NEWS

Scientists win two-year reprieve from controversial new clinical trial policy

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The U.S. National Institutes of Health (NIH) has delayed by two years a controversial new rule that required some basic researchers to register and report their studies as clinical trials.

The reprieve, **announced last week**, follows two years of **pushback from scientists** who say the system they were asked to use is cumbersome and creates extra paperwork. The NIH has promised to make **clinicaltrials.gov** easier to use in the interim.

Scientists are tentatively optimistic about the news.

“We’re not tying a bow around this and saying we’re done,” says **Jeremy Wolfe**, professor of ophthalmology and radiology at Harvard University — and among the first to **raise the alarm** about the new requirement. “We will certainly be keeping an eye on the policies as they evolve and hoping that we can have significant input, but this was an encouraging week.”

The controversy began in 2014, when the NIH **redefined the term** ‘clinical trial’ in a way that included many basic neuroimaging and behavioral studies.

Wolfe and others fought back with an online petition that garnered more than 3,500 signatures and **editorials** in prominent scientific **journals**. The new definition was inaccurate, they warned, and would cause confusion when basic researchers applied for grants.

In response, NIH officials **revised the guidelines** in January 2018 and in November that year created a new category: **Basic Experimental Studies Involving Humans**. They also agreed not to enforce the new policy until September 2019 — and solicited researchers’ comment.

Shoehorned solution:

The agency received 614 responses and has carefully evaluated the concerns, says **Michael Lauer**, deputy director for extramural research at the NIH. For example, staff at the National Library of Medicine tried entering some of the scientists’ studies into the platform and discovered that the process was not straightforward.

Behavioral research might involve several small, related pilot studies before scientists can develop a sophisticated one. Registering and reporting the pilot studies “does require a bit more thought in how you describe [them]” says Lauer.

The NIH plans to improve the platform over the next two years in order to make it more usable. In the meantime, basic researchers aren’t obliged to use clinicaltrials.gov, but must report their results on an open, online platform and alert the NIH.

Some researchers still question what they see as the NIH’s shoehorning of basic research into clinicaltrials.gov.

“It’s not a question of sharing the data, we’re all happy to do that,” says **Lucina Uddin**, associate professor of psychology at the University of Miami in Florida. “[But] there are ways of increasing

accountability without following the same model that clinical trials have followed."

For instance, all autism research funded by the NIH is already reported in the **National Database for Autism Research.**

Inaccurate terminology:

But scientists still object to NIH's revised definition of a clinical trial.

"The arguments for the distinction [between a clinical trial and basic research] have been made, but NIH has yet to fully embrace them," says **Helen Tager-Flusberg**, director of the Center for Autism Research Excellence at Boston University.

The new definition poses other problems too, says Wolfe. For example, members of the public — who can use the database to identify clinical trials that would give them access to new treatments — may end up with basic studies in their search results. He concedes, however, that this problem is "not as urgent" as the administrative burden and confusion around grant applications.

The key to resolving the years-long conflict, says Wolfe, will be whether the NIH fulfills its promise to collaborate with basic researchers to hone the system: "If they're committed to working with our community, we're all in the end pointed in the same general direction."