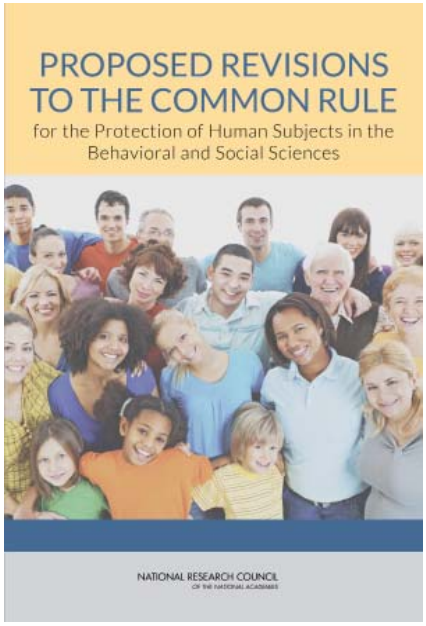
REPORT BRIEF • JANUARY 2014

# Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences




The Federal Policy for the Protection of Human Subjects, known as the Common Rule, outlines basic regulations that aim to protect individuals who participate in biomedical and behavioral research. Since the Common Rule was promulgated in 1981 and updated in 1991, rapid advances in technology and the increasing volume of data available on individuals have changed the landscape for researchers and Institutional Review Boards (IRBs). In July 2011, the U.S. Department of Health and Human Services (HHS) issued an Advance Notice of Proposed Rulemaking (ANPRM) that proposes a general overhaul of the Common Rule to more effectively protect research participants and promote important research.

A report from the National Research Council, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences*, examines those proposed changes as they apply to the behavioral and social sciences and offers recommendations for how to clarify, adapt, and implement them. This brief summarizes those findings and recommendations.

## CLARIFYING THE DEFINITION OF "HUMAN-SUBJECTS RESEARCH"

The National Research Council report recommends that HHS define "human-subjects research" as a systematic investigation designed to develop or contribute to generalizable knowledge that involves direct interaction or intervention with a living individual or obtaining identifiable private information about an individual. Only research that fits this definition would be subject to the Common Rule and oversight by an Institutional Review Board. This matters because the ambiguous boundary has aided IRB mission expansion.

In addition, HHS should clarify that research that relies on publicly available information, information in the public domain, or information that can be observed in public contexts does not meet the definition of human-subjects research – regardless of whether the information is personally identifiable – as long as individuals whose information is used have no reasonable expectation of privacy. This includes digital data, some administrative records, and public-use data files that have been certified as protected against disclosure of identifying information. Investigators must observe the ethical standards for handling

such information that guide research in their particular fields and in the specific research context.

## THREE CATEGORIES OF IRB OVERSIGHT

Studies that meet the definition of "human-subjects research" should fall into one of these three categories:

- studies that should be excused from IRB review;
- studies that should receive expedited IRB review; or
- studies that should receive full IRB review.

These categories are outlined in the ANPRM, but the report offers recommendations for how HHS should more clearly define and implement these categories.

**Excused research.** The report supports the ANPRM's proposal for a new category of studies that are excused from IRB review because the risk they involve is minimal and primarily informational. Informational risk is the potential for unauthorized disclosure of personal or private information. To be considered excused, the risk of this disclosure must be no more than minimal – in other words, no more than what is normally encountered in daily life. Examples of excused research could include use of pre-existing data with private information, or benign interventions or interactions that involve activities familiar to people in everyday life, such as educational tests, ordinary surveys, and focus groups.

The report does not endorse restricting the excused category of research to "competent adults," as proposed in the ANPRM. Instead, HHS should provide guidance for investigators on how to make the informed consent process appropriate for different populations.

Although IRB review is not required for excused studies, both the ANPRM and the report concur that excused research should be subject to potential IRB oversight. Investigators should register their study with an IRB, describe consent procedures, and provide a data protection plan tailored to the specific needs of the study. A small sample of excused studies could be audited to provide accountability. After being registered, an excused study should be able to begin within a week.

**Expedited review.** Studies that have a probability of physical or psychological harm that is minimal or less should qualify for expedited review. HHS should define "minimal risk" as risk of a probability and magnitude that does not exceed the risk ordinarily encountered in daily life or in the routine medical, psychological, or educational examinations or tests of the general population. Expedited review should also apply when a study that might otherwise qualify as excused needs greater consideration because of the nature of the research procedures or the characteristics of the subject population. An example would be a study that includes identifiable information and that is designed to produce clinical changes in health, health-related behaviors, or symptoms.

Affirming a recommendation in the ANPRM, the committee urges HHS to provide guidance that allows for expanding the list of research eligible for expedited review. In its guidance, the agency should also clarify that the types of research listed in the expedited category are examples rather than an exhaustive, limited set of procedures.

To ensure that diverse populations benefit from research and its results, and to avoid subjective overestimations of research harms, the committee recommends the elimination of current regulatory language that identifies certain populations as necessarily "vulnerable to coercion and undue influence" and requires additional but unspecified protection. Rather than requiring full board review for studies involving children and adolescents by default, investigators and IRBs should be advised to use expedited review appropriately for such studies.

In addition, to streamline expedited review and procedures, HHS should eliminate the requirement that expedited research undergo continuing annual review.

**Full review.** If the probability is high that participants will experience a greater-than-minimal risk of harm and if that risk cannot be mitigated by risk-minimizing procedures, a full IRB review is required, the report says. Neither the report nor the ANPRM propose major changes to the category of full review. However, to avoid overestimation of risk, expedited review should be considered the default procedure for social and behavioral science research that is not in the excused category. HHS should provide guidance that full board reviews should occur monthly, and that IRBs will provide feedback within 10 days of the meeting.

## INFORMED CONSENT

The report supports the ANPRM's efforts to improve comprehension of the informed consent process, but urges HHS to afford greater flexibility to investigators and IRBs. For example, consent forms should be shortened so that participants better understand to what they are consenting, but HHS should eliminate regulations that favor written informed consent. Oral or implied consent (if a participant reads through a letter outlining consent provisions, for example, and proceeds with a questionnaire) should be acceptable if appropriate to the study context. The report also recommends that HHS not add any requirement for re-consent for future use of existing research data that does not identify an individual. Re-consent should be obtained only when investigators wish to link pre-existing identifiable data to the collection of new data.

## PROTECTING THE PRIVACY AND SECURITY OF DATA

The report examines how best to protect data used in human-subjects research in the information age, given new privacy concerns and the potential harms that could result from inappropriate disclosure of health, financial, educational, or reputational information.

The report does not support the suggestion in the ANPRM to use the Health Insurance Portability and Accountability Act (HIPAA) as the standard for specifying data protection plans, especially with respect to social and behavioral research. Neither the privacy nor the security rule of HIPAA is sufficient to maintain the confidentiality of research participants' information beyond limiting access to authorized users. HIPAA does not strike the balance between protecting data and promoting worthwhile research.

Instead, researchers and IRBs should draw upon an array of data protection approaches, selecting the methods most appropriate to the level of risk involved in the specific research. A wide range of statistical methods can be used to reduce the risk of disclosure: IRBs and researchers should utilize technical resources and data protection models provided by university research data management service groups, individual IT/protection experts, and specialized institutions. Consideration should be given to developing a future national center to define and certify the levels of information risk of different types of studies and corresponding data protection plans to ensure risks are minimized.

To promote data sharing and protection when linking datasets, the report recommends that investigators must: adhere to original conditions of use, confidentiality agreements, and consents; and prepare a data protection plan that is consonant with these conditions. No further consent is needed for linking the data, unless it is required in the original agreements/consent or unless new data are being collected from human participants.

## IMPROVING IRB PROCESSES

The report includes recommendations for improving IRB processes:

- In revising the Common Rule, HHS should keep the scope of coverage within the present boundaries – research that is federally funded – and not expand to cover all research.
- As the ANPRM proposes, HHS should establish single IRBs of record for multisite studies. (Currently, each site in a multi-site study needs to have its own IRB review.) However, the single-IRB approach should be voluntary rather than mandatory, and it should be phased in gradually.
- In each institution in which research involving human participants is carried out, a system should be developed for the appeal of IRB decisions.

## FUTURE RESEARCH

To correspond with its recommendations, the committee urges that research be conducted in the following areas:

- **Risk of Harms:** building a stronger evidence base for identifying the probability and magnitude of risks in daily life, calculating risk that meets minimal criteria, calibrating potential physical and psychological research harms to no more than minimal risk levels, and understanding actual effects of social and behavioral research on participants.
- **Data Innovations:** studying innovations in the use of non-research information and records and in ways of collecting and linking data.

- **Minimizing Informational Risk:** studying new methods for measuring and quantifying specific informational risk and risk-reduction techniques, and testing disclosure limitation mechanisms.
- **Costs and Benefits:** assessing the effectiveness of the human subjects protection rules and their implementation by studying their costs and benefits.

## COMMITTEE ON REVISIONS TO THE COMMON RULE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH IN THE BEHAVIORAL AND SOCIAL SCIENCES

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**For More Information . . .** This brief was prepared by the Board on Behavioral, Cognitive, and Sensory Sciences (BBCSS) based on the report *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (National Research Council, 2014). The study was sponsored by the Bill & Melinda Gates Foundation, the Alfred P. Sloan Foundation, and the National Academy of Education. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the authors and do not necessarily reflect those of the sponsors. Copies of the report are available from the National Academies Press; (800) 624-6242; http://www.nap.edu or via the BBCSS web page at http://www.nationalacademies.org/bbcss.

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