The Institutional Review Board of The Guthrie Clinic IRB00000918 **570-887-4885** Return this form to: Lori Robinson, IRB Coordinator, Donald Guthrie Foundation

Application for Continuing Review of Research
Form version date: 2025 April

Continuing review of research is required by federal regulations at intervals appropriate to the degree of risk, but not less than once per year. **Continuation of research after expiration of IRB approval is a violation of federal regulations.**	*IRB Office Use Only:* Convened Board Review: ____ Expedited Review: _____

I. General Information

(a) **IRB Number:**
(b) **Status:**
(c) **Protocol ID:**
(d) Title of Study:
(e) Date initially approved:
(f) Principal Investigator:
(g) Departments:
(h) Coordinator(s):
(i) Person Completing this form:
(j) **National Clinical trial number:**

II. Report of Activity

If necessary, use separate sheets to explain any answers

(a) **What is the planned number of participants to be enrolled locally?**
_____ For internal studies, this will be the number stated in the IRB-approved protocol. For multi-site studies this will be an estimate, and the IRB will not consider this estimate to be an enrollment limit of the site.

(b) Provide the following cumulative numbers for the study at Guthrie:

Subjects active _____
Subjects in Follow-up _____
Withdrawals _____
Deaths _____
Screen Failures who signed consent _____
Subjects Completed _____
Sum above= Total Subjects Consented _____

(c) Since the study was last reviewed, have any research subjects withdrawn or been withdrawn from participation? If *yes*, please provide a summary of any withdrawals of subjects locally and at other sites as part of a multi-center trial since the last IRB review, and the reasons for withdrawal, if known._____ [ ]Yes [ ]No

(d) Since the study was last reviewed, have there been any amendments or modifications to the protocol, consent or investigator drug brochure (IDB) not previously reported to the IRB? If *yes*, please summarize the changes.
_____ [ ]Yes [ ]No

(e) Since the study was last reviewed, has anyone complained or expressed a concern about the research to you or to anyone associated with the research? If *yes*, please describe each occurrence and how the issue was resolved. _____ [ ]Yes [ ]No

(f) Has the study expired? If *yes*, please describe any research activity that was conducted after the expiration date and also describe actions that have been implemented to prevent this from occurring in the future. _____ [ ]Yes [ ]No

III. Risk / Benefit Analysis

(a) Since the study was last reviewed, has anything happened in the execution of the protocol that might affect the willingness of subjects to continue participating? If *yes*, explain _____ [ ]Yes [ ]No

(b) Has the profile of adverse events (*ie* , the severity, specificity and frequency) changed since the protocol was last reviewed? If *yes*, explain. _____ [ ]Yes [ ]No

(c) Have the potential or real risks to subjects participating in this protocol changed? If *yes*, please explain the change. _____ [ ]Yes [ ]No

(d) Have the potential benefits to subjects participating in this protocol changed? If *yes*, please explain the change and summarize any unexpected benefits to participants observed at the local site. _____ [ ]Yes [ ]No

(e) Have the potential benefits to others of this protocol changed? If *yes*, please explain the change. _____ [ ]Yes [ ]No

(f) Based on your assessments of the current risks and benefits, is there any change in the risk benefit ratio that would cause the potential benefits to a subject participating in this protocol to be less than the real and potential risks? If *yes*, explain why. _____ [ ]Yes [ ]No

IV. Study Personnel

(a) Have any changes occurred in the professional personnel participating in the study? If *yes* , please explain the change. _____ _____ If *yes*, does this change impair the ability to carry out the study? _____ [ ]Yes [ ]No

(b) Have the licenses, certifications or professional privileges of any personnel participating in the study been restricted or modified? If *yes*, please explain._____ [ ]Yes [ ]No

(c) Have there been <u>any</u> changes in the financial relationship between any member of the research team and the sponsor? If *yes*, please explain. _____ [ ]Yes [ ]No

V. Safety Reports and Audits

(a) Has there been a Data Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC) report or interim safety report that has not yet been submitted to the IRB? If *yes*, submit a copy of the report. If no, indicate expected date of report._____ [ ]Yes [ ]No

(b) Is there any new or relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research? If yes, please explain [ ]Yes [ ]No

(c) Have any unanticipated study-related problems involving risks to subjects or others occurred <u>locally</u> that have <u>not</u> been reported to the Guthrie IRB? If [ ]Yes [ ]No

yes, please submit reports on a separate sheet.

(d) Are there any other multi-center trial reports, such as sponsor assessment of unanticipated problems or adverse events occurring study wide not previously reported to the IRB? If *yes*, please provide. _____ [ ]Yes [ ]No

VI. Supporting Documentation

(a) Summary of amendments since last review are provided in database Follow-up Sheet

(b) Please list:

- Current protocol version: _____
- Current consent(s) version: _____
- Study drug name(s), current IDB version: _____

(c) Please Provide:

- Most recent patient signed consent: _____
- Most recent DSMB report: _____

(Note: Previously submitted forms are available in IRB database)

Attestation of Principal Investigator (or designee)*

I have reviewed this Application for Continuing Review of Research and certify that, to the best of my knowledge, the information provided is accurate.

Signature of Principal Investigator (or designee)* **Date**

_____ _____

*Note: Designee may sign only for protocols closed to enrollment and treatment.