

Research Compliance Assistance Program

Information for Investigators

Minimal 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 Minimal Assistance:

This level of assistance is aimed at protocols that have significant oversight activities in place for the protocol. Included in this level are protocols with industry sponsors who hold INDs, or are conducting a phased clinical trial, and, have formal monitoring bodies empanelled. Also included are foundation- and NIH-funded research which have independent Data and Safety Monitoring Boards (or equivalent) for a single- or multi-site study. Also included are studies without industry, foundation, or NIH support for which the investigator has arranged for an independent DSMB for the study. This includes any protocol monitored by the Pediatric Coöperative Data and Safety Monitoring Board.

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 industry, foundation, or NIH protocol
- Data and Safety Monitoring Plan
 - May be contained in the full protocol or in a separate document
- Master HIPAA authorization
- Name of DSMB/C
- List of DSMB members
- Stopping rules
 - May be contained in the full protocol or in a separate document
- DSMB meeting schedule
- Assurance that all DSMB reports and recommendations will be provided to the RSA in a timely fashion
- Additional (protocol specific requirements) _____