Does 45CFR46 Apply to Registry Activities?

Release of Private Identifiable Information to a Registry

- Yes
- No

Data obtained for clinical or administrative purposes
Additional data collected for secondary research purposes

Use of Registry Data

- Yes
- No

Identifiable Data for Research
De-identified Data for Research

Reference:
http://www.hhs.gov/ohrp/policy/Correspondence/correspondence_regarding_the_application_of_45_cfr_part_46_to_the_activities_related_to_a_national_health_registry.html
Correspondence Regarding the Application of 45 CFR part 46 to the Activities Related to a National Health Registry

OHRP has posted its correspondence with the director of a national health registry in letters dated August 11, 2011 and December 29, 2011 responding to questions about the application of 45 CFR Part 46 to the activities related to the registry, in the belief that others may find the content to be useful. The letters clarify the following points:

- If research conducted by a registry is not part of or supported by HHS, or covered by an HHS federalwide assurance, then the regulatory requirements of 45 CFR 46 do not apply to that research activity even if it would be considered nonexempt human subjects research under those regulations.

- The application of the regulations to an activity depend in part on whether the activity meets the regulatory definition of “research,” which depends on the specific facts of the activity, and not whether it is labeled “quality improvement” or something else.

- A research registry could be designed so that the regulations would not apply to the creation and operations of the registry through various mechanisms, including the use of codes instead of identifiers in the original release of data to a registry, or the use of computer programming to merge identifiable data-sets without any person being able to view the data in identifiable form.

- Institutions holding information originally obtained for clinical or administrative purposes whose agents simply release identifiable private information to a registry are not engaged in any research conducted by the registry, and do not have to meet any regulatory requirements of the 45 CFR 46 in this regard.

- Outside researchers who request the release of non-identifiable private information from the registry for secondary research analyses are not conducting “human subjects” research, and therefore the regulations do not apply to this activity, and there is no requirement for either IRB review or informed consent.

- If healthcare providers enhance or extend their standard of care in follow-up interviews with their patients and those changes would have been implemented regardless of any secondary research purpose, then the data collected through those interviews would not be considered research; in contrast, if part of the reason for the change in interview data collected is for research, then the data collection would be considered part of a research activity.

- Where appropriate, OHRP supports the use of single or central IRB review and approval of research conducted by clinical registries in circumstances where more than one institution is engaged in the research.

OHRP notes that the activities of such registries may also need to meet requirements under the Health Insurance Portability and Accountability Act (HIPAA), administered by the Office for Civil Rights.
Rights (OCR). OHRP encourages institutions with questions about the HIPAA regulations to contact OCR directly, at (800) 368-1019.

OHRP is working to provide helpful information to institutions and the public regarding the applicability of the regulations to the various kinds of activities carried out by health registries and the institutions involved in some way in those activities. OHRP has asked the Secretary’s Advisory Committee on Human Research Protections (SACHRP) to provide recommendations related to this topic, and continues to develop information that can be used to protect human subjects in research and avoid unnecessary confusion and administrative burden.

The links below provide the full text of OHRP’s August 11, 2011 and December 29, 2011 response letters. The registry director agreed to the posting of OHRP's responses to his letters. Comments on this or other topics may be submitted to OHRP by email at ohrp@hhs.gov. Please include the phrase “August 11, 2011 and December 29, 2011 letters regarding registries” in the subject filed. Alternatively, comments may be submitted to:

Office for Human Research Protections
1101 Wootton Parkway, Suite200
Rockville, MD 20852

• OHRP December 29, 2011 response
• OHRP August 11, 2011 response

http://www.hhs.gov/ohrp/policy/Correspondence/correspondence_regarding_the_application_of_45_cfr_part_46_to...
Coming Face to Face with the New Normal in Internet Research

by Elizabeth Buchanan, PhD, Endowed Chair in Ethics, University of Wisconsin-Stout

On Thursday, October 30, PRIM&R will host a webinar, The Future of Internet Research: What We Can Learn from the Facebook Emotional Contagion Study, which will explore the Facebook emotional contagion study and some of the questions that it raised related to internet and social media research. In advance of that webinar, we are sharing different perspectives on the controversy. Last week, PRIM&R’s executive director, Elisa A. Hurley, PhD, explored the reasons for the public outcry, and in this week’s post, webinar presenter Elizabeth Buchanan, PhD, explains what the Facebook study can teach us about the “new normal” in internet research.

When news of the Facebook contagion study hit, I was presenting a session on research ethics to the VOX-Pol summer school at Dublin City University. I had intended to discuss the Belfast Project as an example of social, behavioral, and educational research gone badly—indeed, this project had international intrigue, raised serious issues related to participant privacy and consent, and pushed research regulations to their limits. But, suddenly, with news of Facebook’s newsfeed manipulations, there was a hot new case in internet research to consider. The first responders were quick to call attention to the “creepiness” of the study (the name of the article itself might be responsible for the creepiness factor: “Experimental evidence of massive-scale emotional contagion through social networks”); those responses were quickly followed by questions about user/participant consent and the ethics of deception research. Initial reactions seemed to center around several points:

- This research was definitely “wrong”—individuals should have been told about the research. Deception research is okay, but there are “rules.”
- Facebook isn’t a regulated entity and doesn’t have to follow “the rules.”
- Facebook should exercise some ethical considerations in its research—some called for it to “follow the rules,” even if they aren’t what we are used to.
- Facebook does have rules; they are called “terms of service.” Did Facebook violate something else, like user trust?
- Facebook does research pervasively, ubiquitously, and continuously. “Everyone” knows that.
- Why is this case different? Because the line into an academic, peer-reviewed journal was crossed with—gasp—industry research?
- Why didn’t an earlier version of the study, in 2012, raise such fuss?
It has been a few months since the initial fallout from the study, and we have seen interesting afterthoughts and nuanced thinking on the study from the academic press, popular media, tech journals, and more. For example, there was Mary Gray’s panel titled “When Data Science & Human Subject Research Collide: Ethics, Implications, Responsibilities,” and the Proceedings of the National Academy of Sciences published “Learning as We Go: Lessons from the Publication of Facebook’s Social-Computing Research.” There was also a joint reaction from 27 ethicists in Nature, which argued against the backlash in the name of rigorous science. And, to empirically assess if a “similar” population of users—namely, Amazon Turkers—would respond to research ethics violations in ways similar to the subjects of the contagion study, Microsoft’s Ethical Research Project conducted its own study.

I’ve been studying internet research for a long time—at least a long time in internet years, which are quite similar to dog years. I remember the AOL incident and the “Harvard Privacy Meltdown.” Those, and now the contagion study, are internet research ethics lore. They are perfect case studies.

Recently, I had the good pleasure of presenting on the contagion study at the Society of Clinical Research Associates’ Social Media Conference. There were some in the room who were unaware of the controversy. Others were of the mind that we should expect this sort of thing. And, some were aghast (my anecdotal results align, more or less, with what Microsoft’s Ethical Research Project systematically found!). And, recently, I talked with yet another reporter, but this one asked a very pointed question: “Why are people so upset?”

One reason is that we have finally come face to face(book) with the reality of algorithmic manipulation—we are now users and research participants, always and simultaneously. If we stopped to think about every instance of such manipulation on any social media platform, our experiences as users would be dramatically different. But it is happening, and our interactions on the internet are the subject of constant experimentation. As OKCupid reminded us: “…guess what, everybody: if you use the internet, you’re the subject of hundreds of experiments at any given time, on every site. That’s how websites work.” Welcome to the era of big data research, composite identities, and the “new” frame of research.

The Facebook study also sheds light on a clash between the “human subject,” as defined in existing research regulations, and the data persona that we develop though our interaction with social media. Traditional research regulations are being challenged by new forms of participant recruitment, engagement, and analyses that defy a strict alignment of regulations to praxis. The current era of internet research will only reveal these clashes more and more, and in many ways, the contagion study is a perfect example of this "new normal" in internet research ethics. I mean a few things by this.

First, we’ve been seeing a morphing of the research space for many years in the face of social media. It is becoming more and more difficult to isolate "research" from every day activities and experiences, and it is increasingly more challenging to distinguish the researcher from other stakeholders in the research enterprise. Similarly, distinguishing between users, or consumers/customers, and research subjects is becoming more
complicated. The research spaces of today’s social media are ubiquitous and pervasive.

Second, for years, the computer sciences and, more specifically, computer security research, have been engaged in various forms of research like the contagion study and have been publishing their results widely. However, these researchers have stayed, in general, outside the fray of human subjects research. The dominance of Facebook is obviously a variable in this case, but, as others have stated, this is certainly not the first, nor the last time this kind of research will be conducted.

Third, this case calls into clear view the importance of considering terms of service (and recognizing their inherent limitations vis-a-vis the regulations and the application of the regulations to third-party controlled research) in relation to “consent.” We must acknowledge how differently conceived and understood “consent” is under the framework of human subjects research versus other legal settings. Consider, for instance, that while there are alternatives to research participation, the terms of service acknowledgement is a legal requirement with only one alternative: Don’t use the service. As users agree to the terms of service of various sites, new challenges related to internet research arise. For example, a site may be used as a research venue by a researcher, but the consent conditions are in direct contrast with the site’s terms of service (e.g., research participants are told that their data will discarded after some time, when the terms of service state otherwise). As our research spaces merge, it is critical to understand this distinction between consent and terms of service and conceptualize a flexible approach that fulfills the letter and spirit of ethics and law.

Fourth, the new normal of internet research is also one of identifiability. From the technical infrastructure to the norms of social media (e.g., the norm of sharing), individuals are intentionally and unintentionally contributing to the sharing and use of data across users, platforms, venues, and domains. Within this framework, we are seeing an increase in non-consensual access to data. Data streams are complex, intermingled, and always in flux, and it is, in IRB lingo, becoming impracticable to seek and/or give consent in this environment (think big data, of course). From these streams, and from these diverse data, we can extrapolate theories, patterns, and correlations to individuals and communities. We, individually and collectively, are identifiable by our data streams, hence the targeted ads, newsfeed content, recommendations, and so on, that determine our online experiences. Our online experiences could be very different, and to this end, researchers are studying the ethics of algorithms very closely now. But, the days of anonymous FTP (file transfer protocol) do seem a thing of the past. Anonymous data is simply not valuable in the new normal of internet research.

The Facebook study also demonstrates the importance of reconsidering group harms, secondary subjects, and research bystanders—the internet of today is not about the individual as much as it is about patterns, groups, connections, relationships, and systems of actors and networks. Within this complex nexus, the notion of consent is changing, as is the notion of “minimal risk.” Our everyday realities now include the risks of data manipulation, data sharing, aggregation, and others. Our consent is more often implicit, and that long-standing notion of practicability is ever more important.
In this nexus, we are finding a space for communication between and among researchers of all walks. But, once again, I am brought back to a most fundamental question in research: “What does the research subject get out of it?”

Where do we, the collective research community, go from here? What do the feds think about this? Facebook issued new research guidelines, but are they enough? Would a joint statement from the Federal Trade Commission and the Office for Human Research Protections be useful? What does this case, and the collision of customers and subjects, mean to them? As we academics scurry for special issues and conference panels on the implications of the contagion study, does anyone else, including industry researchers and the subjects of their research, want to weigh in?

Or, will this be simply cast to the cannons of internet research ethics lore? I know that I, for one, am eager to continue the conversation that this study started. To that end, I invite you join me on Thursday, October 30, for a webinar titled The Future of Internet Research: What We Can Learn from the Facebook Emotional Contagion Study.

Please note: Portions of this post were previously published on the IRB Forum; I thank the many contributors across the internet for their thoughts and insights.

TAGS: IDENTIFIABILITY, INFORMED CONSENT, INTERNET, RESEARCH ETHICS, SOCIAL MEDIA, WEBINAR

NO COMMENTS:

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Protecting human research participants in the age of big data

Susan T. Fiske and Robert M. Hauser

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Facebook's experimental manipulation of newsfeed content and the subsequent PNAS publication of significant findings from it (1) have drawn attention to the regulation of human participation in academic research and to the differences between commercial and academic research. Those events were recognized in an Expression of Concern in PNAS (2). In commerce and on the Internet, experimentation is ubiquitous and invisible, and there are no protections for human participants beyond typically unread use agreements. In contrast, academic research is almost always governed by the provisions of the "Common Rule," the US Department of Health and Human Services' Code of Federal Regulations Title 45 Part 46 (45CFR46), "common" because it has been adopted by numerous federal agencies and applied to many research institutions. One might well wonder why academic research is more subject to ethical review than that of business enterprises. Unregulated (Facebook) and regulated (Cornell University) activities were combined in the PNAS publication (1), the former by experimenting with large numbers of unwitting participants, the latter by approving the use of preexisting experimental data as exempt from the university's ethical review.

Susan T. Fiske, chair of the National Research Council Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences, and Eugene Higgins Professor of Psychology and Professor of Public Affairs at Princeton University.

http://www.pnas.org/content/111/38/13675.full
Robert M. Hauser, Executive Director of the Division of Behavioral and Social Sciences and Education at the National Research Council, and Vilas Research Professor and Samuel Stouffer Professor of Sociology, Emeritus, at the University of Wisconsin–Madison.

Time to Revise the Common Rule

Over the quarter century since the last revision of the Common Rule, the technologies of communication, data collection and analysis, and experimentation have transformed radically. Thus, it is time for a forward-looking revision of the Common Rule that will maintain adherence to the principles of the Belmont report of 1978: respect for persons, beneficence, and justice (www.hhs.gov/ohrp/humansubjects/guidance/belmont.html (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)). Revision began in 2011 with a draft of proposed changes that elicited about 1,000 written comments. Thus, with support from the National Science Foundation and a number of private organizations and foundations, the National Research Council (NRC) prepared a consensus report on revision of the Common Rule (3).

Among other tasks, the NRC report recommends human subjects regulations for the age of big data. First, the report defines “human subjects research” (HSR) as “a systematic investigation designed to develop or contribute to generalizable knowledge by obtaining data about a living individual directly through interaction or intervention, or by obtaining identifiable private information about an individual” (Rec 2.1) (3). In practical terms, using publicly available information is not HSR, even if information is identifiable, as long as individuals have no reasonable expectation of privacy (Rec 2.3). Examples include observing, coding, and recording behavior in public places (including certain Internet and other digital data) where an individual has “no reasonable expectation of privacy” (3). For example, analyses of posts to a public forum would not be HSR.

The NRC panel recommended adopting the draft regulation’s new category of “excused” research for nogreater-than-minimal information risk (Rec 2.5–2.7) (3). That is, researchers could register such projects with their institutional review board (IRB). The relevant IRB would have a short, defined period to object, and without an objection the research could proceed. “Excused” projects would have to fit the standard of no-greater-than-minimal risk (i.e., everyday risk), of which IRBs would audit a small random subset. The main
issue would be identity protection, established by registering a privacy-protection plan with the IRB. These recommendations would excuse the reuse of much preexisting data, even with private information, as long as participants’ identities are protected.

The NRC panel recommended extending the “excused” category to include benign interventions or interactions that are familiar in everyday life (educational tests, surveys, focus groups), even if the research queries people’s physical or psychological well-being, as long as participants agree to participate and their identities are protected. Certain public Internet interactions would be included here if they fit the rest of the guidelines.

Understanding Risks in Daily Life

Ambiguity remains, but research can resolve it. To protect human subjects more effectively, according to the no-greater-then-minimal-risk standard, the panel recommends first understanding the risks in daily life of the general population. Otherwise IRBs, researchers, and the public operate on anecdote and hunch. Second, IRBs and researchers need standards “for calculating risk from both the probability and magnitude of harm” (3). HSR protection need not overreact to vanishingly small probabilities of worst-case scenarios (nor underreact to highly probable, greater-than-everyday risk). Third, the panel suggested research on “minimizing potential harms to no-more-than-minimal risk.” Finally, research should “study effects of social and behavioral research on research participants for evidence-based assessments of ‘known and foreseeable’ risk” (3). Research would help take public reactions to the Facebook study out of the realm of speculation and into the realm of evidence.

Given the rapid change in information and technology, ongoing research needs to study (i) innovations in the data use of nonresearch information and records, (ii) new ways of collecting and linking data, and (iii) new methods for measuring informational risk and risk reduction. Ultimately, research needs to test disclosure-limitation mechanisms against actual datasets to develop best practices and to develop disclosure risk-assessment and risk-mitigation strategies, consistent with “big data” used in the social and behavioral sciences.

Future academic studies (covered by the Common Rule) should carefully tailor consent processes to the relevant context and population, not just use standardized, all-purpose forms (Rec 4.1, 4.2) (3). The consent process should not be used to limit institutional or sponsor liability (Rec 4.3) (3).

A Multifaceted Approach

IRB review does not apply to Facebook and other private enterprises, yet they generate data that can benefit humanity. Reuse of those data (or any Common Rule-covered data) requires an array of data-protection approaches (Rec 5.1), such as: (i) a portfolio approach considering safe people, safe projects, safe data, safe settings, and safe outputs; (ii) a range of statistical methods to reduce disclosure risk; (iii) consulting resources and data protection models, such as university research data-management service groups, individual IT/protection experts, and specialized institutions; (iv) use of existing standards for data protection promulgated by the National Institute of Standards and Technology; and (v) developing a national center to define and certify information risk of different types of studies and corresponding data-protection plans to minimize risks (Rec 5.2) (3).

Human subjects protection is an enduring value. It is especially important that the Belmont report principle of
respect for persons—autonomy and protection—must prevail in the age of big data.

Footnotes

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The authors declare no conflict of interest.

References


3. Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences; Board on Behavioral, Cognitive, and Sensory Sciences; Committee on National Statistics; Committee on Population; Division of Behavioral and Social Sciences and Education; National Research Council (2014) *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (National Academies Press, Washington DC).

Online Impact
Stanford Apologizes for Montana Election Mailers

Mailers sent to 100,000 voters in Montana as part of the research project
BY MATT VOLZ, ASSOCIATED PRESS // OCT 24, 2014 // AP STORY, LATEST HEADLINES, NEWS & FEATURES

Stanford University officials apologized for any confusion caused by election mailers arriving at Montana voters’ homes in a research project conducted by political science faculty members.

The university is conducting an inquiry into the research methods of the project by Stanford University and Dartmouth College researchers, Stanford spokeswoman Lisa Lapin said Thursday.

“We do share the concerns that the mailers have caused confusion among voters,” Lapin said. “We sincerely apologize to those voters and we apologize to the secretary of state for the confusion we caused.”

The “2014 Montana General Election Voter Information Guide” mailers carry the Montana state seal and rate how liberal or conservative the four nonpartisan candidates for state Supreme Court are.

Secretary of State Linda McCulloch called the mailers “deceitful” and led voters to believe they came from her office. The mailers crossed a line in attempting to influence voters, she said.

http://flatheadbeacon.com/2014/10/24/stanford-apologizes-montana-election-mailers/
The mailers were sent to 100,000 voters in Montana. Two other states are also in the study: New Hampshire, where voters in one congressional district received 66,000 mailers, and California, where information was sent to 143,000 voters in two congressional districts.

No complaints have been received from those states, Lapin said.

The study is nonpartisan and independent of state officials or candidates, and it was approved by the Dartmouth Institutional Review Board, she said.

That review board approval is key to the school’s investigation into the research, but “conversations are ongoing on campus about the nature and scope of the project,” Lapin said.

Montana judicial elections are nonpartisan, meaning that candidates cannot identify themselves as part of a political party. The rules are meant to ensure an independent judiciary.

Former state solicitor general Lawrence VanDyke is challenging incumbent Justice Mike Wheat, and Billings attorney W. David Herbert is attempting to unseat Justice Jim Rice.

McCulloch said she and Commissioner of Political Practices Jonathan Motl are looking into what laws might have been broken, if any.

“The concern is that it has the appearance of a communication on behalf of the state of Montana when it is not, in fact, a state of Montana communication,” Motl said. “It does not look like a scholarly document.”

The fliers carry the state seal and the title “2014 Montana General Election Voter Information Guide.” Underneath, it places the judicial candidates on a scale from “More Liberal” to “More Conservative,” with President Barack Obama and former Republican Massachusetts Gov. Mitt Romney at either end of the scale.

“Take this to the polls!” a line at the bottom of the mailer says.

The study sought to learn whether voters are more likely to participate in elections if they are provided more information about candidates, Lapin said.