Privacy Vs. Confidentiality

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About Me

– M.S. in Biomedical Regulatory Affairs
  • University of Washington, Seattle

– Research Manager
  • Obstetric-Fetal Pharmacology Research Unit (OPRU)
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– IRB Panel 6, Expedited Manager
  • Stanford University

– Senior Privacy Specialist
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45 CFR 46.111

• Criteria for IRB approval of research.
  – 7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
Privacy refers to persons and their interest in controlling the access of others to themselves.

Stanford HRPP, Chapter 11.1
Privacy

- Interaction occurs in a private setting
  - Clinic room
  - Phone conversation
  - Mailed letter
  - Email
  - Special circumstances ONLY

**eProtocol:**

- 8. Participant Population
  - (g) Recruitment
- 11. Privacy and Confidentiality
  - (a) Interactions
Confidentiality

Confidentiality refers to maintenance of the Researcher’s agreement with the participant about how the participant’s identifiable private information will be handled, managed, and disseminated.

Stanford HRPP, Chapter 11.2
Confidentiality

- How will the data be accessed
  - Medical Records
  - Interview Transcripts
  - Survey Questions
- Obtained with permission or approved Waivers
- Recoded in an anonymous manner
- Stored: Locked file cabinet, Encrypted files on an encrypted and password protected computer

**eProtocol:**
- 11. Privacy and Confidentiality
  - (b)-(i)
- 15. HIPAA
• Criteria for IRB approval of research.
  
  – 7) When appropriate, there are adequate provisions to protect the **privacy of subjects** and to maintain the **confidentiality of data**.

  – Privacy = People
  – Confidentiality = Data
Thank you!

Questions?

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