

Research Compliance Assistance Program

Information for Investigators

Intermediate Level of Assistance

The Research Compliance Assistance Program (RCAP) is designed to assist investigators of GCRC-supported protocols in achieving compliance with State and Federal regulations and guidance, and good research practice standards. The focus is upon assisting investigators in conducting research and documenting their compliance activities in such a way that should an investigator undergo an audit by local or national entities the investigator will be found to have been in compliance with all applicable regulations and standards. The program is structured such that assistance can range from minimal to significant depending upon the needs of the investigator and the type of protocol.

Criteria for Intermediate Assistance:

This level of assistance is aimed at protocols which have only minimal or no invasive contact with human subjects and do not meet any of the criteria of the minimal assistance level. Protocols included in this level may, for example, involve the collection and de-identified use and storage of tissue and fluid samples, or collection of questionnaire data, or accessing data collected for clinical purposes.

The Principal Investigator must provide the following to the Research Subject Advocate:

- Final COMIRB-approved version of the protocol
- Final COMIRB-approved version of the informed consent document
- Full protocol (if different from the GCRC version)
- Data and Safety Monitoring Plan
- Description of labeling conventions and linking documents
- Bioinformatics approval of data security provisions
- Master HIPAA authorization
- Additional (protocol specific requirements) _____