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| TCH IRB Number: | | | Date of Report: |
| The purpose of this form is to provide The Christ Hospital IRB with meaningful data for the review of your request for study continuation. This form must be completed and returned to The Christ Hospital IRB Office at 2139 Auburn Avenue, Room 3140, Cincinnati, Ohio 45219 or electronically to [IRB\_Office@thechristhospital.com](mailto:IRB_Office@thechristhospital.com). | | | |
| **A. Study Information** | | | |
| 1. Study Title: | |  | |
| 1. PI Name: | |  | |
| 1. Sub-Investigators: | |  | |
| 1. Research Staff: | |  | |
| 1. Do all Key Research Personnel (PI, Sub-I’s, Research Staff) maintain current CITI certification? | | | YES -  NO |
| 1. If a multi-centered trial, is above named PI, the lead PI of the study? | | | N/A -  YES -  NO |
| 1. Most recent version and date of the latest IRB-approved protocol: | | | Version:      , Date: |
| 1. Is the most recent version of the Informed Consent Form attached? | | | N/A -  YES -  NO |
| 1. If the study involves the use of an IDE or IND, is a protocol deviation log attached? | | | N/A -  YES -  NO |
| 1. Have there been any modifications or amendments to the IRB-approved protocol that have not been previously submitted to the IRB? | | | YES -  NO  If YES, attach a summary of the modifications or amendments, and an updated copy of the protocol. |
| **B. Study Status (check one box)** | | | |
|  | Active and Enrolling Subjects | | |
|  | Closed to Further Enrollment- Some subjects still receiving research-related interventions | | |
|  | Closed to Further Enrollment- All subjects have completed all research-related therapy/treatment/interventions, and patient interaction is limited to follow-up only | | |
|  | Enrollment on Hold | | |
|  | Study not yet Activated; Keep Open | | |
|  | Study/Review complete; Data Analysis Only | | |
|  | Follow-up Complete by the Study Site; Closure by Sponsor Pending | | |
|  | Chart Review | | |
|  | Survey | | |
|  | Humanitarian Device Exemption (HDE) | | |
|  | Registry | | |
|  | Compassionate Use | | |
| **C. Enrollment** | | | |
| 1. Is the study a retrospective chart review/survey? | | | YES -  NO  If NO, move to the next question.  If YES, complete the following and move to section D:  Number of charts/surveys reviewed:  Number of charts/surveys reviewed since last report: |
| 1. Total number of subjects enrolled: | | | Number enrolled since last report:  If multi-centered trial, number enrolled at other sites: |
| 1. Total number of subjects screened: | | | Number screened since last review:  Total number of screen failures: |
| 1. Total number of subjects actively receiving treatment: | | |  |
| 1. Total number of subjects in follow-up only: | | |  |
| 1. Target Enrollment at your site, if known: | | | If multi-centered trial, target enrollment for all centers: |
| 1. If enrollment is open and no subjects have been enrolled (prospective) or charts reviewed (retrospective), provide an explanation for the lack of research activity: | | | N/A |

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| **D. Risk/Benefit Assessment:** | |
| 1. Have there been any interim findings (either positive or negative) that should be disclosed to subjects who participated in the study? | YES -  NO  If YES, complete the following:  Provide description:  Has this been disclosed to subjects?  YES -  NO |
| 1. Describe any relevant information, including multi-center trial reports, or other finding that may affect the risks associated with this research. Describe and indicate any required modifications to the consent document, if applicable. |  |
| 1. Has the current risk-potential benefit changed based on study results? | YES -  NO  If YES, describe: |
| 1. Has there been any difficulty obtaining/retaining subjects or obtaining informed consent during the entire approval period? | YES -  NO  If YES, describe: |
| 1. Has there been any complaints about the research? | YES -  NO  If YES, describe: |
| 1. Has a state medical board or licensing agency taken disciplinary action against any investigator or staff associated with this study since the last review? | YES -  NO  If YES, describe: |
| 1. Were any subjects withdrawn from study participation for any reason since last review? | YES -  NO  If YES, complete the following:  Number of subjects who voluntarily withdrew:  Number of subjects withdrawn by the PI:  List reason for withdrawals: |
| 1. Does a Data Safety and Monitoring Board (DSMB or DMC) exist for this study? | YES -  NO  If YES, attach a copy of the latest DSMB/DMC report or indicate either:  Report previously submitted  Report not yet received; will submit when available |
| 1. Have any Reportable Events (UAPs) occurred since last review? | YES -  NO  If YES, complete the following:  Number of reportable events:  Describe the reportable events:  Have they been reported to the IRB? ☐ YES - ☐ NO |
| 1. Have there been any instances of non-compliance with the protocol or regulations since last review? | YES -  NO  If YES, complete the following:  Describe:  Have they been reported to the IRB? ☐ YES - ☐ NO |

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| **E. Financial Disclosure Update** | | | |
| Since the last review, do any of the following financial interests/arrangements apply to any key research personnel or their immediate family in relation to the study listed above: | | | |
| 1. **Relationship with Sponsor/Funding Agency**   Been an executive, director, or employee of the sponsor of this study. | | | YES -  NO |
| 1. **Remuneration from Sponsor/Funding Agency**   If Sponsor/Funding Agency is a publicly traded company- Salary or other payments for services (e.g. consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregated value received from a publicly traded entity during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds $5,000. These payments may include: consulting arrangements, payments for service on a board, advisory committee or review panel, including scientific or technical appointments, except as stated below, payments for lectures and similar public appearances, honoraria, paid authorship; OR  If Sponsor/Funding Agency is a non-publicly traded company- Salary or other payments for services, when the aggregated value received from a non-publicly traded company entity during the 12-month period preceding the disclosure exceeds $5,000. | | | YES -  NO |
| 1. **Reimbursed or Sponsored Travel**   Reimbursed or sponsored travel that is related to an investigator’s responsibilities for this study. This includes travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available. However, this disclosure does not apply to travel reimbursed or sponsored by a Federal, state or local government agency, an institution of higher education as defined at 20 U.S.C.1001(a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education. | | | YES -  NO |
| 1. **Equity Interests**   If Sponsor/Funding Agency is a non-publicly traded company, equity interests (e.g. stocks, stock options, or other ownership interests) of any value during the 12 month period preceding or as of the date of disclosure; or  If Sponsor/Funding Agency is a publicly traded company, equity interests (e.g. stocks, stock options, or other ownership interests) that exceeds $5,000 during the 12 month period preceding or as of the date of disclosure. | | | YES -  NO |
| 1. **Royalties/IP**   Income related to intellectual property rights and interests (e.g. patents, trademarks, service marks, and copyrights). | | | YES -  NO |
| 1. **Recruitment Bonuses**   Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study? | | | YES -  NO |
| 1. **Significant Payments of Other Sorts**   Any significant payments of other sorts not aforementioned including monetary values more than $5,000. These may be in forms such as a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation, or honoraria. | | | YES -  NO |
| Note: If the answer to any above question is yes, that investigator with a financial disclosure must submit and attached an updated Disclosure of Financial Interest Form | | | |
| **F. Signature and Attestations** | | | |
| By signing this form, the signatory affirms that they attest to the accuracy and completeness of the information provided herein. | | | |
| Signature: | | Date: | |
| Name: |  | | |
| Title: |  | | |