The purpose of this policy is to establish responsibilities for Principal Investigators (PI) in research.

The Principal Investigator (PI) must be knowledgeable about federal regulations and institutional policies and procedures related to the conduct of research.

The PI bears direct responsibility for the implementation of the research and for ensuring the protection of human participants in research.

The major responsibilities and adherences of the Principal Investigator (PI) are as follows:

- All research team members comply with the findings, determinations, and requirements of the IRB.
- All student members of the research team are provided appropriate supervision.
- Continuing review and approval of the research has been accomplished within the time frame stipulated by the IRB.
- Any changes in research activity, including changes to the protocol, and/or consent form(s), completion or termination of the study, are promptly reported to the IRB. No change in approved research may be initiated without the IRB’s approval except under conditions where it is necessary to eliminate apparent immediate hazards to human participants.
- No research is continued beyond the designated approval period.
- Any unanticipated problems involving risk to subjects and others, and any adverse events are reported immediately to the IRB.
- Any non-compliance with applicable regulatory requirements or determinations is reported immediately to the IRB.
- The protocol number and title of the research are cited in all correspondence to the IRB.
- Any significant new information that may affect the risk/benefit ratio is submitted promptly to the IRB.
- For every expedited / full review IRB protocol, all signed consent forms (if applicable) are maintained for at least three (3) years after completion of the study and are available for compliance review.
- Only consent/assent/parental permission forms stamped with the current approval and expiration dates may be presented to the research participants.
- Requests for information from the IRB are responded to in a timely fashion.

**POLICY TYPE:** ACADEMIC AFFAIRS