

Modification of GCRC Guidelines to Require a Data and Safety Monitoring Plan for All GCRC Protocols

The *November 2001 GCRC Guidelines* state that clinical trials conducted on the GCRC must have a data and safety monitoring plan. This is now modified to state that all protocols conducted on the GCRC must have a GAC-approved data and safety monitoring plan.

Page 11 of the *November 2001 GCRC Guidelines*, in the section regarding Research Subject Advocate, currently states that:

“The RSA will be responsible for ensuring that the GAC-approved data and safety monitoring plan for Phase I, II, and III clinical trials is fully implemented, that the research carried out on the GCRC is in compliance with the IRB-approved protocol, and that serious adverse events are reported in a timely fashion to the IRB and appropriate Federal agencies.”

This section of the *GCRC Guidelines* is now modified to state:

“The RSA will be responsible for ensuring that all protocols hosted by a GCRC have a GAC-approved data and safety monitoring plan that is commensurate with the risks to human subjects. The constitution and membership of an independent data and safety monitoring board must be described for any protocol that places participants at significant risk. Research carried out on the GCRC must comply with the IRB-approved protocol, and serious adverse events must be reported in a timely fashion to the IRB, Data and Safety Monitoring Board (DSMB), Food and Drug Administration (FDA), and to the Office of Biotechnology Activities (OBA, for gene therapy), as appropriate. Serious adverse events include:

Death: Report if the patient’s death is suspected as being a direct outcome of the adverse event.

Life-threatening Injury or Illness: Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that continued participation in a protocol would result in the patient’s death.

Hospitalization: Report if admission to the hospital or a longer hospital stay results because of the adverse event.

Disability: Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient’s body function or structure, physical activities, or quality of life.

Birth Abnormality: Report if there are suspicions that participation in a protocol prior to conception or during pregnancy resulted in an adverse outcome in the child.

Medical or Surgical Intervention: Report if you suspect that participation in a protocol resulted in a condition that required medical or surgical intervention to prevent impairment or damage to a patient.”