CRF 7- ROUTINE FOLLOW-UP POST TREATMENT

A1.Participant's ID number ☐☐☐ - ☐☐☐☐ **A2. Center** _____

P0.**Research staff completing the form** _____

POST TREATMENT FOLLOW-UP

P1. Date of call/visit ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

P2. Were you able to contact the study participant? ☐ Yes ☐ No

P3. If NO, indicate reason (tick one, then DO NOT continue)

- ☐ Study participant does not respond (a minimum of 3 calls made, followed by an email or a letter)
- ☐ Study participant's telephone, address and all other contact information are no longer valid
- ☐ Study participant refuses to respond to messages left with others
- ☐ Participant died (If participant died, investigate and complete CRF14 –"Death during post-treatment follow-up")
- ☐ Other reasons for not being able to contact study participant

P4. If other reasons, specify _____

P5. Has contact information changed? ☐ No ☐ Yes (If YES, update information on "Identification Form"-CRF4)

(IMPORTANT: Review contact information at each call)

P6. Is study participant planning to move to a different address in the next 6 months? ☐ No ☐ Yes
(If YES, please provide new address and telephone number on "Identification form" CRF4)

P7. Comments _____

CHANGES IN HEALTH STATUS SINCE LAST CALL

P8. Has there been any change in study participant's health status since the last call/visit? ☐ Yes ☐ No

P9. Was the study participant hospitalized, for any reason, since the last call/visit? ☐ Yes ☐ No

P10. Did the study participant receive a new diagnosis (for any disease) since last call/visit? ☐ Yes ☐ No

P11. Was the study participant prescribed any new medications since the last call/visit? ☐ Yes ☐ No

P12. If Yes to any of P8-P11 questions: get and document permission to obtain clinical, laboratory, treatment information, and copies of relevant X-rays from their treating physician; AND provide details in the narrative below, including:

A. Names of disease diagnosed
B. Treatment given
C. Hospitals where participant has been hospitalized
D. Treating physicians
E. Dates of hospitalization

_____

_____

_____

_____

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CURRENT SYMPTOMS

Does the study participant have any of the following symptoms TODAY?

P13. Fever/Night sweats? ☐ No ☐ Yes P14. If yes, specify_____

P15. Weight loss without dieting? ☐ No ☐ Yes P16. If yes, specify_____

P17. Cough? ☐ No ☐ Yes P18. If yes, specify_____

P19. Sputum? ☐ No ☐ Yes P20. If yes, specify_____

P21. Other? ☐ No ☐ Yes P22. If yes, specify_____

P23. Physical exam is: ☐ NOT NECESSARY ☐ NORMAL ☐ ABNORMAL

NOTE: Exam must be done if any symptoms is reported

P24. If ABNORMAL, describe : _____

FOLLOW-UP

P25. Is this the last follow-up call with this participant's?

☐ No ☐ Yes **(if YES, complete CRF-8 "End of post-treatment follow up form")**

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READ THIS TO PARTICIPANT:
"This ends our routine questions for this call about your health and any possible development of TB disease since our last call. We plan to call you again in approximately three months. Before ending, however, I would like to ask you if you would be willing to answer a few additional questions about your experience with the treatment taken during the study. The questions are about how you felt physically while taking the treatment and, if you stopped the treatment early, why you took that decision. These questions should take about five more minutes. The questions are not obligatory, and you can stop at any time, or you can choose not to answer any of the specific questions. We will only ask you these questions once. If you choose not to answer some, or all the questions, we will not ask them again on future calls. Do you have any questions or comments about this? Do you have time to answer these additional questions now?"

IF THE PARTICIPANT AGREES TO GO AHEAD, THEN CONTINUE.

INSTRUCTIONS TO INTERVIEWER
IF QUESTIONS ARE OPEN-ENDED THEN PARTICIPANTS ARE ENCOURAGED TO SAY ANYTHING. FOR THESE QUESTIONS, THE MOST LIKELY RESPONSES ARE ALREADY LISTED, SO THAT YOU CAN SIMPLY CHECK THESE OFF IF MENTIONED. BUT DO NOT READ THESE POSSIBLE RESPONSES. IF THE PARTICIPANT SAYS SOMETHING DIFFERENT, THEN WRITE IT DOWN. ALSO, READ THE PREAMBLE IN ITALICS FOR EACH SECTION.

The first questions are about your experience when you were receiving treatment during this trial. We are interested to know how you felt while taking treatment, and whether you experienced any symptoms or discomfort of any kind. Also, whether you completed the treatment and, if you decided to end the treatment early, the reason or reasons why.

Question 1 – When you took the treatment for TB prevention, did you experience any discomfort or side effects?
☐ YES ☐ NO, **go to question 4**

If YES, what symptoms or problems or discomfort did you experience? ***(Let the patient say in their own words but below are some of the more common responses. if they state these – then check off, otherwise write out under 'other':***

- ☐ Gastrointestinal (nausea, vomiting, abdominal cramps, diarrhea)
- ☐ Skin (itching, rash, dryness)
- ☐ Fatigue (low energy, tired)
- ☐ Headache
- ☐ Joint/muscle pains
- ☐ Neurological (numbness, tingling, paresthesia)
- ☐ Weight loss (poor appetite)
- ☐ Dizziness
- ☐ Other – *please write in.*

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Question 2: If you experienced any symptoms or side effects, how much did they affect your day to day living? Read the following answers (they must choose only one):

- ☐ Interfered a lot, could not function as normal.
- ☐ Interfered a little – but could perform all usual tasks and responsibilities at work/school or home
- ☐ Did not interfere with my activities and enjoyment of life at all.

Question 3: If you experienced any symptoms or side effects, how long did they last? (*If symptoms varied, give a total*)

- ☐ Less than a week
- ☐ More than a week but did not last throughout treatment.
- ☐ Lasted the entire time I took the treatment.

Question 4: Did you complete the treatment as recommended by your doctor.

☐ YES, **go to question 7** ☐ NO

If NO, who made the decision to stop treatment (*choose one*)?

- ☐ **You**
- ☐ Your nurse or doctor
- ☐ Someone else. Specify:

Question 5: If you stopped treatment early, what were the main reasons? (*Check any that apply*)

- ☐ The symptoms or side effects that I had during treatment
- ☐ Worries or concerns about possible side effects
- ☐ Inconvenience of treatment and/or inconvenience of the follow-up visits
- ☐ Advice from other people (family members, friends, other doctors or other health professionals)
- ☐ Other reasons. Please specify.

PLEASE READ THE FOLLOWING: In the study, we found that taking double the daily dose was as safe as the standard dose meaning there was no difference at all in the rate of more severe or serious side-effects.

Question 6: If you had known this information before you took the treatment, do you think it would have influenced you in taking the treatment?

☐ YES ☐ NO

PLEASE READ THE FOLLOWING: For the next phase of this study, we are thinking of an option where individuals who start the high dose treatment but develop symptoms or side-effects or discomfort that bothers them, can opt to switch after two weeks to the standard dose of treatment and continue this for another 3 ½ months for a total treatment of 4 months.

Question 7: Do you think this is a good option for treatment? ☐ YES ☐ NO

If you had this option, do you think you would choose this option? ☐ YES ☐ NO

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<u>Question 8</u>: Any other comments or thoughts about your experience in the trial?

☐ no further comments

or: (specify)

The added questions are finished. Thank you for your time.

Finally review again the plans for the next follow-up call, as you would normally do.