# Principal Investigators Are Required To:

- Protect the rights and welfare of human subjects who participate in research.
- Understand the ethical standards and regulatory requirements governing research activities with human subjects.
- Personally conduct or supervise the research.
- Ensure that all staff, collaborators, and colleagues assisting in the conduct of the study are qualified to perform the tasks assigned to them during the study. Qualifications include appropriate training, credentials, education, and expertise.
- Ensure that all staff, collaborators, and colleagues assisting in the conduct of the study are informed about the study, regulations governing research, and organizational policies.
- Ensure that there are adequate resources to carry out the project safely. These include, but are not limited to, sufficient investigator time, space, equipment, and appropriately qualified research team members.
- Ensure that all research activities have IRB approval and other approvals required by sponsors, Franklin University, and other relevant organizations or institutions before human subjects are involved.
- Implement the research activity as it was approved by the IRB.
- Obtain the informed consent of subjects and/or the permission of parent(s) or guardian(s) before they are involved in the research and document consent as approved by the IRB.
- Obtain and keep documented evidence of informed consent of the subjects (or their legally authorized representatives [LARs]).
- Maintain written records of IRB reviews and decisions.
- Obtain IRB approval for any proposed change to the research plan prior to its implementation unless necessary to eliminate apparent immediate hazards to subjects.
- Comply with IRB requirements for the timely reporting of unanticipated problems involving risks to subjects or others including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.
- Obtain continuation approval from the IRB on the schedule prescribed by the IRB.
- Complete the annual check-in requirements as per Franklin University policy.
- Make provisions for the secured retention of complete research records and all research materials.
- Ensure the confidentiality and security of all information obtained from and about human subjects.
- Verify that IRB approval has been obtained from all participating organizations in collaborative activities with other organizations.
- Notify the IRB of any relevant new information that may impact the safety/security of subjects' health or privacy.
- Close all non-exempt research upon completion by submitting a final study report to the IRB.

Adapted from CITI Program training courses.