**APPLICATION TO CONDUCT HUMAN SUBJECTS RESEARCH**

***Required number of copies***: 10 (Memphis IRB only) copies are required for applications reviewed at convened meetings of the IRB. 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)

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| Section I. General Information |

**Date of Submission**:

**Investigator:**

**Title of Study:**

**BMH-IRB #**  **(for office use only)**

**Protocol # or Identifier #**

**IDE / IND # (if applicable)**

**NCT #**

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| --- | --- | --- | --- | --- | --- |
|  | Version | | | | |
|  | Protocol Version  Consent Version |  | | | |
|  | Study Sponsor / Investigator Initiated | | | | |
|  | Name,  Address,  Sponsor contact info |  | | | |
|  | | Good Clinical Practice *[ICH-GCP (E6)]* Are the investigator and the investigator’s employer contractually obligated to adhere to ICH-GCP (E6)? Adherence to ICH GCP (E6) requires additional determinations by the IRB and additional work by investigators. | | **Yes** | No  N/A | |
|  | | Trial registration It is required that studies *involving medical interventions* are registered.  Is this trial registered at ClinicalTrials.gov? | | **Yes**  No | Registry | |
|  | Where will the study procedure(s) be done? List all departments and address Baptist Memorial Hospital (list all sites)   |  |  |  | | --- | --- | --- | |  | Department | Address | |  | Department | Address | |  | Department | Address | |  | Department | Address |   Baptist Clinics (list all sites)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Department | Address |  |  |  | |  | Department | Address |  |  |  | |  | Department | Address |  |  |  | |  | Department | Address |  |  |  |   For any additional sites please attach a separate sheet  Non-BMHCC Site (specify)       Address  *If the study will be done at a non-Baptist institution, you must document approval by an authorized official of the institution. If the institution has an IRB, you must provide documentation that it has either approved this research or accepted the oversight of the Baptist IRB.* | | | |
|  | Has the BMHCC Operational Feasibility Meeting been completed? (hospital studies only) *Please note: The operational feasibility meeting should be completed prior to IRB submissions.*  YES. Supporting Rosters and Documentation included at the end of this application.  N/A | | | |

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| Section II. Investigators If the Principal Investigator is a resident or trainee, the Co-Investigator must have a formal affiliation with the facility where the research will be done. | | |
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| Principal Investigator | | |
| Name, Degree | |  |
| Affiliation | |  |
| E-mail | | @ |
| Phone | |  |
| Credentials(MD, RN, BSN, ETC): | |  |
| Licensure (if required): | |  |
| Updated CV on file with the IRB office: | | Yes       No       Attached |
| Training Complete: | | CITI  FCOI  Sponsorship Training (if applicable)        no |
| BMHCC Financial Disclosure Form (FCOI) | | Submitted disclosure to: research.fcoi@bmhcc.org  YES  NO |
|  | | |
| 1. Does the principal investigator have the necessary experience to direct this research protocol at Baptist?   YES  NO  (If yes, please attach most recent documents listed below)  Updated Curriculum Vitae: YES  NO  Current Medical License: YES  NO  Current Privileges: YES  NO   1. Does the principal investigator have the necessary training to direct this research protocol at Baptist?   YES  NO  (Describe how and when the investigator will obtain appropriate training  List Procedure(s): Sponsor Training: Credentialing at Facility:   |  |  |  | | --- | --- | --- | |  | YES  NO | YES  NO | |  | YES  NO | YES  NO | |  | YES  NO | YES  NO | |  | YES  NO | YES  NO | |  | YES  NO | YES  NO |   (if yes attach documentation ) (if yes attach documentation)   1. Do the Principal Investigator and Sub-Investigator(s) have the necessary credentials and privileges to perform the study procedure? YES  NO  (If yes, please attach) 2. How many active protocols are directed by the Principal Investigator? | | |
| **Administrative contact for this protocol:** | | |
| Name |  | |
| Affiliation |  | |
| E-mail |  | |
| Phone |  | |
| **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.** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | |

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| Section III. Protocol Information Indicate the pages in the protocol and Informed Consent Document (ICD) where information about each item is presented. | | | | |
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| ***Item*** | | ***Protocol Page Number*** | ***ICD***  ***Page Number*** | ***N/A*** |
|  | Objective(s) of the study |  |  |  |
|  | Background |  |  |  |
|  | Study design |  |  |  |
|  | Research setting |  |  |  |
|  | Main outcome to be measured |  |  |  |
|  | Methods or procedures |  |  |  |
|  | Description of test article |  |  |  |
|  | Data or samples to be collected |  |  |  |
|  | Inclusion criteria |  |  |  |
|  | Exclusion criteria |  |  |  |
|  | Vulnerable populations – *Special instructions – consult IRB office(e)* | | | |
|  | Pregnant Women |  |  |  |
|  | Children |  |  |  |
|  | Other |  |  |  |
|  | Length of study |  |  |  |
|  | Each subject |  |  |  |
|  | Entire study |  |  |  |
|  | Number of study sites |  |  |  |
|  | Number of subjects |  |  |  |
|  | Local |  |  |  |
|  | Entire study |  |  |  |
|  | Sample size calculation |  |  |  |
|  | Statistical analysis |  |  |  |
|  | Potential Benefits |  |  |  |
|  | Risks |  |  |  |
|  | Operational oversight (auditing; monitoring) |  |  |  |
|  | Data & safety monitoring plan |  |  |  |
|  | Premature withdrawal of subjects |  |  |  |
|  | Unblinding |  |  |  |

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| Section IV. Test Articles **Does the research involve medicines, drugs, or devices?**  **Yes. Answer the following questions**  **No. Go to Part V**. | | | | | |
| a. | Are any of the test articles considered investigational? | Yes | | No | |
| b. | Is the test article a device?Note: IRB must make an independent determination of SR/NSR status | Yes | | No | |
| c. | Control of test articles | | | | |
| Does the site where the research will be conducted have policies or standard operating procedures for control of test articles?  If Yes, please submit a copy of policies or standard operating procedures for control of test articles.  If No, how will you control the test articles? | | Yes | | **No** |
| d. | Involvement of Sponsor’s personnel | | | | |
| Will **anyone** employed by or representing the sponsor of the research be involved in administering a therapeutic agent; operating a device; collecting data; giving advice about use of the test article; or observing how a test article is used?  If Yes, please explain. | | **Yes** | | No |

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| Section V. Resources Needed for this Protocol **It is the responsibility of the Investigator to determine that any services or facilities needed to conduct the investigation will be available. The IRB may require documentation of availability before approving the research.** | | | | | | |
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|  | Externally Sponsored Research | | | | | |
| Is this research sponsored by a for-profit entity? (eg, drug or medical device manufacturer).  If **Yes**, have the contract and budget been finalized? Yes  No | Yes | | | No | |
|  | Support from BCRI or a Baptist Hospital If this is an investigator-initiated study and not supported by an external sponsor, please submit documentation that funds are available to reimburse BCRI or Baptist Hospital for services. | | | | | NA |
|  | Site Visits Has a sponsor or other external agency visited your research facility to determine whether it is adequate to conduct this protocol?  If **Yes**, who conducted the visit? | | | **Yes** | | No |
|  | Additional resources needed Does this protocol require access to equipment or other resources not normally available to the investigator?  If **Yes**, please describe what arrangements will be made to acquire the necessary resources. | | | **Yes** | | No |
|  | Additional personnel needed Does this protocol require the services of personnel not normally available to the investigator?  If **Yes**, please describe what arrangements will be made to acquire the services of the necessary personnel. | | | **Yes** | | No |
|  | Routine care Does the protocol call for medical/surgical procedures that are NOT part of routine care for treating or diagnosing a disease or condition or for restoring function? (For example, additional endoscopies, imaging studies, or blood samples.)  No. All procedures are considered routine care at the study site institution.  NA. This protocol does not involve medical/surgical procedures  **YES**. Please describe the procedures that are not routine care. | | | | | |
|  | Radiation Do any of the experimental procedures involve radiation?  If Yes, please indicate where in the protocol the use of radiation is described. | | **Yes** | | No | |
|  | Emergency Care If this study presents greater than minimal risk to research subjects, what facilities are available to respond to emergencies?  N/A. Study is minimal risk  *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons. | | | | | |

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| Section VI. Respect for Persons: Informed Consent, Privacy & Confidentiality With very few exceptions, the protocol must describe the procedure to be followed in obtaining an informed and legally effective consent to participate in the research and to use and disclose protected health information.  The investigator must insure that adequate provisions are made to protect the privacy of persons participating in the protocol as well as the confidentiality of their personal information. | | | | | | | |
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|  | Waiver/modification of requirement for informed consent Are you requesting a waiver or modification of the requirement to obtain informed consent from research subjects?  If **Yes**, explain why the waiver is necessary. | | | **Yes** | | | No |
|  | Waiver/modification of requirement to document consent Are you requesting a waiver or modification of the requirement to obtain written documentation of informed consent?  If **Yes**, explain why the waiver is necessary. | | | **Yes** | | | No |
|  | Short consent form Do you anticipate using a short form of the informed consent document? If **Yes**, then additional conditions must be met. Consult IRB office. | | | **Yes** | | | No |
|  | Language understood by subjects In the event that you have a participant that is unable to read or write, what procedures would you use to consent this participant?  Do you expect to enroll any subjects who do not understand English? If **Yes**, then the Informed Consent Document must be in the subject’s language (and submitted with this application) and a qualified interpreter must participate in the consent process.  Who translated the Informed Consent Document?  Who will translate during the consent process? | | | **Yes** | | | No |
|  | Capacity to consent | | | | | | |
|  | Do you anticipate that all adult subjects will be able to give voluntary and informed consent on their own behalf?  If **No**, please answer the following questions:  (1) Who will be approached as the legally authorized representative of the subject?  (2) Will you employ a process to obtain the assent of the research subject?  Yes. Please describe the process.  No. Please discuss why not. | | | Yes | | | **No** |
|  | Initial presentation of protocol Will the initial discussion describing the research occur in conjunction with discussion of a diagnosis or treatment plan for a subject’s disease or condition?  If Yes, how will you explain to the patient the difference between treatment and research? | | | Yes | | | No |
|  | Time frame for obtaining consent Will the initial phase of the consent process and signing the Informed Consent Document occur in a protocol-defined time interval?  If Yes, please explain the circumstances. | | | Yes | | | No |
|  | Venue for presenting consent Where will the discussion about participation and consent take place? | | | | | | |
|  | Potential Subjects’ Reading Level / Assessing Comprehension In the event that you have a participant that is unable to read or write, what procedures are in place to consent the participant? Please describe. | | | | | | |
|  | Research Participant Advocate If this protocol presents challenging ethical issues or has an unusually complicated design that might be difficult for a potential subject to understand, would it be useful to involve a Research Subject Advocate (RSA) in the consent process?  Note: The IRB may require involvement of an RSA as a condition of approval. | | | **Yes** | | | No |
|  | Medications Do you anticipate that potential participants will have been medicated with an agent that might inhibit their ability to understand the consent process?  If **Yes**, please explain the circumstances. | | | **Yes** | | | No |
|  | Respecting privacy Please explain what will be done to respect participants privacy or minimize subjects’ potential embarrassment at the following times: While participating in the research  After participating in the research | | | | | | |
|  | During the consent process; please describe the consent process and how it will be documented (in writing). | | | | | | |
|  | Safeguarding confidentiality of information Does this protocol present any unusual risks to the confidentiality of subjects’ medical information while participating or afterwards? (For example, history of drug use; genetic testing.)  If **Yes**, please explain what will be done to protect confidentiality of subjects’ information. | | **Yes** | | | | No |
|  | Additional concerns about confidentiality Will this protocol collect information about subjects that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?  If **Yes**, explain what will be done to protect confidentiality of subjects’ information. (For example, will a [certificate of confidentiality](http://grants.nih.gov/grants/policy/coc) be sought?) | | | **Yes** | | | No |
|  | Waiver of authorization Will Protected Health Information (PHI) be used and/or disclosed during screening or pre-screening under either a Waiver of Authorization or in a Review Preparatory to Research?  If **Yes**, please explain. | | | **Yes** | | | No |
|  | Data Collection and Storage Describe the Protected Health Information (PHI) to be collected and the source(s) of PHI?  Who or what institution is the custodian of this PHI?  *NOTE:* The *investigator* is responsible for ensuring the security of information collected about research subjects. | | | | | | |
|  | (1) How will data be stored? |  | | | | | |
|  | (2) Where will data be stored? |  | | | | | |
|  | (3) How long will data be stored? |  | | | | | |
|  | (4) Who, besides members of the research team listed on this application, the IRB, institutional officials, the sponsor, and regulatory agencies, will have access to the data? | | | | | | |
|  | (5) Will any protected health information (PHI) be stored on a laptop computer or a portable storage device such as a flash drive, CD, mobile phone, or PDA?  If **Yes**, please describe in detail how the information will be protected. | | | | **Yes** | No | |
|  | The *sponsor* is responsible for ensuring the security of information collected about research subjects. (If applicable, list software and/or vendor) | | | | | | |
|  | (1) How will data be stored? |  | | | | | |
|  | (2) Where will data be stored? |  | | | | | |
|  | (3) How long will data be stored? |  | | | | | |
| r. | Electronic Data Transfer Will any PHI be transferred electronically to a sponsor, non-Baptist site or other entity?  If YES, please describe the data transfer protocol.  If YES, has a data security assessment been completed? Yes  No  If NO, please complete the security assessment and return to Privacy & Security to: Barbara Anson @ [barbara.anson@bmhcc.org](mailto:barbara.anson@bmhcc.org)  Where will the review of PHI take place?  Will the data be taken beyond BMH IT firewall? 0 Yes 0 No  (If yes, please complete the Baptist Research Project Security Assessment Form)  Who will collect the PHI and who will use it?  Briefly describe what you will do with the information.  Beside the investigators listed, will the PHI be disclosed to anyone else?  (If Yes, to whom will PHI be disclosed?) | | | | Yes | No | |

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| Section VII. Recruitment of Research Participants Subject selection must be equitable: The potential risks of participation should be shared by those who might be expected to benefit from the results of the study. Care must be taken not to recruit from groups that might be especially vulnerable to coercion. | | | | | | | | | |
|  | |  | | |  | | |  | |
|  | | Source of research subjects Will research subjects be drawn from the patient population at a Baptist facility?  If Yes, subjects will be:  inpatients  outpatients   inpatients first, then followed as outpatients  other situation (describe)  If No, from where will subjects be recruited? | | | Yes | | | No | |
|  | | Baptist employees as subjects Will Baptist employees be specifically recruited to participate in this study?  If **Yes**, please discuss the rationale for recruiting subjects from this group. | | | **Yes** | | | No | |
|  | | Specific groups to be targeted for recruitment Does the problem or disease entity or condition to be studied predominantly affect a group or community that is identifiable on the basis of factors such as social and economic status, race or gender?  If **Yes**, please describe your plans for recruiting subjects from this group. | | | **Yes** | | | No | |
|  | | Conflict in recruitment Will recruitment of subjects for this protocol conflict with recruitment for any other approved protocol that you or your colleagues are pursuing?  If **Yes**, please explain how you propose to resolve the conflict. | | **Yes** | | | No | | |
|  | | Vulnerable Populations Do you anticipate recruiting subjects from the following vulnerable populations? If yes, check all applicable categories below.  No *NOTE: The age of majority means eighteen (18) years of age or older for the state of Arkansas, and Tennessee.*  *NOTE: The age of majority means eighteen (21) years of age or older for the state of Mississippi.*  *NOTE: Marking the box besides a vulnerable population indicates your understanding of how to protect that group as outlined.*   1. Children:  * Assent will be solicited from subjects age 7 years and older * Investigator will ensure that outside parties (parents/guardians) are not unduly influencing subject to participate  1. Adults with Diminished Decision-Making Capacity *(refer to protocol to see if subjects requiring Legally Authorized Representatives (LAR) are allowed)*  * Assent will be solicited from subjects with limited decision- making capacity * Investigator will ensure an LAR is used when appropriate or required by protocol * Investigator will ensure that outside parties (caregiver/LAR) are not unduly influencing subject to participate * Investigator will provide adequate opportunity for the subject to ask questions and comprehend information  1. Economically Disadvantaged  * Compensation is reasonable in order to eliminate possiblity of undue influence due to financial incentive  1. Educationally Disadvantaged  * Investigator will provide adequate opportunity for the subject to ask questions and comprehend information  1. Visually Impaired or Illiterate  * Investigator will ensure the consent document is read to the subject and that an impartial witness is present. * Investigator will provide adequate opportunity for the subject to ask questions and comprehend information  1. Limited English skills and/or Non-US Citizens  * Subject will be provided with translated documents in native language if unable to read English * Staff/independent interpreter has ability to interpret subject’s native language if unable to comprehend information * Investigator will provide adequate opportunity for the subject to ask questions and comprehend information  1. Pregnant Women  * Possible risks to mother and fetus will be clearly outlined   f | | **Yes** | | | No | | |
| 1. a | | Research participants access to medical care Will subjects be specifically recruited from a group that normally does not have access to standard medical care for the condition being studied in this protocol?  If **Yes**, please discuss the rationale for recruiting subjects from this group. | | **Yes** | | | No | | |
|  | | Genetic TestingDoes any part of the study involve genetic analysis of biological specimens? If Yes, please complete the Genetic Research Form and include it with your IRB application. | | **Yes** | | | No | | |

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| Section VIII. Financial Considerations: Research Subjects | | | | |
| 1. a | Costs to subjects for participating Will subjects be charged for any procedures, tests, costs or supplies that are for research purposes only and are not required for treatment (*eg*, data gathering and tests performed to support FDA filings which would not normally be done for patient care)?  If **Yes**, please describe. | | **Yes** | No |
|  | Out-of-pocket costs for participating Are there any additional costs to subjects that may result from participation in the protocol such as frequent travel or overnight stays? If **Yes**, please describe the additional costs and when potential subjects will be informed of them. | | **Yes** | No |
|  | Payment or reimbursement for participating Will subjects receive any payment for participating in the protocol or for reimbursement for personal expenses?  If Yes, please state how much, how the amount was determined, and the payment schedule. | | Yes | No |
|  | Research-related injury Does the proposed research involve more than minimal risk to subjects?  *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons.  If **Yes**, please answer the following questions. | **Yes** | | No |
|  | Does the contract or funding agreement indicate who will provide care for a research-related injury and who is responsible to pay for it? | Yes | | No |
|  | Is the above description of who will provide care for a research related injury and who is responsible to pay for it consistent with what is stated in the consent document? | Yes | | No |

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| Section IX. Financial Considerations: Investigators **Is the research financially sponsored by an external entity?**  **Yes. Answer the following questions**  **No. Go to Part (d) below**. | | | | | |
|  |  |  | |  | |
|  | Protocol Sponsor In general, only one of the following choices should be answered “Yes” | | | | |
| 1. Is the protocol sponsored by a commercial entity? If yes, who will be paid by the commercial entity? | Yes | | No | |
| 1. Is the protocol sponsored by a federally funded cooperative group or network? | Yes | | No | |
| 1. Is the protocol sponsored by a non-profit group or association?  (*e.g.*, American Heart Assn.) | Yes | | No | |
|  | *If any of the above questions are answered Yes, then all investigators and co/sub investigators must complete the sponsor’s financial disclosure form.* | | | | |
|  | Financial arrangements with investigator or site Is the study sponsored by a commercial entity and is the entity compensating you (the investigator(s)) or your practice for being an investigator or an investigative site?  YES. Please answer the following questions  NO. Go to Section X | | | | |
| (1) Will the compensation be determined in any way by the outcome of the study? If **Yes**, please explain the arrangement. | **Yes** | | No | |
| (2) Is compensation set at fair market value for services? If **No**, please explain how compensation will be determined? | Yes | | **No** | |
| (3) Does the rate of compensation vary according to number of subjects enrolled? If **Yes**, please explain how compensation will be determined. | **Yes** | | No | |
| (4) Does the contract between the sponsor and the institution impose a financial penalty for not enrolling a stated number of patients?  If **Yes**, please explain the penalty. | **Yes** | | No | |
|  | (5) Is payment for screen failures contingent on enrolling a certain number of participants? If **Yes**, please explain the arrangement. | **Yes** | | No | |
|  | (6) Aside from being paid to conduct this study, do you or any of the co-/sub-investigators have any financial arrangement with the sponsor (*eg*, as a consultant or member of speakers bureau)? If **Yes**, please explain the arrangement. | **Yes** | | No | |
|  | (7) Are you or any of the sub/co-investigators entitled to receive royalties for any intellectual property used in this investigaton? If **Yes**, please explain the arrangement. | **Yes** | | No | |
|  | (8) Are you or any of the sub/co-investigators owners, principals, or directors of the entity sponsoring this research? If **Yes**, please explain the arrangement. | **Yes** | | No | |
|  | Additional Information Use this space to explain any financial aspect of the sponsored research agreement that may affect human research participants and that is not covered by the preceding questions. Financial interest should be interpreted broadly to include not only investigators or co/sub- investigators but also their spouses, significant others, domestic partners, or members of their immediate families. | | | | |
|  | Answer the following questions ONLY if the research is not sponsored by an external entity | | | | |
|  | 1. Does this research involve intellectual property created, invented or owned by any of the investigators?   If **Yes**, please describe the intellectual property, the investigators’ involvement in its creation or development, and how this relationship might be disclosed to research participants.   1. Does the principal investigator or any member of the research team, or any member of their immediate families have any financial interest in the outcome of this research?   If **Yes**, please describe the intellectual property, the investigators’ involvement in its creation or development, and how this relationship might be disclosed to research participants. | | **Yes**  **Yes** | | No  No |

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| Section X. Accompanying Documents | | | | | |
|  | | | | | |
|  | Complete protocol – Date and/or Version: |  | | | |
|  | Investigator’s Brochure (if one exists), **10 copies** Details | | |  | |
|  | Pharmacy ID Initiation List |  | NA | | |
|  | BMHCC Credentials/ Privileges Documentation: |  | NA  NA | | |
| Documentation for Study Coordinators |
| Documentation for Principal and Sub-Investigators |
|  | BMHCC operational feasibility meeting supporting rosters and documentation |  | NA | | |
|  | *For FDA-regulated studies*, include copy of approval letter from FDA.  *NOTE: The IRB does not accept redacted FDA letters.* |  | NA | | |
|  | Grant Application (if one exists) |  | NA | | |
|  | Proposed Informed Consent Document(s)  How many?       Version/Date |  | NA | | |
|  | Certificate of Confidentiality |  | NA | | |
|  | Recruitment materials including advertisements intended to be seen or heard by potential subjects (provide description): |  | NA | | |
|  | Measurements and/or questionnaires material to be distributed to research subjects |  | NA | | |
|  | Educational material to be distributed to research subjects. |  | NA | | |
|  | CVs and current licenses of research personnel.   |  |  |  |  | | --- | --- | --- | --- | | Staff | CITI Training Expiration Date | FCOI Tutorial Completion Date | BMHCC FCOI Disclosure Form | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  | NA | |
|  | Letters of collaboration or cooperation (If the proposed research involves a collaboration with non-Baptist researchers or institutions) |  | NA | |
|  | Availability of institutional support or facilities (Sec V) |  | NA | |
|  | ClinicalTrials.gov Posting |  | NA | |
|  | Miscellaneous. Any other material to be submitted for consideration by IRB. |  | NA | |

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| Section XII. Affirmation of Principal Investigator | |
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| As principal investigator of the study being submitted for review, I accept responsibility for:  Conducting the proposed research as described in the application and in compliance with federal and state regulations covering human research subjects and with all determinations of the IRB regarding the proposed research.  Reporting to the IRB about the progress of the proposed research, including any changes in the protocol or informed consent or any unanticipated problems involving risks to subjects or others. | |
| **Signature of Principal Investigator** | **Date** |
| **Print Name** |  |
| **Signature of Co-Investigator (if PI is a Resident or Trainee)** | **Date** |
| **Print Name** |  |