eProst Protocol #: _____

Protocol Title: _____

Department: _____

Faculty Advisor Assurance Statement

The faculty sponsor must be a member of the UM University Faculty. The faculty member is considered the responsible party for the legal and ethical performance of the project.

As sponsor on this research application, I certify that the student or guest investigator is knowledgeable about UM policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human participants in research and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to meet with the student investigator on a regular basis to monitor study progress;
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the student investigator in solving them;
- I will ensure that all investigators and key study personnel have completed the UM CITI human subjects training program;
- I will ensure that the project is performed only by qualified personnel according to the approved IRB application;
- I will ensure that the student investigator does not implement any changes to the approved IRB application 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 human participants, and will report to the IRB within 10 days of such change);
- I will ensure that the student investigator provides non-English speaking participants with a certified translation of the IRB approved consent documents in the subject's first language;
- I will ensure that the student investigator only obtains legally effective informed consent from human participants or their legally responsible representative, only the currently approved date stamped informed consent documents for human participants are used; and a copy of the informed consent is provided to the participant.
- I will ensure that the study investigator promptly reports any unanticipated problems involving risks to participants or others, or any serious adverse events (whether anticipated or not) to the IRB in accordance with UM University IRB Policies and Procedures;

- I will assume the responsibility for the accurate documentation, investigation and follow up of all possible study related adverse events and unanticipated problems involving risks to participants.
- If I will be unavailable to supervise this research personally, as when on sabbatical leave or vacation, I will arrange for an alternate Faculty Advisor to assume direct responsibility in my absence and I will advise the IRB by letter in advance of such arrangements;
- I will ensure that the student investigator promptly provides the IRB with any information requested relative to the project;
- I will ensure that the student investigator promptly and completely complies with an IRB Decision to suspend or withdraw approval for the project; and
- I will ensure that the student investigator obtains continuing review approval prior to the date approval for the study expires. Further, I understand that if the student investigator fails to apply for continuing review, approval for the study will automatically expire and I must ensure that all study activity ceases until IRB approval is obtained;
- I will ensure to immediately notify the IRB upon termination of the study or departure of the student investigator from this Institution.

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.

Faculty Sponsor'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.

Department Chair's Signature _____ Date _____