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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 2021 August 04 |

**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 for Amendments only**

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| (a) | Is this amendment expected to change the willingness of subjects to continue? | No | Yes  Unknown |
| (b) | Does this amendment change the risk/benefit ratio of the study? Provide Sponsor’s assessment (if available): | No | Yes  Unknown |
| (c) | Does the Sponsor require review at a Convened Meeting? | No | Yes  Unknown |

If “Unknown” for any response, explain

If yes to a or b under Risk Assessment, then the amendment must be reviewed at a Convened Meeting, unless the Sponsor does not require review at a Convened Meeting and the IRB Chair or designee concurs with the Sponsor’s assessment

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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): minor changes in previously approved research during the period (of one year or less) for which approval is authorized. To be reported to the IRB at the next convened meeting. **If Revised, Consent must be signed by future enrollees AND (check all that apply)**       \_\_\_\_ Current enrollees in active treatment       \_\_\_\_ Current enrollees in follow-up  **Time frame for obtaining re-consent from current enrollees:** \_\_\_\_ N/A   \_\_\_\_ Next visit or within 90 days        \_\_\_\_  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **After review at a Convened Meeting, this application was:** \_\_\_\_ **Deferred** (see letter to investigator) \_\_\_\_ **Not approved** (see letter to investigator) \_\_\_\_ **Approved**, no modifications required \_\_\_\_ **Approved,** subject to minor changes to be reviewed by IRB Chair or designee **If Revised, Consent must be signed by future enrollees AND (check all that apply)**       \_\_\_\_ Current enrollees in active treatment      \_\_\_\_ Current enrollees in follow-up **Time frame for obtaining re-consent from current enrollees:** \_\_\_\_ N/A         \_\_\_\_ 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** No signature is required for receipt acknowledgement. | IRB approval stamp |