

Researchers rattled by the revised definition of clinical trials

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The U.S. National Institutes of Health (NIH) plans to enforce the new rules which are based on a revised definition of “clinical trials,” beginning in January 2018. The regulations would apply only to research funded by the agency. Autism researchers in the U.S. are anxious about the new government rules designed to boost the transparency of studies involving people. Researchers say that the red tape may paralyze promising projects.

The new definition's interpretation of “intervention” and “outcome” could apply even to studies of basic biological mechanisms. It means that a brain imaging study that tests a person's memory under conditions that interfere with memory might count as a clinical trial. This example has inflamed researchers because it seems far from clinical, reports Spectrum.

“By some readings of this case, virtually all basic research still counts as a clinical trial,” says Nancy Kanwisher, Walter A. Rosenblith Professor of Cognitive Neuroscience at the Massachusetts Institute of Technology (MIT). Others' comments are sharper, going so far as to call the new rules “frankly insane.”

The changes have been in the works for more than three years. But they mostly escaped researchers' notice until August, when the agency released guidance on a rigorous new grant application.

Since then, more than 3,500 researchers have signed open letters to NIH director Francis Collins, urging the agency to seek more input from researchers before implementing the regulations.

In response to this overwhelming response, NIH officials revised the list of hypothetical studies in early September. But the guidelines are still ambiguous, researchers say.

The rules set a high entry bar for researchers involved in discovery science, which sometimes requires more open-ended hypotheses than clinical trials, Kanwisher wrote in one comment. And the regulations “will mislead the public, obstruct scientific progress and create mountains of red tape for everyone involved,” wrote Lauren Hallion, research assistant professor of psychology at the University of Pittsburgh.

Because the new definition of clinical trial no longer has the common-sense meaning it once had, it may also confuse participants into thinking they are helping to test treatments, says John Gabrieli, professor of brain and cognitive sciences at MIT.

Instead of trying to fit clinical standards to basic research, the NIH could have instead added reporting requirements to grant applications for basic research, some say.

"I think the problem arises when you try to take the basic behavioral science peg and squish it into the clinical trials hole; it just doesn't really fit very well," says Jeremy Wolfe, professor of ophthalmology and radiology at Harvard University.

In the meantime, NIH officials are continuing to answer scientists' questions through email. "We see these as living documents," Lauer says of the guidelines.