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| **Overview** |

To ensure the safe and ethical conduct of research involving human subjects at Purdue University, all Purdue faculty, staff, and students who conduct research involving human subjects must be familiar with and understand the underlying ethical principles, federal and state laws and regulations, and policies and procedures that compose Purdue University’s Human Research Protection Program (HRPP).

Any research team member conducting research under the auspices of Purdue University must complete training. Training requirements apply regardless of the location and source of funds supporting the research.

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| **Limited Exceptions** |

Under the Purdue University – Indiana University-Purdue University at Indianapolis (IUPUI) *Human Subjects in Research Cooperative Agreement* for the cooperative review of human subject’s research, Purdue investigators in the Department of Pharmacy Practice, based at IUPUI must submit their IRB protocols for review to the IU IRBs. In doing so, the Purdue investigator must follow all requirements and procedures of the reviewing IRB.

Purdue University principal investigators and key personnel who can provide documentation of their successful completion of a formal educational program in the history, ethics, and regulation of human subjects research which is comparable in scope to accept this documentation of training in lieu of the current requirements for certification. New and/or refresher training will be required four years from the last training completion date.

Non-Purdue University research personnel who have been certified through their own institutional certification process and can provide documentation demonstrating equivalent training to the Purdue requirements, will be considered.

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| **Definitions** |

Principal Investigator- Tenured, tenure-track, research, and clinical faculty of Purdue University are eligible to be Principal Investigators (PIs) on an IRB protocol. Others requesting to submit protocols as the Principal Investigator must obtain approval from the Institutional Official or his/her designee.

Key Personnel- The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

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| **Online Training and Timing of Training Requirements** |

Principal investigators and other Key Personnel must complete the Collaborative Institutional Training Initiative (CITI) Basic Course in either the learner group for Social Behavioral Research or the learner group for Biomedical Research; whichever is most appropriate for the context of the research protocol. Training certification is valid for four (4) years. After four years, a refresher course in the appropriate topic must be taken to keep training current. The refresher course may be taken as frequently as CITI allows but no later than four (4) years after the investigator’s initial successful completion of the CITI online training. If there is a lapse in an investigator’s certification, he or she must complete the entire basic training course to become re-certified. At any time, the IRB may require cross training in the Biomedical Research or Social Behavioral Research learner group if needed.

CITI training for all Key Personnel must be completed prior to an IRB approval. With limited exception, training should be completed for the entire research team before an IRB application is submitted for review.

Principal investigators, key personnel and other research personnel are encouraged to augment CITI training by attending HRPP walk-in office hours, appointments, or on-campus offerings for supplemented training or specialized topics.

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| **Training Documentation** |

Principal Investigators are responsible for overseeing the training of all research team members. The PI must maintain records of training for research personnel and make such records available for inspection at the request of the HRPP, the IRB, research sponsor, or any study monitor.