

HISTORY/BASELINE MEDICATIONS AND PHYSICAL EXAM

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Date of Patient Visit/Contact	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
							mmm	dd	yyyy		
Protocol Number	A	5	2	5	3						
						Institution Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Form Week	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		* Seq. No.	<input type="text"/>	<input type="text"/>	** Step No.	<input type="text"/>	<input type="text"/>
						Key Operator Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

* Enter a '1' if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.
 ** Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

ANTI-FUNGAL/TB MEDICATIONS

Answer '1-Yes,' '2-No' or '3-Not known' to each question.

NOTE: If the answer to any question in this section is 'yes,' record the medication(s) on the CONCOMITANT MEDICATIONS RECORD (CMW0007). (1-Yes, 2-No, 3-Not known)

1. Is the study participant currently taking co-trimoxazole?
2. Is the study participant currently taking fluconazole or itraconazole?
3. Has the study participant taken any medications for the treatment of TB in the past 90 days? (Refer to the list of TB medications in Protocol Section 4.2.)

ARV HISTORY

Answer '1-Yes,' '2-No' or '3-Not known' to each question. (1-Yes, 2-No, 3-Not known)

4. Has the study participant ever had ARV therapy?
If No or Not known, go to question 5.
If Yes, continue.
 - a. Was any therapy within the last 2 years?
 - b. Was any therapy for the prevention of mother-to-child transmission?

PHYSICAL EXAM

Answer '1-Yes,' '2-No' or '3-Not known' to each question. (1-Yes, 2-No, 3-Not known)

5. Does the study participant currently have any of the following:
 - a. Papular rash on chest, back or extremities?
 - b. BCG scar?
 - c. Fungal nail infection?
 - d. Hepatomegaly?
 - e. Splenomegaly?

Pt. No. [][][][][][][] *Seq. No. [][] **Step No. [][] Date [][][] [][] [][][][]
mmm dd yyyy

6. Does the study participant currently have lymphadenopathy? (1-Yes, 2-No, 3-Not known) []
If No or Not known, go to question 7.
If Yes, continue.

Indicate the location of the lymphadenopathy for each of the following:

1-Right side, 2-Left side,
3-Both sides, 4-Not present

a. Temporal, occipital, sub-mandibular, cervical, posterior-auricular: []
If 4, go to 'b.'
If 1-3, continue.

a1. Estimated long axis of largest node: [][] cm

b. Axillary: []
If 4, go to 'c.'
If 1-3, continue.

b1. Estimated long axis of largest node: [][] cm

c. Epi-trochlear: []
If 4, go to 'd.'
If 1-3, continue.

c1. Estimated long axis of largest node: [][] cm

d. Inguinal: []
If 4, go to question 7.
If 1-3, continue.

d1. Estimated long axis of largest node: [][] cm

7. Result of chest auscultation: 1-Normal []
2-Abnormal
3-Not performed
If '1-Normal' or '3-Not performed', go to question 8.
If '2-Abnormal,' continue.

Answer '1-Yes,' '2-No' or '3-Not known' to each question. (1-Yes, 2-No, 3-Not known)

a. Does the study participant currently have any of the following:

a1. Stridor? []

a2. Bronchial breath sounds? []

a3. Decreased breath sounds? []

a4. Rales or crackles? []

a5. Rhonchi or wheeze? []

a6. Pleural rub? []

a7. Fremitus? []

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NEUROLOGY EXAM

¹ Pin Perception
0-Normal
1-Diminished perception as sharp
2-Inability to recognize as sharp or dull
3-Inability to perceive touch of pin
4-Distal hyperalgesia
9-Unable to evaluate or did not assess

Test by applying pin to feet. Compare to contralateral foot and proximal sites on same foot.

Right Foot ¹ Left Foot ¹

8. Perception of Pin:

² Vibration Perception
0-Normal
1-Diminished vibration > 5 seconds compared to examiner
2-Inability to perceive vibration
3-Inability to perceive touch of applied tuning fork
9-Unable to evaluate or did not assess

9. Perception of Vibration:
Test by applying tuning fork (128 hz) to DIP joint of great toe, malleolus, and DIP joint of index finger.

Right ² Left ²

a. Great toe DIP joint:

b. Malleolus:

c. Index finger DIP joint:

³ Romberg Result
0-Normal
1-Breaks stance only with feet in tandem and eyes closed
2-Breaks stance with feet side by side and eyes closed
9-Unable to evaluate or did not assess

Test initially with feet touching side by side, then with feet touching in tandem.
A positive test occurs when the position is maintained with eyes open but ataxia appears when eyes are closed. Position should be held for 10 seconds.

10. Romberg:³

11. Deep Tendon Reflexes:

0-Normal
1-Increased diffusely
2-Increased in legs only
3-Increased in one limb or on one side
4-Decreased diffusely
5-Decreased distally and symmetrically
6-Decreased or absent ankle jerks only
7-Decreased asymmetrically
9-Unable to evaluate or did not assess

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CHEST RADIOGRAPH

12. Was a chest radiograph performed? (1-Yes, 2-No)

If Yes, go to question 13.
If No, specify reason.

a. Specify reason not performed [70]:

CLINICAL DIAGNOSIS

13. Based on your evaluation, was this study participant diagnosed with TB? ... (1-Yes, 2-No, 3-Not known)

If No or Not known, STOP.
If Yes, continue.

a. Was the study participant referred for treatment? (1-Yes, 2-No)

14. Are there any other pertinent comments regarding medication history or physical exam? (1-Yes, 2-No)

If No, STOP.
If Yes, continue.

a. Comments [140]:

