Consortium of Social Science Associations
1701 K Street NW, Suite 1150
Washington, DC 20006
Web: www.cossa.org
Twitter: @COSSADC #WhySocialScience

HHS Announces Final Changes to Human Subjects Research Regulations |

January 24, 2017
By Julia Milton

During the final days of the Obama Administration, the U.S. Department of Health and Human Services (HHS) released the final text for its changes to the Common Rule, the regulations that govern research with human subjects, completing a revision process started in 2011. The Common Rule, which was last updated in 1991, affects research supported by 16 federal departments and agencies, including the Departments of Health and Human Services, Agriculture, Defense, Education, Commerce, Labor, and Veterans Affairs, as well as the National Science Foundation.

Overall, the changes look to be a positive development for the social and behavioral science research community. According to the executive summary, "The final rule is designed to more thoroughly address the broader types of research conducted or otherwise supported by all of the Common Rule departments and agencies such as behavioral and social science research." The rule maintains several proposals from the earlier Notice of Proposed Rulemaking (NPRM) that aimed to reduce the oversight burden on researchers conducting studies that pose no or minimal risk to participants (like a lot of social and behavioral science research). It also declines to adopt several provisions that were controversial in the biomedical research community (although supported by some in the social sciences), including consent requirements surrounding work with de-identified biospecimens, which is likely to lead to a less contentious reception overall.

Timeline of Announcements, Notable Publications, and COSSA Input on the Common Rule

1991: Last revision to the Common Rule
July 2011: Advanced Notice of Proposed Rulemaking (ANPRM) is released
October 2011: COSSA signs on to a Social and Behavioral Science White Paper on the ANPRM
January 2014: National Academies consensus study: Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences
September 2015: NPRM released (see COSSA's analysis)
January 2016: COSSA, ICPSR, and AERA submit a joint comment on the NPRM
July 2016: National Academies report: Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century
January 2017: Final Rule is released
January 19, 2018: Effective date for most provisions

HOT TOPICS are periodic, featured articles prepared by COSSA staff members offering insights into timely issues important to the social and behavioral science community. JULIA MILTON is COSSA's Assistant Director for Public Affairs and Government Relations Associate.

Exempt, Excluded, and Not Research

The NPRM had proposed the creation of a category of "excluded" research activities that would be considered beyond of the scope of the Common Rule regulations (and would undergo no review whatsoever). However, public comment suggested that the addition of this third category to the previously existing categories of "non-research" activities (not subject to the Common Rule) and "exempt" research (which undergoes a limited degree of review only in order to officially determine that the research proposed *should* indeed be exempt) made the regulations more confusing, not less. The final rule rejects the "excluded" category and classifies the activities the NRPM had proposed to be excluded as either "not research" or "exempt."

In defining "research," the final rule retains the existing definition but adds four categories of activities that it explicitly identifies as not research (and therefore not subject to Common Rule regulations): (1) scholarly and journalistic activities (including oral history, journalism, biography, literary criticism, legal research, and historical scholarship), (2) public health surveillance activities, (3) criminal justice activities, and (4) authorized operational activities in support of national security missions.

The final rule expands the categories of research that should be considered exempt from Common Rule consideration (once a determination is made by an institutional review board, or IRB) from six categories in the existing rule to eight. Four categories that were proposed as excluded by the NRPM now fall under the "exempt" category. The eight categories of research are:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices;
(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording);
(3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject;
(4) Secondary research uses of identifiable private information or identifiable biospecimens, for which consent is not required;
(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs;
(6) Taste and food quality evaluation and consumer acceptance studies;
(7) Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research, for which broad consent is required;
(8) Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, for which broad consent is required.

The NPRM had also proposed that IRBs be required to document their determination of whether a study was exempt from the Common Rule, and that HHS would create and distribute a web-based tool to assist IRBs in this process. Because the tool had not yet been created, the final rule drops this requirement.

Informed Consent & Consent for Use of Biospecimens

The revised Common Rule makes several changes to the requirements of informed consent to better emphasize the consent process as one that is intended to inform potential participants, not protect institutions from litigation. The final rule creates a new subsection of the regulations to lay out the general requirements for informed consent. It also mandates that the consent information must be given to participants before any other information (but not that no other information could be part of the consent form, as had been proposed in the NPRM). The new rule requires that informed consent documents "begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject … in understanding the reasons why one might or might not want to participate in the research," and that such information is presented in a way that facilitates comprehension.

By far the most controversial element in the NPRM was its proposal to classify research using biospecimens, such as tissue, blood, saliva, and urine samples (whether or not such specimens were identifiable), as "human subjects research," and therefore subject to regulation, including requirements for obtaining consent (including for secondary research use of specimens that had previously been collected). Nearly half of the comments received on the NPRM were related to this proposal. Overall, those in the biomedical research community felt that subjecting de-identified biospecimens to the Common Rule would place an unreasonable burden on researchers and IRBs who would have to obtain and track consent for potentially millions of people. Others, including some in the social science community, supported the proposal, arguing that it showed respect for participants' autonomy. Ultimately, the final rule drops this proposal, and de-identified biospecimens are not to be considered "human subjects." However, in an acknowledgement of the rapid progress in our ability to identify individuals based on small biological samples, the final rule includes "a new process by which Common Rule departments and agencies can regularly assess the scientific and technological landscape to determine whether new developments merit reconsideration of how identifiability of either information or biospecimens is interpreted in the context of research."

IRB Operations

The final rule adopts the proposal in the NPRM regarding studies that are eligible for expedited review (which may be carried out by an IRB chair or their designee without empaneling the full IRB), which must pose no more than "minimal risk" to participants. The changes to the rule stipulate that the HHS Secretary publish a list of activities that are considered minimal risk (to be evaluated and revised every eight years), and that studies involving only activities on this list are eligible for expedited review, unless the IRB documents a rationale for overriding this presumption.

The final rule also retains the NPRM proposal to require that all U.S. institutions engaged in cooperative research across multiple institutions use a single IRB of record, as opposed to having each institution's IRB review the study separately. In order to give researchers and IRBs time to adjust to this change, this provision will not go into effect for three years after the publication for the final rule (unlike most other changes, which will go into effect one year after publication).