

Revision to the Common Rule: Implications for Behavioral and Social Sciences Research

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Much has changed about the conduct of research in the past quarter century, including the expansion of biospecimen collection for genetics and various assays, the rapid proliferation of consumer technologies used to obtain research data, the increase in data repositories and digital records to facilitate data sharing and integration, and the growing role of the research subject as an actively involved participant in research. The evolving nature of research was a catalyst for the revision of the US government’s [Federal Policy for the Protection of Human Subjects](#), also known as the Common Rule originally promulgated in 1991.

The revised Common Rule becomes effective on January 19, 2018, although one key provision, the mandate for using a single institutional review board (IRB) in cooperative research, takes effect 2 years later. Highlighted here are some of the key changes in exemptions and in the IRB and consent procedures of the revised Common Rule that are particularly relevant to behavioral and social sciences researchers. We refer to the Common Rule that is still in effect today as the “pre-2018 Common Rule.”

Expanded Exemptions Categories

One of the most significant changes in the revised Common Rule is the expansion of categories of human research exempt from IRB review. Under some exempt categories, limited IRB review would be required to ensure there are adequate privacy safeguards for potentially identifiable information, but these revised and expanded exempt categories have important implications for behavioral and social sciences research.

Nearly all of the prior exempt categories from the pre-2018 Common Rule are maintained with some revisions, including research conducted in educational settings (§____.104(d)(1)), research involving surveys, interviews, observation of public behavior, or educational tests (§____.104(d)(2)), research and demonstration projects examining public benefit or service programs conducted or supported by a federal department or agency for program evaluation purposes (§____.104(d)(5)), and taste and food quality evaluation and consumer acceptance studies (§____.104(d)(6)). Although most of the revisions to these exemption categories are minor, behavioral and social sciences researchers engaged in these categories of research should familiarize themselves with the revised Common Rule language.

Another set of exempt categories involves secondary use of identifiable data. The pre-2018 Common Rule limits this exemption to existing data that are either publicly available or recorded in a manner in which subjects cannot be identified. Under the revised Common Rule, this exemption is expanded. Secondary research involving information regulated under the Health Insurance Portability and Accountability Act (HIPAA) is exempted. Research conducted by or on behalf of a federal Department or agency, involves the use of information gathered by a federal Department or agency for nonresearch activities, and is subject to federal privacy protections, also is exempted (§____.104(d)(4)). Two new exemptions require limited IRB review for secondary research use of identifiable information in which broad consent is obtained and there is no plan for return of results to subjects, unless required by law (§____.104(d)(8)), and for the storage and maintenance of this information (§____.104(d)(7)) for secondary research use. The definitions of “identifiable private information” and “identifiable biospecimens” are to be reviewed by federal departments or agencies at least every 4 years to keep pace with changing technical capabilities for identification. These exemptions expand the ability of behavioral and social sciences researchers to use existing datasets for their research.

The new and most relevant exemption for behavioral and social scientists is the exemption for research involving benign behavioral interventions on adult subjects, in which the subject prospectively agrees to the intervention and information collection (§____.104(d)(3)). The Rule defines benign behavioral interventions as “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects” (§____.104(d)(3)(ii)). The investigator must also have no reason to think the subjects will find the intervention “offensive or embarrassing.” Research that uses deception as to the nature or purpose of the research is not considered exempt unless the subject authorizes the deception. The data collected also must be limited to verbal or written responses (including data entry) or audiovisual recording and be protected by safeguards approved under limited IRB review if the information identifies the subjects and is potentially sensitive. Under the pre-2018 Common Rule, many laboratory-based studies that manipulated an independent variable (e.g., studies of cognition, attitudes, learning) would have required IRB review, which could often be expedited. Under the revised Common Rule, these studies can now be exempt from IRB review. That said, behavioral and social scientists should continue to adhere to ethical guidelines of their respective disciplines and, if in doubt as to whether the proposed study meets this benign behavioral intervention exemption, seek consultation from their IRB or other designated institutional official.

New IRB and Informed Consent Revisions

The revised Common Rule includes revisions of IRB and informed consent processes that should facilitate the increasing complexities of modern behavioral and social sciences research while protecting participants. One change, mentioned previously, is the addition of broad consent for secondary research usage (§____.116(d)). The broad consent can be used as a stand-alone consent or in conjunction with seeking consent for a specific study. This broad consent should facilitate data sharing and integration consistent with open science initiatives and leverage the data obtained from participants for more than the specific study for which it was collected. The revised Common Rule has a number of specific requirements that must be met (e.g., the need to specify the time period for use (which could be indefinite), the right to discontinue participation, the types of data included, being informed about future research and return of results) when seeking broad consent, which behavioral and social sciences researchers should be aware of if they are to consider broad consent in their study.

The second relevant revision is the requirement to use a single IRB for certain multisite or cooperative research being conducted at more than one institution (§____.114(b)) in the United States. Researchers involved in multisite or cooperative trials now typically must obtain IRB approval from each institution to conduct the research, sometimes with conflicting requirements from different IRBs to obtain approval. With the single IRB for cooperative research, the various institutions would document this reliance (e.g., execute a reliance agreement with the institution whose IRB will serve as the single IRB for the study). This provision should facilitate the IRB approval of multisite behavioral intervention trials and other cooperative studies involving multiple institutions.

In addition to the broad consent and single IRB provisions in the revised Common Rule, there are other important changes to the consent and IRB process. For example, a new element of consent will require investigators to inform subjects if their biospecimens may be used for commercial profit and if they will or will not have a share in such profits. Another will require the consent information to state whether clinically relevant research results, including individual research results, will be disclosed to the subject and, if so, under what conditions. The revised Common Rule removes the requirement for IRBs to conduct continuing reviews of expedited review protocols or of protocols that have completed all study interventions and are in the data analysis phase.

For behavioral and social sciences researchers, the various provisions of the revised Common Rule will provide greater flexibility and less burden, especially for low-risk studies, while ensuring the rights and welfare of study participants. Any change of policy, especially one that has been institutionalized such as the Common Rule, takes time to implement, but becoming familiar with the revised Common Rule before its effective date will allow researchers to take these changes into account as they plan grant submissions and research protocols for projects beginning in 2018.