|  |
| --- |
| **Application for Amendment**  *\*\*please provide a description of proposed changes\*\**  Protocol Amendment  Consent Form Amendment  Both (Protocol and ICF)  Describe the proposed changes in the protocol and/or consent form below:    Addition of Sub-Investigator/Co-Investigator (If checked, see questions below related to training and/or experience)  Change in Personnel (If checked, see questions below related to training and/or experience)  Recruitment/Patient Materials  Audits/Monitoring/Reporting  Other Information Briefly explain: |

**Submission Requirements:** 10 copies are required for applications reviewed at convened meetings (Memphis IRB only). Applications that can be reviewed by an expedited procedure may be submitted electronically.

**Return this form to:**

Mildred Jenkins [Mildred.Jenkins@BMHCC.org](mailto:Mildred.Jenkins@BMHCC.org) (BMHCC IRB Memphis)

Chanta Wms-Bailey [Chanta.Williams-Bailey@BMHCC.org](mailto:Chanta.Williams-Bailey@BMHCC.org) (BMHCC IRB Memphis)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| General Information | | | | | |
| 1. Date of Amendment Submission to IRB: | | |  | | |
| 1. BMH-IRB Number: | | |  | | |
| 1. Title of Study: | | |  | | |
| 1. Principal Investigator: | | |  | | |
| 1. IDE or IND Number (if applicable): | | |  | | |
| 1. NCT Number: | | |  | | |
| 1. Sponsor (include contact info for sponsor representative): | | |  | | |
| 1. Amendment Version, Date or Identifier: | | |  | | |
| 1. Date protocol initially approved: | | |  | | |
| 1. Date of Last Continuing or Initial Review: | | |  | | |
| 1. IRB Approval End Date: | | |  | | |
| 1. Research Site: | | |  | | |
| 1. Coordinator(s): | | |  | | |
| 1. Person completing this form: | | |  | | |
| **ADDITION OF SUB-INVESTIGATOR/CO-INVESTIGATOR:**  **1.** Does the sub-investigator/co-investigator have the necessary experience to direct this research at protocol at Baptist?  Yes  No (if yes, please attach the most current documents listed below)   * Updated Curriculum Vitae * Current Medical License * Current Privileges   **2.** Does the sub-investigator/co-investigator have the necessary training to direct this research at protocol at Baptist?  Yes (If yes, complete table below)  No (If no, when will the investigator receive the appropriate training?)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | List Procedure(s) | Sponsor Training (If yes, please attach) | | | Credentialing at Facility (If yes, please attach) | | |  | | Yes | No | Yes | No | |  | | Yes | No | Yes | No | |  | | Yes | No | Yes | No |   **3.** Does the sub-investigator/co-investigator have the necessary credentials and privileges to perform this study procedure?  Yes  No (if yes, please attach)  **CHANGE IN PERSONNEL:**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Staff Name** | **Study Role** | **Degree(s)** | **Licensure** | **(CITI and FCOI) Training Completed** | **Type of Change (please describe)** | **Contact Info.** | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | | | | | |
|  | | | | |
| **II. Risk/Benefit Analysis (to be completed by Investigator)** | | | | |
|  | Is this amendment expected to change the willingness of currently enrolled subjects to continue participating? | | Yes | No |
|  | Does the proposed amendment change the risk/benefit ratio for the study?  Provide sponsor’s assessment (if available). | | Yes | No |
|  | Does the sponsor require review of the proposed amendment at a convened meeting of the IRB? | | Yes | No |

|  |  |
| --- | --- |
| **III. Disposition (to be completed by IRB Chair or Designee)** | |
|  | Approved by Expedited Review per 45 CFR 46.110(b)(2) / 21 CFR 56.110(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 IRB at next convened meeting. |
|  | If revised, the Consent Form 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, the Consent Form 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  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Print Name | |