Weeks 30, 35 Visits
Visits 13.0, 14.0

Required forms

- 12-Lead Electrocardiogram (EGS-1, -2)**
- Follow-up Acceptability Questionnaire (FAQ-1~4)
- Follow-up Visit (FUV-1)
- HIV Test Results (HTR-1)
- Injection Site Reaction Evaluation (ISR-1, -2)
- Local Lab Results (LLR-1~4)
- Post-injection Exercise Assessment (PEA-1)*
- Specimen Storage (SS-1)
- Study Medication Satisfaction Questionnaire (SMS-1, -2)*

** Completed only at Week 30 (Visit 13.0)*
*** Completed only at Week 35 (Visit 14.0)*

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HPTN 077 (215) EGS-1 (009)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number – Participant Number – Chk)

12-Lead Electrocardiogram

Date of ECG: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Time of ECG (*24-hr clock*): ☐☐ hr : ☐☐ min

INTERVAL MEASUREMENT					
1. PR interval	☐ *not measurable* OR ☐☐☐ *ms*	Severity Grade *If applicable* ☐	AE Log Page # ☐☐☐ →	*Complete or update AE Log as applicable.*
2. QTc interval	☐ *not measurable* OR ☐☐☐ *ms*	Severity Grade *If applicable* ☐	AE Log Page # ☐☐☐ →	
2a. Reporting method used:	☐ Bazett	☐ Fridericia		
OVERALL ECG FINDINGS				
3. Overall ECG findings	☐ normal *If normal, end of form. Do not submit page 2.*			
	☐ findings as noted in Specific ECG Findings on page 2			

Comments

☐ ☐ ☒ ☐ 13-JUL-15

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0 1 English

Staff Initials/Date

12-Lead Electrocardiogram (EGS-1)	
General Information/Instructions:	
	Record ECG test results on this form when results become available. If an ECG must be repeated, report the averaged values of the ECGs. You may report individual values in the comments.
Item-specific Instructions:	
Items 1 and 2:	Complete or update AE Log for results that meet AE Reporting Criteria and are not associated with a reported diagnosis. Refer to the protocol and the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events* for guidance on grading and AE reporting.
Item 3:	If exam is "normal" end the form and do not fax page 2 to DataFax. The category "findings as noted in Specific ECG Findings" includes all ECGs with findings, including normal ECGs with findings, as well as abnormal ECGs.

HPTN 077 (215) EGS-2 (010)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number | Participant Number | Chk

12-Lead Electrocardiogram

SPECIFIC ECG FINDINGS *For items 4–14, mark all that apply. If no findings for an item, mark "none."*

none
☐ 4. Rhythm
- ☐ sinus arrhythmia
- ☐ sinus bradycardia
- ☐ sinus tachycardia

none
☐ 5. Arrhythmia
- ☐ premature atrial contractions
- ☐ junctional premature contractions
- ☐ premature ventricular contractions
- ☐ ventricular couplets or multifocal PVC
- ☐ atrial fibrillation alternating with NSR
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ atrial or supraventricular tachycardia
- ☐ junctional rhythm
- ☐ accelerated junctional rhythm
- ☐ ventricular tachycardia
- ☐ ventricular flutter/fibrillation
- ☐ wide complex tachycardia
- ☐ multifocal atrial tachycardia
- ☐ wandering atrial pacemaker
- ☐ ectopic atrial rhythm
- ☐ Torsades de Pointes

none
☐ 6. Conduction Disturbance
- ☐ first degree AV block (PR > 200)
- ☐ second degree AV block (Mobitz Type I)
- ☐ second degree AV block (Mobitz Type II)
- ☐ complete heart block
- ☐ right bundle branch block incomplete (QRS < 120)
- ☐ right bundle branch block complete (QRS > 120)
- ☐ left bundle branch block incomplete (QRS < 120)
- ☐ left bundle branch block complete (QRS > 120)
- ☐ nonspecific IVCD (QRS >100 to < 120)
- ☐ nonspecific incomplete IVCD (QRS > 100 to < 120)
- ☐ left anterior hemiblock
- ☐ left posterior hemiblock
- ☐ Wolff-Parkinson-White Syndrome
- ☐ atrial-ventricular dissociation

none
☐ 7. P-Wave Morphology
- ☐ left atrial enlargement
- ☐ right atrial enlargement

none
☐ 8. Axis
- ☐ left axis deviation
- ☐ right axis deviation
- ☐ indeterminate axis

none
☐ 9. Myocardial Infarction
- ☐ hyperacute ST changes
- ☐ Q-waves consistent with MI
- ☐ Q-waves and ST-T changes consistent with MI

none
☐ 10. Ventricular Hypertrophy
- ☐ right ventricular hypertrophy
- ☐ voltage criteria for LVH
- ☐ LVH and ST-T segment changes

none
☐ 11. QRS, ST-T
- ☐ poor R wave progression
- ☐ low voltage QRS
- ☐ nonspecific QRS changes
- ☐ nonspecific ST segment changes
- ☐ nonspecific ST-T wave changes
- ☐ nonspecific T-wave changes
- ☐ peak T-wave
- ☐ early repolarization changes

none
☐ 12. U-wave and Abnormal QT findings
- ☐ U-wave abnormality
- ☐ QTc > 500 msec.*
- ☐ Change from baseline: QTc > 60 msec.

** whichever formula is used (B or F) should be consistent throughout the study.*

none
☐ 13. Drug Effect/Electrolyte Disturbance
- ☐ marked QRS/ST-T abnormalities consistent with electrolyte disturbance or drug effect

none
☐ 14. Other, specify:

_____

_____

_____

12-Lead Electrocardiogram (EGS-2)
General Information/Instructions:
Record ECG test results on this form when results become available.

HPTN 077 (215) FAQ-1 (171)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number Participant Number Chk

Follow-up Acceptability Questionnaire

Assessment Date ☐☐ ☐☐☐ ☐☐
dd MMM yy

STUDY-RELATED INJECTABLE EXPERIENCE

1. I would like you to tell me about your experience with different characteristics of the injections you just received. For each injectable characteristic, I would like you to think about whether it was generally difficult or easy to accept. Then I would like you to tell me how unacceptable or acceptable it was to you: "a little," "somewhat," or "a lot."

Mark only ONE response.
Interview card #6.

		UNACCEPTABLE			ACCEPTABLE		
		1	2	3	4	5	6
		a lot	*somewhat*	*a little*	*a little*	*somewhat*	*a lot*
1a. receiving two injections at a visit		☐	☐	☐	☐	☐	☐
1b. the size or quantity of each injection		☐	☐	☐	☐	☐	☐
1c. the injection site in buttock		☐	☐	☐	☐	☐	☐
1d. receiving injections every 3 months		☐	☐	☐	☐	☐	☐
1e. level of privacy when receiving the injection		☐	☐	☐	☐	☐	☐
1f. any pain at injection site	*none* ☐	☐	☐	☐	☐	☐	☐
1g. any rash or reaction at injection site	*none* ☐	☐	☐	☐	☐	☐	☐
1h. any side effects experienced since last injection	*none* ☐	☐	☐	☐	☐	☐	☐

Follow-up Acceptability Questionnaire (FAQ-1)

Purpose: This questionnaire is used to assess attitudes and experiences about the injectable study product since joining the study.

General Information/Instructions:

- This is an interviewer-administered form.
- Complete this form at weeks 6, 18, and 30.
- Read each question exactly as it is written. Read response options only if indicated. In these cases, hand the participant a response card and read each response aloud to the participant as she reads silently.

Item-specific Instructions:

Item 1: Before reading the first item (1a), hand the response card to the participant.

- Explain that you will list some different characteristics of the injections.
- You want to know how unimportant or important each characteristic was.
- Before giving a response, he/she should first think about whether the reason was important or not important.
- Then, he/she should think about HOW unimportant or important the characteristic was: “a little,” “somewhat,” or “a lot.”
- 1 means that he/she thinks the characteristic was UNACCEPTABLE A LOT and 6 means that he/she thinks that the characteristic was ACCEPTABLE A LOT.

HPTN 077 (215) FAQ-2 (172)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number | Participant Number | Chk

Follow-up Acceptability Questionnaire

INTEREST IN FUTURE INJECTABLE USE FOR HIV PREVENTION

Now I would like to know how interested you might be in using an injectable for HIV prevention, if it were available in the future.

2. After this study is over, if the results find the injection to be safe and to have at least partial effectiveness in preventing HIV, how much do you disagree or agree with the following statements?

Mark only ONE response.
Interview card #5.

	DISAGREE			AGREE		
	1	2	3	4	5	6
	a lot	*somewhat*	*a little*	*a little*	*somewhat*	*a lot*
2a. You would **not** be interested in using the injection.	☐	☐	☐	☐	☐	☐
2b. You would **think** about using the injection, if you felt you were at risk of HIV.	☐	☐	☐	☐	☐	☐
2c. You would **definitely use the injection for some time**.	☐	☐	☐	☐	☐	☐
2d. You would be less interested in using the injection if you had to pay for it.	☐	☐	☐	☐	☐	☐
2e. You would **probably** use the injection for an extended time (i.e., a year or longer).	☐	☐	☐	☐	☐	☐

Item 2f is for female participants only. Male participants go to Preferences for Injectable Characteristics section on page 3.

Mark only ONE response.
Interview card #5.

	DISAGREE			AGREE		
	1	2	3	4	5	6
	a lot	*somewhat*	*a little*	*a little*	*somewhat*	*a lot*
2f. You would be more interested in using the injection if it was for both HIV **and** pregnancy prevention.	☐	☐	☐	☐	☐	☐

Follow-up Acceptability Questionnaire (FAQ-2)	
Item-specific Instructions:	
Item 2:	Before reading the first item (2a), hand the response card to the participant. • Explain that you will read a set of statements meant to assess her/his level of interest in using a product like the one in the study. • You want to know how much he/she disagrees or agrees with the different statements. • Before giving a response, he/she should first think about whether he/she disagrees or agrees overall with the statement. • Then, he/she should think about HOW much he/she disagrees or agrees: "a little," "somewhat," or "a lot." • 1 means that he/she DISAGREES A LOT and 6 means that he/she AGREES A LOT with the statement.
Item 2a:	Read the question as stated. Emphasize the word "not."
Item 2b:	Read the question as stated. Emphasize the word "think."
Item 2c:	Read the question as stated. Emphasize the words "definitely use" and "for some time." (Note: "for some time" means that she would think about using the injections for several rounds.)
Item 2e:	Read the question as stated. Emphasize the word "probably."
Item 2f:	Read the question as stated. Emphasize the word "and."

HPTN 077 (215) FAQ-3 (173)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Follow-up Acceptability Questionnaire

PREFERENCES FOR INJECTABLE CHARACTERISTICS

Finally, I would like to know about any recommendations you might have to make an injectable for HIV prevention more acceptable.

3. If it were possible to change the way the injection was given, what kind of changes would you recommend? *DO NOT read response categories aloud. Mark "none" or all that apply.*

☐ 3a. none

☐ 3b. have only one injection with a larger dose

☐ 3c. have only one injection with a smaller dose

☐ 3d. reduce the volume of liquid of each injection

☐ 3e. increase the duration of protection offered by the injection (reduce frequency of injections)

☐ 3f. receive the injection in the arm, instead of the buttock

☐ 3g. other, specify: _____

☐ 3h. no response/decline to answer

Item 4 is for female participants only. Male participants, go to item 5 on page 4.

4. If you could receive the same level of protection (from pregnancy or disease) by taking one of the following products, which one would you prefer? *Interview card #1.*

☐ oral pill taken every day

Why? _____

☐ injection received once every 3 months

Why? _____

☐ vaginal ring (flexible medicine-filled ring inserted in the vagina, changed once every month)

Why? _____

☐ vaginal gel (inserted in the vagina with an applicator before and/or after sex)

Why? _____

☐ other, specify: _____

☐ doesn't matter

Follow-up Acceptability Questionnaire (FAQ-3)	
Item-specific Instructions:	
Item 3:	Read the question as stated. Do not read the response options. Identify the option or options that most closely fit the participant's own words.
Item 3a:	Mark "none" for item 3a if the participant says there are no changes she would recommend. Only mark "no response/ decline to answer" if the participant refuses to answer the question.
Item 3g:	If "other, specify" is marked, record the participant's response in English on the line provided.
Item 3h:	Mark "no response/decline to answer" only if the participant refuses to answer the question.
Item 4:	Read the question as stated. Hand the response card to participant. Read the options and the descriptions as stated. If the participant describes a different method (for example, condoms), mark "other, specify" and record the participant's response in English on the line provided.

HPTN 077 (215) FAQ-4 (174)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Follow-up Acceptability Questionnaire

Item 5 is for male participants only. Female participants, end of form.

5. If you could receive the same level of protection (from pregnancy or disease) by taking one of the following products, which one would you prefer? *Interview card #8.*

☐ oral pill taken every day

Why? _____

☐ injection received once every 3 months

Why? _____

☐ rectal gel

Why? _____

☐ other, specify: _____

☐ doesn't matter

Follow-up Acceptability Questionnaire (FAQ-4)	
Item 5:	Read the question as stated. Hand the response card to participant. Read the options and the descriptions as stated. If the participant describes a different method (for example, condoms), mark “other, specify” and record the participant’s response in English on the line provided.

HPTN 077 (215) FUV-1 (133)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number Participant Number Chk

Follow-up Visit

Visit Date ☐☐ ☐☐☐ ☐☐
dd MMM yy

1. Is this an interim visit? ☐ *yes* ☐ *no* *If no, go to item 2.*

1a. Reason for interim visit. *Mark all that apply.*

- ☐ 1a1. report new symptoms
- ☐ 1a2. report a social impact
- ☐ 1a3. HIV lab testing
- ☐ 1a4. lab testing other than HIV
- ☐ 1a5. pregnancy testing
- ☐ 1a6. repeat laboratory work including HIV confirmatory testing
- ☐ 1a7. other, specify: _____

1b. Besides this form, what other DataFax forms were completed at this visit? *Mark all that apply.*

- ☐ 1b1. HIV Test Results
- ☐ 1b2. Local Laboratory Results
- ☐ 1b3. 12-Lead Electrocardiogram
- ☐ 1b4. Injection Site Reaction Evaluation
- ☐ 1b5. Specimen Storage
- ☐ 1b6. CD4+/Viral Load Results
- ☐ 1b7. Sexually Transmitted Infections
- ☐ 1b8. Pregnancy Report and History
- ☐ 1b9. Pregnancy Outcome
- ☐ 1b10. other, specify: _____

2. At this visit, how many **new** Adverse Experiences (AEs) have been reported? ☐☐ *Complete a separate AE Log page for each AE. If none, enter 00.*

3. At this visit, how many **new** product holds or discontinuations have been initiated? ☐☐ *Complete a separate Product Hold/ Discontinuation Log page for each hold or discontinuation. If none, enter 00.*

4. At this visit, how many **new** social impacts have been reported? ☐☐ *Complete a separate Social Impact Log page for each event. If none, enter 00.*

Item 5 is for female participants only. Male participants, end of form.

5. What hormone-based contraceptive is the participant currently using? *Mark "none," "not of reproductive potential," or all that apply.*

- ☐ 5a. none
- ☐ 5b. not of reproductive potential
- ☐ 5c. oral contraceptives/birth control pills
- ☐ 5d. injectable contraceptives, specify:
  - ☐ Depo-Provera
  - ☐ NET-EN (norethisterone enanthate)
  - ☐ Cyclofem (Lunelle)
  - ☐ Mesigyna
  - ☐ other, specify: _____
- ☐ 5e. the Patch (Ortho-Evra)
- ☐ 5f. vaginal ring (NuvaRing)
- ☐ 5g. implants
- ☐ 5h. other, specify: _____

Follow-up Visit (FUV-1)	
Purpose:	This form is used to summarize information from each participant follow-up study visit (including interim visits).
Item-specific Instructions:	
Item 1b:	Mark the newly completed forms (in addition to this form) that are being submitted for the interim visit/contact. If "other, specify" is marked, record the form acronym(s) in the space provided.

HPTN 077 (215) HTR-1 (178)

Visit Code . 1

Participant ID

Site Number – Participant Number – Chk

HIV Test Results

Specimen #1 Collection Date: dd MMM yy

1. HIV TEST RESULTS

1a. HIV Rapid Test 1 Kit Code	Not done ☐	kit code	1a1. HIV Rapid 1	non-reactive ☐	reactive ☐
1b. HIV Rapid Test 2 Kit Code	☐	kit code	1b1. HIV Rapid 2	☐	☐
1c. HIV EIA Test Kit Code	☐	kit code	1c1. HIV EIA	☐	☐
1d. HIV-1 RNA Qualitative	Not done ☐	non-reactive ☐	reactive ☐		
1e. HIV-1 RNA PCR	Not done ☐	kit code			
1e1. HIV RNA PCR (plasma)	> ☐ = ☐ < ☐	viral copies/mL	OR	undetectable ☐	

Specimen #2 Collection Date: dd MMM yy

2. HIV TEST RESULTS

2a. HIV Rapid Test 1 Kit Code	Not done ☐	kit code	2a1. HIV Rapid 1	non-reactive ☐	reactive ☐
2b. HIV Rapid Test 2 Kit Code	☐	kit code	2b1. HIV Rapid 2	☐	☐
2c. HIV EIA Test Kit Code	☐	kit code	2c1. HIV EIA	☐	☐
2d. HIV-1 RNA Qualitative	Not done ☐	non-reactive ☐	reactive ☐		
2e. HIV-1 RNA PCR	Not done ☐	kit code			
2e1. HIV RNA PCR (plasma)	> ☐ = ☐ < ☐	viral copies/mL	OR	undetectable ☐	

3. Final HIV Status from local confirmatory testing: negative ☐ positive ☐ indeterminate ☐

Comments:

☐ ☐ ☐ ☒ 27-OCT-14

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0 1 English

Staff Initials/Date

HIV Test Results (HTR-1)	
Purpose:	The HIV Test Results CRF documents the results of HIV testing performed at the site at scheduled and interim visits.
General Information/Instructions:	
	• Record test results on this form as they become available from the local lab. Fax this form to DataFax when the final test results are available and recorded. • If HIV infection is suspected or confirmed during follow-up, complete a Product Hold/Discontinuation Log.
Specimen Collection Date:	Record the date that the specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit. Complete date is required.
Item-specific Instructions:	
Not done:	For each test, mark either the “Not done” box or enter a test result. If the “Not done” box is marked at a visit where that test is required by the protocol, record the reason in Comments.
Kit codes:	• Refer to Atlas for kit codes. If a test kit being used at your site is not listed, contact the SCHARP Project Manager for a new code. • Rapid tests on oral transudate are not allowed per protocol.
Items 1b and 2b:	A second Rapid Test is performed if required per site’s standard operating procedures.

HPTN 077 (215) ISR-1 (128)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number | Participant Number | Chk

Injection Site Reaction Evaluation

Date of Evaluation ☐☐ dd ☐☐☐ MMM ☐☐ yy

1. Was there an injection site reaction? ☐ *yes* ☐ *no* *If no, end of form. Do not fax page 2 to DataFax.*

   1a. Evaluation reported by: ☐ *clinician only* ☐ *clinician and participant* → *Go to item 2.* ☐ *participant only Record onset and resolution dates.*

   dd MMM yy
   Onset date ☐☐ ☐☐☐ ☐☐
   Resolution date ☐☐ ☐☐☐ ☐☐ → *Go to item 2.*

2. Was **right** buttock injected? ☐ *yes* ☐ *no* *If no, go to item 6 on page 2.*

   2a. Injection site reaction present? ☐ *yes* → *Complete Adverse Experience Log, as applicable.* ☐ *no* → *If no, go to item 6 on page 2.*

3. Pain/Itching

	none	*mild*	*moderate*	*severe*	*potentially life-threatening*
3a. tenderness (pain upon touch)	☐	☐	☐	☐	☐
3b. pain without touch	☐	☐	☐	☐	☐
3c. itching	☐	☐	☐	☐	

If any are moderate, severe, or potentially life-threatening, take temperature. Record in item 10 on page 2.

4. Dimensions

	none		*maximum length*	*maximum width*
4a. redness	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*
4b. swelling	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*
4c. induration	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*
4d. bruise	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*

If none, go to item 5. ←

4d1. Color (bruising) ☐ *no discoloration* ☐ *blue* ☐ *yellow* ☐ *yellow-blue* ☐ *black* ☐ *other, specify:* _____

5. Inflammation

	yes	*no*
5a. warm sensation	☐	☐
5b. pulsing sensation	☐	☐
5c. pus containing/pus draining spontaneously	☐	☐
5d. required incision and drainage	☐	☐

If any are yes, take temperature. Record in item 10 on page 2.

Injection Site Reaction Evaluation (ISR-1)	
Purpose:	This form is used to document clinician- and participant-assessed injection site reactions at required safety visits as well as any injection site reactions assessed at other visits.
General Information/Instructions:	
	Complete this form at weeks 6, 9, 13, 18, 23, 30, and 35 and any other visit where an injection site reaction is noted.

HPTN 077 (215) ISR-2 (129)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number Participant Number Chk

Injection Site Reaction Evaluation

6. Was **left** buttock injected? ☐ *yes* ☐ *no* *If no, end of form.*

6a. Injection site reaction present? ☐ *yes* → *Complete Adverse Experience Log, as applicable.*
☐ *no* → *If no, end of form.*

7. Pain/Itching

	none	*mild*	*moderate*	*severe*	*potentially life-threatening*
7a. tenderness (pain upon touch)	☐	☐	☐	☐	☐
7b. pain without touch	☐	☐	☐	☐	☐
7c. itching	☐	☐	☐	☐	

If any are moderate, severe, or potentially life-threatening, take temperature. Record in item 10.

8. Dimensions

	none		*maximum length*	*maximum width*
8a. redness	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*
8b. swelling	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*
8c. induration	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*
8d. bruise	☐	OR	☐☐☐ *mm*	☐☐☐ *mm*

If none, go to item 9. ←

8d1. Color (bruising) ☐ *no discoloration* ☐ *blue* ☐ *yellow* ☐ *yellow-blue* ☐ *black* ☐ *other, specify:* _____

9. Inflammation

	yes	*no*
9a. warm sensation	☐	☐
9b. pulsing sensation	☐	☐
9c. pus containing/pus draining spontaneously	☐	☐
9d. required incision and drainage	☐	☐

If any are yes, take temperature. Record in item 10.

10. Temperature

10a. Was temperature measured? ☐ *yes* → Temperature: ☐☐.☐ *°C*
☐ *no*

Method: ☐ *oral* ☐ *other, specify:* _____
☐ *tympanic*

☐☐☐☒ 27-OCT-14

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0 1 English

Staff Initials/Date

Injection Site Reaction Evaluation (ISR-2)

No additional instructions.

HPTN 077 (215) LLR-1 (152)

Visit Code [ ][ ].[ ] 1

Participant ID [ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]
Site Number / Participant Number / Chk

Local Laboratory Results

Initial Specimen Collection Date [ ][ ] dd [ ][ ][ ] MMM [ ][ ] yy

Item 1 is completed at Enrollment only.	1. HEIGHT [ ][ ][ ] *cm*	2. WEIGHT [ ][ ][ ].[ ] *kg*

	Not done/ Not collected	Alternate Collection Date dd / MMM / yy		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
3. HEMOGRAM	☐	[ ][ ] / [ ][ ][ ] / [ ][ ]				
	Not reported					
3a. Hemoglobin	☐	[ ][ ].[ ]	*g/dL*	☐	[ ][ ][ ]	OR ☐
3b. Hematocrit	☐	[ ][ ].[ ]	*%*			
3c. MCV	☐	[ ][ ][ ].[ ]	*fL*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
3d. Platelets	☐	[ ][ ][ ][ ].[ ]	*x10³/mm³*	☐	[ ][ ][ ]	OR ☐
3e. WBC	☐	[ ][ ][ ].[ ]	*x10³/mm³*	☐	[ ][ ][ ]	OR ☐

DIFFERENTIAL Not done ☐ *If not done, go to item 4 on page 2.*

	Not reported	Absolute Count *cells/mm³*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
3f. Neutrophils	☐	[ ][ ][ ][ ][ ]	☐	[ ][ ][ ]	OR ☐
3g. Lymphocytes	☐	[ ][ ][ ][ ]	☐	[ ][ ][ ]	OR ☐
3h. Monocytes	☐	[ ][ ][ ][ ]			
3i. Eosinophils	☐	[ ][ ][ ][ ]			
3j. Basophils	☐	[ ][ ][ ][ ]			
3k. Atypical lymphocytes	☐	[ ][ ][ ][ ]			
3l. other, specify: _____	☐	[ ][ ][ ][ ]			

Comments

☐ ☐ ☐ ☒ 27-OCT-14

N:\hivnet\forms\PTN_077\forms\p077_LLR.fm

0 1 English

Staff Initials/Date

Local Laboratory Results (LLR-1)

Purpose:	This form is used to collect results from tests performed by site's local laboratory at follow-up visits.
General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	• If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, then round the converted result if necessary.
AE Severity Grade:	• If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either "Not done/Not collected" or enter a test result. If "Not done/Not collected" is marked, provide an explanation in Comments.
Repeat Local Laboratory Tests:	Sometimes it is necessary to repeat a local lab test. • For a repeat test of the ***same*** sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to DataFax. • For a repeat test using a ***different*** sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.

HPTN 077 (215) LLR-2 (153)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Local Laboratory Results

4. ELECTROLYTES

	Not done/ Not collected	Alternate Collection Date dd	MMM	yy		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
4a. Sodium	☐	☐☐	☐☐☐	☐☐	☐☐☐ *mmol/L*	☐	☐☐☐	OR ☐
4b. Potassium	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *mmol/L*	☐	☐☐☐	OR ☐
4c. Chloride	☐	☐☐	☐☐☐	☐☐	☐☐☐ *mmol/L*			
4d. Bicarbonate	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *mmol/L*	☐	☐☐☐	OR ☐

5. RENAL FUNCTION TESTS

	Not done/ Not collected	Alternate Collection Date dd	MMM	yy		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
5a. Creatinine	☐	☐☐	☐☐☐	☐☐	☐.☐☐ *mg/dL*			
					OR ☐☐☐.☐ *µmol/L*	☐	☐☐☐	OR ☐
5a1. Calculated creatinine clearance	☐				☐☐☐.☐ *mL/min*	☐	☐☐☐	OR ☐
5b. BUN	☐	☐☐	☐☐☐	☐☐	☐☐☐ *mg/dL*			
5c. Urea	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *mmol/L*			

6. LIVER FUNCTION TESTS

	Not done/ Not collected	Alternate Collection Date dd	MMM	yy		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
6a. Alkaline phosphatase	☐	☐☐	☐☐☐	☐☐	☐☐☐☐ *U/L*	☐	☐☐☐	OR ☐
6b. AST (SGOT)	☐	☐☐	☐☐☐	☐☐	☐☐☐☐ *U/L*	☐	☐☐☐	OR ☐
6c. ALT (SGPT)	☐	☐☐	☐☐☐	☐☐	☐☐☐☐ *U/L*	☐	☐☐☐	OR ☐
6d. Total bilirubin	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *mg/dL*	☐	☐☐☐	OR ☐

Local Laboratory Results (LLR-2)

General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	• If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, then round the converted result if necessary.
AE Severity Grade:	• If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either “Not done/Not collected” or enter a test result. If “Not done/Not collected” is marked, provide an explanation in Comments on page 3.
Repeat Local Laboratory Tests:	Sometimes it is necessary to repeat a local lab test. • For a repeat test of the ***same*** sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to DataFax. • For a repeat test using a ***different*** sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.
Item-specific Instructions:	
Items 5b and 5c:	Either BUN or Urea are required, not both.

HPTN 077 (215) LLR-3 (154)

Visit Code . 1

Participant ID

Site Number – Participant Number – Chk

Local Laboratory Results

7. OTHER CHEMISTRIES

	Not done/ Not collected	Alternate Collection Date dd	MMM	yy		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
7a. CPK (CK)	☐	☐☐	☐☐☐	☐☐	☐☐☐☐☐ *U/L*	☐	☐☐☐	OR ☐
7b. Glucose	☐	☐☐	☐☐☐	☐☐	☐☐☐ *mg/dL*	☐	☐☐☐	OR ☐
7c. Pancreatic amylase	☐	☐☐	☐☐☐	☐☐	☐☐☐ *U/L*	☐	☐☐☐	OR ☐
7d. Lipase	☐	☐☐	☐☐☐	☐☐	☐☐☐ *U/L*	☐	☐☐☐	OR ☐
7e. Magnesium	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *mg/dL*	☐	☐☐☐	OR ☐
7f. Total protein	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *g/L*			
7g. Phosphorus (Phosphate)	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *mg/dL*	☐	☐☐☐	OR ☐
7h. Total calcium	☐	☐☐	☐☐☐	☐☐	☐☐.☐ *mg/dL*	☐	☐☐☐	OR ☐

Comments

Local Laboratory Results (LLR-3)

General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	• If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, then round the converted result if necessary.
AE Severity Grade:	• If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either “Not done/Not collected” or enter a test result. If “Not done/Not collected” is marked, provide an explanation in Comments.
Repeat Local Laboratory Tests:	Sometimes it is necessary to repeat a local lab test. • For a repeat test of the ***same*** sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to DataFax. • For a repeat test using a ***different*** sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.

HPTN 077 (215) LLR-4 (155)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number | Participant Number | Chk

Local Laboratory Results

Alternate Collection Date

8. SERUM LIPIDS — Not done/ Not collected ☐ → *Go to item 9.* dd ☐☐ MMM ☐☐☐ yy ☐☐

8a. Did the participant fast for at least 8 hours prior to blood collection? ☐ *yes* ☐ *no*

		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
8b. Total cholesterol	☐☐☐ *mg/dL*	☐	☐☐☐	OR ☐
8c. Triglycerides	☐☐☐☐ *mg/dL*	☐	☐☐☐	OR ☐
8d. LDL	☐☐☐ *mg/dL*	☐	☐☐☐	OR ☐
	☐ direct ☐ calculated			
8e. HDL	☐☐☐ *mg/dL*	☐	☐☐☐	OR ☐

Alternate Collection Date

9. URINE TESTS — Not done/ Not collected ☐ → *Go to item 10.* dd ☐☐ MMM ☐☐☐ yy ☐☐

	neg	*trace*	*1+*	*2+*	*3+*	*4+*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
9a. Protein	☐	☐	☐	☐	☐	☐	☐	☐☐☐	OR ☐
9b. Glucose	☐	☐	☐	☐	☐	☐	☐	☐☐☐	OR ☐

Item 10 is for female participants only. Male participants, end of form.

10. PREGNANCY TEST → *End of form.*

10a. Pregnancy Test — Not done/ Not collected ☐ OR ☐ NOT of reproductive potential OR Date of pregnancy test dd ☐☐ MMM ☐☐☐ yy ☐☐

10a1. Test result — *negative* ☐ *positive* ☐ *If positive, complete Pregnancy Report and History.*

Comments

☐ ☐ ☒ ☐ 12-MAR-15

N:\hivnet\forms\PTN_077\forms\p077_LLR.fm

0 1 English

Staff Initials/Date

Local Laboratory Results (LLR-4)

General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	• If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, then round the converted result if necessary.
AE Severity Grade:	• If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either “Not done/Not collected” or enter a test result. If “Not done/Not collected” is marked, provide an explanation in Comments.
Repeat Local Laboratory Tests:	Sometimes it is necessary to repeat a local lab test. • For a repeat test of the ***same*** sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to DataFax. • For a repeat test using a ***different*** sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.
Item-specific Instructions:	
Item 8d:	Either direct or calculated LDL is acceptable.

HPTN 077 (215) PEA-1 (136)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number | Participant Number | Chk

Post-injection Exercise Assessment

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd | MMM | yy

1. Since the participant's last injection, did the participant…

	yes	*no*	
1a. perform any vigorous activities?	☐	☐	*If no, end of form.*

1b. What type of activities? _____

_____

_____

1c. For how long? ***Record in total combined time, in hours and minutes.***

hours ☐☐ *minutes* ☐☐

Post-injection Exercise Assessment (PEA-1)

General Information/Instructions:

- Complete this form at weeks 6, 18, and 30.
- This information should be obtained as part of the participant's targeted history and medical exam.

Item-specific Instructions:

Item 1a:	Vigorous exercise makes you breathe much harder than normal and may include activities such as sports, like soccer, bicycling, or running; also weight training or lifting heavy objects; and various job-related activities or chores such as field work, cutting and fetching firewood, or walking long distances to get and carry water.
Item 1b:	Record the participant's response in English on the lines provided.

HPTN 077 (215) SS-1 (231)

Visit Code . 1

Participant ID
Site Number – Participant Number – Chk

Specimen Storage

Initial Specimen Collection Date
dd MMM yy

1. Plasma for storage

Alternate Collection Date
dd *MMM* *yy*

Time Collected
24-hr clock
hr : min

stored *not stored* *not collected* *not required*

Reason not stored or not collected: _____

2. Rectal swab for GC/CT testing (non-US sites only)

Alternate Specimen Date
dd *MMM* *yy*

stored *not stored* *not collected* *not required*

Reason not stored or not collected: _____

Comments:

Specimen Storage (SS-1)	
Purpose:	This form is used to document the storage of specimens that will be tested at a lab other than the site local laboratory.
General Information/Instructions:	
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Item-specific Instructions:	
Item 1:	Samples collected will also be used for PK and pharmacogenomics testing.
Items 1–2:	• Mark “not stored” if the specimen was collected as required at this visit but was not stored. • Mark “not collected” if the specimen is required to be collected and stored at this visit but was not collected. • Mark “not required” if a specimen is not required and was not collected and stored at this visit.

HPTN 077 (215) SMS-1 (181)

Visit Code ___.___ 1

Participant ID ___ ___ ___ – ___ ___ ___ ___ ___ – ___
Site Number | Participant Number | Chk

Study Medication Satisfaction Questionnaire (SMSQs)

Assessment Date dd MMM yy

Interviewer: Refer to Interviewer Instructions.

The following questions are concerned with your study medication and your experience over the past few weeks. Please answer each question by circling a number on each of the scales.

1. How satisfied are you with your current study medication?	*very satisfied* 6	5	4	3	2	1	0 *very dissatisfied*
2. How satisfied are you with any side effects of your present study medication?	*very satisfied* 6	5	4	3	2	1	0 *very dissatisfied*
3. How satisfied are you with the demands made by your current study medication?	*very satisfied* 6	5	4	3	2	1	0 *very dissatisfied*
4. How convenient have you been finding your study medication to be recently?	*very convenient* 6	5	4	3	2	1	0 *very inconvenient*
5. How flexible have you been finding your study medication to be recently?	*very flexible* 6	5	4	3	2	1	0 *very inflexible*
6. How satisfied are you with your understanding of your current study medication?	*very satisfied* 6	5	4	3	2	1	0 *very dissatisfied*
7. How satisfied are you with the extent to which the study medication fits in with your lifestyle?	*very satisfied* 6	5	4	3	2	1	0 *very dissatisfied*

Study Medication Satisfaction Questionnaire (SMS-1)

HPTN 077 (215) SMS-2 (182)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Study Medication Satisfaction Questionnaire (SMSQs)

8a. Would you recommend your present study medication to someone who is being offered this medication?	*Yes, I would definitely recommend the medication* 6 ☐	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	*No, I would definitely not recommend the medication* 0 ☐
8b. Would you speak well of your present study medication to someone who is being offered this medication?	*Yes, I would definitely speak well of the medication* 6 ☐	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	*No, I would definitely not speak well of the medication* 0 ☐
9. How satisfied would you be to continue with your present form of study medication?	*very satisfied* 6 ☐	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	*very dissatisfied* 0 ☐
10. How easy or difficult have you been finding your study medication to be recently?	*very easy* 6 ☐	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	*very difficult* 0 ☐
11. How satisfied are you with the amount of discomfort or pain involved with your present form of study medication?	*very satisfied* 6 ☐	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	*very dissatisfied* 0 ☐

Not applicable for this protocol.

Please make sure that you have circled one number on each of the scales.

12. Are there any other aspects of the study medication, causing either satisfaction or dissatisfaction that have not been covered by the questionnaire? *yes* ☐ *no* ☐ *If no, end of form.*

12a. If yes, please describe below:

Thank you for taking the time to complete this questionnaire.

Study Medication Satisfaction Questionnaire (SMS-2)