The Guthrie Clinic Institutional Review Board
570-887-4885 Submit to the IRB Office, Donald Guthrie Foundation
Application to Amend an Approved Protocol or Consent Form OR Communication
Form date 2025 Dec 17

I. General Information

IRB Number :

Title of Study:

Date of original IRB approval:

Date of This Request:

Amendments/Communications:

Principal Investigator:

Sponsor:

Person completing this form:

Protocol Status:

Enrollment: Number of subjects enrolled in this study at Guthrie
Number of subjects on active treatment

II. Description (attach documents):

III. Risk Assessment (Amendments only – not for communications)

(a)	Is this amendment expected to change the willingness of subjects to continue?	
(b)	Does this amendment change the risk/benefit ratio of the study? Provide Sponsor's assessment (if available):	
(c)	Does this amendment increase the risks? Provide Sponsor's assessment (if available):	
(d)	Does the Sponsor require review at a Convened Meeting?	
(e)	Describe the Sponsor's requirement for re-consent including subjects (active and/or follow-up) and time frame for re-consent.	

Amendment/Communication:

Disposition (to be completed by IRB Chair or Designee)

_____ **Receipt Acknowledged** (for Communications only)

IRB approval stamp

_____ **Approved by Expedited Review *per* 45CFR46.110(b)(2); 21CFR56.110:** minor changes in previously approved research during the period for which approval is authorized.

Reviewed at a Convened Meeting:

_____**Approved**, no modifications required

_____ **Approved,** subject to minor changes to be reviewed by IRB Chair or designee

_____ **Deferred or not approved** (see letter to investigator)

For Consent Form Changes – Revised consent must be signed by future subjects.

IRB does not require reconsent.

_____ IRB requires patient notification to active subjects but no signed reconsent required.

Reconsent is required as below:

_____ IRB concurs with Sponsor requirements for reconsent. Reconsent subjects as required by the Sponsor according to Sponsor required timeframe.

_____ IRB does not concur with Sponsor reconsent requirements.

_____ IRB requires reconsent of:

_____ Currently enrolled subjects in screening and active treatment

_____ Currently enrolled subjects in follow-up

Time frame for obtaining re-consent from current subjects:

_____ Next visit or within 90 days _____ Other

Conflict of interest statement: I do not have a personal, scientific, or financial interest in this research.

_____

Signature of IRB Chair or Designee **Date** *IRB approval stamp*