

## **RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR CONDUCTING HUMAN SUBJECTS RESEARCH**

### Who is Principal Investigator (PI):

The term Principal Investigator (PI) implies specific responsibilities and interactions for conducting research.

### General Responsibilities of Principal Investigator:

The PI is responsible for assuring compliance with applicable federal, state, and local regulations, and University policies and procedures pertaining to ethical conduct of research. The PI bears ultimate responsibility for the scientific, technical, administrative, and ethical aspects of the research project, even when certain tasks have been delegated to co-investigators or research assistants.

### Responsibilities Before and During IRB Review:

- Complete the required initial investigator training in human subjects protection. The online course is provided by the Collaborative Institutional Training Initiative (CITI) at [www.citiprogram.org](http://www.citiprogram.org).
- Submit an application to Cayuse, the IRB's electronic submission and review system.
- If the application is returned with comments, address the comments and re-submit the application for review.
- Wait for IRB approval. The IRB must approve the study before it can be implemented.

### Responsibilities After IRB Review:

- Adhere to an IRB approved study plan (protocol) as well as applicable laws, regulations, and institutional policies.
- Use the IRB approved, stamped consent documents for obtaining and documenting informed consent.
- Submit an annual renewal application to the IRB for expedited and full board review studies.
- Submit an amendment to the IRB if a change to an IRB-approved study is required. The IRB must review and approve the changes before they are implemented unless the change to the study is initiated to prevent an immediate hazard to subjects.
- Submit reportable events to the IRB, as applicable. Reportable events include adverse events, unanticipated problems involving risks to subjects, protocol deviations, data safety monitoring reports, and protocol changes initiated to eliminate immediate hazard to subjects.
- Create and maintain a filing system of essential documents including, but not limited to IRB approvals, approved protocols, original signed informed consent forms, other materials required by regulatory agencies and funders/sponsors. Documents may be saved electronically as appropriate, although signed informed consents, parental permissions, child assents, and any other agreements with patients or their legally authorized representative must be saved in original format.
- Submit a final report to close out a study when it is completed or terminated.
- If the PI leaves GSU, she/he is responsible for closing the study at GSU and/or transferring it to his/her new institution.