Ethical considerations for future data stewards

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With thanks to Camille Nebeker

Overview

New Technologies ➤ New Research Projects ➤ New Ethical Challenges

New Sources of Data

Imaging

Mobile

Pervasive Sensing

Social Media

Location Tracking

New Methods = New Data Types

Wearable Cameras	GPS Tracking	Smart Phones	Social Media

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Commercial Products

Jawbone Up 24 · Garmin Vivofit · Fitbit Flex · Basis B1 Band · Misfit Shine · Withings Pulse O2 · Nike Fuelband SE · BodyMedia LINK Armband
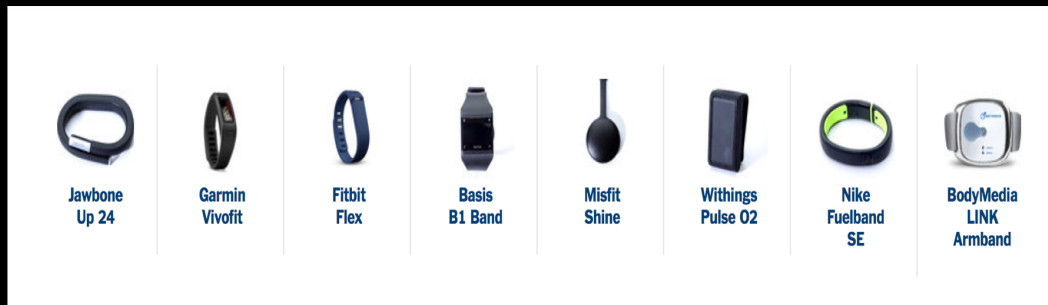
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New Ethical Challenges

Research possibilities and ethical questions in an increasingly smart and connected environment.	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.

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.

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

The
Belmont
Report

Ethical Principles
and Guidelines for
the Protection of
Human Subjects
of Research

The National Commission
for the Protection of Human Subjects
of Biomedical and Behavioral
Research

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.*

Federal Regulations 45 CFR 46

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

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

HUMANS Study Activity

Key Considerations

1. Data science can have powerful consequences, some unforeseen

2. People have differing expectations for data sharing and privacy

3. How can data scientists be good stewards of personal information?

Thank You

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