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Non-OSU Employee Collaborator Assurance

**Oklahoma State University – Stillwater Campus**

**IRB Office**

***Instructions: Please submit this form along with a copy of the Non-OSU-Employee Collaborator’s CV showing education and research experience. A description of the Collaborator’s role and responsibility must be included in the protocol.***

**Institutional Organization: Oklahoma State University**

**Federalwide Assurance (FWA): 0000493**

**Name of OSU Principal Investigator**: [OSU Researcher]

**Non-OSU Investigator’s Name:** [Non-OSU Researcher or Non-OSU Organization]

**Specify Research Covered by this Agreement:** [IRB Number; Study Title]

1. The Non-OSU-Employee Collaborator understands and hereby accepts the responsibility to comply with the standards and requirements of the Belmont Report, the Department of Health & Human Services (HHS) regulations, and relevant OSU institutional policies and procedures for the protection of human subjects, and to protect the rights and welfare of human subjects involved in research conducted under this Assurance.
2. The Non-OSU-Employee Collaborator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this Assurance.
3. The Non-OSU-Employee Collaborator will abide by all determinations and requirements of the OSU Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the OSU IRB, including but not limited to directives to terminate participation in designated research activities.
4. The Non-OSU-Employee Collaborator will complete any educational training required by the OSU IRB prior to initiating research covered under this Assurance.
5. The Non-OSU-Employee Collaborator will report promptly to the Principal OSU Lead Investigator any proposed changes in the research conducted under this Assurance. The Non-OSU-Employee Collaborator will not initiate changes in the research without prior OSU IRB review and approval, except where necessary to eliminate apparent immediate hazards to research participants.
6. The Non-OSU-Employee Collaborator will report immediately to the Principal OSU Lead Investigator any protocol deviations and/or unanticipated problems involving risks to research participants or others in research covered under this Assurance.
7. The Non-OSU-Employee Collaborator, when responsible for enrolling research participants, will obtain, document, and maintain records of informed consent for each such participant or each participant’s legally authorized representative.
8. The Non-OSU-Employee Collaborator will provide all information requested by the Principal OSU Lead Investigator in a timely fashion.
9. The Non-OSU-Employee Collaborator will not enroll research participants in the research study under this Assurance until authorized in writing by the Principal OSU Lead Investigator.
10. The Non-OSU-Employee Collaborator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research participant, and that the research participant’s rights and welfare must take precedence over the goals and requirements of the research.
11. The Non-OSU-Employee Collaborator understands that their failure to comply with the terms of this Assurance may result in immediate termination of the collaborative project.

Non-OSU-Employee Collaborator - Signature Date

**OSU PRINCIPAL INVESTIGATOR ASSURANCE**

By my signature, I certify that the Non-OSU-Employee Collaborator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to participate as key study personnel on this study in accordance with the research protocol. Additionally,

**I agree to communicate with the Non-OSU-Employee Collaborator on a regular basis to monitor study progress.**

**I agree to promptly report protocol modifications, deviations, and/or unanticipated problems as defined by OSU IRB policy to the OSU IRB, as applicable.**

**If I will be unavailable; e.g., sabbatical leave, vacation, or resignation, I will arrange for an alternate to assume responsibility during my absence, and I will submit a modification to the OSU IRB in advance.**

**When the Non-OSU-Employee Collaborator has finished his/her human subjects research duties on this research project, I will provide all necessary documents for modifying or terminating the study to the IRB.**

OSU Principal Investigator – Signature Date