THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Principal Investigator (PI) Responsibilities

Researchers are ultimately responsible for the conduct of their research. Though research responsibility may be delegated to research staff, researchers must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility. The University of Arizona is responsible for ensuring that faculty, staff, and students are in compliance with University, sponsor, and state and federal regulations.

The PI of an approved research study is responsible for the following:
• Conduct the study in strict accordance with the current IRB-approved research protocol. Submit all changes for approval prior to implementation, except where a change may be necessary to eliminate an apparent immediate hazard to a given human subject.
• Ensure that prospectively obtained and appropriately documented informed consent is obtained in accordance with the current IRB-approved.
• Ensure, if applicable, that the project is renewed prior to the expiration of the project.
• Promptly report all reportable items and non-compliance per the 'reporting local information' guidance.
• Maintain adequate records during and after the study concludes of research data, outcomes, reportable items, and communications with the IRB and sponsor.
• Ensure that all research staff, collaborators, or colleagues assisting in the conduct of the research study have the appropriate training and credentials to conduct the research; and are appropriately informed of (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks; (iv) adverse event reporting requirements; and (v) data collection and record-keeping criteria.
• Promptly respond to all requests for information or materials solicited by the IRB and HSPP.
• Request IRB approval for any proposed amendment prior to implementing such amendment.
• Obtain initial approval and renewal of research in a timely manner to maintain IRB approval throughout the life of the study.
• Promptly conclude or transfer research activities when the PI leaves the institution or completes the study.
• Ensure that human research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
• Ensure, if applicable, that conduct of the research study adheres to Good Clinical Practice (E6) guidelines, FDA guidance on data retention, and regulations related to FDA drugs (21 CFR 312) or devices (21 CFR 812).
• Do not accept 'finder's fees' or 'bonus payments'.

The PI of the study and IRB are mutually responsible for ensuring that:
• Risks to research subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk
• Risks to human subjects are reasonable in relation to the anticipated benefits
• Selection of human subjects and patients for research participation is equitable
• Individuals and the IRB are adequately informed of the risks and benefits of research and any change that may affect their willingness to continue to participate in the research study
• Informed consent of human subjects will be obtained in advance of research participation or appropriately waived
• The privacy of human research subjects is protected and the confidentiality of data is maintained
• Appropriate additional safeguards are included in the study to protect the rights and welfare of human subjects who are likely to be vulnerable to coercion or undue influence