THE UNIVERSITY OF ARIZONA Research & Partnerships

Investigator Roles & COI Disclosures in eIRB

Background

The purpose of this guidance is to help researchers select the correct roles in eIRB and to provide information about the Conflict of Interest (COI) research certification requirement.

An **IRB Investigator** means any person **engaged** in human subject research activities including, but not limited to, employees who for the purposes of the research study obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. The University of Arizona follows the Office of Human Research Protections (OHRP) guidance on Engagement of Institutions in Research to determine engagement. Additionally, the U.S. Food & Drug Administration considers a clinical investigator to mean an individual who is directly involved in the treatment or evaluation of research subjects (21 CFR § 54.2(d)). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Sub-investigator" includes any other individual member of that team.

Employees **would not** be considered an IRB investigator if they meet **all** the following criteria:

- services performed do not merit professional recognition or publication privileges;
- services performed are typically performed for non-research purposes (a part of the employees' day to day job); and
- the employees do not administer any study intervention being tested or evaluated under the protocol.

Investigator Roles in eIRB

Principal Investigator (PI) The PI is the individual bearing ultimate responsibility for the design, conduct, reporting, and the management of human research.

Advisor is the person who oversees and monitors the conduct of student research by communicating regularly with the Principal Investigator (student researcher) and assists with the resolution of any problems or concerns encountered during the research. The Advisor also assures that the IRB is notified in the event of an adverse event or unanticipated problem.

Co-Investigator (Co-I) is responsible for the proper conduct of the human subject's research.

Responsible Physician is the person responsible for ensuring that all medical procedures that are part of the study will have a suitable physician present during the procedures (as applicable). A responsible physician is required when the study includes medical procedures that the PI is not licensed for.

Research Staff are study team members who intervene or interact with human subjects and/or access identifiable information for research purposes.

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eIRB Research Certification Requirements

All personnel **listed in eIRB** must complete a COI Research Certification in eDisclosure for **each** study they are listed on in eIRB. This requirement applies to New Projects and when adding new staff to an existing protocol. The study specific Research Certification must be completed before the study is approved by the IRB.

Personnel **not listed in eIRB** are independently responsible for ensuring that they have submitted all appropriate certifications and are in compliance with the Conflicts of Interest & Commitment Policy. Instructions for completing a Research Certification can be found on the Office for Responsible Outside Interests (OROI) webpage, eDisclosure Information. Please contact the OROI at coi@arizona.edu with questions about COI Research Certifications.

Project Funding

- For unfunded studies, COI Research Certifications are automatically generated in eIRB and are available in each Investigator's "My Inbox" tab.
- For externally funded research, a Triggering Event (TE) is created from UAccess Research (UAR) for those research personnel listed on the Institutional Proposal (IP) or Award. In cases where research personnel listed in eIRB are **not** listed on the Award or IP, a manual Research Certification will be created by OROI, as requested by Human Subjects Protection Program (HSPP) staff.
    - HSPP staff will review the eDisclosure Analytics Dashboard to determine if investigators have completed their annual COI certifications and if they have disclosed any outside interests.
    - If investigators have completed their annual COI certification and have not disclosed any outside interests, HSPP staff will proceed without any further COI review.
    - If investigators have not completed their annual COI certification or have disclosed outside interests, HSPP staff will request that OROI manually create Research Certifications for these investigators.
    - Once the Research Certification is created, those investigators will need to log into the e-Disclosure system and complete their disclosure. The Research Certifications are available in each Investigator's "My Inbox" tab.
- If a protocol has multiple awards, it is the responsibility of the IRB Principal Investigator to notify COI or SPS which personnel should be listed on which award(s) as a Conflict-of-Interest Discloser.

Non-UA Investigators/Collaborators

Collaborators and unaffiliated investigators who are listed as External Team Members in eIRB must complete the University's OROI training and the Disclosure Form for Subcontractors, Consultants, and Collaborators if their institution is not affiliated with a Federal Demonstration Partnership (FDP) Clearinghouse Organization. These collaborators will need to include the eIRB submission number and the eIRB short title in their disclosure to link with the study.