eProst Protocol #: _____

Protocol Title: _____

Department: _____

Principal Investigator's Assurance Statement

I certify that the information provided in this application is complete and accurate.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to the study protocol and any stipulations imposed by the UM Institutional Review Board.

I understand that, should I use the project described in this application as a basis for a proposal for funding (either intramural or extramural), it is my responsibility to ensure that the human participants' involvement as described in the funding proposal(s), is consistent in principle, to that contained in this application. I will submit modifications and/or changes to the IRB as necessary, in the form of an amendment, to ensure these are consistent.

I agree to comply with all UM policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human participants in research, including, but not limited to:

- Ensuring all investigators, study coordinators, and key study personnel have completed the UM CITI human subjects training program;
- Ensuring the project is conducted by qualified personnel following the approved IRB application and study protocol;
- Ensuring that orientation, education and in-service sessions take place whenever non-research personnel will be contributing data or interventions to the study, e.g. floor nurses, radiology, interventional cardiology and laboratory personnel;
- Implementing no changes in the approved IRB application, study protocol, or informed consent document without prior IRB approval in accordance with UM IRB policy (except in an emergency, if necessary to safeguard the well-being of a human participant, and will report to the IRB within 10 days of such change);
- Providing non-English speaking participants with a certified translation of the IRB approved consent documents in the subject’s first language;
- Obtaining the legally effective informed consent from human participants or their legally responsible representative, using only the currently approved date-stamped informed consent documents, and providing a copy to the participant, if applicable;
- Promptly report to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or others that occur in the course of the research in accordance with UM University IRB Policies and Procedures;

- Notifying the IRB in writing of any adverse events that are unexpected, serious, and/or more severe than anticipated within ten (10) working days;
- Reporting all deaths, regardless of causality, within ten (10) working days;
- If unavailable to conduct this research personally, as when on sabbatical leave or vacation, I will arrange for another investigator to assume direct responsibility for the study. Either this person is named as another investigator in this application, or I will notify the IRB of such arrangements;
- Promptly providing the IRB with any information requested relative to the project;
- Promptly and completely complying with an IRB decision to suspend or withdraw approval for the project;
- Immediately notifying the IRB upon termination of the study or departure of the Principal Investigator from this Institution;
- Obtaining Continuing Review approval prior to the date the approval for the study expires. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all study activity must cease until IRB approval is granted;
- Maintain accurate and complete research records, including, but not limited to, all informed consent documents for a minimum of 5 years from the date of study completion;
- Maintain any authorization documents to use or disclose PHI for 6 years from the date authorization is obtained when applicable; and
- Fully informing the UM IRB of all locations in which human participants will be recruited for this project and being responsible for obtaining and maintaining current IRB approvals/letters of cooperation when applicable.

Principle Investigator's Signature _____ Date _____

By my signature, I certify that I have evaluated this research application for soundness of research design and scientific merit in accordance with departmental policy and the adequacy of facilities and resources.

Division Chief's Signature * _____ Date _____

Department Chair's Signature * _____ Date _____

If the research involves medical interventions and the P.I. is not a qualified physician, a M.D. or D.O. must be named as a medically responsible investigator to oversee the medical issues associated with the study.

☐ Not applicable

Name of Medically Responsible Investigator _____

Signature of Medically Responsible Investigator	Date