|  |
| --- |
|  |
| **Request To Use External IRB** |
|  |
|  |
| **Baptist Policy S.IRB.1217 – Use of External IRB’s**Baptist may allow an external IRB to review and oversee research sponsored by another entity – either commercial or non-profit - under the following conditions:1) The IRB is registered with OHRP and the institution that sponsors it is accredited by the Association for Accreditation of Human Research Protection Programs. (The accreditation requirement may be waived if the Executive Director of Baptist Clinical Research Institute determines that the policies and procedures of the IRB are at least as rigorous as those used by Baptist.)2) An Authorization Agreement between Baptist and the external entity addresses how noncompliance, unanticipated problems involving risks to subjects or others, suspension and termination, and disclosure of financial interest are handled.3) When a decision to allow external review of a protocol involving inpatients at a Baptist hospital, the members of the IRB that would normally have reviewed the protocol will be informed via meeting agendas of decisions to allow external review.*\*\*\*Submit this form and required attachments to the Baptist Institutional Review Board Office to* Baptist.IRB@bmhcc.org *. If you have any questions, please call the IRB office at 901-226-1677 or 901-226-1678\*\*\****Investigator Information**

|  |  |
| --- | --- |
| **Date of Submission:**       |  |
| **Investigator(s)** | **Name:** | **Contact: Phone No. and Email Address** |  |
| Principal Investigator |       |       |  |
| Sub-Investigator |       |       |  |
|  Sub-Investigator |       |       |  |
|  Sub-Investigator |       |       |  |
|  Administrative Contact |       |       |  |

**Does the investigator(s) have the appropriate credentialing for the procedures on the proposed studies?**[ ] YES [ ] NO (If yes, please attach.)**Does the PI or Sub-PI have a financial conflict of interest?** [ ] **YES** [ ] **NO** (If yes, please submit the Baptist FCOI Disclosure Form)**Other Members of The Research Team:***Study Role: Include all aspects of the study protocol (i.e. study intervention/procedures, regulatory, follow-up visits, blinded staff, drug storage and dispensing, accountability etc.)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Licensure** | **Study Role** | **Degree(s):** | **Contact Info.** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

**CVs and Current Licenses of Research Personnel:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Most recent CV/Resume on file with the IRB:** | **CITI Training Expiration Date** | **FCOI Tutorial Completion Date** | **BMHCC FCOI** **Disclosure Form** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

**Study Information:**

|  |
| --- |
| Title of Study:        External IRB of Record:        |
| Protocol or Identifier No.       NCT No.       IDE/IND No. (if applicable):        |
| Sponsor       Investigator-Initiated       Other (Specify)      |
| Where will the study activities take place? *(please list all site locations, departments, and addresses)*

|  |  |  |
| --- | --- | --- |
| Site Location | Department | Address: |
|        |        |        |
|        |        |        |

Inpatient or Outpatient Study?       *Please note: If this is an Inpatient study the operational feasibility meeting should be completed prior to IRB submission.* |

**Required Attachments:*** Research Protocol
* Informed Consent Documents *(if applicable)*
* Informed Consent document must be reviewed by Legal, Bryan Griffin, Staff Attorney (Bryan.Griffin@bmhcc.org) prior to IRB submission.
* Operational Feasibility Document (*if applicable*)
* Authorization Agreement between BMHCC IRB and the External IRB of Record
 |