OHRP Webinar Lecture Series

Conducting Internet Research: Challenges and Strategies for IRBs

Assessing Privacy and Identifiability, and Maintaining Confidentiality

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DISCLAIMER

This presentation does not constitute legal advice. The views expressed are the presenter's own and do not bind the U.S. Department of Health and Human Services or its operational components, including the Office for Human Research Protections.

OUTLINE

- What is Internet research
- How specific requirements of the HHS protection of human subjects regulations apply to research using the Internet
- Discussion of challenges in managing the ethical issues and regulatory considerations, focusing on assessing privacy and identifiability of subject information, and maintaining confidentiality.
- Possible developments on the Federal horizon relevant to Internet research

Setting the Stage: What is Internet Research?

- Internet research
  - Internet used as a tool for conducting research
    - Examples: online survey, subject recruitment, email or chat interviews
  - Internet as a location or site for conducting research
    - Examples: Collecting data about or observing online environments such as chatrooms, gaming sites, virtual worlds
  - Internet as a source of information
    - Examples: data mining from social media site; collecting data from online datasets, databases, repositories

"Recommendation Concerning Internet Research and Human Subjects Research" SACHRP, approved March 13, 2013, Att. B, p1-2.

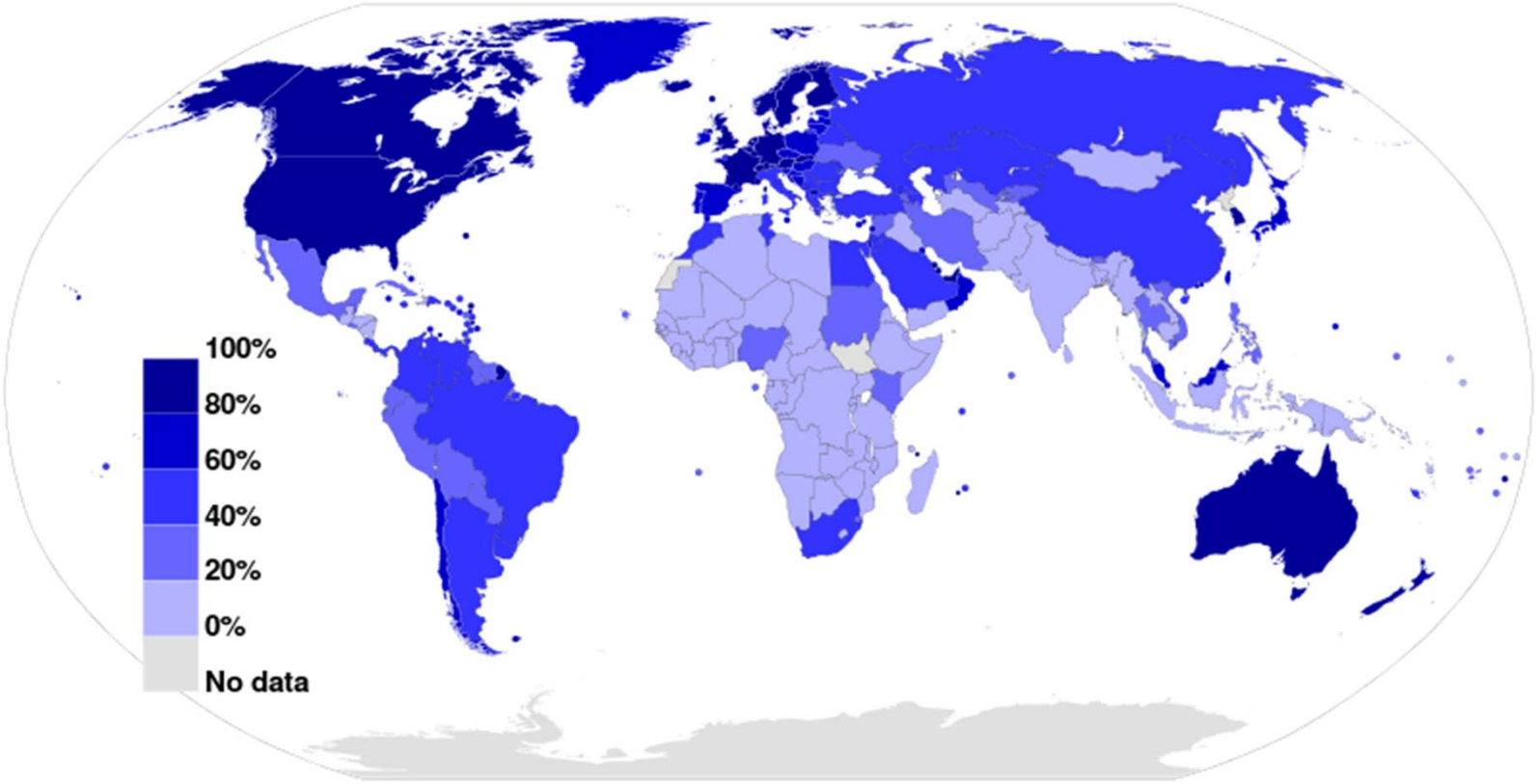
What Types of Internet Research Do IRBs Encounter?

- As of 2007, IRBs reviewed:
  - Online Survey Research (98%)
  - Online Ethnography (1%)
  - Other (Data sets) (1%)

    E. Buchanan, C. Ess, "Internet research ethics and the institutional review board: current practices and issues," Newsletter, ACMSIGS Computers and Society, Volume 39 Issue 3, December 2009

- Times have changed! What IRBs encounter now:
  - Data-scraping bots, mechanical turks, virtual dentistry education simulation, subject recruitment/retention via social media, online clinical trials

WITH INCREASING INTERNET SATURATION…



Internet penetration world map, updated June 28, 2013, Wikimedia Commons: http://en.wikipedia.org/wiki/File:InternetPenetrationWorldMap.svg

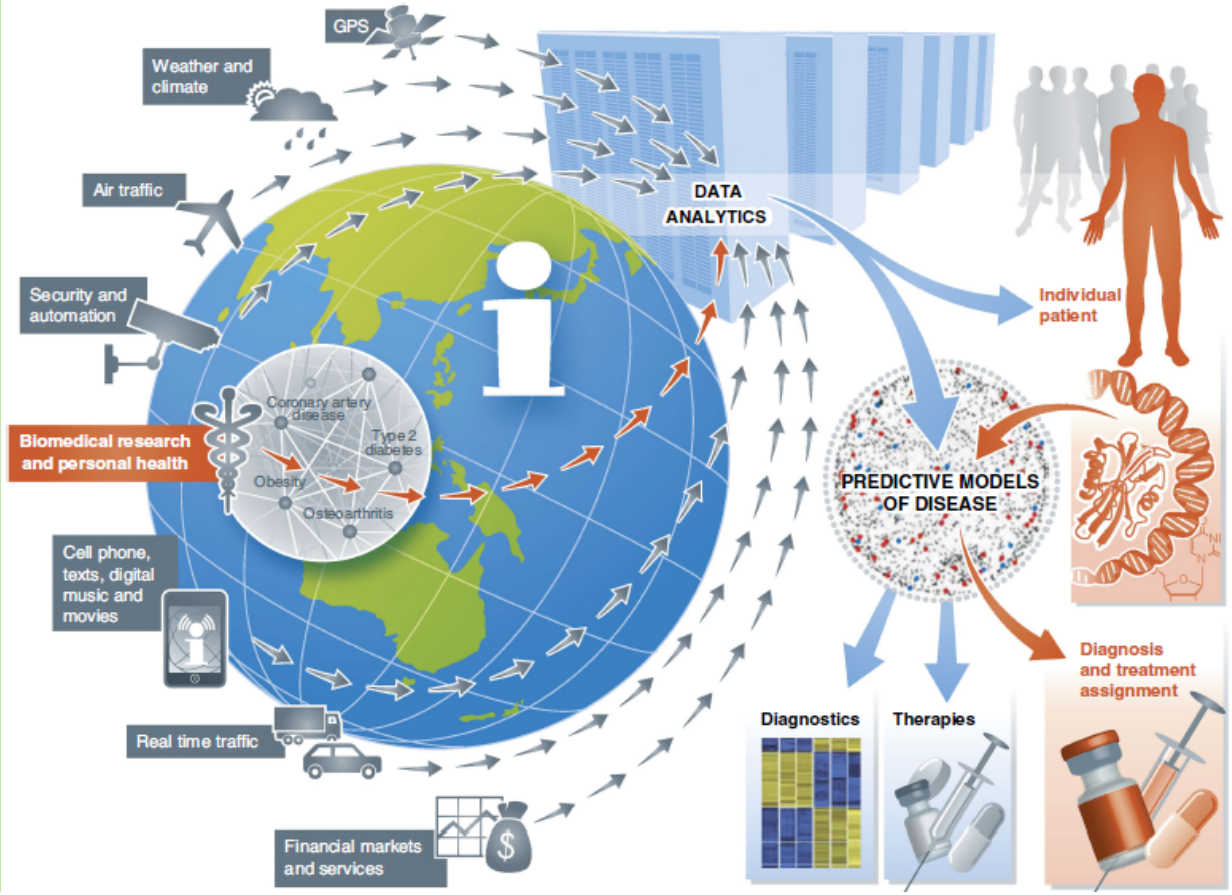
…AND WIDESPREAD SOCIAL MEDIA USE…

Social media – Internet-based applications that allow creation and exchange of user-generated content

Provide mechanisms for users to interact:

--chat, instant messaging, email, video, file sharing, blogging, discussion groups

PLUS THE GROWING AVAILABILITY OF BIG DATA…



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The New York Times **Science**

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Unreported Side Effects of Drugs Are Found Using Internet Search Data, Study Finds

By JOHN MARKOFF
Published: March 6, 2013 | 160 Comments

Using data drawn from queries entered into Google, Microsoft and Yahoo search engines, scientists at Microsoft, Stanford and Columbia University have for the first time been able to detect evidence of unreported prescription drug side effects before they were found by istration's warning system.

FACEBOOK
TWITTER
GOOGLE+
SAVE
E-MAIL
SHARE
PRINT
REPRINTS

Using automated software tools to examine queries by six million Internet users taken from Web search logs in 2010, the researchers looked for searches relating to an antidepressant, paroxetine, and a cholesterol lowering drug, pravastatin. They were able to find evidence that the combination of the two drugs caused high blood sugar.

The study, which was reported in the Journal of the American Medical Informatics Association on Wednesday, is based on data-mining techniques similar to those employed by services like Google Flu Trends, which has been used to give early warning of the prevalence of the sickness to the public.

The F.D.A. asks physicians to report side effects through a

EDITORIAL
The changing privacy landscape in the era of big data
Molecular Systems Biology 8: 612; published online 11 September 2012; doi:10.1038/msb.2012.47

…BIG DATA THAT MAY BE IDENTIFIABLE…

GENETIC DATA + AGE+ REGION, COMBINED WITH GENEOLOGY WEBSITE AND GOOGLE SEARCHES = 5 INDIVIDUALS (AND THEIR FAMILY MEMBERS) IDENTIFIED

GENETICS

Genealogy Databases Enable Naming Of Anonymous DNA Donors

CAMBRIDGE, MASSACHUSETTS—One afternoon in March last year, Yaniv Erlich sat down at his computer to do an experiment. Before he became a geneticist here at the Whitehead Institute for Biomedical Research, Erlich was a white hat: a hacker hired by banks and credit card companies to break into their computer systems and identify weaknesses. Now he was about to do something similar with genome databases. With little more than the Internet, Erlich wondered, is it possible to identify people who anonymously donate their DNA for research? In other words, could he hack someone's name from their genome data?

Hunched over the computer with him was Massachusetts Institute of Technology undergraduate (and now Ph.D.) student Melissa Gymrek who had helped develop an algorithm to extract genetic markers from DNA sequences. By applying the algorithm to an anonymized genome from a research database and doing some online sleuthing with popular genealogy sites, they came up with a

Privacy concerns have been raised about publicly accessible genome data before. A study 5 years ago showed that individuals whose genomes were in seemingly anonymous pools of DNA data could be identified by certain genetic markers, known as single nucleotide polymorphisms, or SNPs (*Science*, 5 September 2008, p. 1278). But this is the first time that people have been identified without needing a sample of their DNA as a reference.

Erlich's team exploited two tricks. The first is that metadata about anonymous DNA donors, such as age at the time of donation and state of residence, is often included with their sequences. Erlich started with the genomes of 32 men of northern and western Euro-

records matching Y-STR to surnames.

When he plugged the 10 genomes with the most recoverable Y-STR markers into those genealogy databases, eight strongly matched to surnames of Mormon families in Utah. Ultimately, he was confident of his guesses for the surnames of five of the genome donors.

Erlich then gathered more information on each one using online resources such as public record search engines and obituaries. He hit the jackpot with metadata in records from Coriell Cell Repositories, a facility in New Jersey that provides cells from the 1000 Genomes Project donors to researchers. With that, he identified family members who had donated their own genomes to the same project, including women.

"I was surprised but not flabbergasted," Rodriguez says. The managers of the 1000 Genomes Project were aware of the risks posed by the metadata and genealogy Web sites, but, she says, "We didn't realize how easy it was to access this information." They immediately removed donors' ages from the publicly available metadata—critical for Erlich's method—but Rodriguez admits that this is only a short-term fix.

This has "huge implications" for the way consent is obtained from DNA

= Increasing Use of Internet for Research

NOTE:

- The HHS protection of human subjects regulations do not specifically reference Internet research
- OHRP has no formal written guidance specifically on Internet research

March 13, 2013: SACHRP voted to provide recommendations re internet research

- SACHRP= Secretary's Advisory Committee on Human Research Protections
- SAS and SOH subcommittees developed recommendations for SACHRP to make to Secretary of HHS and Assistant Secretary of Health re Internet research
- Available on OHRP website: http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf
- **Recommendations are not official OHRP guidance**, as not yet adopted by HHS or OHRP

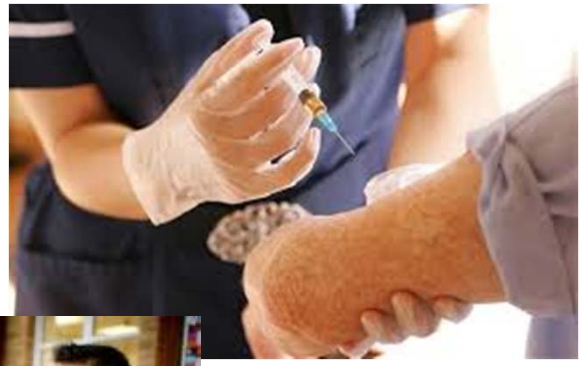
In the Absence of Specific Internet Regulations/Guidance…

Apply the existing regulations and OHRP guidance!

Question for contemplation: How different is Internet research from other types of research?

Is it special?

vs.



Some of the Big Regulatory Issues related to Internet Research

- What is “private”?
- What is “identifiable”?
- How to protect subjects’ privacy and confidentiality interests?
- Minimizing risk when using sensitive online data
  - Current sensitivity vs. future sensitivity

Some of the Related Regulatory Decision Points

- Is the activity research?
- Does the research involve human subjects?
- Does the human subjects research qualify for exemption from the regulatory requirements?
- Does the research present no more than minimal risk such that it may be reviewed via expedited review (if it meets a category)?
- Informed consent – obtained or waived/altered? How to describe confidentiality protections?

What is Research?

- Research: systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 46.102)
- Studying Internet sites or using Internet as a research tool
  - Studying online social networks
  - Online context as ethnographic field site (chat rooms, gaming research)
  - Data mining/scraping from Internet sites
  - Web-based surveys
  - Web-based interviews

HUMAN SUBJECTS – IDENTIFIABLE PRIVATE INFORMATION

45 CFR 46.102(f): "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information

- Private information: "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)."

Privacy on the Internet?

How to interpret “reasonably expect that no observation or recording is taking place” or “reasonably expect will not be made public”

- IM, tweet, email, Facebook profile, chatroom discussion, listserve posting – what is reasonable expectation of privacy in each?
- Or is everything on the Internet that I can see public?

or

?

When is an expectation of privacy "reasonable"?

- People in online environments that are presumptively public often act as if they are in private space
  - Caused by online feelings of anonymity, norms of the Internet space, reduced inhibitions, separation of people from text
- Expectations of privacy may not equate with reality of privacy (or lack thereof)

Asa Rosenberg, "Virtual world research ethics and the private-public distinction," International Journal of Internet Research Ethics, v.3, December 2010:

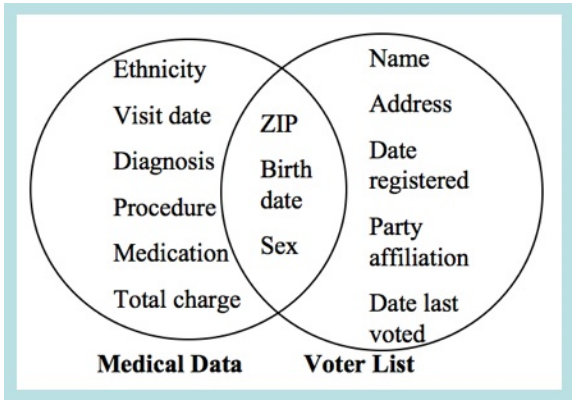
http://ijire.net/issue_3.1/3_rosenberg.pdf

How may the IRB assess whether information obtained via the Internet should be considered private?

- Regulatory standard of "reasonable" does not depend on individual subject's own expectation of privacy
- How to consider what expectations of privacy in the information are "reasonable"
  - Get information about the environment
  - Get information about the users
  - Review Terms of Service, site policy

Human Subjects – Identifiable Private Information (2)

- Identifiable
  - Individually identifiable = subject's identity readily ascertainable by the investigator or associated with the information
  - Structure of social network, search terms, purchase habits, movie ratings on Netflix may uniquely identify individual
    - Zip code + sex + DOB enough for Professor Latanya Sweeney to uniquely identify 87% of US population (de-identified medical data linked to voter info re-identified patients by name)



  - Question for contemplation: given demonstrated ability to reidentify individuals from anonymized or aggregated data, is this a meaningful decision point?

How Can the IRB Assess Identifiability?

- When will the subject's identity be "readily" ascertainable by the investigator or associated with the information?
  - Consider the investigator, e.g. Professor Latanya Sweeney vs. Professor Laura Odwazny
  - Consider the potential identifiers or partial identifiers
    - Direct quotes easily traceable to Twitter account even if handle is removed
  - Consider likelihood of reidentification with triangulation, not just whether it is theoretically possible

AVATARS

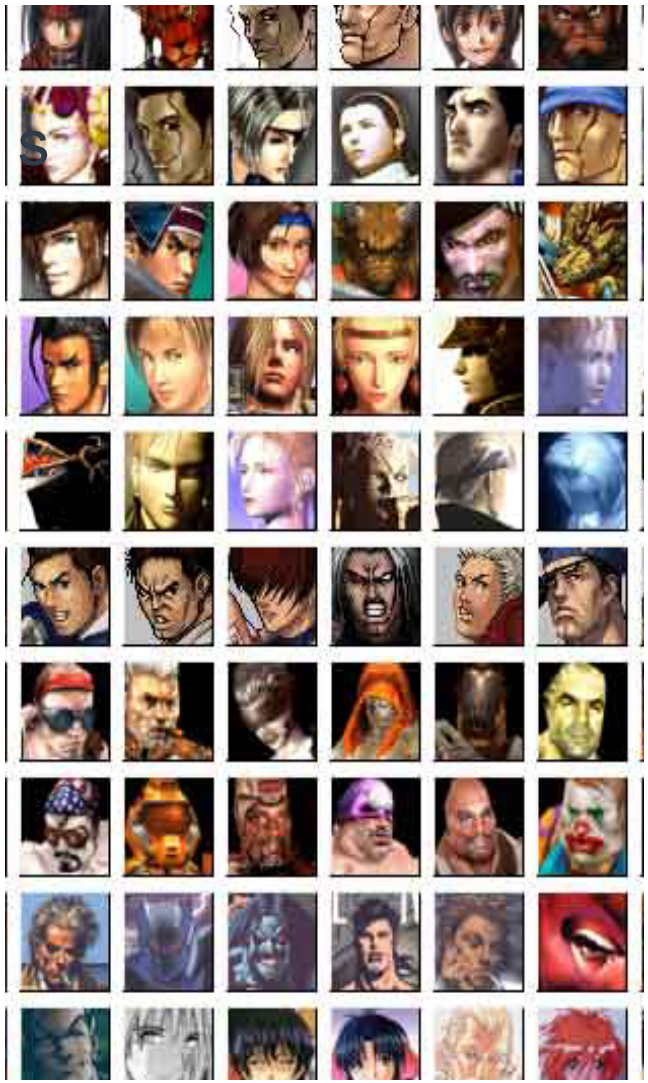
Is information obtained via an avatar information about a human subject?

--Human/bot?

--Interaction/intervention?

--Private and identifiable?

Sensitivity of information obtained from avatar observation akin to information obtained by observing humans?



Relevant Exemptions – Online Education

- 45 CFR 46.101(b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Internet locale could be an "established or commonly accepted educational setting" and online education could be a "normal educational practice"
- Examples:
  - Evaluating the conduct of a web-based class
  - Assessing the efficacy of the use of social media site to disseminate class information
  - Comparison of virtual simulation training to traditional training – ex/ online dentistry procedures conducted in Second Life

Relevant exemptions – Educational Tests, Survey and Interview research, Observation of Public Behavior

- 45 CFR 46.102(b)(2), unless: information is recorded in a manner whereby subjects can be identified AND disclosure of the responses could reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- What is "recorded in a manner whereby subjects can be identified" when the Internet is used?
- What is "observation of public behavior" online?

RELEVANT EXEMPTIONS – DATA MINING

- 45 CFR 46.101(b)(4) -- collection or study of existing data/specimens, if sources are publicly available or if information is recorded by investigator in such a manner that subjects cannot be identified
  - When is information "recorded in an identifiable manner"?
  - When are data, documents, or records publicly available on the Internet?
    - Does "publicly available" include large datasets purchased/obtained from Google or Facebook?
    - What if data are restricted -- available only to 'friends', listserve members?

EXEMPTION 4 CONTINUED: "RECORDED IN A MANNER WHEREBY SUBJECTS MAY BE IDENTIFIED…"

- Is an email address an identifier?
- Do tweets contain identifiers?
- Does the inclusion of IP address make information identifiable?
  - Note: For HIPAA, OCR has stated position (below); OHRP has no formal guidance

The second is the "Safe Harbor" method:

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(E) Fax numbers	(M) Device identifiers and serial numbers
(F) Email addresses	(N) Web Universal Resource Locators (URLs)
(G) Social security numbers	(O) Internet Protocol (IP) addresses

IF NOT EXEMPT… IRB REVIEW

Challenges in IRB review of Internet research:

- Requirement that risks be minimized
  - Two main sources of risk:
    - Participation --No direct contact with subjects; more difficult to deal with individual reactions (intervention, debriefing, follow-up)
    - Breach of confidentiality
- Eligible for expedited review?
  - Must be minimal risk and fall within expeditable research category

Minimal risk

- Probability and magnitude of harm/discomfort in the research not greater than ordinarily encountered in daily life or during routine physical or psychological examinations/tests (46.102(i))
  - Gateway to expedited review; waiver of consent and documentation; no need to explain compensation or any treatments for research-related injury in consent; Subparts B, C, D categories of permissible research
- Risks associated with data security breach, likelihood of access by 3rd parties alter conception of minimal risk in Internet research?
  - Less privacy, more observation in general in daily life

Internet-Based Subject Recruitment

- Facebook page
- YouTube video
- Matching algorithm on social media sites (e.g., PatientsLikeMe)
- “Push” method (e.g., Inspire.com)

OHRP Guidance on Subject Recruitment

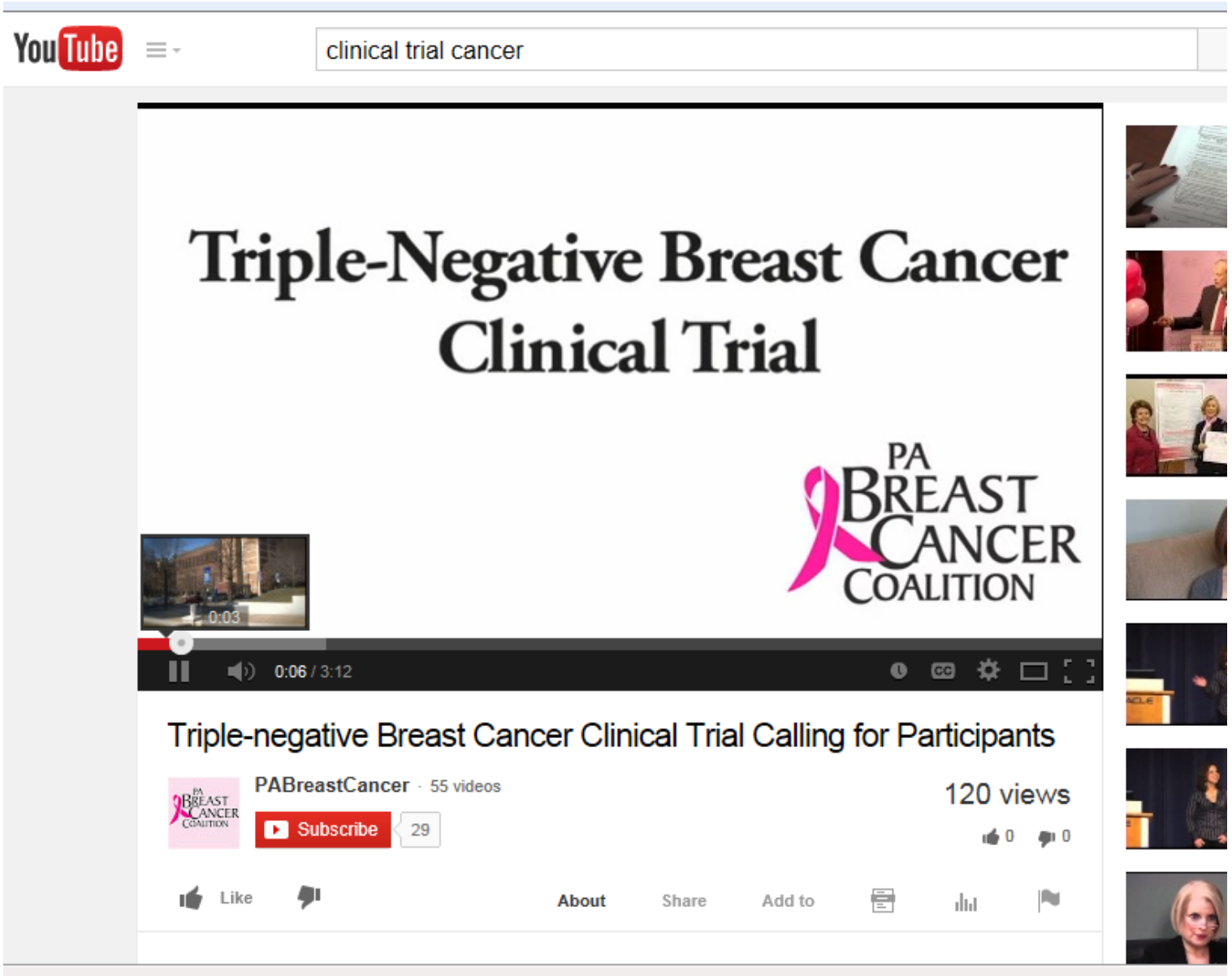
- OHRP considers subject recruitment part of informed consent
  - Recruitment plan must receive IRB review/approval prior to initiation

- OHRP guidance on IRB review of clinical trial websites http://www.hhs.gov/ohrp/policy/clinicaltrials.html
- No IRB review needed for descriptive information:
  - study title
  - purpose of the study
  - protocol summary
  - basic eligibility criteria
  - study site location(s)
  - how to contact the study site for further information

OHRP Guidance (continued)

- IRB review needed if additional information provided
  - Description of research risks/potential benefits
  - Solicitation of identifiable private information (e.g. eligibility survey)
  - Incentives – monetary and non-monetary
- What needs to be reviewed:
  - Recruitment plan, not the actual webpage
    - But screen shots may be helpful to the IRB

Recruitment via YouTube Video



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Research

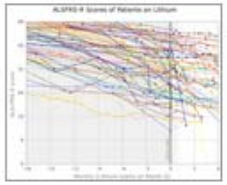
- Clinical Trials
- Research Tools
- Public Research and Presentations
- Publications from Our Team
- Publications that feature PatientsLikeMe
- R&D Policy

Suggestions? **Let us know**

Research Tools

Clinical Trials Tool

We've integrated PatientsLikeMe with ClinicalTrials.Gov to develop a clinical trials matching tool! This allows you to find trials you might be eligible for (including trials of drugs, devices, therapy, or non-interventional studies such as genetics or questionnaires) based on your age, sex, conditions, and location. Click now to find out about trials for patients like you.



ALS Lithium Study - The Results

In 2008, a small Italian study was published suggesting that the drug Lithium could slow the progression of ALS. In response, hundreds of members of PatientsLikeMe began taking the drug and using a new tool and a matching algorithm to conduct a patient-lead observational study. The results of that study, published in Nature Biotechnology, show that we were unable to replicate the promising findings of the Italian group, but that PatientsLikeMe may provide a useful way of conducting observational studies faster and cheaper than existing trial methods.

PatientsLikeMe Research

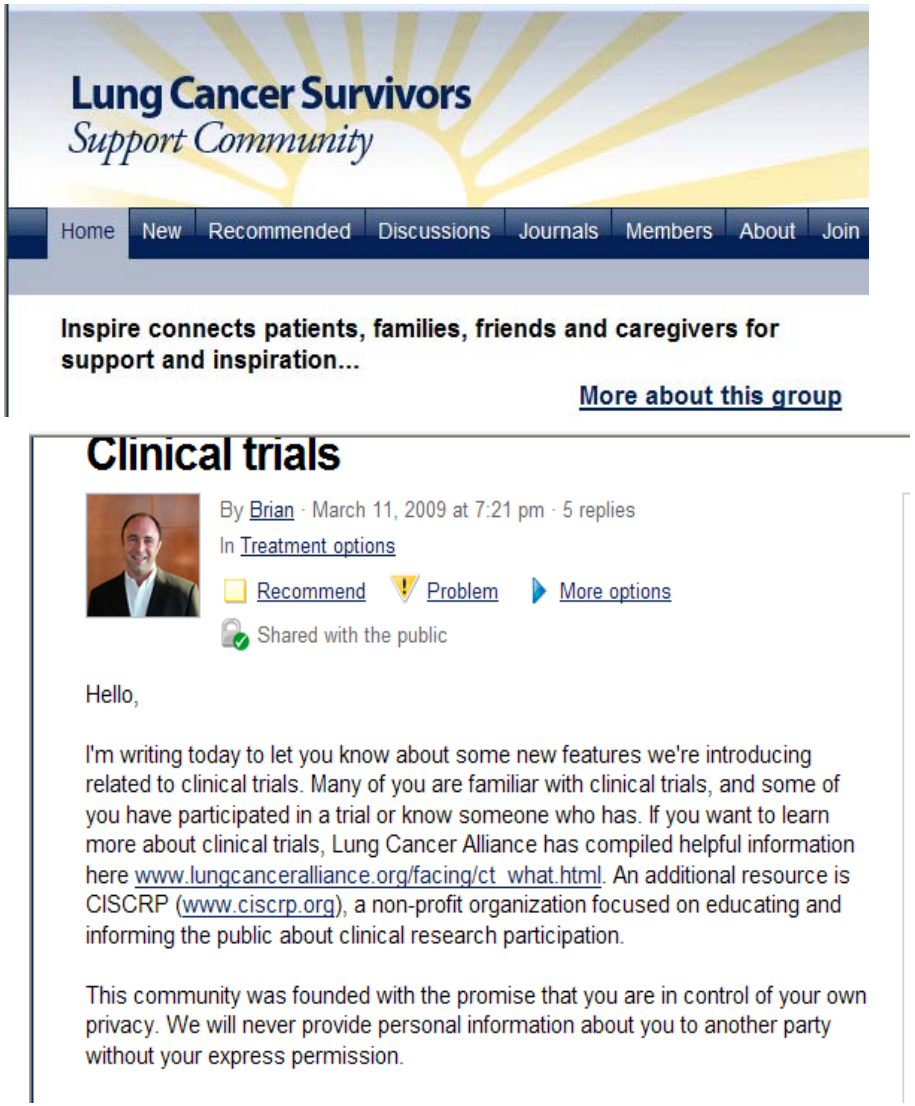
In collaborations with patients, academics and industry leaders, the research team designs and runs studies that contribute the understanding of each of the conditions we serve and the evolution of the site itself. This new research tab will be where we will collect and present our patient tools and research findings. If you would like to contribute ideas about the design of the site or this page please let us know through the suggestions box or link to send the research team an email.

Meet the Research Team

The research team brings a variety of expertise to the design of PatientsLikeMe and the study of the data collected here. Our team's specialities include genetics, sociology, psychology, nursing, drug discovery, predictive modeling, and user behavior.

Shivani Bhargava

Social Media as Recruitment Tool: "Push" Method



Blog post from the founder of Inspire.com (3/1/09):

"I'm writing today to let you know about some new features we're introducing related to clinical trials…What's new is that from time to time we'll tell you about clinical trials in which you may be interested in participating. If you're not interested in participating, simply do nothing. If you do think you might be interested, we'll provide a link where you'll be able to read about a trial, decide if you are interested in participating, and fill out a short survey to see if you may qualify. If it appears that you may qualify, we'll put you in touch with the physicians conducting the trial so that you can learn more and find out if you do qualify."

Considerations with Use of Social Media for Recruitment

- Nature of social media data – easily transmitted quickly within and outside of social network
  - If recruitment method can identify an individual, any potential downstream harms?
  - What happens if recruitment information goes viral?
- Uncontrolled following discussion among viewers/bloggers: interactive, not static
  - Subsequent posts in effect add to posted information from user perspective?
- Must PI/IRB actively monitor social media sites used for recruitment for accuracy of information posted in comments, information about possible unanticipated problems?

Informed Consent in Internet Research

Consent Procedures

- Consider waiver of consent and/or documentation, if appropriate
- A “portal” can be used to provide consent information.
  - Subjects must click through consent page to get to survey
- Where documentation required – consider alternatives to traditional documentation
  - Electronic signatures (state and local law dictate acceptable form)
  - OHRP FAQ on electronic signatures: http://answers.hhs.gov/ohrp/questions/7260

CONSENT PORTAL FOR ONLINE SURVEY

ONLINE WELL-BEING INTERVENTIONS

- Home
- News & Updates
- i-well Study
- Mental Health & Well-Being
- Fact Sheets + External Links
- Sources of Help
- Research Team & Contact Us

Enroll in 2013 Study

Welcome to the OWIUS website!

You should only be reading this if you are a student at Otago University this year and/or in 2012 and have followed the link here.

To enroll in the study, please read the Information Sheet and Consent Form which follow this page. On submitting the consent form you will receive an email with your own user ID# and the link for the online well-being survey for this study.

Enrolment and access to the online survey will close on 30 September 2013.

Thank you.

click to go to >> Information Sheet

Challenge: Protecting Confidentiality while Obtaining Consent in Internet Research

- Sometimes no direct researcher – subject interaction
  - Interaction could be through avatar, profile, survey tool
- Not always clear who subjects are
  - Fluidity of group membership, identity assumed online may differ from actual identity
- May not be desirable or feasible to obtain documentation of consent
  - May provide more identifiable subject information than necessary (could increase risk); fluid group membership, e.g. chat rooms
  - Subjects may be surveilled unknowingly to them or the researcher (key stroke monitoring, spyware)
  - Digital maleficence

Description of Confidentiality Protections in Informed Consent

- 45 CFR 46.116(a)(1)(5) – informed consent must include statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- "Locked file cabinet in locked room" description not sufficient for Internet research!
- Regulatory requirement pertains to "identifying" records: consider potential identifiability of research data obtained using the Internet

Consider When Describing Confidentiality Protections Including…

- **How subject information is transmitted via the Internet**
  - Survey host (e.g., Zoomerang, Survey Monkey) used? Will host retain identifiable information? Will the transmission be encrypted?
- **How information is maintained**
  - Individually identifiable form, de-identified aggregate form?
  - Cloud storage?
- **Circumstances in which subject information might be disclosed outside the research team**
  - Data sharing and data use agreements increasingly being required by funding agencies (NIH, NSF mandates)
  - Remember funding agency access rights and possible mandatory disclosure to OHRP, FDA, ORI, other oversight agency
  - Patriot Act allows access to cloud

Consider When Describing Confidentiality Protections (2)

- **Data security plan**
  - Explain the efforts to protect the data, e.g., secure servers, computers not connected to university network
- **Do not absolutely guarantee confidentiality of subject information**
  - Unrealistic and likely inaccurate
- **If aggregated de-identified data will be made publicly available, consider the likelihood of re-identification of individual subjects whether this should be described**

On the horizon…

ANPRM seeking comment on possible areas of change to the Common Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 46, 160, and 164

Food and Drug Administration

21 CFR Parts 50 and 56

Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators

AGENCIES: The Office of the Secretary, HHS, and the Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Office of the Secretary of the Department of Health and Human Services (HHS) in coordination with the Office of Science and Technology Policy (OSTP) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on how current regulations for protecting human subjects who participate in research might be modernized and revised to be more effective. This ANPRM seeks comment on how to better protect human subjects who are involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

The current regulations governing human subjects research were developed years ago when research was predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site. Although the regulations have been amended over the years, they have not kept pace with the evolving human research enterprise, the proliferation of multi-site clinical trials and observational studies, the expansion of health services research, research in the social and behavioral sciences, and research involving databases, the Internet, and biological specimen repositories, and the use of advanced technologies, such as genomics. Revisions to the current human subjects regulations are being considered because OSTP and HHS believe these changes would strengthen protections for research subjects.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 26, 2011.

ADDRESSES: You may submit comments, identified by docket ID number HHS–OPHS–2011–0005, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Enter the above docket ID number in the "Enter Keyword or ID" field and click on "Search." On the next Web page, click on "Submit a Comment" action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions] to:* Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Office for Human Research Protections (OHRP), Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone: 240–453–6900 or 1–866–447–4777; facsimile: 301–402–2071; e-mail: *jerry.menikoff@hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

U.S. Federal regulations governing the protection of human subjects in research have been in existence for more than three decades. Twenty years have passed since the "Common Rule," (codified at Subpart A of 45 CFR part 46) was adopted by 15 U.S. Federal departments and agencies in an effort to promote uniformity, understanding, and compliance with human subject protections.[1]

Existing regulations governing the protection of human subjects in Food and Drug Administration (FDA)-regulated research (21 CFR parts 50, 56, 312, and 812) are separate from the Common Rule but include similar requirements.

The history of contemporary human subjects protections began in 1947 with the Nuremberg Code, developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis. The Code captures many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects.

Similar recommendations were made by the World Medical Association in its Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, first adopted in 1964 and subsequently revised many times.

Basic regulations governing the protection of human subjects in research supported or conducted by HHS (then the Department of Health, Education and Welfare) were first published in 1974. In the United States, a series of highly publicized abuses in research led to the enactment of the 1974 National Research Act (Pub. L. 93–348), which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission). One of the charges to the National Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines to assure that such research is conducted in accordance with those principles. In 1979, the National Commission published "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as the Belmont Report (*http://www.hhs.gov/ohrp/policy/belmont.html*) which identified three fundamental ethical principles for all human subjects research—respect for persons, beneficence, and justice.

Based on the Belmont Report and other work of the National Commission, HHS revised and expanded its regulations for the protection of human subjects in the late 1970s and early 1980s. The HHS regulations are codified at 45 CFR part 46, subparts A through E. The statutory authority for the HHS regulations derives from 5 U.S.C. 301; 42 U.S.C. 300v–1(b); and 42 U.S.C. 289.

In 1991, 14 other Federal departments and agencies joined HHS in adopting a uniform set of rules for the protection of human subjects, the "Common Rule," identical to subpart A of 45 CFR part 46 of the HHS regulations.

The Common Rule requires that Federally funded investigators in most instances obtain and document the informed consent of research subjects, and describes requirements for institutional review board (IRB) membership, function, operations, research review, and recordkeeping. The regulations also delineate criteria for, and levels of, IRB review. Currently, except for human subjects research that

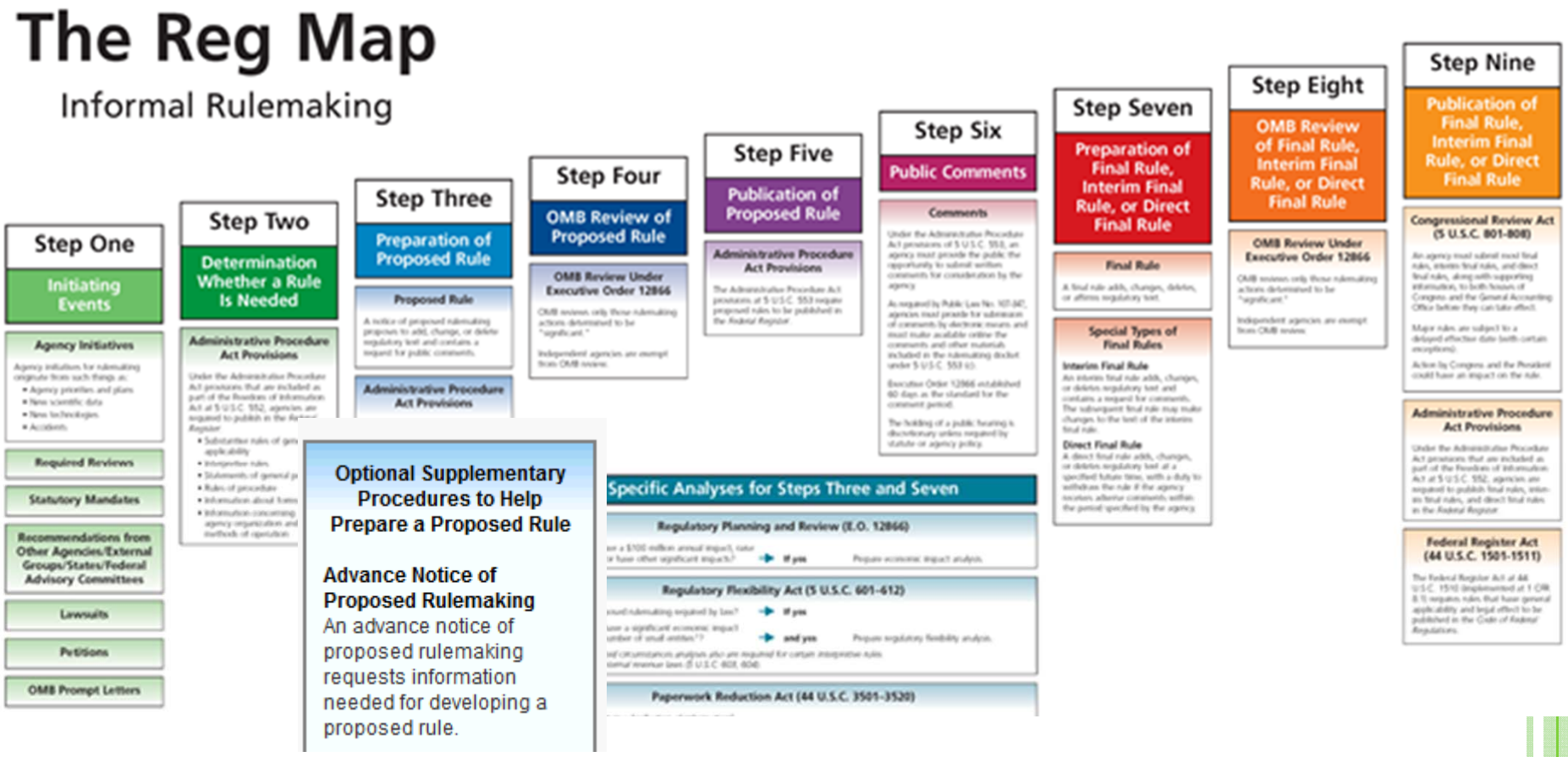
- Published July 26, 2011 by HHS "in coordination with the Office of Science and Technology Policy":

  "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators"

1000+ comments received

Federal Rulemaking Process

http://www.reginfo.gov/public/reginfo/Regmap/index.jsp



↑ OHRP is in Step 3

ANPRM– Implications for Internet research

- To protect from informational risks (inappropriate use/disclosure of information), mandatory data security measures “modeled on” HIPAA?
- Apply Common Rule to all institutions receiving support from CR agency?
- No continuing review for most minimal risk research?

ANPRM – Proposals for "Excused" Research

- Add a new category of minimal risk SBR involving competent adults?
- Additional requirements for "excused" (formerly exempt) research?
  - Consent, oral or written, depending, with waiver contemplated
    - Oral w/o documentation for educational tests, surveys, focus groups, interviews
  - Data security standards

TIMEFRAME FOR NPRM? AS OF APRIL 10, 2014, FALL 2013 REGULATORY PLAN INCLUDES…

OFFICE of INFORMATION and REGULATORY AFFAIRS
OFFICE of MANAGEMENT and BUDGET
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HHS/OASH **RIN:** 0937-AA02 **Publication ID:** Fall 2013

Title: Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators

Abstract: The Department is considering revisions to the current human subjects regulations in order to strengthen protections for research subjects.

Agency: Department of Health and Human Services(HHS) **Priority:** Other Significant

RIN Status: Previously published in the Unified Agenda **Agenda Stage of Rulemaking:** Proposed Rule Stage

Major: No **Unfunded Mandates:** No

CFR Citation: 45 CFR 160; 45 CFR 164; 21 CFR 56; 21 CFR 50

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	07/26/2011	76 FR 44512
ANPRM Comment Period End	10/26/2011	
NPRM	04/00/2014	

Additional Information: Includes Retrospective Review under E.O. 13563.

Regulatory Flexibility Analysis Required: Undetermined **Government Levels Affected:** Undetermined

Federalism: No

Included in the Regulatory Plan: No

RIN Data Printed in the FR: No

Thank You and Stay Tuned!

Questions for OHRP?
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E-mail: OHRP@hhs.gov