Ethics, Oversight, and Research involving "Big Data"

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The growth of data available for research purposes

- Personal health data online has grown exponentially
  - much "created" or at least added by individuals themselves
- Evolving functionality and applications of web, mobile and social media have created a new research environment
  - Uses of data are increasingly different than researcher-participant interactions

Collecting Big Data

- What is the right data to collect?
- How to collect it?
- How much to collect?
  - From where?
  - How to determine what is relevant?
- What does it mean?
  - and how to validate what we think it means?
- BUT,
- What are conditions or limitations of use?
- What is the relevance of public health vs. other uses? and
- What about ethics?

Health-related data

- Information 'actively' supplied by individual users
  - medical histories, genomic data, web and app uses
- Personal information collected passively while users interact online, social media, increasingly via mobile
  - Location, content, behavior
- Disclosures to users of the potential collection and uses of personal data vary dramatically

How have we come to research ethics protections?

- 1970s approaches to research *protection* being employed in 2017ff contexts
  - Regulations in substantial part driven by reaction to scandal and desire to prevent exploitation of subjects
  - Consent conceptualized as between researchers and subjects
    - Are these concerns relevant today?
    - Are they relevant for research using Big Data?
      - Web-oriented "consent" standards are de facto practice
        - » Different than research consent
      - Consumer platforms being used for research purposes
        - » Terms of service, etc. on websites, phones, smart devices
  - Regulatory or contractual standards vs. ethics
    - IRBs are applying rules crafted for a different species of research

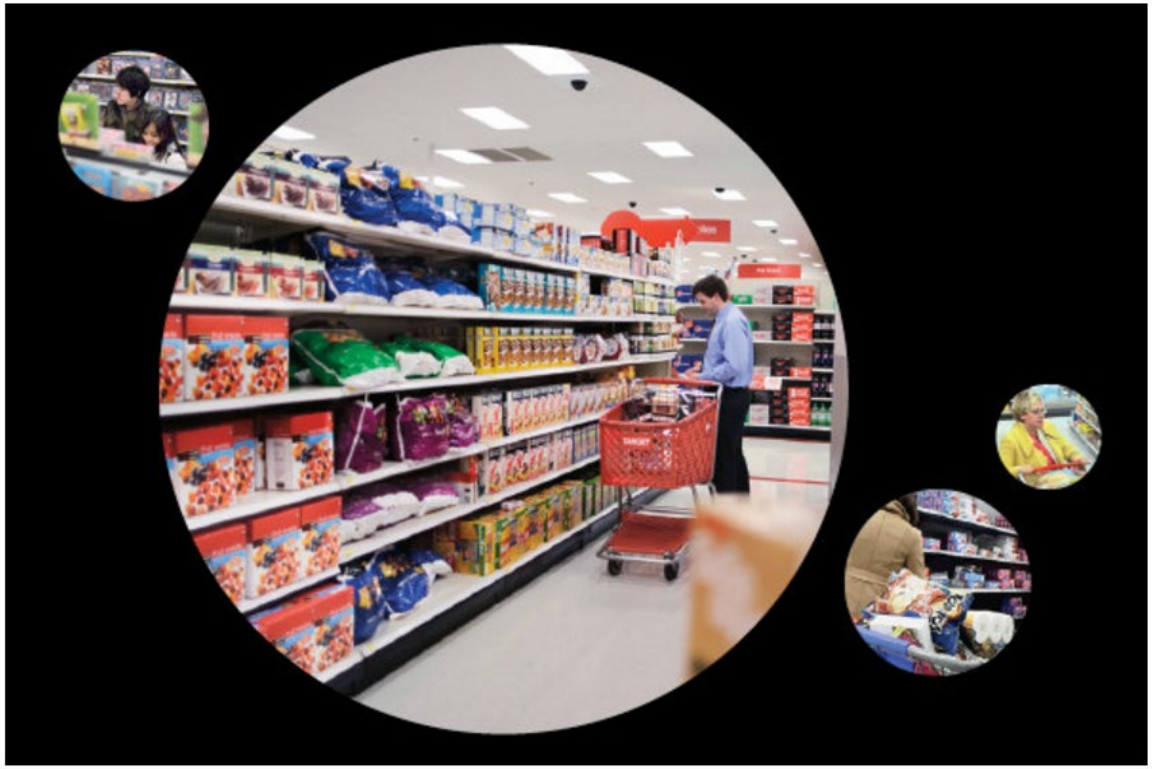
Consent in an evolving research environment

- What do we hope to achieve in the consent process?
  - Disclosure of information
  - Understanding
    - Of uses, by whom, for how long, possibility of secondary disclosures, etc.
    - Of risks and potential benefits
  - Voluntary participation
  - The evolving concept of control of information
- Collection of information for research purposes as a condition of use
  - Three concerns
    - General consent rather than consent to specific research use
    - Disclosure is boilerplate, which calls into question meaningfulness or even awareness
    - Based on consumer agreement rather than informed consent to research
- Opt-in to research
  - Seems closest to satisfying conventional criteria of informed consent
- Opt-out of research
  - Not clear how consistent these approaches are with informed consent for research
- These are all carryovers from more consumer-oriented web environment

Magazine

How Companies Learn Your Secrets

By CHARLES DUHIGG FEB. 16, 2012



Issues outside of the the “traditional” research environment

- Social media content as research data
  - Are terms of service enough?
  - What do we mean by the public nature of social media content?
    - For all to see may be different than for all to use
  - Among the required protections for traditional research participation is opportunity to opt out
    - How to accommodate when terms of service effectively *require* participation?
    - Legal standards may be met, but not the sprit of how we understand the ethics of consent
- What criteria are important in determining whether and under what conditions consent may be required?
  - Identified vs. anonymous?
    - Is there a threshold of metadata collection before identifiability?
- Should the purpose of research be a factor in determining the levels of protection necessary?
  - public health vs research for marketing, recruiting, or other business-related motives
    - Individual rights are trumped by public health; not so in other areas

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OPINION

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Opinion: Learning as we go: Lessons from the publication of Facebook's social-computing research

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and application of regulations continue to evolve as a result (13, 14). As Fiske and Hauser recently argued in PNAS, research involving human participants in social-computing environments suffers from a similar mismatch of the realities of research and the policies gov-

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The shortcomings of existing approaches

- **Regulatory fit**
  - **What counts as research on human participants?**
  - **What ethics oversight applies to private sector and collaborative research?**
- **Informed consent and the meaning of protection of participants**
- **Confusion over relevance and applicability of state and international jurisdictions**
- **Rules for publication**

What to do about them?

- New thinking about consent in data-rich contexts
  - At a minimum, modify disclosures
  - Committing to levels of privacy protection
  - Optimally, modifying consent to more dynamic, context specific process, with control over data and its uses
- Allowing individuals to manage use of data about them
  - Privacy, control, access
- Create standards for ethically acceptable access and uses
  - Inadequate or poor fit of stds => credibility suffers
    - eg, access to Facebook data
  - Opportune moment with growing incentives for change

Proposals for a new framework

- Drawing on Vayena et al.
  - Closing old and new gaps in required oversight
  - Clarity
    - Definitions
      - What and who counts as research?
    - Standards for privacy protection
    - Learn from evolving best practices
  - Create and offer new process and technological solutions
    - Beyond consent and de-identification
    - Safe harbor for use of endorsed solutions
  - Calibrated oversight
    - Tiered access to data
    - Variable access based on criteria of risk-benefit
  - Wider stakeholder involvement in development of approaches
    - Researchers
    - IRB professionals and members
    - Industry
    - Regulators
    - Ethics and privacy experts
    - Journal editors
    - Research participants