Altru HEALTH SYSTEM

Institutional Review Board/IRB-00002563

Continuing Review

Date: _____ IRB # _____

Principal Investigator: _____

Department: _____ Phone # _____

Research Coordinator: _____ Phone # _____

Project Title: _____

_____

_____

INVESTIGATOR COMPLETE:

1. Is it an Expedited Review? ……..……. ____ Yes ____ No
2. Date of Original Approval: _____
3. Date of Last Approval: (if applicable) _____
4. Is project completed? (all research done, enrollment close & patients follow-up complete) ____ Yes ____ No
   if yes, complete questions 7-13. If no, complete questions 5-13.
5. Is the research permanently closed to the enrollment of new subjects?..... ____ Yes ____ No
6. Have all participants completed all research-related interventions? ……..... ____ Yes ____ No
7. Give a brief statement of the progress of the project (i.e., number of subjects entered, length of time since study initiated, length of time projected to go on, etc.)

8. Have any subjects withdrawn or been removed from the research due to AE or safety concern? ____ Yes ____ No
   If yes, state how many have withdrawn and describe the circumstances:

9. Have there been any complaints/concerns about the research since the last IRB review?.... ____ Yes ____ No
   If yes, please report the complaints/concerns and your response/action.

10. Any unanticipated problems involving risks not detailed in your original application? ….. ____ Yes ____ No
11. Any serious adverse events (SAE) at your site since last review? …… ____ Yes ____ No
12. Any SAE, safety update, action letter, IND or other at another site since last review? ..... ____ Yes ____ No
13. Any unexpected mortality or morbidity since last review? …… ____ Yes ____ No

If yes to any of the above (7-13), please provide a detailed summary below. Need to write a more detailed summary about the adverse events, problems, etc. (i.e., the types of adverse events, numbers, trends).

*(**Example:** There were 6 adverse events during the past year, four of which occurred in patients at other sites and 2 occurred at this site. Three of the events were constipation thought to be related to the study drug; two were shortness of breath thought not to be related to the study drug; and one was a petechial rash thought to be possibly related.)*

Also, make certain adverse events/mortality reports have been submitted and are on file in the IRB office.

14. Any protocol changes, consent form changes or amendments since last review? …… ____ Yes ____ No

If yes, list and describe changes below (make certain protocol changes/amendments have been submitted and are on file in the IRB office).

15. Number of subjects enrolled since last review: _____

16. Total number of subjects enrolled since project initiated: _____

17. Have all PIs involved with the research completed the IRB Education Requirements? ..... ____ Yes ____ No

(Education requirements must be completed before the IRB can grant continued approval for the research project).

A copy of the <u>current informed consent</u> document (with, if possible, the IRB Approval dated stamp); the DSMB Report; any outside adverse event report and a copy of any local adverse event must be submitted with this report to the: IRB Office, Altru Hospital, 1200 S. Columbia Rd, Grand Forks, ND 58201. Email: mreese@altru.org.

_____ _____

Signature of Principal Investigator Date

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IRB USE ONLY:

θ Continue approval based on Expedited Review

θ Continue approval based on Full Board Review

θ Suspend approval, pending investigation

_____ _____

Signature of IRB Chairperson/Designee **Date**

θ Next Review required before _____

Form last updated 7/11/2022 *Completed by:*_____