Understanding Privacy and Confidentiality:
A Training for Researchers, Faculty, and Students

Privacy and Confidentiality

1. **Privacy**
   - About people
   - We control access that others have to ourselves
   - Right to be Protected
2. **Confidentiality**
   - Extension of privacy
   - Identifiable data
   - An Agreement about maintenance and who has access to Identifiable Data
   - HIPPA- *protects patients from inappropriate disclosures of "Protected Health Information"* (PHI)

Definitions

- Privacy – about people and our sense of being in control of others access to ourselves or to information about ourselves with others.
- Confidentiality – treatment of identifiable, private information that has been disclosed to others; usually in a relationship of trust and with the expectation that it will not be divulged except in ways that have been previously agreed upon.

Privacy and Confidentiality: two principles of the Belmont Report

- **Respect for Persons:**
  - Individuals should be treated with autonomous agents
  - The right to privacy and the right to have private information remain confidential

- **Beneficence**
  - Do not harm
  - Minimize and maximize possible benefits

- **Maintaining privacy and confidentiality helps to protect participants from potential harms including psychological harm such as**
  - embarrassment or distress;
  - social harms such as loss of employment or damage one's financial standing;
  - and criminal or civil liability

Per HHS and FDA Regulations

46.111 (a 45 CFR) (7)
21 CFR 56.111 (a)(7)

The IRB shall determine that where appropriate:

1.) adequate provisions are made to protect the privacy of subjects

2.) to maintain confidentiality of data.

Requirements of provisions to protect the privacy of the research participants?

- Will the participants have an expectation of privacy?

  YES – adequate provisions for maintaining privacy are required

  NO – provisions are needed

- Will participants think that the information sought is any of the researcher's business? If NO, provisions will be required.
- Will participants be comfortable in the research setting? If NO, provisions are required.

Privacy Issues

Points for consideration by researcher:

- The proposed subject population?
  - What are the cultural norms of the proposed subject population? Some cultures are more private than others.
  - What are the ages of proposed subject population? There may be age differences in privacy preferences (e.g., teenagers less forthcoming than older adults)

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- The proposed recruitment methods: How are potential participants identified and contacted?

  Acceptable methods –
  - Advertisement; notices
  - Introduction letter sent to colleagues to distribute to eligible individuals – interested party contacts researcher
  - Primary care staff contact those patients that qualify to determine interest

  Unacceptable methods –
  - Search through medical records for qualified subjects or existing database (e.g. registry); then have a researcher with no previous contact with potential subject recruit; this method violates the individuals' privacy
  - Recruit subjects immediately prior to sensitive or invasive procedure (e.g. in waiting room prior to medical procedure)
  - Retain sensitive information obtained at screening without the consent of those who either failed to qualify refused to participate for possible future studies participation.

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Additional Points to Remember regarding Sensitivity and Privacy

- The greater the sensitivity = The greater the need for privacy
- Privacy is in the eye of the participant, not the researcher or the IRB

Requiring provisions to maintain the confidentiality of collected data

1. Will confidentiality of identifiable date be offered?
2. Are there legal/ethical requirements?
3. Will release of data cause risk of harm?

If yes to any of these 3 points – adequate provisions for maintaining confidentiality of data are required

If no to all – Not needed

Maintaining Confidentiality

- Restrict access to data (password protect, lock)
- If data stored on a computer: maintain on a standalone computer or no network connection
- Use encryption software
- Minimize storage of subject identifiable data on a laptop
- Certificates of Confidentiality – protects data from being subpoenaed
- Waiver of Documentation of informed consent – the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Points to remember

- The IRB decides on a case-by-case basis whether there are

a.) adequate provisions to protect the privacy of subjects and

b.) to maintain the confidentiality of the identifiable data during each phase of research project.

- The committee must consider:

a.) the sensitivity of the information collected and

b.) the protections offered to the subjects.

- In social/behavioral research: the primary risk to subjects is most often an invasion of privacy or a breach or confidentiality.

Points to remember

The informed consent process requires that

a.) subjects be informed of the precautions that will be taken to protect the confidentiality of the data and

b.) be informed of whom will or may have access.

(This allows subjects to decide about the adequacy of the protections and the acceptability of the possible release of private information.)