Independent Investigator Agreement

V20220818

Independent Investigator Agreements are used when Purdue University researchers collaborate with key personnel whose employer/home institution does not have an IRB.

Please see guidance [here](https://www.irb.purdue.edu/docs/400-290%20External%20Collaborator_Sites%20Flowchart.pdf) to ensure that the Independent Investigator Agreement is the correct form for your external research personnel. Upload the completed and signed form to [Cayuse IRB.](https://purdue.cayuse424.com/)

***Use this form only if non-exempt human subjects research will be conducted for a federally-funded project.***

**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 Protocol Number**

**Federal Research Sponsoring Agency (e.g. NSF, NIH):**

**Federal Research Sponsored Project Title:**

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

Identify the study-specific procedures to be performed by the Investigator. If special credentials are necessary for this activity, please include explanations and relevant training/certifications.

1. By signing below, each Investigator and PI, has reviewed, 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) Standard Operating Procedures ([www.irb.purdue.edu/sops](http://www.irb.purdue.edu/sops)) and;
* agrees 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](mailto:fcoi@purdue.edu) for additional information regarding this requirement.

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

**Independent Investigator Information**

Name:                   Degree(s):

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

Mailing Address:       Email:

Signature: Date:

**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

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| **HRPP/IRB OFFICE USE ONLY**  **This section is completed by the HRPP/IRB Office. It does not need to be signed prior to submission of an IRB protocol or amendment.**  **For Purdue University (Purdue University FWA Signatory Official or Designee)**  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_  James L. Mohler, PhD.  Associate Vice President of Scientific Integrity, Research Compliance, Research Integrity Office  Institutional Official  610 Purdue Mall  West Lafayette, IN 47907-2040  765-496-6071  OR  Ianthe Bryant-Gawthrop, MS, CIP (o/b/o Mohler)  Senior Director, Research Regulatory Affairs  610 Purdue Mall  West Lafayette, IN 47907-2040  765-494-7458 (v)  [irb@purdue.edu](mailto:irb@purdue.edu) |