

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

- Tissue Subset Specimen Storage–Blood (TSB-1)
- Tissue Subset Hair Specimen Collection (TSH-1)

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Visit Code

1

HPTN 069 (109)

TSB-1 (220)

Page 1 of 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**

**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: \_\_\_\_\_

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

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## **Tissue Subset Specimen Storage—Blood (TSB-1)**

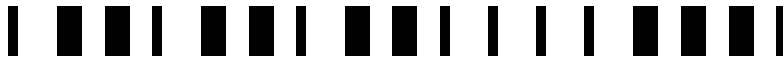
**Purpose:** This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

**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.



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: \_\_\_\_\_  
 occipital [ ][ ] 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 [ ]

6c. Bleaching? .....

dd [ ][ ] MMM [ ][ ][ ][ ] yy [ ][ ] OR [ ]

6d. Permanent wave? .....

dd [ ][ ] MMM [ ][ ][ ][ ] yy [ ][ ] OR [ ]

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.