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

- Risks to subjects are minimized: (i) by using procedures, which are consistent with sound research design and which, do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Research with Human Subjects

Declaration of Helsinki (2000)

Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject (this is especially important when the human subjects are healthy volunteers)

Bankert and Amdur, 2006

Research with Human Subjects

Declaration of Helsinki (2000)

The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods.

Bankert and Amdur, 2006

Research with Human Subjects

Nuremberg Code (1949)

"The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment"

Bankert and Amdur, 2006

Research with Human Subjects

Review Criteria

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

- Risks to subjects are minimized: (i) by using procedures, which are consistent with sound research design (Blood draw) and which, do not unnecessarily expose subjects to risk
  - Adequate knowledge about the laboratory where the blood draw will be performed
  - Frequency of blood drawn
  - Total blood volume
  - Health of the study subject
  - Age of study subject
  - Venous or arterial blood draws

Research with Human Subjects

Review Criteria

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- Risks to subjects are minimized: (i) by using procedures, which are consistent with sound research design (PET Scan) and which, do not unnecessarily expose subjects to risk
  - Adequate knowledge about the laboratory where the PET scan will be performed
  - Exposure to radiation including exposure from participation in other studies
  - Enclosed of confining equipment
  - Need for immobilization
  - Need for sedation (not otherwise needed)

Research with Human Subjects

Review Criteria

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- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
  - Spinal fluid – sample removed during clinical procedure
  - Bone marrow – extra sample removed during clinical procedure
  - Bowel biopsy – performed while the subject is undergoing clinical procedure (consider extra sedation)
  - Brain stimulation – additional electrode applied

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