

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

Policy No: 141

Original Date: 2/14/2002

Data and Safety Monitoring Plan

Previous Date: none

Rev. Date: 03/21/06

Purpose: To outline the components of a Data and Safety Monitoring Plan for research studies conducted on or as part of the GCRC.

Procedure:

1. Each study conducted on the GCRC will have an identified plan for monitoring subject safety and regulatory compliance prior to its implementation on the GCRC or approval by the GAC. A Data and Safety Monitoring Plan must be identified at the time of the Research application to the GCRC.
2. The Principal Investigator may meet with GCRC staff, preferably the Research Subject Advocate (RSA) to obtain assistance in plan development prior to submission of their research to the GCRC.
3. Plans may be outlined as follows, and initiated where appropriate to the protocol.
 - a. Plan 1: Minimal Risk study, not a clinical trial
 - i. The study is not a clinical trial. It does not test a drug, biologic, device or novel model of therapy.
 - ii. The principal investigator will serve as the data monitor for this study.
 - iii. The investigator will provide interim reports as required to the IRB, and the JHBMC-GCRC RSA.
 - iv. Serious adverse events will be reported to the IRB and the JHBMC-GCRC RSA according to established IRB guidelines.
 - v. Adverse events will be reported to the IRB, and JHBMC-GCRC RSA according to established IRB guidelines.
 - vi. The JHBMC-GCRC RSA will summarize serious events at regular intervals for review by the GAC. The frequency of serious adverse events will be monitored at appropriate intervals by the RSA in collaboration with the GCRC Biostatistician.
 - b. Plan 2: Minimal risk study
 - i. This may test an approved drug with a well-known adverse event profile, and include physiologic measurements that carry little risk to the participant or blood sampling.
 - ii. The principal investigator will serve as the data monitor for this study.
 - iii. The investigator will provide interim reports as required to the IRB, and the JHBMC-GCRC RSA.
 - iv. Serious adverse events will be reported to the IRB and the JHBMC-GCRC RSA according to established IRB guidelines.
 - v. Adverse events will be reported to the IRB, and JHBMC-GCRC RSA according to established IRB guidelines.
 - vi. The JHBMC-RSA RSA will summarize serious events at regular intervals for review by the GAC. The frequency of serious adverse events will be monitored at appropriate intervals by the RSA in collaboration with the GCRC Biostatistician.

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- c. Plan 3: More than minimal risk study
- i. The principal investigator may serve as the monitor if the study is appropriate (e.g. physiologic testing that includes measurements that carry more than minimal risk to participant). If the risk to the study exceeds this, an external monitor or Data Safety Monitoring Board will be appointed for the study and has no conflict of interest as defined by the JHU Conflict of Interest Committee.
 - ii. The investigator will provide interim reports as required to the IRB, and the JHBMC-GCRC RSA.
 - iii. Serious adverse events will be reported to the IRB and the JHBMC-GCRC RSA according to established IRB guidelines.
 - iv. Adverse events will be reported to the IRB, sponsor, the JHBMC-GCRC RSA, and the FDA (if indicated) according to established IRB guidelines.
 - v. The Principal Investigator will provide the monitor (or Data Safety Monitoring Board) and the JHBMC-GCRC RSA a tabulation of the number of subjects enrolled, number of specific adverse events (defined as any medical occurrence in a subject regardless of causal relationship with the study, as determined by the investigator) and a summary of the study at regular intervals.
 - vi. The frequency of these reports will vary depending on rate of enrollment of subjects. Subject confidentiality and the randomization of subjects will be preserved.
 - vii. The GAC and IRB will receive interim reports at regular intervals.
 - viii. The frequency of serious adverse events and adverse events will be monitored at appropriate intervals by the RSA in collaboration with the GCRC Biostatistician.
- d. Plan 4: Large, Multicenter study
- i. The sponsor will appoint an independent Data and Safety Monitoring Board (DSMB) to monitor the accumulating data in this protocol.
 - ii. There will also be a separate steering committee. The steering committee usually consists of a chairman, a set of investigators representing the clinical centers, the clinical monitor and a statistician. The steering committee provides overall scientific and operational direction for the trial through consideration of recommendations from other working committees. The steering committee has the ultimate responsibility for deciding whether the recommendations of the DSMB should be implemented.
 - iii. The DSMB is responsible for monitoring study progress, outcomes, and safety and to make recommendations in regard to protocol changes. The DSMB approves the procedures used to monitor the study, for consideration of early stoppage of any of its components and will make recommendations when appropriate based on the regular review of all pertinent study data, including adverse effects and unblinded outcome data.
 - iv. The coordinating center will provide study data for review by the DSMB. The DSMB will report its recommendations to the Principal Investigator. This will be forwarded to the IRB and JHBMC-GCRC RSA.
 - v. Serious adverse events will be reported to the IRB and the JHBMC-GCRC RSA according to established IRB guidelines. Adverse events will be reported to the IRB, sponsor, the JHBMC-GCRC RSA, and the FDA (if indicated) according to established IRB guidelines.

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- vi. The frequency of serious adverse events and adverse events will be monitored at appropriate intervals by the RSA in collaboration with the GCRC Biostatistician.
 - vii. The GAC and IRB will receive interim reports at regular intervals.
- e. Plan 5: High risk protocols or protocols involving at-risk populations
- i. The protocol may include a potentially high-risk intervention, drug or device. This would include gene therapy. Alternatively the subject population may be considered high risk (e.g. subjects who cannot provide informed consent, such as people with dementia, children, and subjects who are at risk of excessive coercion). The JHBMC-GCRC RSA will provide ongoing audit of consent, and collection of data, and provide ongoing review of adverse event reporting in this group.

Originator: Program Director
Associate Program Director
Research Subject Advocate

Reference: Recommendations to General Clinical Research Centers (GCRCs) for Patient Safety in Clinical Research, November 2001

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