Final Rule Updates Protections for Research Participants: What You Need to Know

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IN JANUARY 2017, THE US Department of Health and Human Services finalized several changes to the Federal Policy for the Protection of Human Subjects—also known as the "Common Rule" because it has been adopted by sixteen federal departments and agencies—with the goal of modernizing the system that governs research participants.[1] The Common Rule was originally promulgated in 1991, at a time when research was "conducted predominantly at universities and medical institutions, and each study generally took place at a single site," according to the US Department of Health and Human Services. The final rule takes into account that research with human participants has "grown in scale and become more diverse and data has become more digital."[2]

The final rule has two overarching objectives: to strengthen the safeguards protecting individuals who participate in scientific research and to reduce administrative burden for researchers.[3,4] These revisions are particularly germane to registered dietitian nutritionists (RDNs) who conduct social, behavioral, and clinical research.[5,6]

The general compliance date for the revised Common Rule, also known as the "2018 Requirements," was delayed until July 19, 2018 by an interim final rule. Shortly thereafter, a Notice of Proposed Rulemaking published on April 20, 2018, proposed an additional 6-month delay (January 21, 2019) for general compliance with the 2018 Requirements, creating an opportunity for regulated entities to take advantage of three burden-reducing provisions during the delay period.[7]

These provisions are permitted but are not required for some studies during the delay period and include the following: A revised definition of "research," which deems certain activities not to be considered research; an allowance for no annual continuing review of certain categories of research; and the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research. If institutions choose to implement these three burden-reducing provisions for particular studies, such studies will be subject to the 2018 Requirements beginning on January 21, 2019.[7]

This article describes the implications of the revisions to the Common Rule, outlines policy changes relevant to RDNs, and identifies next steps for policy implementation.

CHANGES TO THE COMMON RULE

The provisions promulgated in the final rule include key modifications that are particularly relevant to RDNs: A requirement for informed consent documents to provide a concise explanation, at the beginning of the document, describing the project's scope, including its risks and benefits; permission to use broad consent from a subject on stored identifiable data or identifiable biospecimens for future research as an alternative to seeking IRB approval to waive the consent requirement; and a requirement to use a single IRB when multiple US-based institutions engage in cooperative research.

Patient Consent and Broad Consent

"As a researcher, I'm excited about these changes. I always want to make sure that study participants are making a fully informed decision on whether to participate in a study, and I'm hoping that these changes will help them get the best information in the most understandable way," said Elizabeth Yakes Jimenez, PhD, RDN, LD, a research associate professor, Departments of Pediatrics and Internal Medicine, University of New Mexico Health Science Center, Albuquerque, and director of the Nutrition Research Network, Academy of Nutrition and Dietetics. "I think it's great that new consent forms will be required to have key information—such as the fact that participation is voluntary, the purpose of the study, the duration, study procedures, and expected risks and benefits—located at the very top of the form. I think it's going to help more participants to be better informed about making a decision to participate in a research study."

Research involving human subjects is a fundamental base of the nutrition and dietetics profession because it informs the "development of practice guidelines, assesses the impact of nutrition and dietetics programs and services on health outcomes, and determines priority areas for nutrition interventions."[8]

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"As a science-based profession, we rely on human subjects to predict what issues might occur, to test hypotheses, to understand whether interventions are effective or not, and to improve outcomes," said Alison Steiber, PhD, RDN, chief science officer, Research, International, and Scientific Affairs, Academy of Nutrition and Dietetics. "And because we know the history of human subject research is fraught with missteps, it is incredibly important that we as dietitians, and we as people leading research, understand the importance of human subjects' protections. These protections allow us to inform the person who's participating in the study what's going to be asked of them, what the study is intended to do, and really, how much time, effort, pain, and so on that they should expect by participating in our study," said Steiber, who noted that without these protections in place, people could lose trust in researchers, and may avoid participating in future studies. "Science will suffer," she said.

Broad consent, a new type of regulatory consent under the Common Rule, permits the use of identifiable private information and biospecimens for additional research, and is intended to serve as an alternative to traditional informed consent under specific circumstances. Before the Final Rule, researchers were required to either use de-identified data or obtain an IRB waiver of consent.

"It is expensive and time consuming to collect data and biological specimens, and new research questions may arise after a study begins," explained Yakes Jimenez. "Broad consent allows researchers to ask participants if they will consent to the storage, maintenance, and use of identifiable data and biospecimens to answer new research questions beyond the current study. In order to use broad consent, researchers must explain the general types of research that will be conducted with the data and specimens and keep track of who agreed to broad consent and who refused. Any secondary research that is conducted must fall within the general types of research that were mentioned in the broad consent, and must exclude data and biospecimens from individuals who refused to grant broad consent."

The final rule also established new exempt categories of research based on the level of risk posed to participants.[9] The rule previously contained six exempt categories, and the revised rule includes eight exempt categories, including exemptions particularly relevant to RDNs. "Exemption 3 [Benign Behavioral Interventions in Conjunction with the Collection of Information From Adult Subjects] may be of interest to RDNs, as it allows the research involving 'benign behavioral interventions' with adults," said Yakes Jimenez. "An example of this might be a study evaluating the provision of educational materials on healthy eating and physical activity habits to adults. Under Exemption 3, RDNs could collect anonymous data on this benign behavioral intervention via surveys or interviews, observation, and audiovisual recordings, but they could not collect data via any physical procedures, such as blood draws, blood pressure, or an activity tracker. Self-exemption will be permitted for exemption 3, as long as the data are collected anonymously and are not sensitive in nature."

IRBs and Cooperative Research

As of January 20, 2020, multicenter research studies will be permitted to use a single IRB, which helps ensure that studies are not subject to different or conflicting board decisions regarding patient protections.

"Previously, studies that were conducted across multiple sites required IRB approval at each site," said Yakes Jimenez. "This isn't so bad if you have a few sites, but it can create a major delay and confusion in large multisite trials. We're excited to see how the Single IRB of Record model works moving forward, as it has significant implications for the Academy's Nutrition Research Network (NRN), which is designed to conduct multisite trials with RDNs in many different practice settings. For example, the NRN is currently preparing to launch a study designed to validate diagnostic criteria for malnutrition and to examine optimal staffing of registered dietitian nutritionists to treat malnutrition. We plan for this study to involve 60 to 120 sites, which is a lot of individual IRBs. Luckily, we've gotten permission to pilot the single IRB of record model for the study, which we hope will reduce barriers to having sites participate, and also reduce confusion in trying to manage research procedures across such a large study, providing better protection for study participants. Because the new regulations are being rolled into place, we'll still have to provide the option for sites to fully review the study at a local IRB, if they prefer, but we're hoping that a lot of sites will be on board to help us pilot the new procedures."

"With this new rule we have the ability to have one central IRB that others can choose to adopt and to use that approval for themselves," added Steiber. "Were going to have to wait and see how that plays out with the larger medical centers and whether they'll trust that, but this rule really gives us an enhanced ability to conduct multisite research."

"Members need to be aware that the IRB is an important component to research," Steiber said. "I found out that there are people collecting data for what I would deem research purposes who were doing it without an IRB because they thought 'Ah, it's just observational.' I would say that any time an RDN is partaking in a research activity, and you are questioning whether to submit it for review, always ask. The IRB is there to protect the researcher, the participant, and the facility—whether it's in public health, or an outpatient clinic, or in the hospital setting. When in doubt, ask the question."

NEXT STEPS

The revisions to the Common Rule are intended to ensure that research involving human subjects is conducted with the highest ethical standards and practices. The Academy/Commission on Dietetic Registration Code of Ethics for the Nutrition and Dietetics Profession includes a reference to research. Specifically, Principle 1: Competence and professional development in practice, Standard d: Interpret, apply, participate in, and/or generate research to enhance practice, innovation, and discovery, directly relates to this revised Common Rule.[10] Unfortunately, implementation of the final rule will include some anticipated complications, especially regarding process infrastructure enhancements and training. "I think it is always challenging to make major changes to rules and regulations. These changes will result in some significant modifications

to IRB standard operating procedures and informed consent templates and require training efforts with investigators," said Yakes Jimenez. "In particular, the Single IRB of Record provision requires substantial coordination and communication between IRBs, which in general did not exist in the past. This may involve purchasing computer software and getting it up and running, and it is important to note that not all IRBs currently have an electronic submission system, and not all IRBs that have an electronic system use the same one, so there are some significant technology-related barriers to communication between IRBs currently, which will take some time and effort to resolve."

"I suggest that RDNs go in and talk to their IRBs and ask what changes they can expect if they submit in early 2019," said Steiber. "Even though there are federal regulations that impact all IRBs, how each IRB interpenetrates those regulations will vary. I think it's really important to talk to the IRB that you submit to most often and ask about the changes that you should expect regarding their protocol and their application."

Advances in research to further uncover the role of food and nutrients and their implications for health and disease would not be possible without human participants. The revisions to the Common Rule are intended to protect these volunteers, reduce administrative burden, and foster collaboration between researchers.

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