**Individual Investigator Agreement**

Commitment Statement of an Individual Investigator to Institutional Human Subject Protection Policies and IRB Oversight at The University of Scranton

This form is to be completed by an individual investigator taking part in human subjects’ research from an institution without its own FWA and/or IRB, including researchers from non-US institutions. The research protocol in which the investigator is participating must be primarily sponsored by a University of Scranton faculty or staff member.

**Name of Institution with the Federalwide Assurance (FWA):** The University of Scranton

**Applicable FWA #:** 00025601

**Individual Investigator’s Name:** \_\_\_\_\_\_\_\_\_\_

**Individual Investigator’s Institution**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Specify Research Covered by this Agreement:** \_\_\_\_\_\_\_\_\_\_ (IRBNet Title and ID#)

1. 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; 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); 4) the relevant institutional policies and procedures for the protection of human subjects; 5) and applicable international law, policies, and regulations.
2. 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 and as described in the University of Scranton’s IRB policy and the designated IRB protocol approval.
3. 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.
4. 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.
5. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
6. 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.
7. The Investigator will report immediately to the IRB any adverse events or unanticipated problems involving risks to subjects or others in research covered under this Agreement. If applicable, any FDA reporting or other sponsor reporting requirements must also be followed.
8. The Investigator, if and 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 national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.
9. 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.
10. The Investigator will not enroll or engage with subjects in research under this Agreement prior to its review and approval by the IRB.
11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state and international law.
12. The Investigator acknowledges that he/she is responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.

**Investigator Signature**: \_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_

Last Name: \_\_\_\_\_\_\_\_\_\_

First Name: \_\_\_\_\_\_\_\_\_\_

Middle Initial: \_\_\_\_\_\_\_\_\_\_

Degree(s): \_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_

City: \_\_\_\_\_\_\_\_\_\_

State/Province: \_\_\_\_\_\_\_\_\_\_

Zip/Country: \_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_

**FWA Institutional**: The University of Scranton

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_

Last Name: \_\_\_\_\_\_\_\_\_\_

First Name: \_\_\_\_\_\_\_\_\_\_

Middle Initial: \_\_\_\_\_\_\_\_\_\_

Institutional Title: \_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_

City: \_\_\_\_\_\_\_\_\_\_

State/Province: \_\_\_\_\_\_\_\_\_\_

Zip/Country: \_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_

Questions regarding this form, the IRB process, or the above research protocol, or concerns regarding the above protocol, should be directed to Kathryn Yerkes, Assistant Provost/IRB Administrator, at 570-941-6567, or email Kathryn.yerkes@scranton.edu .