099.0	001.0	01 for IR-1 (02, 03... for add'l inductions) <u>use</u> <u>corresponding</u> <u>visit code for</u> <u>all other CRFs</u>	Visit # (001.0- 004.0)	Week # (01-03 for Detox Arm and, 01-52 for Substitution arm)	Week # (001.0-052.0)	004.0, 008.0, 012.0, 016.0, 020.0,	024.0/ 026.0	028.0, 032.0, 036.0, 040.0, 044.0, 048.0	052.0	078.0, 104.0, 130.0, 156.0
Acceptability Assessment	AA-1				R (Visit 004.0 only)				R		R	
Adverse Experience Log	AE-1	X	X	X	X	X	X	X	X	X	X	X ⁷
Concomitant Medications Log ⁸	CM-1	X	X	X	X	X	X	X	X	X	X ⁹	R
Pregnancy Report and History ³	PR-1				X	X	X	X	X	X	X	X
Pregnancy Outcome ³	PO-1				X	X	X	X	X	X	X	X
Missed Visit ¹⁰	MV-1				X			X	X	X	X	X
Termination ¹¹	TM-1				X	X	X	X	X	X	X	R (required by wk 56)

⁷ At the final visit, all unresolved AE Logs must be re-submitted with status marked "Continuing at end of study participation".

⁸ CM-1 is submitted once after the intervention period, or when requested by SCHARP. The CRF can be updated and resubmitted as many times as needed during the time the participant is on the study drug up to week 52.

⁹ CM-1 should have all recorded medications marked with the "Date Stopped" date or have the "Continuing at end of study" box checked. If no medication was reported during the study, mark the box "No medication taken throughout reporting period" and fax the CRF at the final visit.

¹⁰ Use MV-1 only for missed follow-up visits, not to be used for missed intervention visits.

¹¹ TM-1 is submitted after all study visits are complete, or when the site determines that the participant is no longer enrolled in the study.

7.9 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.

7.10.1 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.

7.10.2 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.

7.10.3 Asking Sensitive Questions

This study is about a very sensitive subject: HIV and drug use. 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.

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 she/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.

7.10.4 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.

7.10.5 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 speaking before you record his/her response and go on to the next item.

7.10.6 Reading Items Aloud

Read all items to the participant **exactly as worded**, and speak clearly. Do not re-phrase 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.

7.10.7 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.

7.10.8 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.

7.10.9 Probing

One of the major goals of the interviews is to obtain accurate information on many behaviors related to HIV and drug use. 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, she/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 time to think more carefully about the question.
- **Non-verbal Probe:** The non-verbal probe is used by giving hand or facial gestures that may help the participant come up with an answer. Remember that all such gestures must be neutral and non-judgmental.
- **Specification Probe:** The specification probe is used by asking the participant to give a more precise answer. Although a participant may give an answer that he or she considers accurate, it may not be specific enough. For example, an item asks the number of times the participant did something and she/he answers with a range (“5 to 10”). Ranges are not acceptable for this type of interviewing. In this case, the probe, “Can you be more specific?” is often enough to help the participant choose the most accurate response.
- **Historical Probe:** The historical probe is used by asking whether the event in question occurred around major holidays or personal events such as a birthday or other life event. Some items require the participant to recall dates. Referencing a calendar can also help the participant remember dates.

7.10.10 Checking Your Work

After the interview and while the participant is still there, review the forms for accuracy and completeness so you can complete an item that might have accidentally been missed. Once the participant has left, review the forms more thoroughly.