

Investigator's Statement of Assurance

I certify that the information provided in this application is complete and accurate. I understand that by submitting this application via the ERICA online system I am providing a legally valid signature, equivalent to a paper signature submission.

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 University of Utah 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 University of Utah 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 and key study personnel have completed the University of Utah IRB approved human subjects training program;
- Ensuring the project is conducted with adequate resources to protect participants including but not limited to time, equipment, space, and by qualified personnel following the approved IRB application and study protocol;
- Implementing no changes in the approved IRB application, study protocol, or informed consent document without prior IRB approval in accordance with University of Utah IRB policy (except in an emergency, if necessary to safeguard the well-being of a human participant, and will report to the IRB within 5 days of such change);
- Obtaining the legally effective informed consent from human participants or their legally responsible representative, using only the currently approved date-stamped informed consent documents prior to that participant's involvement in the research, 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 University of Utah IRB Policies and Procedures;
- 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 and completely complying with an IRB decision to place an administrative hold suspend or withdraw approval for the project;
- Obtaining Continuing Review approval prior to the date the approval for the study expires. I understand if I fail to apply for continuing review, IRB approval for the study will automatically expire, and all study activity must cease until IRB approval is granted;
- Maintaining accurate and complete research records, including, but not limited to, all informed consent documents indefinitely (if applicable);

- Maintaining any authorization documents to use or disclose PHI indefinitely from the date authorization is obtained; and
- Fully informing the University of Utah 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.