**Ancillary Individual Personnel**

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| **INSTRUCTIONS for INVESTIGATORS:** |
| 1. Complete this form to list external (non-KSU) Co-Investigators and key personnel. Use Appendix A to list KSU Co-Investigators and key personnel. 2. Do NOT begin data collection prior to receiving notification from the KSU IRB that the research (or, if applicable, the IRB Authorization Agreement or Individual Investigator agreement) has been fully approved.   **DEFINITIONS** ***Key personnel:*** *Individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.*  ***Engaged individual:*** *Those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by KSU.*  ***Financial Conflict of Interest:*** *An interest of an individual (or his/her immediate family) of monetary value that would reasonably appear to be affected by the research or an individual’s interest in any entity whose financial interests would reasonably appear to be affected by the research. Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).*  ***Non-Financial Conflict of Interest:*** *An interest other than monetary of an individual (or his/her immediate family) in the design, conduct, or reporting of the research or other interest that competes with the obligation to protect research participants and potentially compromises the objectivity and credibility of the research process.*  ***Immediate Family****: An Investigator’s or Key personnel’s spouse or domestic partner and dependent children.* |

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| **Personnel Management** | | | | |
| Describe how the PI will oversee the activities performed by external personnel. | | | | |
| Click or tap here to enter text. | | | | |
| **Ancillary Personnel Information** | | | | |
| Name (Last, First, MI): | | Click or tap here to enter text. | Title: | Click or tap here to enter text. |
| Organization: | | Click or tap here to enter text. | Degree: | Click or tap here to enter text. |
| E-mail: | | Click or tap here to enter text. | Phone: | Click or tap here to enter text. |
| 1. Have the Co-Investigator(s)/Key personnel completed the CITI online (or equivalent) training? | | | Yes **[Include copy with submission]**  No | |
| 1. Describe the role/activities performed in study (e.g., subject recruitment, informed consent): | | | | |
| Click or tap here to enter text. | | | | |
| 1. Where will the Investigator or Key Personnel perform the research activities? | | | at KSU  at external research site | |
| 1. Does external Investigator or Key personnel have a Conflict of Interest related to the research?  *Refer to definitions above.* | | | Yes  No | |
| **If yes, explain:** | Click or tap here to enter text. | | | |
| 1. Does external Investigator or Key personnel have a patent or, pending patent that could be conceivably related to this research project? | | | Yes  No | |
| **If yes, explain:** | Click or tap here to enter text. | | | |
| 1. Has/will external Investigator or Key personnel receive funds or, other resources (including equipment, devices, etc…) from a Sponsor or funding agency/entity for purposes of this research project? | | | Yes  No | |
| **If yes, explain:** | Click or tap here to enter text. | | | |
| **Investigator Attestation** | | | | |
| I agree to follow all applicable policies and procedures of Kent State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:   * The above-named Individual Investigator has reviewed:  1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects. * The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement. * The Investigator 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 agreement. * The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities. * The Investigator will perform the research as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources. * The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB. * The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement. * The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects. * The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement and will provide significant new findings that may relate to the subjects’ willingness to continue to participate. * The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or 2 national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB. * The Investigator acknowledges and agrees to cooperate in the IRB’s responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion. * The Investigator will maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants; records will be retained for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the institution. * Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.   I verify that the information provided in this form is accurate and complete.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Signature of Ancillary Personnel Date | | | | |