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 46.117

Research with Human Subjects

Review Criteria

Confidentiality

- Obligation to keep private information that has been collected from being shared with others
  - An individual can be wronged even if he/she is not harmed
  - Individuals have a right to expect that information others have about them will be kept confidential and only used for their original purposes

Dunn & Chadwick, 2002

Research with Human Subjects

Studies can collect information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability or reputation (i.e., "sensitive" information) or could involve them in criminal or civil litigation. Examples of this type of data include:

Genetic information

Psychiatric conditions

Sexual attitudes or practices

Substance abuse or other illegal behaviors

Dunn & Chadwick, 2002

Research with Human Subjects

Investigators must design studies to maximize data confidentiality to avoid unintentional release or other disclosures.

Dunn & Chadwick, 2002 (page 80)

Research with Human Subjects

Certificates of Confidentiality may be obtained from DHHS to protect study data from involuntary disclosure through subpoena

Dunn & Chadwick, 2002 (page 80)

Research with Human Subjects

Confidentiality is supported by the principle of "respect" and "beneficence" in the Belmont Report. Respect allows an individual the ability to exercise autonomy and the right to have their records and data kept confidential. Beneficence requires that risks are minimized and benefits are maximized and that risks do not outweigh the benefits to subjects and to others.

Dunn & Chadwick, 2002 (page 79)

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

FAR BEYOND