Computing and Ethics: always the twain shall meet

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What is an IRB and why
What does this have to do with supercomputing

1. What is and Why IRB (protect human subjects)
   - Emphasis on Human Rights (from Belmont report to UNESCO)

2. Trends in human subject research (major changes over recent years)
   - Changes in types of research
     - Presumption that research is medical only (Pop, Behavioral)
     - National to global
     - Dramatic changes in technology (handling, storing, transfer data)
       - Genomic, imaging, infectious disease
     - Impact on supercomputing environment
       - Size & sensitivity of data (giant computer room to a chip)
         - eg: genomic; imaging data; global issues
Purpose of IRB Review

1. To assure, both in advance & by periodic review, that appropriate steps are taken to protect the rights & welfare of humans participating as subjects in the research & to maximize the safety

2. To assess the scientific merit of the research & methods

3. To promote fully informed and voluntary participation by prospective subjects who are themselves capable of making such decisions
What the IRB Reviews: Research with Human Subjects

• **Research:**
  • Systematic investigation designed to develop or contribute to generalizable knowledge
  • Includes research development, testing & evaluation.

• **Human subject:**
  • Living individual about whom an investigator
  • Professional or student - conducting research obtains:
    1. Data through intervention or interaction with the individual, or
    2. Identifiable private information.
Recent genesis of regulations?

**Belmont Report (1979)**
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- GOAL: autonomy, **beneficence, non-maleficence**, justice

- The **Common Rule** (1991) → Institutional Review Boards
- Most recent proposed *revision*: 2016 (significant issues)

**International**

http://www.hhs.gov/ohrp/humansubjects/commonrule/
Who are the key stakeholders?

- Expansion and complexity of key stakeholders
  - Researchers
    - Local, national, multi-national
    - Public and private sector
  - Funding agencies and their diverse interests
  - Regulators
    - NIH/ORI
    - FDA
    - Research Institutions and their respective IRBs
Securing Research Data

• Data Ownership

• Data Classification (type & risk)
  • FIPS; FISMA

• Data Collection (location & device)

• Storage
  - Impact on supercomputing environment
  - Size & sensitivity of data (giant computer room to a chip)
  - eg: genomic; imaging data; global issues
Securing Research Data

• Storage
  ▪ Impact on supercomputing environment
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• Access & Termination (users & data)

• Monitoring (technical and physical)

• Compliance
  • (HIPAA; FERPA, etc, federal sponsors)
Security Controls

1-2) Inventory of:
   Authorized & Unauthorized Devices
   Authorized & Unauthorized Software

3) Secure configurations for hardware & software on Mobile Devices, Laptops, Workstations and Servers

4) Continuous vulnerability assessments

15) Account Monitoring and Control

5) Controlled use of administrative privileges

https://www.sans.org/media/critical-security-controls/SANS_CSC_Poster.pdf
Security Controls

7) Email & Web browser Protections
8) Malware Defenses
10) Data Recovery Capability
14) Controlled Access Based on Need to Know
16) Security Skills and Appropriate Training

☑ DUAs and requirements

https://www.sans.org/media/critical-security-controls/SANS_CSC_Poster.pdf
Challenges & Issues

• Geography
  • local, international

• Securing data from offsite
  (local agencies; paper collection of surveys; downloading from cloud for analysis; international transfer of data or bring data to other countries via laptops)

• DB with PII from multiple agencies or countries

• Transfer of PI to another institution
Challenges & Issues

• Data recovery
• Data Destruction
• Audio and/or video data collection
• Sensitive topics & confidentiality
Panel Details

• 9:45-noon (break during this time)

• Wed 5 minute talk (each) followed by 20 minute panel: Panel:
  • Intro - Center for Trustworthy Cyberinfrastructure;
  • IRB & InfoSec (Irene J & Erin F) 10:10-10:30
  • Break and then 11:00-11:20 panel

• Audience:
  • Room full of Engineers; core research services (administrators)
  • (Not familiar with IRB and it’s implications)
  • Other research Admins
  • Some Info Tech specialists
Regulations, policies and guidelines
http://bioethics.od.nih.gov/IRB.html#guidance

Responsible conduct of research
http://bioethics.od.nih.gov/researchethics.html#policies

A Guide to Handling Scientific Misconduct Investigation in NIH’s intramural programs

Ethics, codes and standards
http://bioethics.od.nih.gov/IRB.html#policies
HANDOUT- Why protect human subjects?

- **Fundamental** ethical concern for human rights
- Broad concern for responsible science, including research ethics
- In compliance with **Federal law** and **institutional policy**, all research projects involving human subjects or human material and conducted by the faculty, the staff and students of the research institution, must be reviewed and approved by an IRB
- Increasingly, peer reviewed journals will not accept articles based on research involving human subjects if that research has not been approved by an IRB.