

Research Compliance Assistance Program

Information for Investigators

Significant 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 Significant Assistance:

This level of assistance is aimed at protocols which have more than minimal contact with human subjects and do not meet the criteria for minimal assistance. This level will include many investigator-initiated studies. All protocols assigned to this level of assistance will be provided with protocol initiation assistance from both the Research Subject Advocate (RSA) and the Research Institute. In addition, the PI and the RSA will meet at 3 months (or at 10% of enrollment, whichever is first) to discuss the conduct of the protocol to date and determine if changes are needed. Thereafter, the RSA will conduct a yearly evaluation of the protocol timed to occur at the time of COMIRB continuing review.

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
- Bioinformatics approval of data security provisions
- Master HIPAA authorization
- Additional (protocol specific requirements) _____

Protocols Monitored by the Coöperative Pediatric Data and Safety Monitoring Board (CPDSMB)

The Coöperative Pediatric Data and Safety Monitoring Board (CPDSMB) was created in 2002, supported by a joint GCRC-TCH policy, as a system for monitoring research protocols requiring independent monitoring for any of a variety of reasons. This Coöperative is comprised of independent DSMBs each of which focuses upon research in a specialty or subspecialty of pediatrics. e.g. Pulmonary, Endocrine, Metabolic The RSA and a representative from the Research Institute at The Children's Hospital are members of all the boards. Clinician members are included according to the focus of the research

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being monitored and include UCHSC faculty both from TCH and at National Jewish Medical and Research Center.

If a protocol will be monitored by this DSMB the RSA will act as administrator for the DSMB and will create the following with the PI's assistance.

- A more-detailed (DSMB level) DSMP
- Protocol stopping rules
- DSMB meeting schedule
- DSMB charter

The RSA will provide any of the documents created to entities associated with the protocol upon request of the investigator. This could include institutes, funding or regulatory entities.

PIs of a CPDSMB monitored protocol will be expected to provide access to protocol data for review by the DSMB at specified intervals.

e.g.

- Summary data
- SAE/AE reports
- Presentation of data in the open session of the DSMB (if applicable)

DSMB Communication with the Principal Investigator

After each DSMB meeting the principal investigator will receive correspondence from the DSMB regarding the protocol. Typically, the DSMB will ask for clarification of some issues or have questions for the principal investigator after the DSMB meeting (to which a timely response is expected). Upon receipt of requested clarification and answers the DSMB will issue its recommendations to the PI. There are three recommendations that can be made: continue the protocol unchanged, continue the protocol with modifications, or halt the protocol (if stopping criteria have been met). Per COMIRB policy, any DSMB recommendation must be sent to the COMIRB.

If the DSMB determines that there are deficiencies in the conduct of the protocol that must be corrected, the DSMB will provide the investigator with a plan and deadlines for correcting the deficiencies. The RSA will work closely with the investigator to implement such plan and assist the investigator in interacting with the COMIRB or other regulatory entities in this regard.