PI Eligibility for Human Subjects Research

Principal Investigator

Human subjects research activities must be overseen by a Principal Investigator (PI) who assumes responsibility for protecting the rights, well-being, and safety of human research subjects, as well as assuring compliance with all applicable regulations and requirements.

Eligibility to serve as Principal Investigator is determined in accordance with the Iowa State Provost's PI Eligibility Guidelines as administered by the Office of the Vice President for Research. **Research projects must have an eligible PI (and Supervising Investigator, when required) to remain active and under Institutional Review Board (IRB) oversight.**

Supervising Investigators

Under the Provost's guidelines, some individuals (e.g., graduate or undergraduate students, etc.) are eligible to serve as PI only with the supervision of an eligible Co-PI (i.e., a Supervising Investigator). In these instances, the Supervising Investigator must be named on IRB applications and agree in writing to supervise the project, normally through signing the IRB application.

To serve as Supervising Investigator, an individual must either

- Be a Category 1 or 2 PI, as defined in the Provost's PI Eligibility Guidelines, or
- Have a current PI waiver from the Office of the Vice President for Research that permits serving as PI on compliance protocols. Individuals with a PI waiver are automatically deemed to be a Category 1 or 2 PI and thus eligible to serve as Supervising Investigator.

Special IRB Requirements

To ensure appropriate project supervision and adherence to additional requirements associated with certain types of research, the IRB requires that an individual eligible to independently serve as PI (without a Co-PI as Supervising Investigator) MUST be named as PI on IRB applications for the following:

1. Research under an FDA Investigational Device Exemption.
2. Research under an FDA Investigational New Drug Application.
3. Research that will be registered at ClinicalTrials.gov.
4. Research that involves reliance agreements.
5. Federally-funded research, except when the individual is the PI on the federal award (e.g., a dissertation grant).
6. Data/specimen repository or recruitment registry projects.
7. Research submitted through the Exempt Review Wizard.

Importantly, this requirement is not intended to diminish student involvement in the research or the IRB process; student-researchers can still draft IRB applications, participate in the IRB review process, carry out study procedures (with appropriate supervision), etc.

Changes to PI or Supervising Investigator

Appropriate project oversight is essential in ensuring protection of research participants. Therefore, research must be supervised by an eligible PI (including a Supervising Investigator, when applicable) to remain active under IRB oversight. When a PI or Supervising Investigator is no longer eligible or is unable to supervise the project, oversight of the project must be formally transferred to an eligible PI/Supervising Investigator via an approved Amendment for Modification application.

Projects that are not transferred to an eligible PI/Supervising Investigator may be administratively closed to IRB oversight. Unless continuation is necessary to ensure the safety or well-being of participants, *all human subjects research activities must stop upon closure*.

Document History

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