

**Research Compliance Assistance Program
Pediatric General Clinical Research Center
(UCHSC & TCH)**

Compliance Documentation Plan

I. Rationale

The Research Compliance Assistance Program (RCAP) is designed to assist GCRC-supported investigators achieve 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.

II. The Role of the Research Subject Advocate (RSA)

NCRR guidance specifies that the GCRC Research Subject Advocate (RSA) will be responsible to facilitate compliance with applicable regulations and standards in the conduct of all research supported by a GCRC. In the Pediatric GCRC this is not interpreted to mean that the RSA has the responsibility to police regulatory or standards compliance but rather to provide the assistance, resources and expertise necessary for the investigator to achieve compliance with the applicable regulations and standards. The RSA, however, must document that protocols are compliant with the applicable regulations and standards.

III. Data and Safety Monitoring Plans

NCRR requires that all GCRC-supported protocols must include Data and Safety Monitoring Plans. This is currently being accomplished through written guidance created by the RSA and provided to investigators along with individualized assistance as needed. As of December, 2002 compliance with this requirement is 100%.

IV. Regulatory Notebooks

Beginning in June, 2003 a representative of the Research Institute has been providing assistance to GCRC-supported investigators in the creation of regulatory notebooks and source documentation as requested by the RSA. Beginning in August, 2003 this notebook will be part of the protocol initiation meeting and the three month and subsequent yearly evaluations of protocols receiving significant assistance under the RCAP (See Staged Assistance Plan).

V. Document Locator Sheets

GCRC-supported research is unique from a regulatory compliance documentation perspective. Compliance-related documents are not located in a single location but may, of necessity, be in the GCRC administrative offices, or any of the GCRC units. For this reason a compliance document locator sheet will be maintained in each of these locations to assure that any compliance document can be located quickly by all GCRC personnel. This will minimize many of the difficulties that arise during site visits and regulatory audits.