**PRINCIPAL INVESTIGATOR CHANGE AGREEMENT**

**Date:**

**IRB #:**

**Study Title:**

**Previous PI Name:**

**Signature of Previous PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***As the new Principal Investigator for the research, I acknowledge the following:***

I received and reviewed a copy of the protocol, consent form, Investigator’s Brochure, if applicable, and other study documents in their entirety, and will conduct the research according to the approved protocol.

I will ensure that all research staff complies with the requirements of the protocol, and for reporting all incidences of non-compliance to Office of Research Compliance (ORC).

I further ensure:

* All research staff assisting in the conduct of the research is informed about their obligations in meeting the requirements of 21 CFR Parts 50, 56 and/or 45 CFR 46, and have the training and education to follow the requirements.
* No member of the study staff, including sub-Investigators, has an actual or perceived Conflict of Interest with the study, and if one is present that it is reported so it can be reviewed and effectively managed so to not interfere with the study progression and data.

I will ensure that research participants are kept fully informed of any new information that may affect their willingness to continue participation in the research. For responding appropriately and adequately to all inquiries, complaints, or concerns from research participants and reporting any concerns that affect the safety, rights, or welfare of the participant. Promptly report any changes to the participant population, or in the vulnerability of participants.

I will keep adequate, current, and accurate records of research data, outcomes, and unanticipated problems to permit an ongoing assessment of the risks/benefit ratio. Storing this information in a secure and confidential manner such as a password protected database, or locked filing cabinet to which direct access is controlled and/or monitored. Maintain each participant’s information in such a way as to protect the privacy of the individual and the confidentiality of the data.

**My signature below indicates that I agree to assume the responsibilities for the safe and ethical conduct of the research and to abide by the decisions and requirements of the IRB. I understand that it is my obligation to review the reporting responsibilities in the original IRB approval letter. I understand I may contact the IRB staff at any time with questions or concerns about these requirements. I understand that failure to comply with the above requirements may result in regulatory action by the ORC and/or the IRB.**

**The information provided on this document is true and accurate to the best of my knowledge.**

**Principal Investigator (type):**

**Signature of Principal Investigator:**

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**Date:**

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