

This box for Research Office use only

Study ID:

Date Received:

APP NOT APP

Research Operational Review

**Clinical Trial Feasibility Worksheet**

In order to initiate a clinical research study at any Baptist Health facility, a complete and signed copy of this form must be submitted to the Baptist Health Regulatory Manager. This document contains information used to determine if your trial is eligible for activation at any Baptist facility, so it is very important that the information provided is as accurate as possible. An explanation of the necessity for each item requested can be obtained by contacting the Baptist Health Regulatory Manager (baptistresearchregulatory@bhsi.com). **Please see instructions for submission of completed worksheets on the final (signature) page of this document. Submission must include the protocol, most recent informed consent document, coverage analysis document, and the IRB submission form in order to be reviewed.**

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| **Trial Info:** |  | Protocol Title: |  |

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|  | Proposed Start: | | Length of Trial: | |  | Type of Trial: Treatment  Investigator Initiated?  Yes  No | | | | |  |  | | |
|  | **Baptist Facilities to Conduct Research/Expected Enrollment** | | | | | |  | | |  | | |
|  | Baptist Health Corbin  Baptist Health Floyd  Baptist Health Hardin  Baptist Health Lexington  Baptist Health Louisville | |  | Baptist Health Madisonville  Baptist Health Paducah  Baptist Health Richmond  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  | | |  | | |
|  | **Choose one of the following funding sources**: Choose an item.  This Study is funded, wholly or in part, by funds from a Federal Agency. | | | | | | | | | | | | | |  |
|  | If you checked the box above, please provide the grant award #: | | | | | | | | | |  | | | |
|  |  | | | | | | | | | | | | | |
|  | | Please enter the Grants.gov ID Registration Number, if applicable: | | | | | |  | | | | | |
|  | | Please enter the Clinicaltrials.gov Registration Number, if applicable: | | | | | | |  | | | | |

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| **Principal Investigator Information:** ***Name, Credentials, Department, Email, Phone*** | | | | | | | |
| Baptist Health Corbin  Baptist Health Floyd  Baptist Health Hardin  Baptist Health Lexington  Baptist Health Louisville  Baptist Health Madisonville  Baptist Health Paducah  Baptist Health Richmond  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  | | | | | | |
|  | | |  |  |  |  | | |
| **Sub-Investigator Information: *Name, Credentials, Department, Email, Phone*** | | | | | | | |
| Baptist Health Corbin  Baptist Health Floyd  Baptist Health Hardin  Baptist Health Lexington  Baptist Health Louisville  Baptist Health Madisonville  Baptist Health Paducah  Baptist Health Richmond  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  | | | | | | |
| **Primary Clinical Research Coordinator Information:** ***Name, Email, Phone*** | | | | | | | |
| Baptist Health Corbin  Baptist Health Floyd  Baptist Health Hardin  Baptist Health Lexington  Baptist Health Louisville  Baptist Health Madisonville  Baptist Health Paducah  Baptist Health Richmond  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | |  |  | |  |  |  |  |  | | --- | --- | | **Has the primary clinical research coordinator been credentialed through Baptist Health Facility?**  Yes  No | | | If yes, please list Baptist facilities: | | | | | | |
| ***Any Principal Investigators, Sub-Investigators, or Clinical Research Coordinators that have a financial relationship with the trial sponsor outside of the proposed trial must complete a financial interest disclosure worksheet.*** | | | | | |

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| **Sponsor Information**:  Sponsor Name:  Contact Name: | | |
| Address: | | |
| City/State/Zip: |  |
| Country: |  |
| Email Address: |  |

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| **Trial Design:** |  | **Briefly describe the purpose and methodology of the study:** | | | | | |
|  | | **Describe the target group of subjects for this study (age, sex, diagnosis, etc.):**  Click or tap here to enter text. | | | | | |
|  | | **Summarize the procedure(s) to be conducted with enrolled subjects:** | | | | |
|  | | **State the risks that participation in the study may pose to the subjects:**  Click or tap here to enter text. | | | | |
|  | | **State what potential benefits this study may provide subjects enrolled:**  Click or tap here to enter text. | | | | |
|  | | **Will this project require the use of any hospital resources or assistance from hospital staff outside of those needed for routine patient treatment?**  Yes  No | | | | |
|  | | If yes, please refer to the ***Operational Plan*** document provided. | | | | |
|  | | **Is the study article (device, procedure, drug) FDA approved?**  Yes, for the indication and patient population included in the protocol    Yes, for other indication, explain.   No, explain Click or tap here to enter text. | | | | |
|  | | **Will the patient be compensated for his/her involvement in the study?**  Yes  No  **Are drugs, devices, etc. being provided free of charge by the study sponsor?**  N/A  No  Yes, explain | | | | |
| Thank you for completing the Baptist Health Clinical Trail Feasibility Worksheet. By signing below, you are verifying that the information contained herein is correct to the best of your knowledge. Any changes to the information collected on these forms should be communicated to the Study Coordinator and the Baptist Health Regulatory Manager in a timely fashion (within 24 to 48 hours). If you have any questions about the content of this form, please feel free to contact the Baptist Health Regulatory Manager at 859-260-6363. **Please print and sign THIS PAGE of the Worksheet. Email a complete electronic copy to Baptistresearchregulatory@bhsi.com and send the original to Baptist Health Research; Attn: Regulatory; 1800 Nicholasville Road, Suite 401; Lexington, KY 40503.** Please retain a copy for your records. Submission of this worksheet DOES NOT constitute approval to begin research, please see approval information below. | | | | | | | | |
| FOR EXTERNAL USE ONLY: | | |  |  |  |  |
| Person completing form | | |  | Signature: Person completing form |  | Date |
|  | | |  |  |  |  |
| **Approval:**  Prior to beginning your clinical trial at a Baptist Health facility (including identifying or enrolling subjects), you must submit this document in its entirety to Baptist Health Regulatory. You will receive a copy of this page including either the signatures of the applicable senior leader assigned as research reviewer to your specialty (at minimum one Content Area Approver and the Baptist Health Associate Vice President of Research) OR an explanation for the rejection of your proposed clinical trial including actions necessary to re-submit your proposal. If your study is approved pending revisions, the necessary revisions will be outlined below the signature lines.  **In order for your proposal to be reviewed by Baptist Health Research, please include a copy of the full text of the study protocol, IRB submission form, and the IRB version of the informed consent with your submission of this worksheet.** | | | | | | | | | | |

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| **Reviewer Signature Page:** | |
| BH Corbin Reviewer Name:  BH Floyd Reviewer Name:  BH Hardin Reviewer Name:  BH Lexington Reviewer Name:  BH Louisville Reviewer Name:  BH Madisonville Reviewer Name:  BH Paducah Reviewer Name:  BH Richmond Reviewer Name:  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Rejection Explanation: | |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date |        |  |  |  | | --- | --- | --- | | Signature: Person completing form |  | Date | |