# INDIANA UNIVERSITY INSTITUTIONAL REVIEW BOARD (IU IRB) Agreement to Extend FWA to Non-Affiliated Research Personnel

IU IRB Study #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of IU Principal Investigator (PI): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Non-Affiliated Research Personnel (Investigator): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Indiana University (IU) agrees to extend its Federalwide Assurance for the Protection of Human Subjects (FWA00003544) to cover Investigator for his/her participation in the above-referenced protocol.
2. PI agrees to direct and appropriately supervise research activities performed by Investigator.
3. Investigator has reviewed all of the following:
   1. [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html)
   2. [45 CFR 46](https://www.ecfr.gov/cgi-bin/text-idx?SID=ead4945ad27c7818fd53b40e35034c28&mc=true&tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl) and [21 CFR 50](https://www.ecfr.gov/cgi-bin/text-idx?SID=ead4945ad27c7818fd53b40e35034c28&mc=true&tpl=/ecfrbrowse/Title21/21cfr50_main_02.tpl) (for research subject to FDA regulations)
   3. IU Federalwide Assurance (FWA00003544)
   4. [Terms of the FWA](https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html)
   5. [IU Human Research Protection Program (HRPP) Policies](https://research.iu.edu/policies/human-subjects-irb.html)
4. Investigator agrees to:
   1. Protect the rights and welfare of human subjects involved in research conducted under this Agreement;
   2. Comply and conduct research in accordance with the standards and requirements stipulated in the documents listed in provision 3 above, the IU IRB-approved documents and conditions of approval, and all federal, state, or local laws or regulations regarding protection of human subjects;
   3. Promptly cooperate with and respond to all requests for information from the PI or IU IRB;
   4. Cooperate with the PI in conducting research under this Agreement in accordance with the IU HRPP Policies, including but not limited to:
      1. Providing information for IU IRB review, including any special considerations to be considered by the IU IRB;
      2. Completing all required training per the IU HRPP Policy on Research Personnel Responsibilities prior to conducting or participating in research covered under this Agreement;
      3. Reporting and resolving any potential conflicts of interest;
      4. If responsible for enrollment of subjects, obtaining and documenting informed consent from the subject or the subject’s legally authorized representative as required by 45 CFR 46 and the IU HRPP Policy on Informed Consent, unless waived by the IRB;
      5. Retaining research records in accordance with the IU HRPP Policy on Research Data Management; and
      6. Reporting any potential reportable events to the PI for reporting per the IU HRPP Policy on Reportable events.
5. Investigator will not:
   1. Begin research under this Agreement, including enrollment of subjects or performance of any protocol-specific procedures, prior to review and approval by the IU IRB; or
   2. Initiate changes to research under this Agreement without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
6. This Agreement does not preclude the investigator from taking part in research not covered under the Agreement.

**Signatures:**

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

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

IU Institutional Official: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_