

Series 300 Definitions | Institutional Review Board

Definitions from Series 300 of the Standard Operating Procedures

Investigator

An investigator is an individual involved in the performance of human subjects research activities who performs one or more of the following activities:

1. Obtaining information about or biospecimens from living individuals by intervening or interacting with them for research purposes
2. Obtaining identifiable biospecimens or private, identifiable information about a living individual for research purposes
3. Obtaining the voluntary informed consent of individuals participating in research
4. Studying, interpreting, analyzing, or using identifiable biospecimens or identifiable, private information for research purposes; or
5. Communicating with the IRB or other institutional review entity regarding the performance of the research project.

An investigator's primary concern must be the protection of the rights and welfare of human participants in all research activities. All investigators must be trained and listed on an active protocol prior to carrying out any of the aforementioned activities.

Principal Investigator

In addition to the definition of "investigator," above, a Principle Investigator is an individual whose training, expertise, qualifications, and role with the institution demonstrates that they are able to take full responsibility for research involving human participants. The Principal Investigator (PI) must be a benefited employee of the institution whose job functions allow them to ensure the presence of appropriate resources for the safe and effective conduct of human subjects research. They must have an oversight rule that allows them to manage the activities of others carrying out responsibilities for the research, and they must be knowledgeable about the professional and ethical codes of conduct which govern both the research and the disciplinary area in which the research is being carried out. Students may not serve as a Principal Investigator on human subjects research projects.