CRF 10 - ADVERSE EVENT FINAL EVALUATION FORM

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

AF0. Research staff completing the form _____

ADVERSE EVENT FINAL EVALUATION

AF1. Event number C C C C

AF2. Date of completion of CRF10 C C C C C C C C C
D D M M M Y Y Y Y

AF3. Was this considered an adverse event by the study team? c Yes **(go to AF5)** c No **(go to AF4, then STOP)**

AF4. **If NO**, which is the action regarding study medication? (choose one)

c Treating team does not think this was an adverse event and study medication is restarted. **(STOP HERE)**

c Treating team does not think this was an adverse event, but participant refuses to restart study medication. **(STOP HERE and competed End of treatment form-CRF6)**

AF5. **If YES** to question AF3, which is the action regarding study medication after the adverse event? **(choose one)**

c Assigned study medication restarted successfully

AF6. Date restarted C C C C C C C C C
D D M M M Y Y Y Y

c Study medication held due to pregnancy, may restart therapy after end of pregnancy

c Study medication is permanently discontinued because study participant refused further therapy **(COMPLETE End of treatment form, CRF 6)**

c Study medication is permanently discontinued, study team did not restart study drug and no alternative therapy is given **(COMPLETE End of treatment form, CRF 6)**

c Study medication is permanently discontinued, study team did not restart study drug but started alternative therapy **(COMPLETE End of treatment form CRF 6)**

AF7. The alternative treatment is _____

AF8. Alternative treatment started on date: C C C C C C C C C
D D M M M Y Y Y Y

CRF 10 - ADVERSE EVENT FINAL EVALUATION FORM

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

FINAL IMPRESSION OF TREATING TEAM

AF9. Final impression of grading severity **(see SOP)**

c Grade 1 c Grade 2 c Grade 3 c Grade 4 c Grade 5

AF10. Final impression of relationship to therapy

c Unsure c None c Unlikely c Possible c Probable

AF11. If study medication was permanently stopped, reason for stopping study medication* **(Choose one)**

c Death c Hepatotoxicity c Hematologic c Drug interaction c Gastrointestinal intolerance

c Pregnancy c Rash c Other AF12.If other, Specify_____

*** NOTE If the study medication was already completed but the AE occurred less than 30 days after completing study drugs, choose the most important reason for this adverse event.**

AF11.1 After evaluation of final adverse event report, in the opinion of site PI, this event is:

☐ Expected, (i.e. listed in protocol, and/or well-known and described adverse event with study drug)

☐ Unexpected

CRF 10 - ADVERSE EVENT FINAL EVALUATION FORM

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

DESCRIPTION OF ADVERSE EVENT

AF13. Total number of visits the study participant had between the date of first evaluation for this adverse event and the date of resolution of this adverse event: C C

AF14. Date of resolution of adverse event C C C C C C C C C
D D M M M Y Y Y Y

AF15. **Description of adverse event and resolution**

Please provide details of what happened from the onset until the complete resolution of the adverse event. Make sure that all the following points below are mentioned in the narrative (If any of the points below are not known, please write "NOT DONE" or "NOT KNOWN")

1. Date treatment started and indication.
2. Date of onset of AE including initial symptoms, and/or lab results.
3. What were the results of initial evaluation of the AE: history of other possible causes (as food, other drugs, alcohol etc.), symptoms, physical exam, lab tests, other specialists' consultations.
4. When was the study drug held
5. What happened - provide sequence of events especially hospitalization, resolution of abnormalities - symptoms or lab tests. Was a re-challenge made with the study drug? Was an alternative therapy given.

Note: Provide as much detail as possible without specifying the planned duration (4 months or 2 months) of the study medication. Use exact dates (i.e. 19-Jan-2020) as much as possible.

CRF 10 - ADVERSE EVENT FINAL EVALUATION FORM

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

----------ONLY IN PAPER CRF----------

Date Final Adverse Event Form (CRF10) was submitted to coordinating center:

C C C C C C C C C

D D M M M Y Y Y Y

_____ _____

PRINT name site Principal Investigator (PI) Signature of site PI

_____ _____

PRINT name person completing the form Signature of person completing the form