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| Upon completion of research activities, the investigator must submit a Study Closure Report to the IRB. Until notification of closure is received, TCH IRB oversight of the research will remain active, including Continuing Study Review as appropriate.  Complete this closure form when the following have been accomplished:   1. All subjects have completed all study related visits, procedures and follow-up. 2. No further access to identifiable subject data is required for research purposes (data analysis, manuscript preparations, etc.). 3. If Industry-Sponsored- The sponsor/sponsor representative has completed a close-out visit at your site.   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** | |
| TCH IRB Number: |  |
| Study Title: |  |
| Sponsor: |  |
| Principal Investigator: |  |
| Study Closure Date: |  |
| **B. Closure Details** | |
| Please indicate reason for study closure [Check any that apply]:  All research activities including data analysis and reporting are complete.  Human Subjects involvement is complete (e.g. there is no follow-up planned with subjects, data no longer contain identifiers, and there are no identifying codes to the de-identified data that can link the data to individuals).  The research is no longer funded.  The PI never initiated the study.  The research project has been open for a period of three or more years and the PI has enrolled no subjects in the study, collected no data from records, nor collected/received specimens during this interval.  The PI is leaving the institution. [Study closure at TCH may be appropriate even if the PI intends to continue the research activities at another institution.]  The Sponsor is requesting closure. Explain:  The study is being closed for another reason. Explain: | |

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| **D. Summary of Research** | |
| Total number of subjects enrolled/charts reviewed at TCH: |  |
| Have there been any reportable events or other unanticipated problems at your site that have not been previously reported to TCH IRB? | NO - YES (If yes, please attach) |
| Provide a summary of outcomes and conclusions to include a statement of the extent to which the specific aims of the protocol were addressed, and the impact of the study on the relevant scientific/medical issues under investigation.  Whenever possible, include a separate final summary or any publications with this form. |  |

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| **E. 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: |  | |

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| All study records must be retained by in a secure location by the principal investigator for **at least three (3) years** after the study closure date. For FDA-regulated and/or federally funded, supported, and conducted research, there are specific requirements that must be followed. It is the responsibility of the principal investigator to be familiarized with any applicable requirements. |

**IRB Action \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Approved  More Information Requested

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ Steve Roberts, M.D., IRB Chair. (or designee) Date