

Ethical considerations for future data stewards

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With thanks to Camille Nebeker

Overview



New Sources of Data



Mobile



Imaging



Pervasive
Sensing











Social Media



Location Tracking

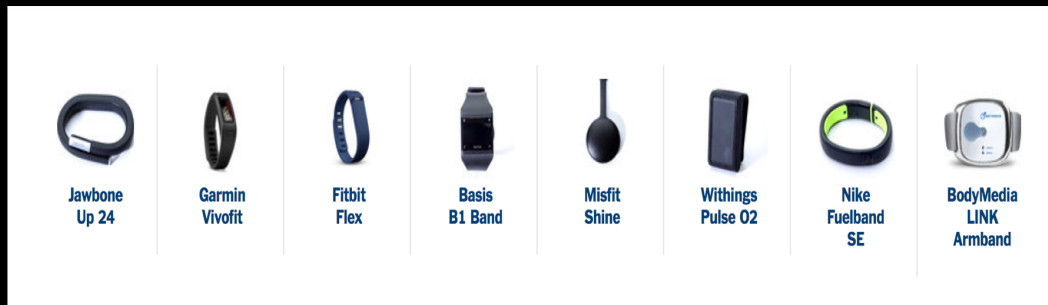
@crebker

New Methods = New Data Types

Wearable Cameras	GPS Tracking	Smart Phones	Social Media
			 <p data-bbox="1367 824 1703 865"> The CORE UCSD @UCSDtheCORE · Apr 5 Rasheed Al-Kotob proudly represents our #COREethics team @UCSDH #PublicHealthWeek #mHealth #DigitalHealth #research_ethics @APHA </p>
			

@cnebeker

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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.”*

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.”



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/>



The screenshot shows the official website of the Office for Human Research Protections (OHRP), part of the U.S. Department of Health & Human Services (HHS). The page features a blue header with the HHS logo and navigation links. A blue arrow points to the 'Regulations' link in the left sidebar. The main content area displays the OHRP mission statement and a recent announcement titled 'HHS Announces Proposal to Improve Rules Protecting Human Research Subjects'. The right sidebar contains a 'Spotlight' section with a date 'September 1, 2011' and a link to a Federal Register notice.

U.S. Department of Health & Human Services
HHS.gov

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Office for Human Research Protections (OHRP)

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

HHS Announces Proposal to Improve Rules Protecting Human Research Subjects

Changes under consideration would ensure the highest standards of protections for human subjects involved in research, while enhancing effectiveness of oversight

The U.S. Department of Health and Human Services has announced that the federal government is contemplating various ways of enhancing the regulations overseeing research on human subjects. Before making changes to the regulations – which have been in place

Spotlight

September 1, 2011
HHS Announces Extension of the Comment Period on Proposal to Improve Rules Protecting Human Research Subjects. Federal Register notice announcing extension can be read at <http://www.gpo.gov/fdsys/pkg/FR-2011-09-01/pdf/2011-22341.pdf>.

The Secretary's Advisory Committee on Human Research Protections (SACHRP) will meet October 4 and 5, 2011 in Room 3000 of the Hubert H. Humphrey Building, Independence Avenue S.W., Washington, D.C., 20201.

For further information on SACHRP, see <http://www.hhs.gov/ohrp/sachrp/index.html>.

Next Previous Highlight all Match case

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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