Responsibilities of the Research Team

Modified: April 2018

Background:

When conducting human research, the UF IRB has certain expectations for the research team members, outlined below.

1. **Principal Investigator (PI)**

   The Principal Investigator has the primary responsibility for ensuring the ethical conduct of the research study. This includes protecting human subjects’ rights, safety and welfare, protocol compliance, and adherence to institutional, state and federal regulations and guidance. The PI is responsible for ensuring that all those involved with the research are sufficiently knowledgeable of the research being performed, that informed consent is appropriately obtained from each participant and for appropriately maintaining study records. The PI is also responsible for complying with the financial and administrative policies and regulations associated with the award, overall fiscal management of the project, and conflict of interest disclosure.

   The PI oversees all aspects of a clinical trial or research study from protocol design, recruitment, data collection, analysis and interpretation of results, but some tasks can be delegated to other research team members (Co-Investigators and Key Personnel). The PI is responsible for ensuring that all research team members have appropriate education, training and qualifications to assume delegated study tests. All study team members are responsible for ensuring that the conduct of the study is compliant with institutional, state, federal and industry guidance and regulations.

2. **PI Proxy**

   A PI Proxy is someone who has all the authority and responsibility for the study, when the PI is otherwise unavailable. The PI Proxy must be listed as a Co-Investigator on the protocol, and must have the credentials needed to be the PI of such a study.

3. **Co-Investigator (Co-I)**

   The Co-Investigator may perform all or some of the PI functions, but they do not accept primary responsibility for the research study. For a particular study, the co-Investigator is under the supervision of the PI and is responsible for performing study-related procedures and/or to make important study-related decisions in compliance with the ethical conduct of the study.

4. **Research Coordinator/ Research Nurse**

   The Research Coordinator/Nurse oversees and coordinates the daily activities of clinical or social/behavioral research studies. For clinical studies, they work closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. Research Coordinators/ Research Nurses generally manage participant enrollment and ensure compliance with the protocol and other applicable
regulations. This includes but is not limited to, participant recruitment, obtaining informed consent, educating participants on the details of the research study, assessing participant eligibility, facilitating participant care and follow-up per protocol, creating source documentation, assisting in the assessment of toxicities/adverse events and reporting serious adverse events per IRB and sponsor requirements.

5. **Regulatory Coordinator**

The Regulatory Coordinator is typically responsible for drafting or editing the protocol document and submitting new protocols, protocol amendments, continuing reviews and safety reports to the appropriate IRB for review. They are responsible for maintaining regulatory binders in accordance with sponsor specifications and general industry standards. They often are the keepers of the delegation of authority log for key personnel involved in the study.

6. **Data Coordinator**

The Data Coordinator is responsible for the overall data management of a research study. Data points for analysis must be extracted from multiple source documents and entered into specific databases. Data coordinators ensure accurate and timely data entry in electronic databases, electronic case report forms (eCRFs) or paper case report forms (CRF). They work closely with sponsor monitors and resolve any data queries that may be generated. They also work closely with the research team in the study development process to identify key data points for collection and analysis for investigator initiated trials.

7. **UF Student Researchers – that are not functioning as one of those identified above**

Supervision by faculty members is required for any research performed by students/trainees in any role, to ensure the proper conduct of research and protection of subject rights and welfare. See Investigator Guideline on “Student Research” for more information regarding approved roles for students in research at UF.