Data, Regulations Ethics and Society

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01//31/19

Research on Research Ethics

NIH
NSF
ORI
RWJF
UC San Diego
ACTRI
CA-DOR
IBM
WFF

Research Literacy: BRIC is education designed to increase research literacy and awareness of ethical and regulatory dimensions. The BRIC programs have received support from the NIH, NSF, ORI and local sources.

@UCSD_BRIC | bric.ucsd.edu

Tech Ethics: CORE is a learning community developed to elevate safe conversations about ethical, legal and social implications of research and innovation. The CORE initiative is supported by the Robert Wood Johnson Foundation.

@COREethics | thecore.ucsd.edu

CORE Connected & Open Research Ethics

Determinants of Health

Current estimates indicate genetics explain an important but modest portion (~30%) of an individual's variability in health. Health behaviors (e.g., physical inactivity, diet, tobacco use) explain an additional 40% of variance, with the remaining variance attributed to environmental factors, social circumstances, and healthcare utilization and delivery.

Image courtesy of Dr. Kevin Patrick, Principal Investigator, Health Data Exploration Project

Sources of Data Used in Digital Research

Imaging

Mobile

MISST

Pervasive Sensing

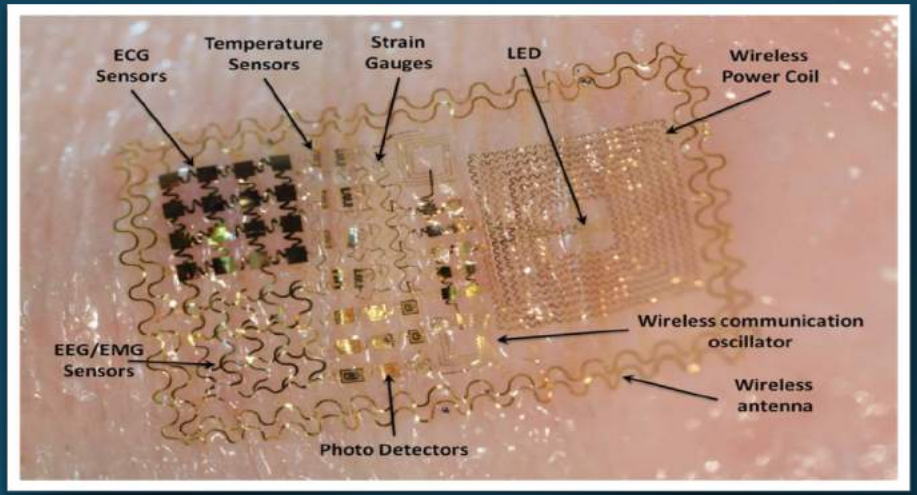
Social Media

Location Tracking

Visual Methods

Increasing interest in studying "free-living" behavior "in the wild" prompts increased use of visual methods.

Sensing Methods

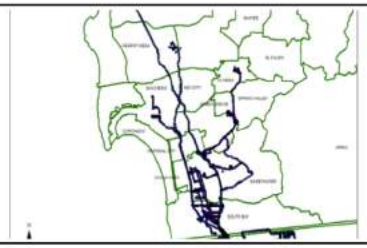
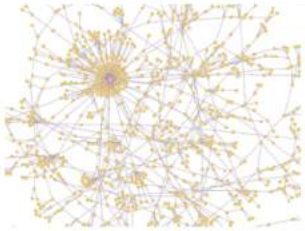


Passive, Pervasive, Ubiquitous

With permission of Dr. Todd Coleman, UC San Diego Professor of Electrical & Computer Engineering and CORE Advisor

Social Media Methods

New Methods = New Data

Wearable Cameras	GPS Tracking	Smart Phones	Social Media
			
			

Commercial Products

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Nebeker, C., Harlow, J., Giacinto-Espinoza, R., Linares-Orozco, R., Bloss, C., Weibel, N. (2017) Ethical and regulatory challenges of research using pervasive sensing and other emerging technologies: IRB perspectives, *American Journal of Bioethics: Empirical Bioethics* 8:4, 266-276, DOI: 10.1080/23294515.2017.1403980

Characteristics of Digital Research

We live in an increasingly smart and connected environment and research methods and tools are changing.

- Now people can monitor or be monitored and/or intervened with 24/7, on the fly and in real time.
- Research isn't exclusively an academic venture – industry, non profits and citizens are in the game.
- We can now know 'everything' at a granular level using new digital technologies.
- Promising data anonymity may not be realistic.
- Not all in this emerging digital research ecosystem are regulated.

Your Computer May Know You Have Parkinson's. Shall It Tell You?

Making Headlines

The Techlash of 2018

Ethical, Legal and Social Implications

- Research Literacy
- Cultural Literacy
- Data Literacy
- Bystander Rights
- Risk / Benefits

- OHRP
- FDA
- Liability
- Privacy Expectations
- Intellectual Property

- Downstream impact
- Unknown Unknowns
- Sociotechnical systems
- Privacy expectations

What Might be Unknown Unknowns?

HEAL THYSELF, ALGORITHM

If AI is going to be the world's doctor, it needs better textbooks

By Dave Gershgorn · September 6, 2018

Fitbit leans hard into healthcare with a new enterprise offering

Fitbit Care can help businesses and organizations keep employees healthy.

Emerging Ethical Issues

Increased availability of wearable or mobile imaging, sensing and tracking technologies.

Paradigm shift for health researchers – new methods for measurement, monitoring and intervening.

While these technologies may offer more accurate means of understanding behavior in context, they also introduce new challenges.

What is Research – the Regulations

The terms "Research" and "Human Subject" are defined in the Code of Federal Regulations in the section that focuses on protection of research subjects (45 CFR 46).

"a systematic investigation … designed to develop or contribute to generalizable knowledge."

Definition: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

What is a Human Subject?

A 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."

Definition: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

Differences between Research & Service

- Research is carried out to gain new knowledge by answering questions about something that is currently unknown or not well understood.

- A research study may not directly benefit a study participant.

Federal Regulations 45 CFR 46

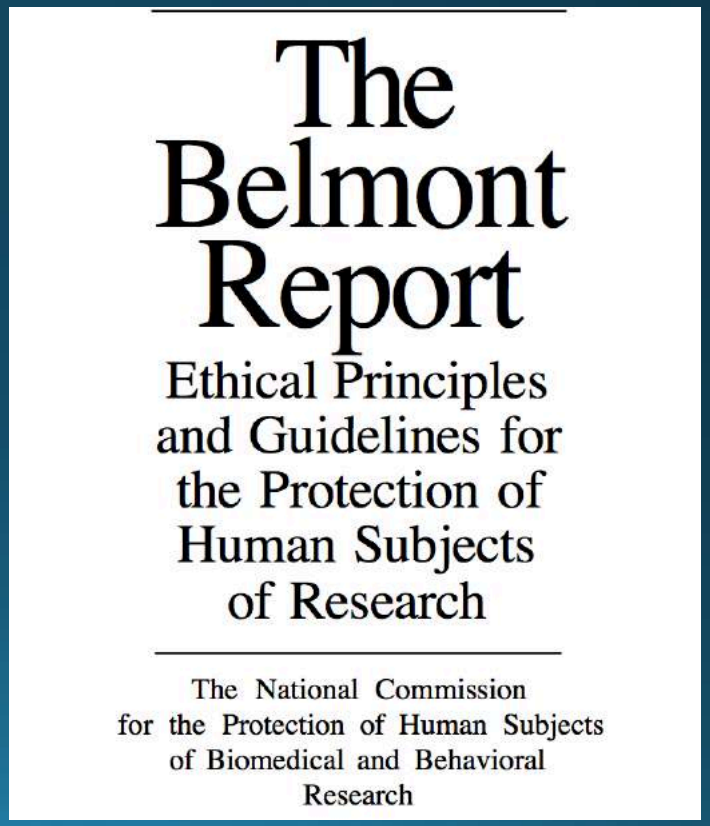
- You can access the regs via: http: www.hhs.gov ohrp

Federal Regulations - 45 CFR 46

- *Requires oversight of human subjects research by an Institutional Review Board*
- *Provides details on requirements for involving human subjects in research*
- *States requirements for policies, procedures and responsibilities of researchers who involve human participants in their research.*

The Belmont Report

- **Respect for Persons**: recognizes a persons right to make an informed decision
- **Beneficence**: reflects an obligation of the researcher to carefully consider study risks and designs the study to ensure social and scientific value
- **Justice**: emphasizes treating participants fairly and appropriate subject selection



Stakeholders and Responsibilities

Federal	Provide guidance, Develop Regulations, Manage Assurances
Institutional	IRB
	Administration
Investigator	Plan and conduct ethical and responsible research
Participant	Understand involvement as a participant

Investigator Responsibility

Obtain and maintain training in human research ethics.

Plan thoughtful and responsible research. If a student, work with advisor to get guidance and make sure advisor reviews the entire protocol in advance of submission.

Submit research protocol to IRB for review and respond to questions/comments to secure approval.

Carry out protocol as approved. Changes to the protocol require approval in advance.

Communicate with participants and IRB.

Institutional Review Board

Required by federal regulations to review federally funded research.

Reviews research to determine whether research complies with regulations and ethical principles.

Decisions may be appealed, but not overturned.

Approval is valid for up to one year.

The Research Plan

- Summary of literature
- Study purpose
- Research design
- Participant selection and recruitment
- Informed consent process and documentation
- Study risks and benefits
- Participant privacy
- Data confidentiality
- Investigator experience
- Potential Conflicts

Summary

- What is research?
- What is a human subject?
- What are the differences between research and service programs?
- Why do we have regulations and ethical principles?
- How are Respect, Beneficence and Justice demonstrated?
- Who are the key stakeholders in protecting human subjects?
- Informed Consent – Process and Documentation
- Regulatory Updates

Discussion / Activity –HUMANs Study

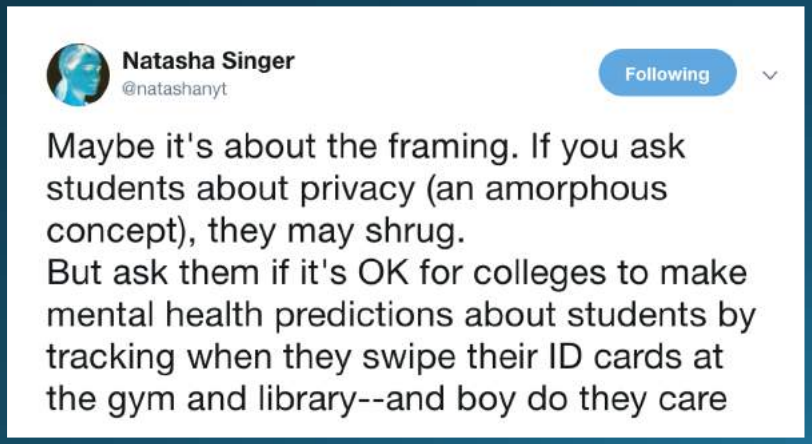
- HUMAN Study
- 10K participants
- Multi-dimensional data sources
- Longitudinal study design

- Discuss and evaluate for 15 minutes
  - 3 groups of 6-7
  - Assign a note taker and speaker
  - Identify risks, benefits and other considerations

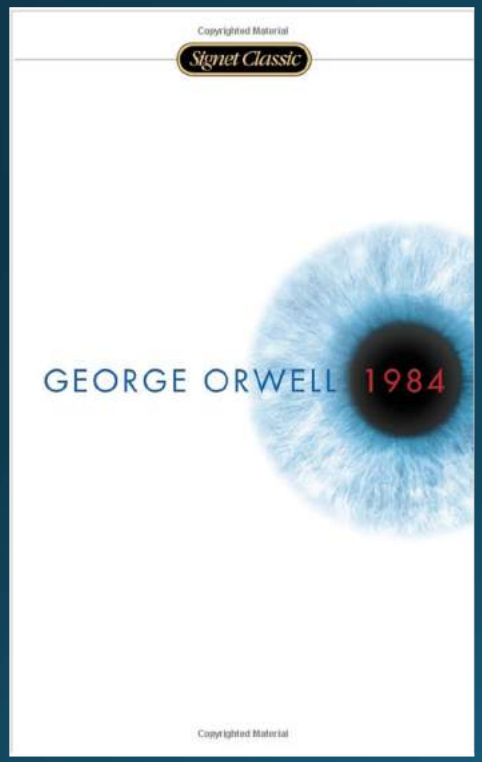
What Do You Need to Know?

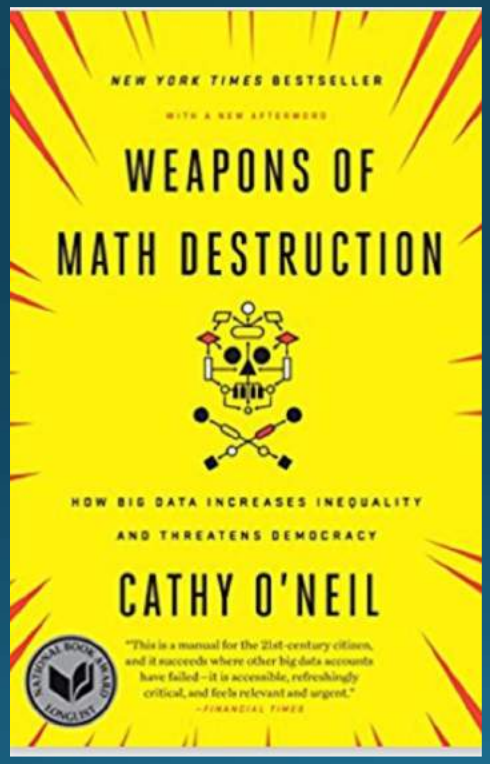
Talk to and Learn from Consumers

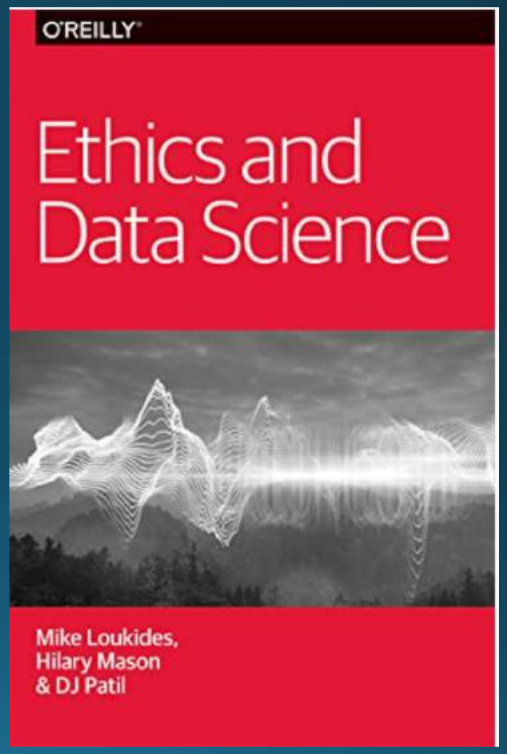
"If they're [AI] so sensitive, they know three weeks before we know what's going wrong with our bodies. It seems to me that that kind of information could really be compromised, and seniors could, uh, who are very vulnerable, could really be hoodwinked more easily."



What to Read…







https://www.amazon.com/dp/B07GTC8ZN7/ref=cm_sw_r_cp_ep_dp_fKyLBboYWVH94_

https://www.luminary-labs.com/imagining-unintended-consequences-fictional-stories-ethics-technology-future-humanity/

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We asked: How Might People Shape Ethical Practices?

1

Tool Makers

make innovative technologies used in health research

2

Participants

participate in studies contribute data to advance knowledge

3

Researchers

conduct health studies using 21st century tools/methods

4

IRBs

reviews research risks and benefits to make sure participants are protected from harm

CORE
Connected
& Open
Research Ethics

The CORE is a "research ethics" learning community where people share their expertise to shape ethical practices in the digital age.

thecore.ucsd.edu

@COREethics

linkedin.com/company/core-ucsd

Robert Wood Johnson Foundation

The Resource Library

Search for and share IRB-approved research protocols, best practices, and institutional policies

The Network

Connect with members who share an interest in the ethical design and appropriate review of MISST research

The Q&A Forum

Post Questions and share interdiciplinary expertise (i.e. research, privacy, technology, regulations)

Thank You!

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