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|  **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 (BMHCC IRB Memphis)

Chanta Wms-Bailey Chanta.Williams-Bailey@BMHCC.org (BMHCC IRB Memphis)

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| General Information |
| 1. Date of Amendment Submission to IRB:
 |       |
| 1. BMH-IRB Number:
 |       |
| 1. Title of Study:
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| 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:
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| **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?)

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| --- | --- | --- |
| 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.** |
|       |       |       |       |       |       |       |
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| **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 |

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| **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-upTime 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-upTime 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 |