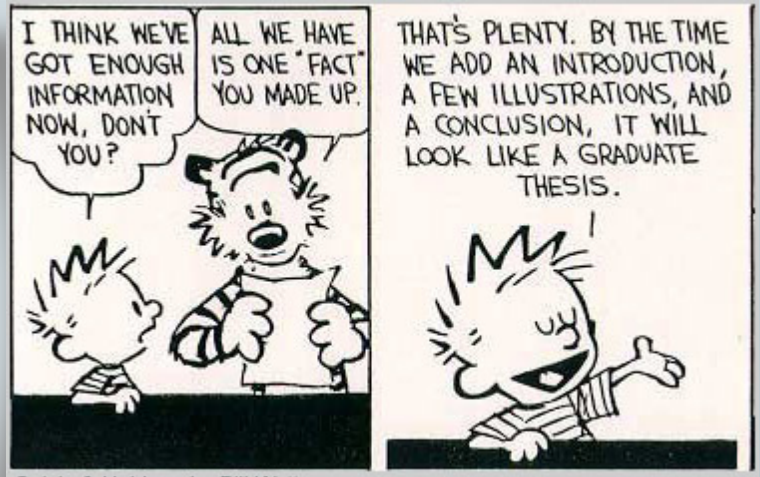
Responsible Conduct in Research
&
Human Subjects Research

CS5/692
LECTURE 1



Calvin & Hobbes, by Bill Watterson

Goals

- *Brief* introduction to Responsible Conduct of Research
- History of Human Subjects in Research
  - Rationale for ethical governing bodies and regulations
- Where to go for more information?

What is RCR?

- Responsible Conduct of Research
- "*The practice of scientific investigation with integrity.*"
  - Seems obvious?
    - As we'll see, there is clearly a need for regulation
      - And…an iterative process for review of regulations
  - Many funding agencies and many universities now require basic RCR training for all researchers and many students

9 Basic Components of RCR

- Collaborative Science
- Conflicts of Interest and Commitments
- Data Acquisition, Management, Sharing, & Ownership
- **Human Research Protections**
- Lab Animal Welfare
- Mentoring
- Peer Review
- Publications Practices and Responsible Authorship
- Research Misconduct

World War II as Impetus for First Guidelines

- Nuremberg Code (1947)
  - "Research" conducted on humans during WWII without their consent
  - Subsequent trials led to creation of ethical code for human subject research
  - Introduced *Informed Consent* and *Voluntary Participation*

International Guidelines for Research

- Declaration of Helsinki, 1964
  - World Medical Association's contribution
  - Multiple revisions to 2013
  - Basic statement of ethical principles for medical research involving human subjects
  - Calls for prior and ongoing approval for research
  - Basis for "Good Clinical Practices"

Not enough…

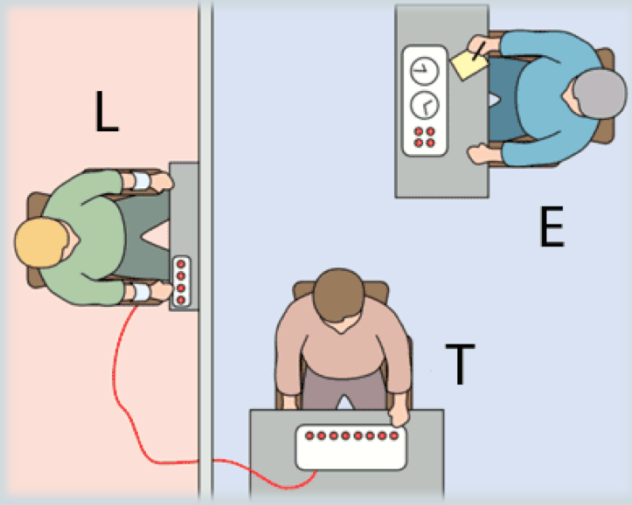
- Thalidomide (1950's)
  - 12,000 pregnant women given non-FDA approved drug
- Radiation research
  - Extensive research in 1940's – 60's
  - Generally on poor, vulnerable populations, including many pregnant women, fetuses, newborns, and children with disabilities

Not enough…

- Tuskegee Syphilis Study
  - Alabama, 1932-1973
  - Funded by US Public Health Service
  - 600 African American males, low income, promised free medical treatments
  - Blatant unethical practices: actively denying treatment, coercive practices, withholding medical information, no informed consent
  - Only ended when story of study became public. Even still, no apology from government until more than 20 years later.

Not Enough…

- Psychological experimentation
- Milgram experiments at Yale (1961-63)
  - Coercion, obedience, deception



Milgram, S. (1973). The perils of obedience. *Harper's*, *247*(1483), 1973.

National Research Act of 1974

- Congress forced Department of HHS to come up with some rules
  - Title 45 of the Code of Federal Regulations, Part 46
    - 45 CFR 46
  - National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1979)
    - This commission released The Belmont Report of 1979
      - Continues to guide ethical practice in research
  - Established modern IRB system

"Common Rule"

- 1991: Federal adoption of 45 CFR 46, Subpart A
  - Additional protections for:
    - Pregnant women, human fetuses, and neonates
    - Children
    - Prisoners

Related Week 1 Readings

- Steneck:
  - Chapter 1: Rules of the Road
  - Chapter 3: The Protection of Human Subjects
- Excerpt from Skloot R., "The Immortal Life of Henrietta Lacks":
  - Preface
  - First Chapter
- Radiolab segment, "Henrietta's Tumor"


Compass
your guide to learning & development at OHSU
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My Team
Help Resources Center
Welcome, Jill
BROWSE
CALENDAR
TRANSCRIPT
DASHBOARD
Compass is an instrument designed to guide you and your employees on the journey to performance excellence. Use the navigation tools t
complete assigned courses and manage important tasks. Discover new ways to inspire your team and lead them in the right direction. No m
Compass is here to help you stay on course and achieve your goals!
My To Dos
My Assigned Training
No assigned training
MacBook Air

Additional Resources

- CITI training
- Office of Research Integrity
  - Case studies
- *The Immortal Life of Henrietta Lacks*
  - *Novel by Rebecca Skloot*
  - *HBO movie premieres April 22*
- *The Deadly Deception*
  - Recommended Nova video on the Tuskegee Syphilis Study
- Former President Bill Clinton's Presidential Apology for Tuskegee Syphilis Study. "I AM SORRY."