Independent Investigator Agreement

V20180208

Name of Institution Providing IRB Oversight: Purdue University

Purdue University Federalwide Assurance (FWA) number: FWA00001548

Purdue University Principal Investigator (hereafter known as “PI”):

Purdue University IRB Ref.#:

Identify by name the Independent Investigators covered by this agreement, hereafter known as “Investigators”

Identify the study-specific procedures to be performed by each Independent Investigator (i.e. name/role/responsibilities)

CONFIRM by checking box: Attached are the CV and CITI training certificate for each Independent Investigators.

1. Each Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in

* *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*
* the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46
* the FWA and applicable Terms of the FWA for the institution referenced above
* the Purdue University Human Research Protection Program (HRPP) Guideline 207 *Researcher Responsibilities*

and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

1. Each 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.
2. Each Investigator will abide by all determinations of the Purdue University (PU) Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the PU IRB, including but not limited to directives to terminate participation in designated research activities.
3. Each Investigator will complete the Collaborative IRB Training Initiative (CITI) training appropriate to the Investigator’s role in the research as required by PU prior to initiating research covered under this Agreement.
4. Each Investigator will report promptly to the PI who will then report to the PU 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.
5. Each Investigator will report immediately to the PI who will report immediately to the PU IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
6. Each 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 (or other international or national equivalent) and stipulated by the PU IRB.
7. Each Investigator acknowledges and agrees to cooperate with the PI in PU 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 PI and IRB in a timely fashion.
8. Each Investigator will not enroll subjects in research under this Agreement or perform any protocol specific procedures prior to its review and approval by the PU IRB.
9. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law. However, such medical care may not be included as part of research.
10. This Agreement does not preclude any Investigator from taking part in research not covered by this Agreement.
11. Each 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.
12. This Agreement, once signed by the Purdue University FWA Signatory Official, is in effect until whichever of the following occurs first:

a) a named Investigator ceases work on the research covered by this agreement, or

b) the research covered by this agreement ends, or

c) a named Investigator begins employment at, or enrolls in a program at, an institution holding an FWA.

1. Each Investigator who also meets the definition of Investigator from Purdue’s Individual Financial Conflict of Interest Policy (i.e., a person “responsible for the design, conduct or reporting of research or project results” (see <http://www.purdue.edu/policies/ethics/iiib2.html> ) will disclose any and all Significant Financial Interests (SFIs) if those SFIs are related to protocols for research with Human Subjects reviewed by Purdue’s IRB Committees.

SFIs that need to be disclosed include ownership interests in a company/entity that may be impacted by the outcome of the research projects and/or remuneration > $5,000 received from related consulting activities; a complete definition of SFIs can be found at: http://www.purdue.edu/policies/ethics/iiib2.html#definitions. Contact fcoi@purdue.edu for additional information regarding this requirement.

**Independent Investigator Information**

Name:                   Degree(s):

(*Last*) (*First*) *(Middle Initial)*

Mailing Address:       Email:

Signature: Date:

INSERT INVESTIGATOR INFORMATION & SIGNATURE FOR EACH PERSON TO BE COVERED BY THIS AGREEMENT

**Independent Investigators’ affiliated Institution, if Investigator has an affiliated Institution:**

Name of Institution:

Signatory’s Institutional Role, providing oversight of the Investigator:

Name:

(*Last*) (*First*) *(Middle Initial)*

Mailing Address:       Email:

Signature: Date:

**Purdue Principal Investigator Information**

Name:                   Degree(s):

(*Last*) (*First*) *(Middle Initial)*

Mailing Address:       Email:

Signature: Date:

**Purdue University Department Head Information**

Department Name:

Department Head Name:                  .

(*Last)* (*First*) *(Middle Initial)*

Department Head Signature: Date

**For Purdue University (Purdue University FWA Signatory Official or Designee)**

**Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_

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