Dealing with Data Securely: 
Non-technical Thoughts Concerning 
Data Security and Management

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Objectives

- Review and identify challenges and obstacles for data security and protection of confidentiality
- Identify best practices for IRBs in the review of researchers’ plans for protection of data and confidentiality
- Identify strategies for institutions to work with researchers and IRBs to develop and implement data management/security strategies.
Introduction

- When I started in the field.....
  - Locked filing cabinet in a locked office

- Now......
  - Not so much, to say the least
  - It’s a new world for Data

Introduction

- New Environment for Data
  - More data and more private data
  - New expectations and requirements to share data
  - New technologies to:
    - Collect
    - Use/Analyze
    - Share
    - Store
    - Hack/steal/lose data

- So a double/triple dose of
  - Opportunities
  - Risks/vulnerabilities
Introduction

- So….. What is
  - An IRB to do to be prepared?
  - A HRPP to do to be prepared?
  - An Institution to do to be prepared?

- Think in terms of
  - Expertise
  - Technology
  - Requirements

What is to be Done? Avoid This

Hey, Rock beats paper because it’s harder!

No, paper beats the scissors, you fool!

I got a paper cut from scissors once…

What about a stapler? Doesn’t this beat paper?

What really happens at IRB meetings...
What is to be Done?

- Option: Put IT experts on the IRB
  - Kinda a waste of expertise
  - Not practical
  - Risk of being idiosyncratic rather than systematic

- Option: Institutionalize It

What is to be Done?

- From Institutional Perspective: An Integrated Approach
  - Do we know what data we have?
  - As data is owned by institution – not researcher - need for institutional policies and process for collection, use, access, sharing and storing of this institutional data
  - IRB one component of institutional data oversight community
    - May well be central component for some activities, but not the only component
    - Who else and how to collaborate?
    - How do these units work together
Data Plan

- Pull Together all Interested/Affected Parties
  - IRB
  - Office and committee representatives
  - Researchers
  - IT
  - Security
  - Operations
  - Library
  - Privacy/HIPAA/GC
  - Institutional partners: For Whom IU Serves as IRB of Record
    - Hospitals
    - Partnering research institutes

Data Plan

- Begin the Conversation
  - Or, it may seem, negotiations

- Acceptable Systems Initially
  - Absolutely no overlap for collecting, transmitting, computing, storing, archiving
  - Thus the negotiation part

- In the face of this
  - Narrowed the group
  - Drafted white paper
  - Re-gathered the group
  - Discussed, negotiated, cajoled, etc. till we reached a consensus
Data Plan

- Integrate Selected Systems into IRB Application
  - Accepted systems identified
  - Selection of any one of them means approvable
  - Use of any not identified
    - Required justification
    - Review by expert as consultant to IRB
  - Conduct education with IRB staff and members

From Concept to Reality

- Implementation
  - Negotiations continued
  - Application language
  - Reports
    - To whom
    - Including what information
    - Real-time or delayed
  - Institutional security signoff required prior to IRB approval?
  - Approval letter language
  - Education to research community
  - Research compliance staff not trained/equipped to provide
From Concept to Reality

- Phased Implementation
  - First step
  - Data subject to HIPAA
  - Highest compliance risk
  - Researchers dealing with this data already have some familiarity with security requirements
  - Collection of limited information
  - When using system on list
    - No further action required
  - When using system not on the list, researcher must either:
    - Confirm the system they are using has institutional IT security approval
    - Commit to completing institutional security review prior to use of system
  - Consider whether collection of detailed information may do more harm than good

Researcher Response

- Lots of Questions
  - Be ready with list of people who can assist – most likely not IRB or research compliance office
    - Departmental IT
    - Institutional IT
    - HIPAA Security Officer
    - Contracts
  - But no resistance from researchers
  - Helpful to know preferred systems
  - Often speeds initiation of research by moving discussion regarding IT needs earlier in the process
Institutional Response

- Ready to move to Step 2
- But what is Step 2?
  - Back to negotiations with various stakeholders
  - But now we have data to guide decisions
    - Identify IT needs
    - Targeted education (not from research compliance)
    - Targeted communication
- Discussions regarding security of sponsor-provided systems

What We’re Working on Now

- Data Management guidance
- Applying same process to research data not subject to HIPAA
- Consideration of holding IRB approval pending IT system certification
- Consideration of IRB’s role in encouraging or even mandating data sharing
Wrap Up

- Key Points in the Process
  - Identify the Goal
  - Identify and involve the best parties to be part of the process
  - Recognize that compromises have to be made, pet systems may be rejected, feelings may be hurt
  - Don’t let the discussion/process wander too far off track
  - Keep pushing the agenda and goal

- Questions and Discussion