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 reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonable be expected to result. (In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.)

Research with Human Subjects

The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility

Bankert and Amdur, 2006

Research with Human Subjects

- Risks usually associated with whether a harm may occur…both in chance and severity
- Benefits may also be associated with chance and magnitude

Research with Human Subjects

While the most likely harm are psychological or physical in nature, the most likely benefit to subjects could also be psychological or physical in nature (or no harm or benefit to subjects is actually anticipated). More than likely…knowledge would be the result of the research.

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 investigation drug for a condition for which there is no treatment are reasonable in relation to anticipated benefits subjects could benefit from the investigational drug, if any, to subjects, and the importance of the knowledge that may reasonable be expected to result.
  - Drug side effects – if known
  - Drug treatment effects – if efficacy is known
  - Knowledge (future drug development) for others with this condition

Research with Human Subjects

Review Criteria

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

- Risks to subjects investigational drug for a condition for which there is no treatment are reasonable in relation to anticipated benefits subjects could benefit from the investigational drug, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
  - Drug side effects – blindness, death
  - Condition – debilitating
  - Drug treatment effects – some efficacy is shown from preliminary studies

Research with Human Subjects

Review Criteria

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

- Risks to subjects investigational drug for a condition for which there is no treatment are reasonable in relation to anticipated benefits subjects could benefit from the investigational drug, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
  - Drug side effects – blindness, death
  - Condition – mild musculo-skeletal deterioration
  - Drug treatment effects – some efficacy is shown from preliminary studies

Research with Human Subjects

Review Criteria

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

- Risks to subjects investigation drug for a condition for which there is no treatment are reasonable in relation to anticipated benefits subjects could benefit from the investigational drug, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
  - Drug side effects – side effects unknown
  - Condition – mild musculo-skeletal deterioration
  - Drug treatment effects – some efficacy is shown from preliminary studies

Research with Human Subjects

Review Criteria

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

- Risks to subjects investigational drug for a condition for which there is no treatment are reasonable in relation to anticipated benefits subjects could benefit from the investigational drug, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
  - Drug side effects – side effects known and are mild headache, tingling fingers
  - Condition – mild musculo-skeletal deterioration
  - Drug treatment effects – efficacy is shown from preliminary studies

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