Stony Brook University

FAR BEYOND

IRB Meeting - Discussion

Research with Human Subjects

Review Criteria

Each IRB member should participate in the criteria for IRB approval of research

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects

Code of Federal Regulations 45 CFR 46.117

Research with Human Subjects

Review Criteria

Data Safety Monitoring plan

- Describe procedures for safety monitoring
- Reporting of serious adverse events
- Reporting of unanticipated problems involving risks to subjects or others
- Description of interim safety reviews and procedures planned for transmitting the results to the IRB

Research with Human Subjects

The IRB has the authority to require a DSMB as a condition for approval of research where it determines that such monitoring is needed.

Research with Human Subjects

Monitoring may be conducted in various ways or by various individuals or groups, depending on the size and scope of the research effort. These exist on a continuum from monitoring by the principal investigator in a small phase I study to the establishment of an independent data and safety monitoring board for a large phase III clinical trial.

Research with Human Subjects

Monitoring is commensurate with the nature, complexity, size and risk involved. The Plan should include the following:

- Name of the Data Safety Monitoring Board
- Independent status (when appropriate)
- Composition of the Board
- Parameters to be assessed
- Mechanism to determine when to continue, modify, or stop a study
- Frequency of monitoring and content of reports
- Procedures for reporting to the IRB

Research with Human Subjects

Review Criteria

The IRB approves only those studies where this requirement is satisfied. If the criteria is not satisfied, the study must be deferred

Bankert and Amdur, 2006