



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, there are adequate plans to protect the privacy of subjects and to maintain the confidentiality of data

Code of Federal Regulations 45 CFR 46.111

Research with Human Subjects

Review Criteria

Privacy

- *Extent of the control over the timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.*
 - *In determining the degree of privacy of the information, the IRB should use the standard of a reasonable member of the research population and consider whether such a reasonable member would consider the information collected in the research to be private*

Amdur & Bankert, 2002 (page 169)

Research with Human Subjects

Review Criteria

Privacy

- *In addition, the IRB should consider whether the reasonable member would consider the release of the information without permission to be an invasion of privacy*

Amdur & Bankert, 2002 (page 169)

Research with Human Subjects

Review Criteria

Privacy

- *For research involving unique cultures, the IRB should consider having a representative of the culture on the IRB or consulting with individuals knowledgeable of feelings about privacy within the culture*

Amdur & Bankert, 2002 (page 170)

Research with Human Subjects

Review Criteria

Privacy

- *The IRB should also consider privacy during the subject recruitment process. The manner in which subjects are identified and approached for participation in research may constitute an invasion of privacy. For example, if a medical record is searched and individuals are found who fit the criteria for inclusion into the study, the study team may want to contact these individuals with whom they have had no previous contact. These individuals may rightly feel that their privacy has been violated*

Amdur & Bankert, 2002 (page 170)

Research with Human Subjects

Review Criteria

Privacy

- *Another potential breach of privacy is the collection of sensitive information during the screening process and subsequent retention of the information without consent from the individual.*
 - *This is problematic particularly when the individual declines to participate in the research or does not meet study criteria.*

Amdur & Bankert, 2002 (page 170)

Research with Human Subjects

Review Criteria

Privacy

- *IRBs must consider the projection of privacy as part of their ethical and regulatory duty to protect the rights and welfare of human subjects...particularly during subject recruitment*

Amdur & Bankert, 2002 (page 175)

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