

Principal Investigator's Responsibilities

The principal investigator (PI) bears direct responsibility for the implementation of the research and for ensuring the protection of study participants. The PI must comply with all federal regulations and institutional policies and procedures related to the conduct of research.

The PI must ensure that:

- All members of the research team comply with the findings, determinations, and requirements of the IRB;
- Research activities are conducted according to the IRB approved protocol;
- All student members of the research team are provided appropriate supervision;
- Team members listed on protocol have completed the IRB required training;
- Only approved informed consent documents are presented to the study participants; and
- Signed informed consent documents are stored and maintained according to federal, state and institutional guidelines;

The PI must immediately report to the [IRB office](#):

- Any changes to research activities, including modifications to the protocol and/or informed consent document(s), and completion or termination of the study. **Proposed changes to the protocol may not be initiated without the IRB's approval**, except under conditions where it is necessary to eliminate immediate risks to human participants;
- Adverse events, research-related injuries, and/or unexpected problems affecting the rights or safety of research participants;
- Any non-compliance with applicable regulatory requirements or determinations; and
- Any significant new information that may affect the risk/benefit ratio of the research study.