

ADDITIONAL CRFs REQUIRED FOR TISSUE SUBSET PARTICIPANTS: TREATMENT DISCONTINUATION BETWEEN WEEK 24 AND 48

- Tissue Subset Specimen Storage–Blood (TSB-1)
- Tissue Subset Specimen Storage–Rectal (TSR-1, TSR-2)
- Tissue Subset Specimen Storage–Cervicovaginal (TSC-1)
- Tissue Subset Hair Specimen Collection (TSH-1)

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Visit Code

1

HPTN 069 (109)

TSB-1 (220)

Participant ID

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Site Number Participant Number Chk

Tissue Subset Specimen Storage—Blood

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min
 :

1. Plasma for PK

stored not stored not collected

Reason not stored or not collected: _____

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min
 :

2. PBMC for PK

stored not stored not collected

Reason not stored or not collected: _____

Complete item 3 for Week 24 and 48 visits only. All other visits, end of form.

3. Date and time of last study dose: : (24-hr clock)

Comments: _____

Tissue Subset Specimen Storage—Blood (TSB-1)

Purpose: This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

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:

- **Items 1–2:**
 - Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
 - Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.



Visit Code

HPTN 069 (109)

TSR-1 (223)

Page 1 of 2

Participant ID

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Site Number Participant Number Chk

Tissue Subset Specimen Storage—Rectal

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

hr min
 :

1. Rectal fluid (sponge) for PK

stored not stored not collected not required

Reason not stored or not collected: _____

If tissue was not collected, end of form.

- 2. Was any blood seen on the sponge?

yes	<input type="checkbox"/>	no	<input type="checkbox"/>
yes	<input type="checkbox"/>	no	<input type="checkbox"/>
- 3. Was any brown-tinged discoloration seen on the sponge?

yes	<input type="checkbox"/>	no	<input type="checkbox"/>
yes	<input type="checkbox"/>	no	<input type="checkbox"/>
- 4. Was any fecal matter seen on the sponge?

yes	<input type="checkbox"/>	no	<input type="checkbox"/>
yes	<input type="checkbox"/>	no	<input type="checkbox"/>

If no, go to item 5 on page 2.

- 4a. 1/4 sponge covered in stool 1/2 sponge covered in stool 3/4 sponge covered in stool sponge completely covered in stool

Comments: _____

Tissue Subset Specimen Storage—Rectal (TSR-1)

Purpose: This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

General Information/Instructions: Complete this form only for tissue subset participants who consented to the collection of rectal specimens.

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:**
 - Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
 - Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.
 - Mark the “not required” box if a specimen is not required to be collected and stored at this visit.
- **Item 4a:** Choose the option that best describes the amount of stool observed on the sponge.



Visit Code

HPTN 069 (109)

TSR-2 (224)

Participant ID

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Site Number Participant Number Chk

Tissue Subset Specimen Storage—Rectal

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy hr min
 :

5. Rectal Tissue

stored not stored not collected not required

5a. Tissue for PK

Reason not stored or not collected: _____

5b. Tissue for ex-vivo HIV Challenge

Reason not stored or not collected: _____

5c. Tissue for GALT

Reason not stored or not collected: _____

If tissue was not collected, end of form.

- 6. Was any blood seen on the tissue? yes no
- 7. Was any brown-tinged discoloration seen on the tissue? yes no
- 8. Was any fecal matter seen on the tissue? yes no **If no, end of form.**

8a. 1/4 tissue covered in stool 1/2 tissue covered in stool 3/4 tissue covered in stool tissue completely covered in stool

Comments: _____

Tissue Subset Specimen Storage—Rectal (TSR-2)

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 5:**
 - Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
 - Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.
- **Item 5a:**
 - Mark the “not required” box if a specimen is not required to be collected and stored at this visit.
- **Item 8a:** Choose the option that best describes the amount of stool observed on the tissue.



Visit Code

1

HPTN 069 (109)

TSC-1 (227)

Participant ID

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Site Number Participant Number Chk

Tissue Subset Specimen Storage—Cervicovaginal

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

:
hr min

1. Cervical Tissue

stored not stored not collected not required

1a. Tissue for PK

←

Reason not stored or not collected: _____

1b. Tissue for ex-vivo HIV Challenge

stored not stored not collected

←

Reason not stored or not collected: _____

If tissue was not collected, go to item 3.

2. Was any blood seen on the sample?
NOT APPLICABLE FOR THIS PROTOCOL.

yes no

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

:
hr min

3. Cervicovaginal Fluid for PK

stored not stored not collected not required

←

Reason not stored or not collected: _____

If fluid was not collected, end of form.

4. Was any blood seen on the sample?

yes no

Comments: _____

Tissue Subset Specimen Storage—Cervicovaginal (TSC-1)

Purpose: This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

General Information/Instructions: Complete this form only for tissue subset participants who consented to the collection of cervicovaginal specimens.

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:**
 - Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
 - Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.
- **Item 1a:**
 - Mark the “not required” box if a specimen is not required to be collected and stored at this visit.



HPTN 069 (109)

TSH-1 (270)

Visit Code .

1

Participant ID

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Site Number Participant Number Chk

Tissue Subset Hair Sample Collection

Visit Date

dd MMM yy

1. Was hair collected successfully?

yes no

If yes, go to item 2.

1a. Reason collection was unsuccessful. Mark all that apply.

- insufficient quantity of hair
- participant declined hair collection after counseling; specify reason: _____
- other, specify: _____

End of form.

2. Number of thatches collected at each site:

scalp hair pubic hair other, specify: _____
 If scalp hair, go to item 2a. occipital other, specify: _____
 If pubic hair or other, go to item 3.

2a. Location on scalp: Mark all that apply.

3. Natural hair color. Mark only one.

- black brownish blonde red
 - brown reddish brown doesn't know
 - blonde reddish blonde totally gray
- Go to item 5.

4. Any gray hair (natural color)?

yes no If no, go to item 5.

4a. Amount of gray hair:

- less than half about half more than half

5. Natural hair texture.

Mark only one.

- completely straight wavy but not curly loose curls tight curls

6. Hair treatment in the last 3 months?

yes no If no, end of form.

6a. Color?

dd MMM yy OR not done If not done, go to item 6b.

6a1. Type of color process?

- permanent semi-permanent washout unknown

6b. Highlighting?

dd MMM yy OR not done

6c. Bleaching?

 OR not done

6d. Permanent wave?

 OR not done

6e. Straightening with chemicals or heat?

 specify: _____ not done OR

Comments: _____

Tissue Subset Hair Sample Collection (TSH-1)

Item-specific Instructions:

- **Item 1a:** Mark “insufficient quantity of hair” if the participant’s hair was too short (< 1cm) or not enough strands (less than ~100 strands of hair) were able to be collected.
- **Item 2a:** If “other, specify” is marked, record the specific location where the scalp hair was collected. An anatomical location is not required (i.e., it is okay to record “side of head”).
- **Items 3–6:** These items are based on participant self-report. They should be answered for the type of hair sample that was collected. If a participant is unsure how to answer any of the items, tell him/her to take his/her best guess.
- **Item 6a1:**

Permanent	dye with a developer and ammonia
Semi-permanent	dye with low levels of peroxide and/or ammonia
Wash-out	shampoo, spray, or gel dye

- **Item 6e:** Record “chemicals” or “heat” on the specify line. If chemicals were used, also record the name of the chemical if it is known.