

Research Roles and CITI Learner Groups	Version	1.0
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Overview

Purdue offers multiple Learner Group options for both the CITI Basic and Refresher Courses. Each Learner Group is tailored to a specific type of research and/or the investigators role in the research study. At a minimum, Purdue's Education Policy for Conducting Human Subjects Research requires Users to complete the Learner Group corresponding most closely with their role in the research. However, we strongly recommend all Users, regardless of their role or type of research conducted, choose to complete on of the following Learner Groups to fulfill their CITI certification requirement.

- Biomedical Research for Investigators and Key Personnel or
- Social Behavioral Research for Investigators and Key Personnel

Alternate Learner Groups are offered but should only be selected under very specific circumstances.

Research Role Definitions

Co-Investigator (Co-I) refers to a subset of key personnel who have special responsibilities on research studies. While the Principal Investigator (PI) has ultimate responsibility for the conduct of the research study, Co-Is also are obligated to ensure the study is designed and conducted in compliance with applicable laws, regulations and institutional policy governing the conduct of human subjects research. Co-Is must be qualified by training and experience to conduct his or her responsibilities on the research study. Only the following individuals may serve as co-investigators on IRB applications:

- University faculty and staff, including those with temporary Purdue appointments such as visiting professors.
- Trainees including undergraduates, graduate students, clinical and postdoctoral fellows.
- Individuals who are not Purdue faculty, trainees or staff provided they meet the other qualifications defined above.

Consultant refers to someone who provides professional or expert assistance related to a study but is not "engaged" in human subjects research. Hence a consultant neither interacts with subjects nor has access to private identifiable information (e.g., video or audio recordings, signed consent forms, data with direct identifiers, code keys, or data with indirect identifiers from which subject identities could reasonably be deduced, etc.).

Investigator is a generic term referring to any individual involved in the conduct of human subjects research regardless of his or her specific role in the research study or the type of research conducted. Investigators can be faculty members, students, staff, etc. The term

“Investigator” is an overarching term and should not be confused with the terms “Principal Investigator” or “Co-Investigator” both of which denote a specific role and level of authority in a research study. Principal investigators, co-investigators, key personnel and non-key personnel are all considered “Investigators”.

Key Personnel are members of a research team who contribute in a substantive, measurable way to the scientific or scholarly development, execution or interpretation of a research study.

Learner Group refers to a curriculum option developed to correspond with a specific type of research and/or an investigator’s specific role in the conduct of a human subjects research study. Purdue offers multiple Learner Group options by which investigators can fulfill both the CITI Basic Course and Refresher Course certification requirements.

Non-Key Personnel are research personnel who do not contribute in a substantive way to the scientific/scholarly development or execution of a study but are engaged in human subjects research and either interact with subjects or access private identifiable information. Non-key personnel do not act independently (e.g., decision-making, etc.) in the execution of a study and are always supervised by the principal investigator or key personnel.

Principal Investigator (PI) refers to the investigator who leads and directs the study and has ultimate responsibility for the integrity, design, conduct, and analysis of a research study in addition to their obligation to ensure the study is designed and conducted in compliance with applicable laws, regulations and institutional policy governing the conduct of human subjects research. PIs must be qualified by training and experience to conduct his or her responsibilities on the research study. Only permanent University employees holding a Ph.D. or equivalent research degree may serve as principal investigators on IRB applications.

Users are investigators who take Human Subjects Research training through CITI.

CITI Learner Groups

Purdue offers five (5) CITI Learner Group options from which users can choose to fulfill both the Basic Course and the Refresher Course. The Learner Groups are described below.

Biomedical Research for Investigators and Key Personnel

Completion of this Learner Group is required of all investigators and key personnel who will engage in the conduct of biomedical human subjects research. Investigators whose research involves both biomedical and social behavioral procedures should select the biomedical Learner Group unless their research is predominantly social science involving only a few minor physiological procedures, such as a study investigating effects of stress on relationships that involve the collection of saliva to track hormone levels verifying the presence of stress. When in doubt, we recommend completing the Biomedical Learner Group training.

Social Behavioral Research for Investigators and Key Personnel

Completion of this Learner Group is required of all investigators and key personnel who will engage in the conduct of social, behavioral, educational and all other non-biomedical research. As stated above, investigators whose research involves both biomedical and social behavioral procedures should select the biomedical Learner Group unless their research is predominantly social science.

Investigators and Research Personnel Conducting Exempt Research Only

Investigators whose research consistently qualifies for exemption may choose to complete this Learner Group to fulfill their CITI certification. **NOTE:** If an investigator who completes this Learner Group later becomes engaged in the conduct of non-exempt research, whether s/he serves as the PI on that study or as other key personnel, s/he will have to complete the training for either Social Behavioral Research for Investigators and Key Personnel or Biomedical Research for Investigators and Key Personnel, whichever is most appropriate for the type of research conducted. This means that investigator may have to repeat modules previously taken under the Exempt Learner Group. We cannot guarantee that any credit will transfer from one Learner Group to another. We strongly recommend investigators opt for either the Social Behavioral or Biomedical training due to this aforementioned possibility as well as these latter trainings being more comprehensive.

Non-Key Personnel

Investigators whose role in the conduct of human subjects research meets the definition of non-key personnel may choose to complete this Learner Group to fulfill their CITI certification. **NOTE:** If an investigator who completes this Learner Group later meets the definition of key personnel in a human subjects research study, s/he will have to complete the training for either Social Behavioral Research for Investigators and Key Personnel or Biomedical Research for Investigators and Key Personnel, whichever is most appropriate for the type of research conducted. This means that investigator may have to repeat modules previously taken under the Exempt Learner Group. We cannot guarantee that any credit will transfer from one Learner Group to another. We strongly recommend investigators opt for either the Social Behavioral or Biomedical training due to this aforementioned possibility as well as these latter trainings being more comprehensive.

Cooperative Extension Service (CES) Extension Educators

This Learner Groups is to be completed ONLY by Extension Educators who are employees of the Cooperative Extension Service.

Regulations and References

[Education Policy for Conducting Human Subjects Research](#)

[Collaborative Institutional Training Initiative](#)