

# Basic scientists still feel pinch of new NIH clinical trial policy

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Basic researchers who study the brain and human behavior thought lawmakers had come to their rescue in March by blocking the National Institutes of Health (NIH) in Bethesda, Maryland, from redefining their studies as clinical trials. But NIH officials are still pushing ahead with new requirements that scientists say make no sense and will cripple their research.

What some see as NIH's narrow interpretation of a directive from lawmakers has researchers up in arms as they navigate confusing new rules and paperwork. The clinical trial policies "are not appropriate for fundamental research," a group of societies wrote in an email to NIH this week.

The issue goes back almost a year, when researchers [became aware that a new NIH definition of clinical trials would encompass many basic studies involving human subjects](#). Since January 2018, these projects must now go through a new submission and review process and will need to be registered and have results reported on [clinicaltrials.gov](#), a public database, among other requirements aimed at improving rigor and transparency in clinical research.

Last summer, several scientific and university groups, individual scientists, and [more than 3500 petition signers](#) protested that filing studies that aren't testing drugs or other treatments on [clinicaltrials.gov](#) would confuse the public. They were also worried that redefining their studies as clinical trials would make it harder to get funding. In response, NIH spent months [tweaking a set of "case studies" that exempt some basic work](#), such as certain brain imaging studies, but still sweep up much fundamental research, says Sarah Brookhart, executive director for the Association for Psychological Science (APS) in Washington, D.C.