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| **Application for Continuing Review of Research**  **Continuing review of research is required by federal regulations at intervals appropriate to the degree of risk, but not less than once per year. Continuation of research after expiration of IRB approval is a violation of federal regulations.** |

**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)

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| Date of Submission: | BMH-IRB Number: | Principal Investigator: |
| Title of Study: | | |
| IDE or IND Number (if applicable): | NCT Number: | Protocol Number: |

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| General Information | | | | | |
| 1. Date initially approved: | | | | | |
| 1. Date of last continuing review: | | | | | |
| 1. Expiration date for current approval: | | | | | |
| 1. Sponsor *(Name, address, contact information):* | | | | | |
| 1. Study site: | | | | | |
| 1. Coordinator(s): | | | | | |
| 1. Person completing this form: | | | | | |
| 1. **Report of Activity: If necessary, use separate sheets to explain any answers** | | | | | |
|  | When the protocol was initially approved, how many subjects were authorized for enrollment?       NA | | | |
|  | How many subjects have been enrolled at Baptist since the study initial review or last continuing review? | | | |
|  | Describe the type of research and provide the following cumulative numbers for the study at Baptist:  **Data Research Device Drug Tissue**    Enter the cumulative numbers for the study at Baptist:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | Total Subjects Consented | Total Subjects Completed | Subjects In Treatment | Subjects In Follow-Up only | Withdrawals | Screen Failures |   Provide an explanation for the withdrawals:  Do the withdrawals have an effect on the study risk?  Yes  No  If yes, please explain: | | | |
|  | Is this protocol being carried out at sites not under the jurisdiction of this IRB? If yes, how many subjects have been enrolled at all sites?  If unknown, please comment: | | Yes | No |
|  | Is the rate of accrual at *your site* consistent with your initial projection? (Answer NA only if the trial is in follow –up phase and not recruiting.) | | Yes  NA | No |
|  | Is the rate of accrual for *the entire study* consistent with the sponsor’s initial projection? (Answer NA only if the trial is in follow –up phase and not recruiting.)  If you answered “No” to either of the preceding questions, please explain why the accrual rate is lower than expected and what will be done to address the issue? | | Yes  NA | No |
|  | Does 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 have addressed the conflict? | | Yes | No |
|  | Since this protocol was last approved, has anything happened to change the way informed consent will be sought? Specifically: | | Yes | No |
|  | Who will provide consent?  Who will conduct the consent discussion?  What is the waiting period between informing a prospective participant and obtaining the person’s consent?  What steps will be taken to minimize the possibility of coercion or undue influence?  What is the language understood by the prospective participant or the legally authorized representative?  If you checked any of these questions, please explain what was changed. | |  |  |
|  | Since the study was last reviewed, has anything happened in the execution of the protocol that affects the conduct of this study? If *yes*, explain. (Use a separate sheet if necessary.) *A statement from the Data Safety Monitoring Board/Data Monitoring Committee or sponsor indicating that it has reviewed interim findings satisfies this requirement.* | | Yes | No |
|  | Since this protocol was last approved, has anyone complained or expressed a concern about the research to you or to anyone associated with the research? If *yes*, please describe each occurrence and how the issue was resolved. | | Yes | No |
| **III. Risk/Benefit Analysis** | | | | |
|  | | Since the study was last reviewed, has anything happened in the execution of the protocol that might affect the willingness of subjects to continue participating?  If *yes*, explain. | Yes | No |
|  | | Has the profile of adverse events (*i.e.*, the severity, specificity and frequency) changed since the protocol was last reviewed?  If *yes*, explain. (If this protocol is being conducted at other sites, you may have to obtain this information from the sponsor.) | Yes | No |
|  | | Have the risks to subjects participating in this protocol changed? If *yes*, please explain the change. | Yes | No |
|  | | Have the potential benefits to subjects participating in this protocol changed?  If *yes*, please explain the change. | Yes | No |
|  | | Have the potential benefits to others of this protocol changed?  If *yes*, please explain the change. | Yes | No |
|  | | Based on your assessments of the current risks and benefits, can you still conclude that risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result? If *no*, please explain why. | Yes | No |
| 1. **Study Personnel & Study Site** | | | | |
|  | | Have any changes occurred in the professional personnel participating in the study?  If Yes, please explain. | Yes | No |
|  | | Have the licenses, certifications or professional privileges of any personnel participating in the study been restricted or modified? If Yes**,** please explain. | Yes | No |
|  | | Have there been any changes in the financial relationship between any member of the research team and the sponsor? If Yes**,** please explain. | Yes | No |
|  | | Have there been any changes in the terms of the contract (clinical trial agreement) or the budget for this trial? (For example, has the sponsor offered a recruitment bonus?) If Yes, please explain. | Yes | No |
|  | | Have in-services been conducted with study staff, hospital staff and/or affiliated staff?(Please include roster if applicable) | Yes | N/A |
| 1. **Safety Reports & Audits** | | | | |
|  | | Since the study was last reviewed, has there been a Data Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC) report or interim safety report received?  If Yes, submit a copy of the report. If no, indicate expected date of report. | Yes | No |
|  | | Since the study was last reviewed, has anything appeared in the pertinent medical literature that might affect the willingness of subjects to continue participating?  If Yes, please explain.       A statement from the DSMB/DMC or sponsor indicating that it has reviewed the relevant literature satisfies this requirement. | Yes | No |
|  | | Have any unanticipated events involving risks to subjects or others occurred locally that have not been reported to the Baptist IRB? If *yes*, please submit reports on a separate sheet. | Yes | No |
|  | | Since the study was last reviewed, has the study been monitored or audited *locally*?  If YES, attach findings on a separate sheet. | Yes | No |
|  | | Please attach a report describing any instances of noncompliance (such as protocol deviations or protocol violations or instances of noncompliance) that occurred during the last approval period. |  | NA |

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| 1. **Study Status and Supporting Documentation**   ***Specific Instructions:***   * **If the sponsor approves** one of the required options provided in the revised ICF template, then the research site should include that option in the revised ICF and submit it to the IRB along with the continuing review application. * **If the sponsor does not agree** with the required options, then the language that the sponsor proposes should be submitted to Tanda Grisham-Williams, Esq. for review at [tanda.grisham-williams@bmhcc.org](mailto:tanda.grisham-williams@bmhcc.org). The agreed-upon language should then be added to the ICF and submitted to the Baptist IRB for approval.   ***To ensure that all ICFs are updated with the required language,  please adhere to the following guidelines:***   * All previously approved consent forms must be submitted to the BMHCC-IRB at the time of continuing review submissions. * For continuing reviews, if the study is **(a)** open to enrollment or **(b)** is closed to enrollment but currently enrolled subjects are receiving active study treatment and/or **(c)** subjects are completing follow-ups, then the ICF must be updated with the required language. | | | | |
|  | Are subjects still being enrolled? If yes, please attach the following documents:   * + Most recently approved protocol   + Most recently approved informed consent document   + Most recently signed informed consent document. \*\*Please redact subject’s name on all copies\*\*   + Items requested in (d) below. | | Yes | No |
|  | Is the study permanently closed to enrollment BUT currently enrolled subjects ARE receiving active study treatment and/or completing follow-ups?If yes, please list the current version and date of the protocol | | Yes | No |
|  | Is the study permanently closed to enrollment AND subjects ARE NOT receiving active study treatment BUT undergoing follow-up assessment only?  Yes  No  If yes, please include the following documents:  (If unsure whether these documents exist, please contact the sponsor or refer to the original protocol)   * report(s) from Data Safety Monitoring Board/Data Monitoring Committee * interim reports * multicenter trial reports * sponsor’s assessment of severity, specificity and frequency of adverse events occurring study-wide * sponsor’s assessment of adverse events and unanticipated problems occurring study-wide * For FDA-regulated research, a copy of the sponsor’s annual report to FDA * BMHCC Staff Research In-Service documentation | | | |
| (d) | |  |  |  | | --- | --- | --- | | Data Analysis only. | Yes | No | | | | |
| (e) | Attachments: Summary of Protocol (use posting at ClinicalTrials.gov if available)  Study Objective(s):       Main Outcome to Be Measured:  Study Design:       Methods or Procedures: | | | |
| 1. **Statement of Principal Investigator: I have reviewed this Application for Continuing Review of Research. To the best of my knowledge, the information provided is accurate.** | | | | |
| **Principal Investigator (please print)** | | |  | | | |
| **Signature of Principal Investigator** | | | **Date** | | | |