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| Protocol Information  |
| Date of Submission:       | CHOP IRB Number:       |
| **Protocol Title**:       |
| A signed, scanned copy of this form must be submitted along with the change in PI request in the eIRB system. |

By signing this form, the new Principal Investigator certifies and accepts the following obligations to protect the rights and welfare of human subjects in this study:

* I agree to personally supervise and conduct the investigation.
* All the information provided in this application represents an accurate description of the study.
* All project personnel will conduct the study in compliance with all applicable federal, state, and local laws and regulations and all applicable CHOP policies and requirements.
* No changes will be made to the protocol or consent form without prior IRB approval (except in an emergency to safeguard the well-being of subjects).
* Valid informed consent/assent will be obtained from all research subjects or their legally authorized representatives (as applicable).
* All project personnel involved in the process of consent/assent will be trained properly and will be fully aware of their responsibilities relative to obtaining consent/assent according to the CHOP IRB’s policies, state laws, and applicable federal regulations. Only the currently approved, IRB stamped consent forms or recruitment scripts will be used.
* Written/electronic reports of unanticipated problems to research subjects, including serious adverse events that are unanticipated and related, will be promptly sent to the IRB In accordance with their reporting guidelines.
* The IRB will be informed immediately of any significant negative changes in the risk/benefit relationship of the research.
* All required research records will be maintained and made available when requested for IRB or ORCRA inspection.
* The IRB will be notified promptly of any violations to the federal research regulations (45 CFR 46 / 21 CFR 50 & 56), FDA regulations (21 CFR 312 & 812 when applicable), HIPAA regulations (45 CFR 164), state and local laws, and CHOP IRB policies for the protection of human subjects.
* As required by the HIPAAA Privacy Rule, the minimum individually identifiable private information needed is being requested to achieve the goals of the research as described in this application (if applicable to the study).
* All study personnel have completed the HIPAA educational training as mandated by CHOP and have current IRB CITI certification.

If unable to direct this research personally, as when on leave or vacation, the PI will arrange for a co-investigator to accept responsibility in his/her absence. Note: If the PI is no longer an employee of CHOP or the University of Pennsylvania, or changes employment status to NTP, the PI will transition the study to another PI.

Print Name of **New** Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_Signature of New PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Failure to comply with any of the applicable regulations, laws, CHOP IRB policies, and the provisions of the IRB-approved protocol may result in suspension or termination of this research project and notification by the IRB to appropriate hospital officials, study sponsor and governmental agencies. In addition to the IRB’s actions, the CHOP Chief Scientific Officer may impose additional conditions or restrictions.

Print Name of **Current** Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_Signature of Current PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Division/Department Reviewer:**

**Does the Principal Investigator have the appropriate qualifications to conduct the study?** [ ]  Yes [ ]  No

**Are there an adequate number of potentially eligible subjects to suggest that it is feasible to conduct the study?** [ ]  Yes [ ]  No

**Does the Principal Investigator have adequate time to conduct and supervise the study?** [ ]  Yes [ ]  No

**Are there any other factors that would limit the Principal Investigator’s ability to successfully conduct the study?** [ ]  Yes [ ]  No

**Additional Comments:**

Print Name of **Division/Department Reviewer:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_Signature of Division/Department Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_