**Project Title:** Title

**CU PI:** Name.

**CU PI must sign the bottom of this document to verify that institutional requirements, regulations and policies have been/will be met. The signed attestation must be provided to the CU IRB Office before the Reliance Agreement will be finalized.**

**Local Requirements**

Local required human subject research training is complete and current for CU investigator and key personnel.

If applicable, conflict of interest in regard to this project has been disclosed to CU Compliance Office.

**Conduct of Study**

I have reviewed the proposal and will conduct the project in full compliance with the reviewing IRB’s determinations, institutional policies of Campbell University, and applicable federal and state regulations.

The protocol will be conducted as approved the reviewing IRB. Protocol deviations will be reported to the reviewing IRB per their policies and procedures. Documentation of protocol deviation will be kept in the project regulatory files, and if applicable, in the subjects project files.

Required agreements for date or sample/specimen transfer (e.g. data use agreements, material transfer agreements, etc.) will be in place prior to receiving or transferring data or samples/specimens.

The project coordinator, co-investigators and other key personnel will be added to the reviewing IRB application.

All research personnel at CU understand their role in the project and have access to the most current IRB approved project protocol and consent form, if applicable.

No subject will be enrolled into this project until the IRB approval letter from the reviewing IRB has been received.

A copy of the initial IRB approval letter will be provided by the CU PI to the CU IRB Office.

If applicable, the informed consent process will be conducted as approved by the reviewing IRB in order to ensure that potential research subjects understand the purpose of the project, the procedures they are being asked to undergo, the potential risks, benefits, and alternatives of the project, their rights as a project subject, and have sufficient time to decide about participating. Subjects will not be enrolled in the project nor will project procedures be conducted until such informed consent is obtained.

Subjects will be kept fully and promptly informed of any new information that may affect their willingness to continue to participate in the project.

Current and accurate records of data, outcomes and adverse events will be maintained to permit an on-going assessment of the risks/benefits ratio of participation. The privacy of the subjects and the confidentiality and security of the data will be maintained per institutional policy.

Reportable events will be reported to the reviewing IRB in a timely manner according to the policies of the reviewing IRB. A reasonable effort will be made to ensure that subjects who have suffered an adverse event associated with participation receive adequate care to correct or alleviate the consequences of the adverse event to extent possible.

The CU IRB Office will be contacted regarding any UPIRSO, serious and continuing non-compliance, suspension or termination that occurred at CU.

The Lead Principal Investigator for the project will be provided with information from this site regarding project progress as required for continuing review by the reviewing IRB.

Name Date

CU PI signature Date