

# Human Subjects Protocols: Privacy Considerations

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# Outline

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- **Increased Privacy Enforcement Climate**
- **Issues the Privacy Office encounters with protocols**
- **Panel Expertise – How You Help Us Protect Study Participants**
- **Data Security & Management Concerns**

# Increased Privacy Enforcement Climate

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- OCR increasing enforcement efforts
- Recent resolution agreements with academic medical centers – e.g. Mass General and UCLA
- State Attorneys General now have the ability to enforce HIPAA

# Issues the Privacy Office Encounters with Protocols

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- Section 11b: Specify the PHI you will be using in your protocol
  - Not enough specificity/overbroad
- Section 11c: Describe how the data will be maintained
  - Needs to clearly describe a reasonable plan
- Waiver of Authorization form
  - Data that will be used/viewed must be listed

# Issues the Privacy Office Encounters with Protocols (cont'd)

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- Authorization form and consent form should be consistent in terms of how participants' information will be used/disclosed
- Authorization form should not contain language about “future use”

# Panel Expertise – How You Help Us Protect Study Participants

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- We rely on you to review and determine:
  - Whether the information researchers say they need for a study is really the minimum necessary
  - Whether the information requested jibes with the stated study purpose

# Data Security & Management

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- “In a locked cabinet” is not enough
  - Even “On a password protected computer” is not enough
- All protocols should have clear and specific statements covering data security and management.
  - Must cover encryption, backup, passwords, secure transfer, training, etc.

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Questions?



# Contact Information

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