



Vaccine Dose C (≥ 16 weeks after dose A)

1. Visit date: ____/____/____ (dd,mm,yyyy)

2. Place of interview:

- 0 interviewed at Study clinic (outpatient)
- 1 interviewed at home
- 2 interviewed in hospital (inpatient)
- 3 other _____

3. Did you experience any serious vaccine related side effects that you have not already reported since last visit?

0 no

1 yes **If yes, fill out form SAE**

Any of the following are considered serious adverse events (SAE): reactions that are fatal, life threatening, permanently disabling, require hospitalization or extension of hospitalization, cancer, congenital anomaly or birth defect, overdose of study vaccine/drug, wrong study vaccine/drug

Yes No

1 0

4. Are you pregnant now?

5. If no, result urine pregnancy test 1 pos 0 neg 2 not done

5a. If pos, expected date of delivery : ____/____/____
(mm,yyyy)

If pregnant, reschedule vaccine dose when NOT pregnant. Continue with this form and regular follow-up visits.

6. Temperature (axillary): _____ °C

If temperature ≥ 38 °C, defer vaccination for 1 week, evaluate to see if other treatment needed, and go to #16.

7. Does the patient have symptoms suggesting acute infection?

0 no

1 yes **If yes, defer vaccination for 1 week, go to #16.**

Note: If recent hospitalization or outpatient treatment suggest possible TB, order diagnostic studies for TB (see numbers 12-15 on reverse) and complete Form T.

8. Interval history:

a. any hospitalization since last study visit (not yet reported)?

1 yes 0 no

date: ____/____/____ to ____/____/____ diagnosis: _____ treatment: _____

date: ____/____/____ to ____/____/____ diagnosis: _____ treatment: _____
(mm,yyyy) (mm,yyyy)

b. any opportunistic infection since last study visit (not yet reported)?

	Yes	No	date (mm,yyyy)
herpes zoster (shingles).	<input type="checkbox"/> 1	<input type="checkbox"/> 0	____/____/____
pneumonia.	<input type="checkbox"/> 1	<input type="checkbox"/> 0	____/____/____
thrush.	<input type="checkbox"/> 1	<input type="checkbox"/> 0	____/____/____
chronic diarrhea (≥ 3 stool/day for ≥ 3 wks, past).	<input type="checkbox"/> 1	<input type="checkbox"/> 0	____/____/____
Kaposi's sarcoma.	<input type="checkbox"/> 1	<input type="checkbox"/> 0	____/____/____

c. treatment in clinic or by doctor (including today) since last study visit? (example: treatment for malaria)

1 yes 0 no

date: ____/____/____ diagnosis: _____ treatment: _____

date: ____/____/____ diagnosis: _____ treatment: _____
(mm,yyyy)

9. Medications within last 3 months

Yes No

malaria treatment.	<input type="checkbox"/> 1	<input type="checkbox"/> 0	drug: _____	
trimethoprim/sulfa.	<input type="checkbox"/> 1	<input type="checkbox"/> 0		date started: _____
HIV antiviral therapy.	<input type="checkbox"/> 1	<input type="checkbox"/> 0	drug(s): _____	____/____/____
typhoid treatment.	<input type="checkbox"/> 1	<input type="checkbox"/> 0	_____	____/____/____
isoniazid (INH) for latent TB (pos PPD).	<input type="checkbox"/> 1	<input type="checkbox"/> 0	_____	____/____/____
other, specify: _____	<input type="checkbox"/> 1	<input type="checkbox"/> 0		(mm,yyyy)



weight _____ kg Karnofsky score _____ (see card)	throat exam Yes No thrush: <input type="checkbox"/> 1 <input type="checkbox"/> 0 other: <input type="checkbox"/> 1 <input type="checkbox"/> 0 _____	lymph nodes >=1 cm Yes No : Yes No <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th colspan="2">left</th> <th colspan="2">right</th> </tr> </thead> <tbody> <tr> <td>cervical</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> </tr> <tr> <td>axillary</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> </tr> <tr> <td>inguinal</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> </tr> <tr> <td>epitrochlear.</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 0</td> </tr> </tbody> </table>		left		right		cervical	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 0	axillary	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inguinal	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 0	epitrochlear.	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 0																								
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- 11. Features suggestive of TB** Yes No
- a. cough >= 2 weeks 1 0
 - b. 5 kg weight loss since last visit 1 0
 - c. fever >= 2 weeks 1 0
 - d. other clinical suspicion of TB . 1 0

if ANY are yes, go to #12-15 for TB diagnostic studies, and complete Form R when results are back.

If ALL are no, go to #16

explain: _____

TB diagnostic studies Yes No

- 12. Sputum obtained today? 1 0
- 13. 2 or 3 sputum cups given to patient? 1 0
- 14. Blood collected
- 15. Patient given x-ray order slip? 1 0

3 sputum samples needed
Instruct patient to collect additional sputa each morning, keep as cool as possible, and bring back within a week.

- 1. Disinfect skin with tincture of iodine, let dry, then disinfect with alcohol, and let dry
- 2. Draw the following blood tube and indicate time of collection on blood tube time: _____

1 Green top 7 ml (TB blood culture) 1 0 **Blood drawn by (tRN):** _____
 name code

16. Date/time of next scheduled visit: 0 morning _____ / _____ / _____
 1 afternoon _____ / _____ / _____ (dd,mm,yyyy)

return in 1 week if deferred today; otherwise, return in 8 weeks for dose D (unless pregnant)

- 17. Appointment card completed? 1 0
- 18. Patient paid? 1 0
- 19. Form completed by (study nurse): _____

SSA patients: return in 7 days

name code

For patients in Substudy A, go to page 3 and draw blood BEFORE giving vaccine/placebo

- 20. Action taken:
 - 0 immunization deferred; put form in 'pending' bin
 - 1 vaccine/placebo dose C given on right arm
 - 1 check here if vaccine had to be given on left arm
- 21. Record box vaccine/placebo came from: _____
- 22. Date vaccine/placebo given: _____ / _____ / _____ (dd,mm,yyyy)
- 23. Injection given by (tRN): _____
 name code
- 24. Form checked by (study MD): _____
 name code

Comments: _____

