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| **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 2024 June 11 |

**I.      General Information**

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| 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 | |

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| **II.      Description (attach documents):** |

1. **Risk Assessment (Amendments only – not for communications)**

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| (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. |  |

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| **Amendment/Communication:** |
| **IV. Disposition of Communication  \_\_\_\_\_\_Receipt Acknowledged (**No signature required.)  IRB acknowledgment stamp |
| **Disposition of Amendment** **(to be completed by IRB Chair or Designee)** |
| **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* |  |