

How should human subjects regulations change?

A guide to “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators” for scholars in the social sciences, humanities, and journalism, and the organizations that serve them.

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Introduction

Most university-affiliated scholars—both faculty and students—in the United States who conduct research about living people have, at one time or another, found themselves in contact with their universities' human subjects protections office or their institutional review board (IRB). These bodies oversee not only medical and psychological experimentation, but also interviews, surveys, focus groups, and participant observation.

In the vast majority of cases, after completing some online training, filling out some forms, and perhaps modifying their consent forms or other plans, non-biomedical researchers are able to proceed with little delays. Some researchers find the process helpful, either because it clarifies their thinking about their projects or because it protects the rights and welfare of the people they plan to study. Others find it unhelpful but a minor inconvenience.

Many researchers, however, are angry at the IRB system. Some object to the requirements as infringements on their academic freedom or find that the process significantly interferes with their work as researchers and teachers. When these scholars ask why their universities require them to submit their plans for approval, they are told that the universities are bound to obey a set of federal regulations on human subjects research. First promulgated in 1974, these regulations were revised in 1981 and adopted by more than a dozen federal agencies in 1991, and are therefore now known as the Common Rule.

On 26 July 2011, 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) issued an advance notice of proposed rulemaking (ANPRM), opening up the regulations for substantial revision.¹ The ANPRM concedes that there are problems with the way IRBs review social science, and notes that “Over-regulating social and behavioral research in general may serve to distract attention from attempts to identify those social and behavioral research studies that do pose threats to the welfare of subjects and thus do merit significant oversight.”

The ANPRM presents various possible changes and poses 74 questions about them. It requests comments from interested parties within a 60 day period, ending at 5 pm on 26 September 2011. This gives scholars the best opportunity in more than 30 years to reshape the basic rules that govern their interactions with the people they study.

This document is intended to provide guidance to scholars in the social sciences, humanities, and journalism by helping them understand the significance of the questions posed by the ANPRM. Specifically, it seeks to simplify the response process by presenting scholars in these fields not with all 74 questions in the ANPRM, but with the ten broad questions that should most concern them. This is a work in progress, and I welcome questions or comments at zschrags@gmu.edu.

¹ Department of Health and Human Services, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," *Federal Register* 76, No. 143 (26 July 2011).

1. What forms of research should be subject to the Common Rule?

The most basic question posed by the ANPRM is what kinds of research should be covered by federal regulations.

The current Common Rule "applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research."

It defines "research" as

a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

and "human subject" as

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.

These definitions are both broad and vague, and over the years universities have struggled to understand how far they extend. For example, most universities do not consider journalism to be covered, but some have required journalism students to submit their projects for review. Most universities do require oral historians to submit their plans to IRB offices to see if they fall under the definition of research, but some do not.

The ANPRM's Question 25 specifically asks whether the regulations should be clarified to exclude some forms of scholarship:

Question 25. Are there certain fields of study whose usual methods of inquiry were not intended to or should not be covered by the Common Rule (such as classics, history, languages, literature, and journalism) because they do not create generalizable knowledge and may be more appropriately covered by ethical codes that differ from the ethical principles embodied in the Common Rule? If so, what are those fields, and how should those methods of inquiry be identified? Should the Common Rule be revised to explicitly state that those activities are not subject to its requirements?

Scholars who would like less IRB intrusion in their work have three basic options as they respond to this question.

1. Define some forms of scholarship as non-generalizable and therefore not subject to regulation

As noted above, the current regulations define research as work "designed to develop or contribute to generalizable knowledge." Since the 1990s, some federal officials and universities have held that journalism, biography, and oral history do not meet this criterion and are therefore not subject to regulation. However, the boundaries of generalizability have proven hard to define, and historians have felt uncomfortable describing their work as something other than research.

2. **Rewrite the definition of research to exclude some forms of scholarship in other terms.**

The ANPRM anticipates substantial revision of the Common Rule, so this might include a rewriting of the definition of research. In particular, definition could be rewritten to reflect the statute (42 USC 289) that serves as the authority for the regulations. That statute governs only “biomedical and behavioral research.” If the regulations were rewritten to apply only to biomedical and behavioral research, and these terms were adequately defined, then IRBs might no longer cover anthropology, folklore, geography, history, journalism, political science, sociology, and other fields in the social sciences and humanities.

3. **Accept that the Common Rule covers a broad range of scholarship, but carve exceptions for particular methods**

Redefining “research” is not the only path to deregulation contemplated by the ANPRM, so a third possibility would be to accept Common Rule jurisdiction but limit its impact on particular methods.

2. What ethical principles govern different kinds of research?

In its reference to “ethical codes that differ from the ethical principles embodied in the Common Rule,” the ANPRM’s question 25 raises an important issue not adequately addressed in the ANPRM itself.

As the ANPRM notes, the Common Rule is intended—in part at least—to make research conform to “the principles of respect for persons, beneficence, and justice.” This is a reference to the *Belmont Report*, a document produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1978 and based on traditions of ethics in medical and psychological experimentation. Some social scientists feel that the basic principles of the Belmont Report apply equally well to their work, but others have objected, particularly to the notion that the instruction “do no harm” describes the ethical duty of a scholar who may be studying the misdeeds of powerful individuals and groups. In Canada, such objections have led to explicit recognition of the values of critical inquiry and academic freedom being encoded in the second edition of the edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

Scholars may wish to comment on the applicability of the *Belmont Report* to their work in their responses to Question 25.

3. Would scholars fare better if their work were “excused”?

Under the current Common Rule, most social research is exempt from oversight unless “any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.” But these are exceedingly vague terms. Since the mid-1990s, the federal recommendation that investigators not be permitted to make the exemption determination, combined with the threat of federal sanction for incorrect determinations, has led institutions to insist that only IRB members or staff can determine a project to be exempt. Thus, “exempt” no longer means exempt, leaving researchers unhappy and IRBs overwhelmed with work.

Section 3 of the ANPRM imagines replacing this “exempt” status with a new “Excused” category with the following characteristics:

- The current exemptions would no longer operate. Instead, various types of research that present risks to privacy but not immediate psychological or physical risks would be deemed “Excused.”
- “Oral consent without written documentation would continue to be acceptable for many research studies involving educational tests, surveys, focus groups, interviews, and similar procedures.”

- Excused research would be subject to "mandatory data security and information protection standards for identifiable information and rules protecting against the inappropriate re-identification of de-identified information that is collected or generated as part of a research study to minimize informational risks and thereby eliminate the need for IRBs to review informational risks of the research. For purposes of the Common Rule, we are considering adopting the HIPAA [Health Insurance Portability and Accountability Act] standards regarding what constitutes individually identifiable information, a limited data set, and de-identified information, in order to harmonize these definitions and concepts."
- Though deidentification would be the norm, the rules for Excused research would explicitly "allow subjects to authorize researchers to disclose the subjects' identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition."
- Institutions might be required to audit a sample of excused research, but they would be discouraged from the "current practice of routinely requiring that research that meets the current exemption categories undergo some type of review before it is permitted to proceed." Instead, "researchers would file with their institution or IRB a brief registration form (about one page long) that provides essential information about the study, including, for example, information about who will be the principal investigator, and the purpose of the study. The researchers would then be authorized to begin conducting the study after the filing (unless the institution chose to review that filing and determined that the research did not qualify as Excused)."

Potential advantages

Were the Excused category implemented, it might offer advantages to social scientists.

- The criteria for excusal would be more objective than the current criteria for exemption.
- Researchers could begin their work more quickly.
- IRBs might be less likely to insist on written consent forms.
- Real names might be explicitly allowed

Pitfalls

However, depending on the precise language of the eventual regulations, the change could bring little relief or actually increase burdens

- Subjective criteria for questions could be re-introduced

Question 16 of the ANPRM proposes denying Excused status for "surveys and related methodologies" involving "topics that are emotionally charged, such as sexual or physical abuse." We can imagine disputes over what topics are emotionally charged.

- Geographical indicators could trigger IRB review

The HIPAA Privacy Rule requires that data must be stripped of identifiers of "all geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes." Unless modified, this would prevent many social scientists from identifying the site of their research, a scholarly norm.

- Photography and videotaping could trigger IRB review

The HIPAA Privacy Rule requires that data must be stripped of “full-face photographic images and any comparable images.”

- Participant observation and focus groups could trigger IRB review

It is not clear how the HIPAA Privacy Rule would work when information is gathered from focus groups or when researchers converse in community settings.

- The use of real names could trigger IRB review

When institutions do impose IRB authority on oral history and other research in which participants are generally identified, they can generally rule it exempt under the current Common Rule. But this category may disappear under the present proposal.

If that happens, this kind of research would be an awkward fit for the new “excused” category, which emphasizes privacy. While the new category rules “allow subjects to authorize researchers to disclose the subjects’ identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition,” its clear emphasis is on preserving the confidentiality of information. The present Common Rule does not require anonymity, but its emphasis on confidentiality has led IRBs to impose inappropriate demands on researchers, such as requiring oral historians to anonymize their narrators or destroy recordings and transcripts. If, as is likely, institutions determined that real-name research was not eligible for the new excused category, IRBs would find themselves reviewing research the ANPRM considers only a distraction.

Alternatively, institutions allow real-name research to proceed under the excused category. But if that were the case, then historians, journalists, and folklorists would find themselves submitting forms that said only that they did not intend to follow most of the provisions of the excused category. This could be nothing but a waste of time and paper.

- Unreasonable data security requirements might be imposed

The ANPRM suggests requirements for “the use of reasonable and appropriate encryption for data maintained or transmitted in electronic form and strong physical safeguards for information maintained in paper form.” This could be consistent with the professional practices of social researchers, but past experience has shown the danger of relying on IRBs’ and administrators’ sense of what is “reasonable.”

- A waiting period could delay research and increase administrative burden

Question 19 imagines “a brief waiting period (e.g. one week) before a researcher may commence research after submitting the one-page registration form, to allow institutions to look at the forms and determine if some studies should not be Excused.”

This could defeat the ANPRM’s design to “discourage having each of these registration forms undergo a comprehensive administrative review prior to commencing the study or even afterward.” For what is a determination that some studies should not be Excused if not an administrative review at least as comprehensive as the ones currently used for exemption? A waiting period risks imposing prior review on all studies and retrospective review on some, thus increasing, rather than decreasing, the administrative burden.

The requirement would be particularly onerous for researchers who want to react to breaking events or whose research builds on daily observations and lacks defined starting and ending points

Questions 14-22 of the ANPRM concern the proposed Excused category. Scholars should consider all of the above concerns as they prepare their responses.

Question 14: Are these expansions in the types of studies that would qualify for this Excused category appropriate? Would these changes be likely to discourage individuals from participating in research? Might these changes result in inappropriately reduced protections for research subjects, or diminished attention to the principles of respect for persons, beneficence, and justice?

Question 15: Beyond the expansions under consideration, are there other types of research studies that should qualify for the Excused category? Are there specific types of studies that are being considered for inclusion in these expansions, that should not be included because they should undergo prospective review for ethical or other reasons before a researcher is allowed to commence the research?

Question 16: Should research involving surveys and related methodologies qualify for the Excused category only if they do not involve topics that are emotionally charged, such as sexual or physical abuse? If so, what entity should be responsible for determining whether a topic is or is not emotionally charged?

Question 17: What specific social and behavioral research methodologies should fall within the Excused category? Under what circumstances, if any, should a study qualify for the Excused category if the study involves a form of deception (and if so, how should “deception” be defined)?

Question 18: Currently some IRBs make determinations regarding whether clinical results should be returned to study participants. How should such determinations be made if the study now fits in the Excused category? Can standard algorithms be developed for when test results should be provided to participants and when they should not (e.g., if they can be clinically interpreted, they must be given to the participants?).

Question 19: Regarding the Excused category, should there be a brief waiting period (e.g. one week) before a researcher may commence research after submitting the one-page registration form, to allow institutions to look at the forms and determine if some studies should not be Excused?

Question 20: The term “Excused” may not be the ideal term to describe the studies that will come within the proposed revision of the current category of exempt studies, given that these studies will be subject to some protections that are actually greater than those that currently exist. Might a term such as “Registered” better emphasize that these studies will in fact be subject to a variety of requirements designed to protect participants? We welcome other suggestions for alternative labels that might be more appropriate.

Question 21: Is it appropriate to require institutions holding a Federalwide Assurance to conduct retrospective audits of a percentage of the Excused studies to make sure they qualify for inclusion in this category? Should the regulations specify a necessary minimum percentage of studies to be audited in order to satisfy the regulatory requirements? Should some other method besides a random selection be used to determine which Excused studies would be audited?

Question 22: Are retrospective audit mechanisms sufficient to provide adequate protections to subjects, as compared to having research undergo some type of review prior to a researcher receiving permission to begin a study? Might this new audit mechanism end up producing a greater burden than the current system? Do researchers possess the objectivity and expertise to make an initial assessment of whether their research qualifies for the Excused category? By allowing researchers to make their own determinations, without prospective independent review, will protections for some subjects be inappropriately weakened? If allowing researchers to make

such determinations without independent review would generally be acceptable, are there nonetheless specific categories of studies included in the proposed expansion for which this change would inappropriately weaken protections for subjects? And will the use of a one-page registration form give institutions sufficient information to enable them to appropriately conduct the audits?

Scholars may also wish to endorse one of two proposals—not mentioned in the ANPRM—that would simply remove from IRB oversight any study based solely on interactions with competent adults.

In 1979, twelve scholarly and educational organizations offered the following formula:

These regulations do not apply to research using legally competent subjects that involves neither deceit nor intrusion upon the subject's person nor denial or withholding of accustomed or necessary resources.²

In 2006, the American Association of University Professors offered similar proposal:

Research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, [shall] be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption.³

4. Would a change in the definition of research prohibit the reuse of data sets?

The present Common Rule states that "Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." So if a data set has been stripped of its identifiers, it is no longer subject to regulation, no matter the circumstances in which the data were first collected.

The ANPRM proposes changing this so that some information that is not individually identifiable would be covered by the Common Rule:

With regard to the researchers' use of *pre-existing data* (i.e. data that were previously collected for purposes other than the currently proposed research study):

a. If the data was originally collected for *non-research* purposes, then, as is currently the rule, written consent would only be required if the researcher obtains information that identifies the subjects. There would accordingly be no change in the current ability of researchers to conduct such research using de-identified data or a limited data set, as such terms are used in the HIPAA Rules (see Section V), without obtaining consent.

b. If the data was originally collected for *research* purposes, then consent would be required regardless of whether the researcher obtains identifiers. Note that this would be a change with regard to the current interpretation of the Common Rule in the case where the researcher does not obtain any identifiers. That is, the allowable current practice of telling the subjects, during the initial research consent, that the data they are providing will be used for one purpose, and then after stripping identifiers, allowing it to be used for a new purpose to which the subjects never consented, would not be allowed. (44519, emphases in original.)

² J. W. Peltason, "Comment on the Proposed Regulations from Higher Education and Professional Social Science Associations," *IRB: Ethics and Human Research* 2 (February 1980), 10

³ "AAUP: Research on Human Subjects: Academic Freedom and the Institutional Review Board (2006)", n.d., <http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm>.

The next several paragraphs of the ANPRM claim that this would not hinder research much, because "in most instances, the consent requirements described above would have been met at the time that the biospecimens or data were initially collected, when the subject would have signed a standard, brief general consent form allowing for broad, future research. This brief consent could be broad enough to cover all data and biospecimens to be collected related to a particular set of encounters with an institution (e.g. hospitalization) or to any data or biospecimens to be collected at anytime by the institution."

But it could be hard to ensure that every survey included appropriate language, especially since the ANPRM itself stresses that "oral consent without written documentation would continue to be acceptable for many research studies involving educational tests, surveys, focus groups, interviews, and similar procedures." And if a scholar could not document that survey respondents or interview subjects had consented to the reuse of their responses, it might be impossible to use even numerical summaries or published quotations.

Scholars concerned about this should reply to two ANPRM questions:

Question 45: Under what circumstances should future research use of data initially collected for non- research purposes require informed consent? Should consent requirements vary based on the likelihood of identifying a research subject? Are there other circumstances in which it should not be necessary to obtain additional consent for the research use of currently available data that were collected for a purpose other than the currently proposed research?

Question 46: Under what circumstances should unanticipated future analysis of data that were collected for a different research purpose be permitted without consent? Should consent requirements vary based on the likelihood of identifying a research subject?

5. How should IRBs evaluate risk?

The current regulations allow IRBs to approve research only after determining that

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

The ANPRM acknowledges that "the system has been criticized as not adequately calibrating the review process to the risk of research. Critics have raised concerns that some IRBs spend considerable time reviewing minimal risk research, and that some IRBs have a tendency to overestimate the magnitude and probability of reasonably foreseeable risks." It also acknowledges that "it is not clear that . . . [IRB] members have appropriate expertise regarding data protections." And it hints that IRBs may be violating the instruction not to consider the possible long-range effects of applying knowledge gained in the research.

Scholars in many disciplines in the humanities and social sciences have published accounts of cases in which they feel that IRBs overestimated the risks of their research or inappropriately considered its long-range effects. These scholars and the organizations that represent them should reply to the following ANPRM questions.

Question 4: Should the regulations be changed to indicate that IRBs should only consider “reasonably foreseeable risks or discomforts”?

Question 5: What criteria can or should be used to determine with specificity whether a study’s psychological risks or other nonphysical, non-information risks, are greater than or less than minimal?

Question 6: Are there survey instruments or specific types of questions that should be classified as greater than minimal risk? How should the characteristics of the study population (e.g. mental health patients) be taken into consideration in the risk assessment?

Question 27: The Common Rule currently states (45 CFR 46.111(a)(2)) that an IRB “should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among the research risks that fall within the purview of its responsibility.” Do IRBs correctly interpret this provision as meaning that while they should be evaluating risks to the individual subjects participating in a study, it is not part of their mandate to evaluate policy issues such as how groups of persons or institutions, for example, might object to conducting a study because the possible results of the study might be disagreeable to them? If that is not how the provision is typically interpreted, is there a need to clarify its meaning?

As they prepare their responses to these questions, scholars may wish to propose language that would require IRBs to evaluate risk based on empirical evidence, rather than their members’ intuition.

6. *Should researchers have the right to appeal?*

The present Common Rule does not forbid institutions from establishing a process by which IRB decisions can be appealed, though it does forbid institutional officials from approving research without an IRB’s concurrence. (That is, an official can send a proposal to a different IRB or send it back to the IRB that rejected it for reconsideration, but the official cannot simply reverse the IRB’s decision.) Some scholars have complained that this provision encourages arbitrary decisions.

Scholars who wish to see an appeals process should respond to the following question:

Question 28: For research that requires IRB approval, the Common Rule does not currently require that the researcher always be allowed some form of appeal of a decision (e.g., disapproval of a project). Some institutions have voluntarily chosen to provide appeal mechanisms in some instances, by, for example, allowing the researcher to present the project to a different IRB, or by having it reviewed by a special “appeal” IRB that is composed of members chosen from among the membership of the institution’s other IRBs. Should the Common Rule include a requirement that every institution must provide an appropriate appeal mechanism? If so, what should be considered acceptable appeal mechanisms? Should such appeal mechanisms, or different ones, be available for appeals asserting that the investigation is not research, or that the research does not require IRB approval?

7. *Should institutions be required to identify rules that go beyond federal requirements?*

Some human protections staffers and consultants claim that “the federal regulations are the ‘floor,’ not the ‘ceiling.’ They set minimum standards and specify the least that you can do, not what you should do.”⁴ They have persuaded IRBs and institutions to impose stricter requirements on researchers than are required by the federal regulations.

⁴ Jeffrey Cohen, “Answering Questions,” *HRPP Blog*, 11 December 2010, <http://hrpp.blogspot.com/2010/12/answering-questions.html>

As the ANPRM notes, IRBs and institutions sometimes fail to distinguish between federal requirements and institutional requirements, making it difficult for researchers to know how to challenge rules that they perceive as inappropriate.

Scholars concerned about this practice should answer the following two questions.

Question 13: Given the problems with the current system regarding wide variations in the substance of IRB reviews, would it be appropriate to require IRBs to submit periodic reports to OHRP in the instances in which they choose to override the defaults described in Sections B(1), B(2)(a)(ii), and B(2)(b) above? Should IRBs have to report instances in which they require continuing review or convened IRB review of a study which involves only activities identified as being on the list of those eligible for expedited review? If an IRB that chose to override these defaults was required to submit a report to OHRP, would this provide useful information about any lack of appropriate consistency among IRBs so that clarifying guidance could be provided as needed, or provide useful information to OHRP about the possible need to revise the expedited review list or the continuing review requirements?

Question 29: As noted above, IRBs sometimes engage in activities beyond those that are required by the regulations. For example, an IRB might review some studies for the purpose of determining whether or not they qualify for exemption (the new Excused category), or might review studies involving the analysis of data that is publicly available. Would it be helpful, in furtherance of increased transparency, to require that each time an IRB takes such an action, it must specifically identify that activity as one that is not required by the regulations?

8. *Should the federal government regulate research that it does not fund?*

The current Common Rule governs only research that is directly funded by one of the agencies that have adopted it. The federal government has encouraged universities to pledge to hold all research conducted by their affiliates to the same requirements, which gives federal regulators the power to investigate breaches of those standards and penalize institutions for those breaches, even for research not funded by those agencies. A growing number of universities have ceased offering such pledges. These universities may still require researchers to submit projects for IRB approval, but the institution cannot be held accountable by federal regulators for any breach.

The ANPRM expresses concerns “that the current regulatory system does not adequately protect all research subjects. For instance, only some research studies funded by certain Federal agencies or those that involve the development of products subject to regulation by the FDA, are subject to the Common Rule or similar protections. As a result, there are many studies that are not subject to any such Federal oversight, even though they may involve substantial risks to the subjects.” It proposes that institutions that receive any federal funding for research with human subjects from a Common Rule agency be required to impose the regulatory standards on all research conducted there.

Scholars concerned about this extension of federal power, especially those who would like to see institutions free to develop alternative methods of research oversight, may wish to comment on this issue.

Question 71: Should the applicability of the Common Rule be extended to all research that is not Federally funded that is being conducted at a domestic institution that receives some Federal funding for research with human subjects from a Common Rule agency?

9. *What data should federal regulators collect?*

The ANPRM notes that the requirements for the reporting of adverse events vary by agency and are stored in separate datasets, and that there is no requirement for “the collection of data about the numbers of participants in various areas of research—information that is needed for characterizing the magnitude

and severity of any risks.” The ANPRM proposes the “Consolidation of data reported using consistent vocabularies and terms [to] allow for more powerful and meaningful analyses of safety information across types of research studies than are possible at present.”

Scholars may support such data collection as a means of assembling evidence that could be used to align the oversight system with actual risks. They may also be concerned that some reporting requirements could be burdensome, e.g., if qualitative researchers were forced to assemble quantitative data simply to meet this requirement.

Scholars may also be concerned about the implication of question 69, which seems to suggest that data would be accessible only to federal agencies and not the general public.

And they may wish to note that the ANPRM seems not to envision the collection of data about adverse events and unanticipated problems that result from IRB review. They may wish to suggest a means by which researcher and participant complaints about IRB decisions could be reported to a central authority.

Question 68: With regard to data reported to the Federal government:

a. Should the number of research participants in Federally funded human subjects research be reported (either to funding agencies or to a central authority)? If so, how?

b. What additional data, not currently being collected, about participants in human subjects research should be systematically collected in order to provide an empirically-based assessment of the risks of particular areas of research or of human subjects research more globally?

c. To what types of research should such a requirement apply (e.g., interventional studies only; all types of human subjects research, including behavioral and social science research)? In addition, are there other strategies and methods that should be implemented for gathering information on the effectiveness of the human subjects protection system?

Question 69: There are a variety of possible ways to support an empiric approach to optimizing human subjects protections. Toward that end, is it desirable to have all data on adverse events and unanticipated problems collected in a central database accessible by all pertinent Federal agencies?

10. *How should the federal government revise regulations in the light of experience?*

Finally, scholars may wish to comment on the need to revise these regulations more frequently than once every thirty years, and the need for various disciplines to be represented in the revision process.

Since the mid-1960s, the regulation of human subjects research has been dominated by those concerned with medical and psychological experimentation. Current advisory bodies, such as the Presidential Commission for the Study of Bioethical Issues and the Secretary's Advisory Committee on Human Research Protections lack experts in the methods and ethics of the social sciences, humanities, and journalism.

The Canadian Panel on Research Ethics offers a promising alternative model. Because its members are appointed by the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC), the panel is more representative than its U.S. counterparts. And it has shown itself to be responsive to the concerns of researchers. The second edition of its Tri-Council Policy Statement, released in 2010, offers sensible guidance on organizational research, Internet research, and qualitative research—topics that U.S. bodies have scarcely addressed. Australia likewise expects its guidelines be “reviewed at least every five years.”

The ANPRM does not ask how often and by whom the regulations should be revised. It does raise the issue of the revision of a small part of the regulatory system in question 9:

Question 9: How frequently should a mandatory review and update of the list of research activities that can qualify for expedited review take place? Should the list be revised once a year, every two years, or less frequently?

Scholars who would like a regulatory system that is more informed by the perspectives of all who must follow it, and that is more responsive to changes in research methods, may wish to raise these issues in their comments on question 9.

Resources

Ezekiel J. Emanuel and Jerry Menikoff, "Reforming the Regulations Governing Research with Human Subjects," *New England Journal of Medicine*, 25 July 2011, <http://healthpolicyandreform.nejm.org/?p=14979&query=OF>

A helpful introduction to the ANPRM, written by two federal officials who presumably had a hand in its drafting.

Department of Health and Human Services, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," *Federal Register* 76, No. 143 (26 July 2011).

The ANPRM itself is available online. It includes instructions for submitting comments.

Text: <http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm>

PDF: <http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf>

Institutional Review Blog, <http://www.institutionalreviewblog.com/>

I am providing continuous coverage on some of the issues raised by the ANPRM and links to press coverage of the issue. To see only posts related to the ANPRM, use the link <http://www.institutionalreviewblog.com/search/label/ANPRM>

Zachary M. Schrag. *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*. Baltimore: Johns Hopkins University Press, 2010.

The origins of the over-regulation the ANPRM seeks to address.