SAINT LUKE’S HOSPITAL INSTITUTIONAL REVIEW BOARD

PRINCIPAL INVESTIGATOR AGREEMENT

By signing this document, I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the Principal Investigator for this study confirms that:

1. I have adequate time and resources to conduct this study in a scientifically and ethically appropriate manner.
2. I accept responsibility for the scientific conduct of this study and for the rights and welfare of human subjects.
3. I agree to monitor the safety of the subjects under investigation and the integrity of the data.
4. I agree to provide reasonable medical care for study subjects for medical problems arising during the clinical investigation or to provide a referral.
5. I accept responsibility to ensure that all study personnel are adequately trained and qualified for their role(s).
6. I am not currently debarred by the FDA from involvement in clinical research studies, nor am I involved in any regulatory or misconduct investigation by the FDA or DHHS.
7. I will ensure that all those who are delegated tasks related to this study are capable through expertise, training, experience and credentialing to undertake those tasks.
8. I will ensure that only members of my research team for this particular study, perform tasks related to this study.
9. I will submit any amendments to the protocol or consent form to the IRB for approval prior to implementation.
10. I will report any problems with the research, in accordance with SLHS policies and procedures, as well as regulatory and sponsor requirements.
11. For FDA-regulated research involving an investigational product, I agree to control the product and maintain accurate disposition records of the product under investigation.
12. I will report any protocol deviations and/or violations from the currently approved protocol to the IRB office.
13. I will promptly report to the IRB any unanticipated problems in accordance with the SLHS policy related to reporting of unanticipated problems.
14. I agree to maintain adequate, accurate, and complete research records during the study (and to retain study records after the completion) and I recognize the authority of the IRB (and federal officials if applicable) to inspect those records.
15. I will promptly respond to all requests for information or materials solicited by the IRB office, including the timely submission of the research study for IRB renewal.
16. I will conduct the study in strict accordance with the current IRB approved protocol except where a change may be necessary to eliminate an apparent immediate hazard to a research subject.
17. I agree to obtain and document informed consent from each human subject or the subject’s legally authorized representative, unless some or all elements of informed consent or its documentation are waived by the IRB.
18. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
19. I will ensure that the conduct of the research study adheres to Good Clinical Practice guidelines and any federal requirements, as applicable.
20. I will learn the written policies and procedures of Saint Luke’s Hospital IRB and Human Research Protection Program.
21. At the request of the IRB, I will attend the IRB meeting at which my research is reviewed, and be available for questions from the IRB office.

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Principal Investigator Signature Date