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# Now In Effect, Changes to Clinical Trials Prove Vexing; One-Size-Fits-All Approach Questioned

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For Michelle Meyer, associate director of research ethics in Geisinger Health System's Center for Translational Bioethics and Health Care Policy, complying with NIH's new clinical trial requirements was a bit like birth by fire. But she's not really complaining, and in fact, Meyer thinks NIH should abandon its "tortured" definition of a clinical trial and simply apply the requirements "to everything it funds."

On Feb. 16, Meyer submitted her first NIH grant application as a principal investigator. Her proposal is a behavioral health study that, as she put it, "proposes to randomize people, literally, to see one piece of paper versus another piece of paper. And that is now considered a clinical trial." At one point she reached out to the Twittersphere, desperate for help. She also worries that trial design may be compromised and fears the tumult may spill over into peer review.

Under the new policy, all clinical trials must be reported on ClinicalTrials.gov. At the same time, NIH launched the new FORMS-E Application Package to be completed by those seeking funding for clinical trials. The agency called the package a "primary component of NIH's initiative to enhance the stewardship of clinical trials," and said it puts all clinical trial and human subjects related information "into one place, and also expands the information required for studies that meet the NIH definition of a clinical trial."

Meyer's observations and experiences may be telling of others in the research community who are complying with NIH's controversial requirements, now in effect for funding applications with due dates on or after Jan. 25. Much of the public complaints about the new policy have centered on the expanded definition of clinical trials, amid concerns that it scoops up basic research trials as well as social science and behavioral studies that pose little to no risk to subjects (*RRC 9/21/17*).

While the clinical trial requirements are new for some studies, NIH actually revised the definition in 2014 as follows:

"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

To further clarify the term, NIH also defined prospectively assigned, intervention and health-related biomedical or behavioral outcome.