GCRC Guidelines - Archive

Guidelines for the General Clinical Research Centers Program (September 2005)

Guidelines for the General Clinical Research Centers Program (April 2005)

Division for Clinical Research Resources Program Guidelines (Draft - March 17, 2004)

Guidelines for the Clinical Research Programs - November 2001

Guidelines for the Clinical Research Programs - April 2001

- Addition to GCRC Guidelines Regarding Data Sharing Plan:

  The Final NIH Statement on Sharing Research Data (February 26, 2003) states that "Starting with the October 1, 2003 receipt date, investigators submitting an NIH application seeking $500,000 or more direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible."

  All new and competitive renewal GCRC applications, starting with the October 1, 2003 receipt date, are therefore required to include a section in the application to be entitled, "Data Sharing Plan."

  The November 2001 GCRC Guidelines, on pages *Supplement I-6* and *I-7*, give a required structure of the Table of Contents of the application. In "Part III. Resources and Environment," subparts A through L are specified ending with "L. Clinical Research Feasibility Funds." This is now amended to require an additional subpart "M. Data Sharing Plan."

  For NIH policy related to data sharing, please see: http://grants.nih.gov/grants/policy/data_sharing/.

- Modification of GCRC Guidelines Regarding Information Required With Unpresented Protocols in Competitive GCRC Applications - April 2003: The phrase "investigators' peer-reviewed funding on page *Supplement I-28* of the GCRC Guidelines is changed to "peer-reviewed funding supporting this protocol".

- Modification of GCRC Guidelines Regarding Activity in Non-accredited Facilities - April 2003 modifies the GCRC Guidelines to allow certain research activity to be conducted in non-accredited facilities.

- Modification of GCRC Guidelines Regarding Data Safety and Monitoring Plans - November 2002 modifies the GCRC Guidelines to require a data safety and monitoring plan for all GCRC protocols.

- Modifications of GCRC Guidelines Regarding Payment to Research Subjects - June 2002 modifies the GCRC Guidelines to allow payment to research subjects under specified conditions.

- Instructions for Preparing a GCRC Supplemental Application - April 2, 2002

- GCRC Modified Classification for Rare Disease Research - March 15, 2002 allows a local GCRC Advisory Committee (GAC) to classify certain rare disease protocols as Category A, rather than Category D.