

***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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HPTN 069 (109)

TSB-1 (220)

Visit Code

1

**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**

dd MMM yy

**Time Collected (24-hr clock)**

hr min  
 :

1. Plasma for PK

stored  not stored  not collected

Reason not stored or not collected: \_\_\_\_\_

**Alternate Collection Date**

dd MMM yy

**Time Collected (24-hr clock)**

hr min  
 :

2. PBMC for PK

stored  not stored  not collected

Reason not stored or not collected: \_\_\_\_\_

Comments: \_\_\_\_\_

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## 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

1

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

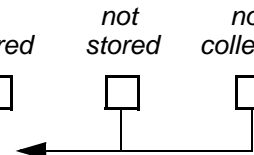
Time Collected (24-hr clock)

dd MMM yy 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: \_\_\_\_\_

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## 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: \_\_\_\_\_

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## **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? .....

yes no

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

hr min  
 :

3. Cervical 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: \_\_\_\_\_

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## 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

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]  
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.      If pubic hair or other, go to item 3.

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

occipital [ ] other, specify: \_\_\_\_\_

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 [ ] 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? .....

dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] OR [ ] not done

6d. Permanent wave? .....

dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] OR [ ] not done

6e. Straightening with chemicals or heat? .....

dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] specify: \_\_\_\_\_ OR [ ] not done

Comments: \_\_\_\_\_

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## 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.