6. Community Individual Investigator Agreement

NOTE – This is a sample of the official documentation from our University of Pittsburgh, Institutional Review Board, which is processed and signed by the IRB administrators to complete IRB approval of all participants’ who have completed the Community Partners Research Ethics Training.

Community Individual Investigator Agreement
Community Partner Research Ethics Certification

Name of Institution with the Federalwide Assurance (FWA): University of Pittsburgh
Applicable FWA #: 00006790

Individual Community Investigator’s Name: ___________________________________________

Project Principal Investigator Name and IRB Protocol Number: _________________________

Specify Research Covered by this Agreement:
______________________________________________________________________________

(1) The above-named Community Individual Investigator has participated and completed the University of Pittsburgh Community Research Ethics training. In accordance with this training, the Community 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.

(2) The Community 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.

(3) The Community 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 Community 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 Community Investigator will complete the “Community Partner Research Ethics Training and Certification” developed by the Community PARTners (Community Engagement CORE) of the University of Pittsburgh Clinical and Translational Science Institute (CTSI) and approved by the University of Pittsburgh IRB prior to initiating research covered under this Agreement.
6. Community Individual Investigator Agreement

(6) The Community 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 Community Investigator will report immediately to the listed Principal Investigator any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Community 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 national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

(9) The Community Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(10) This Agreement DOES NOT preclude the Investigator from taking part in research not covered by this Agreement.

(11) The Investigator acknowledges that he/she is primarily 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.

Community Investigator Signature: _____________________________ Date _______________
Name: ______________________________________________________ Degree(s): _____________
(________________________) (________________________) (________________________)
Address: __________________________________________________ phone #: __________________
______________________________________________________________
(________________________) (________________________) (________________________)

Principal Investigator Signature: _______________________________ Date _______________
Name: ______________________________________________________ Degree(s): _____________
(________________________) (________________________) (________________________)
Address: __________________________________________________ phone #: __________________
______________________________________________________________
(________________________) (________________________) (________________________)

FWA Institutional Official (or Designee):
Signature: ________________________________ Date ___________
Name: Randy P. Juhl, PhD.
Institutional Title: Vice Chancellor for Research Conduct and Compliance
Address: University of Pittsburgh, 132 Cathedral of Learning
4200 Fifth Avenue, Pittsburgh, PA 15260 Phone Number: 412-624-9111