The Digital Locked File Cabinet: A Problem of Metaphor

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Background: IRB

• Established by US Code in 1974
• Response to research abuses of early 20th century
  – Tuskegee Syphilis Study, 1932 - 1972
• Governed by Office for Human Research Protections in Department of Health and Human Services
Tuskegee Prosecution
Fred D. Gray, Prosecutor

1. Government knew the participants had syphilis and failed to treat them.

2. Public Health Service failed to fully disclose to participants that they had syphilis and were participating in a study, and that treatment was available for syphilis.

3. Public Health Service led participants to believe they were being properly treated, when in fact, they were not being meaningfully treated.

4. Public Health Service failed to obtain the participants' written consents to be part of the study.

5. Study was racially motivated and discriminated against African Americans

6. No rules or regulations governing the Study.
US Code: Protection of Human Subjects

- Title 45 part 46
- Created 1974; most recently revised 2005
- Primarily Biomedical and Behavioral Research
- Applies directly to all federally conducted or funded research
- Generally applies to all human-subject research within the purview of US law
- Can be superseded by more stringent local laws
- May be superseded by foreign regulations if they are equivalent or stricter, if US research is outside US
What is Human Subjects Research?

• 45 CFR 46.102(d):
  
  • **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which considered research for other purposes. For example, some demonstration and service programs may include research activities.
What is Human Subjects Research?

• 45 CFR 46.102(f):
  • *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains
    1. Data through intervention or interaction with the individual, or
    2. Identifiable private information.
Researcher Obligations

1. Minimize subject risks through sound research methodology (46.111a(1))
2. Risks appropriate to benefits (46.111a(2))
3. Equitable Subject Recruitment (46.111a(3))
4. Informed Consent (46.111a(4) and (5))
5. Monitor data for subject safety (46.111a(6))
6. Appropriately protect privacy and confidentiality of subjects (46.111a(7))
Human Subjects Research in a Digital Age

- Online Surveys
- No face-to-face communication
- Written Consent is impossible
- Traditional Data security measures do not apply
Interpretation

• Regulations that do not strictly translate must be applied metaphorically
• Spirit and intent, not letter, often must be used to interpret Digital equivalents
Challenges to Interpretation

• Panels make individualized, case-by-case decisions
• IRB Panels typically contain important researchers at the institution
• Panels ill-equipped to understand nuances of internet data security issues
Aids to Interpretation

• IRBs typically have IT consultants
• University central policy may provide institutional best-practices
• IT industry best-practices can be used by both the IRB and researchers as a guide
CLA-OIT Survey Services

Case Study
Development of Service

- Used IRB guidelines and industry best practices
- Consulted with IRB to achieve IRB-compliant processes and operations
- Informed IRB about issues with current IRB procedures
- Our process has never been rejected on an IRB protocol
Key Issues

• Informed Consent
• Required Answers
• Data security
Informed Consent

• Title 45 part 46.117 states that
  (a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and **signed by the subject** or the subject's legally authorized representative. A copy shall be given to the person signing the form.

  [*emphasis mine*]
Informed Consent (2)

• Signature collection is not practical in most online research settings
• Vast majority of population is not set up for federally-recognized “digital signatures” – not even IRS uses them
Informed Consent (3)

• Compromise with IRB:
  – Consent form is FIRST page of survey
  – Consent form is identical to paper requirements
  – Check box or “yes/no” selection in place of signature line that says, “I have read the above consent form. I have asked any questions I may have and have received answers. I consent to participate in this study”.
  – Affirmative answer is required to move forward
Informed Consent (4)

• IRB application must explicitly explain this procedure for every project
• Some specific cases have required:
  – Paper, signed consent forms
  – Paper, unsigned consent forms
  – Consent form without required checkbox
  – No consent form at all
Required Answers

- IRB regulations tightly restrict a researcher’s right to require a participant to answer a question.
- Face-to-face “required answers” are different from online “required answers”.
- Since participants can never be truly forced to answer a question online, generally it is acceptable to require answers online.
Required Answers (2)

• This is the only issue on which we continue to have inconsistent results with the IRB
  – Some IRB reviewers simply deny any protocol that says it will “require” anything of participants
  – Others require explicit mention in the consent document that a participant may leave the survey at any time without penalty
  – Most times, issue seems to slip under the radar
Data Security

Traditional gold standard of data security:

– Data Stored in Locked File Cabinet
– File Cabinet housed in Locked Office
– Key to office given only to those who need it
– Key to file cabinet given only to researcher(s) who absolutely must have access
Data Security (2)

Characteristics:

– High standard of security:
  • Multiple layers of protection from outsiders
  • Strictly controls who has access

– Not invincible:
  • locks can be broken, file cabinets can be moved
  • Allows convenient access to authorized parties
Digital Equivalent:

- Multiple Layers of protection:
  - Encryption of ALL data
  - Dedicated database server for online research use
  - Database server only accepts db connection from dedicated web survey server
  - No unnecessary services or jobs on server
  - Firewall database for extra layer of protection
  - Machine must meet all other industry standards and institutional regulations
Final Note

- IRB Approval of submitted IRB Protocol controls rules and conditions for each study individually
  - Never say “If the IRB signs off we’ll do it” unless you mean it! – don’t depend on the IRB to be your enforcer
  - If a researcher fails to mention some exception in the protocol, you can’t do it
  - We give every researcher a block of text that contains our exceptions; we expect them to include it