|  |
| --- |
| **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 24 August 2016  |

**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):**     |

1. **Risk Assessment for Amendments only**

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

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

|  |
| --- |
| **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  |