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The New Common Rule: More Freedoms but More Responsibilities

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Editorial

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Editorial

The Common Rule (45 cfr part 46) guides the ethical treatment of human subjects in most research conducted in the U.S. Based on the principles spelled out in the Belmont Report (U.S. Health & Human Services, 1979), the Common Rule was established for the protection of the welfare of human research participants. Beginning January, 2018, numerous revisions to the Common Rule will go into effect [1]. The overarching goal of these changes is to lighten the burden of researchers who must comply with mounting rules and regulations while maintaining protections of human subjects. Not surprisingly, the revisions have been lauded by researchers [2]. But these changes have also raised concerns from research administrators and compliance officers [3]. As a researcher and the chair of my universities IRB, I see cause for both celebration and caution as these rules go into effect.

I would like to highlight three of the major revisions to the Common Rule as they will apply to research in the social/behavioral and biomedical fields. Other changes are not specifically tied to the Common Rule and concern the treatment of biospecimens and the single IRB of record. The full text of the new rules may be found at: http://wayback.archive-it.org/3926/20170127095200/ https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html.

The first revision concerns the end of the continuing review. Under the current Common Rule, researchers were expected to first secure approval from an IRB before beginning their data collection. Once approved, the researcher would conduct a study for a year or two, depending upon the home institution=s policies for continuing review. As the study approval approached expiration, the researcher would be required to submit a new set of forms detailing the status of the research and note the occurrence of any Aadverse events@ that could merit a complete re-review of the study.

Continuing reviews posed additional administrative work for a study=s PI or research manager. In the past, PIs needed to keep a running tally of participants, maintain reports of research findings, and note whether there were any unexpected outcomes from the current study protocol that could potentially change the Arisk level@ of the study. If study approval expired before the continuing review was submitted, the researcher was considered Aout of compliance@ by the institution, and steps had to be taken to bring the study back into compliance. It was also possible that the IRB would re-review the entire study and request additional changes to the protocol in order to give its re-approval. Happily, the new Common Rule no longer requires a continuing review for minimal risk studies. Once a study receives IRB approval (or exemption), the researcher may collect data for as long as is necessary.

Researchers should be particularly pleased with the second revision to the Common Rule. Under the current provisions, many IRBs required researchers to submit their proposals to a detailed review either by a single individual or the full board. Typically, the review process involved returning the proposal to the researcher (sometimes several times) in order to make revisions and add more detail about procedures, participant recruitment, and measurement instruments. The average amount of time for revisions could take several weeks to several months. Many researchers criticized the process, often justifiably, as too bureaucratic and wasteful of their time and energy.

The new rules dramatically change the approval process. Beginning in 2018, researchers conducting minimal risk studies may request that their studies be considered for exemption by the IRB. Although the Exempt designation has been available for many years, its application by IRBs has been quite stringent. IRBs will now be expected to give most minimal risk studies only Alimited review.@ The new applications forms will be simpler, easier to navigate, and require considerably less detail about the study protocol and associated measures. Best of all, the lengthy turnaround time from application submission to approval (or exemption) will be cut substantially.

Several Exempt categories have been revised or added. The most significant changes include Exempt Category 2, which has been expanded to include the collection of sensitive, identifiable data. The researcher must still confirm that participant confidentiality guarantees and appropriate data security measures are in place. But, IRBs will be less likely to request justification for asking for such information from participants. Exempt Category 3 will now permit studies to employ benign behavioral (or psychological) interventions on adult research subjects without full board or expedited review. These include the use of different stimuli for experiments in cognitive and other areas of psychology. Finally, Exempt Category 4 will allow for use of identifiable, private information (and bio-specimens) for which prior consent is not required. This provision is not limited to existing data, but the information must be publicly available.

Changes to the consent process constitute a third major revision. The new regulations will require that the informed consent form employ a clearer and more explicit statement about the nature and purpose of the research for the potential participant to consider. Subjects must also be expressly informed as to whether or not their data (or bio-specimens) will be used in future research. Alternatively, researchers may select to use a Abroad consent form@. Under broad consent, participants may allow their data to be used in the future without being re-consented or being informed about the additional studies in which it will be used.

In essence, the new regulations provide significant new freedoms to researchers and reduce the need to complete lengthy and detailed forms for their studies seeking IRB approval. While these changes are very welcome in the research community, researchers must remember that we are not entirely without obligation. To borrow a phrase, Awith greater freedom comes greater responsibility.@ Nowhere is this clearer than in the need to take our own steps to protect and promote the Belmont Report=s ethical principle of Arespect for persons.@ Under the new Common Rule, it will be imperative for researchers to ensure that participants understand fully what is expected of them, to remind them repeatedly of the voluntary nature of their participation, and to do so in the most courteous manner possible. We remain indebted to our participants for their willingness to subject themselves to our scientific methods and procedures. We must continue to hold ourselves to the highest standards in assuring their ethical and humane treatment [4].

The IRBs and the agencies that govern them have heard the demands to give more weight to researchers= needs in evaluating ethics applications. Clearly, the new Common Rule will mean less frequent and in-depth scrutiny of our research and study protocols by IRBs. At the same time, we researchers must accept the idea that the job now falls more heavily on us to police ourselves and our research assistants in carrying out our studies. Research participant's= welfare must continue to be one of our highest priorities in our labs and in the field. Now, more than ever, we must be vigilant in the protection of the respect, beneficence, and justice our research subjects expect and deserve.

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