Information Security and The Institutional Review Board:

A ROADMAP FOR SECURING RESEARCH DATA AT YOUR INSTITUTION

Martin Manjak, University at Albany
Warren Petrofsky, University of Pennsylvania
Kyle Stephens, University of Pennsylvania
What We'll Cover Today

- What is an Institutional Review Board (IRB)
- What does the IRB process entail
- How did InfoSec get involved with the IRBs at our institutions
- What are the benefits of working closely with your IRB
- How can you get involved in the IRB process at your institution
University at Albany

- 1 of 4 University Centers in SUNY system
- 18k Grads & Undergrads from 100 countries
- 120 Masters and Doctoral programs
- ~1000 Faculty
- Primary Schools
  - Criminal Justice
  - Public Policy (Rockefeller College)
  - Public Health
  - Social Welfare
- Carnegie Classification: Research University- Very High Research Activity
University of Pennsylvania

- An Ivy League institution based in Philadelphia, PA
- ~ 10,000 student body with a standing faculty around 3,800 made up of 12 schools and multiple centers
- Associated with three hospitals: The Hospital of the University of Pennsylvania, Pennsylvania Hospital, Penn Presbyterian Medical Center
- Abramson Cancer Center of the University of Pennsylvania
- Carnegie Classification: Research University- Very High Research Activity
What is the Institutional Review Board?

• An IRB is the regulatory body designated to promote the rights and welfare of human research participants

• There are three types of review: exempt review, expedited review, and review by the convened committee

• Federal regulations outline the bulk of how human subject research should be carried out

• These regulations can be supplemented by state and local law and institutional policy
Exempt, Expedited, and Full Committee Reviews

- **Exempt** - reviews of projects that are minimal risk and very common such as surveys, interviews, and public observations.
- **Expedited** - reviews of experiments or identifiable secondary data analysis. Projects could involve randomization or interact with participants in significant ways.
- **Full Board review** - reviews of projects that are greater than minimal risk. These projects may involve collecting information which may be socially damaging to participants or collecting criminal information.
## IRB Structures at Albany and Penn

### Albany
- **4 Boards**
  - 1 SBER
  - 1 SBER/Biomed
  - 1 BioSafety-RcbRNA
  - 1 Animal Safety
- Boards registered w/OHRP - Office of Human Research Protections (USG)
- IRBs managed by Office of Regulatory Research Compliance (ORRC)

### Penn
- **8 IRB boards**: 7 medical boards and 1 social and behavioral
- Exemptions and Expedited reviews are determined and completed by IRB staff
- Over 11,000 current protocols
The IRB Review Process

1. Application for Review
2. IRB Administrative Review
3. IRB Review Board
   - Or Members
4. Approval
5. PI reviews & responds
6. Revised Application

External Nodes:
- Research Topic Identified
  - Or Annual Review
- CITI
  - Human Subjects Research Training
- Questions
  - Issues
  - Deficiencies
  - Changes
**How did Information Security get involved?**

**At Albany**
- Contacts from individual researchers looking for the "security guy" to sign
- Data owners increasingly require confirmation of specific controls (BLS)
- More research conducted using broader array of IT tools (Survey Monkey)

**At Penn**
- Individual IRB reviewers looking for help evaluating the security of a particular process
- Investigators requesting help meeting requirements of data providers or the IRB
- Incident response involving IRB data
What's it like to be on the IRB?

- **Training** - There is a formalized training process for IRB members, meant to explain the history of the IRB and the main ethical standards/regulations currently written into law.

- **Reviews** - For each IRB meeting you will likely be assigned to be a primary or secondary reviewer of initial submissions and/or continuing reviews or modifications.

- **Meetings** - You will give recommendations about the protocols you reviewed, and will raise questions or concerns about any of the other protocols, as they are reviewed.
Other ways Information Security is Involved in Research Activities

Participate in agency audits of researchers

"Applied Research" and export controls (maybe institutional privacy or compliance officer)

- Prof. John Reece Roth
War Stories - Marty

Researcher wants to study alternatives to outlawed practice in foreign state. All responses (including audio recordings) kept on researcher's laptop. 

*We required the researcher to use encryption.*

Multiple researchers sharing data across multiple computers in US and China with many restrictions on data sharing (?!)

Required stand-alone machines. Data shared via CDs through snail mail...but,

"Each research team member will receive the data file as a form of CD from the recipient researcher via email."

Umm, no they won't.
More War Stories - Warren and Kyle

• Are users of a social network subjects?

• Is it the IRB's problem if a protocol involves violating the Terms of Use of a web service, or breaking the law?

• How should IRB reviews interact with Campus IT policies (Acceptable Use, etc.)?

• Why does no one think of email backups?
Sample Protocol for discussion

- Study to examine speeding habits of risk averse IT Security Staff
  - Quantitative:
    - Ask 100 IT Security Staff to install a GPS device in their car that will upload their speed and location throughout their daily commute
    - They will also be asked to tag each of their LinkedIn connections they deem most likely to speed or commit a crime
  - Qualitative:
    - Ask these security staff to complete a survey about risk aversion online at www.surveygorilla.com
    - Questions will include their personal history of illegal drug use, criminal record, and the riskiest thing they’ve ever done at work
Lessons Learned

If you weren't there to review this, this protocol might have been approved.

It's not easy to predict in advance which protocols are going to have security and privacy concerns.
Ways to Replicate This at Your School

Tell your VP of Research that you attended this boss presentation at the SPC and you really want to participate in the protocol review process

Introduce yourself to your director of the Office of Research Regulatory Compliance

If you have existing policies regarding network connectivity, servers, leverage that with researchers

Act as a consultant for project
Acknowledgments

Special Thanks to:

UAlbany
• Adrienne Bonilla, Director, ORRC
• Judy Guldenstern, Administrative Assistant, ORRC

• UPenn
• Yvonne Higgins, Executive Director of the IRB
• Megan Kasimatis Singleton, Assistant Director for Education and Training
Contact Us

Martin Manjak, mm376@albany.edu
Warren Petrofsky, petrofsk@sas.upenn.edu
Kyle Stephens, kstep@upenn.edu
Links & Resources

http://www.internetresearchethics.org/
http://www.hhs.gov/ohrp/
http://www.upenn.edu/regulatoryaffairs
http://www.albany.edu/research/compliance/