

NIH delays controversial clinical trials policy for some studies

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Basic brain and behavioral researchers will get more than a year to comply with a new U.S. policy that will treat many of their studies as clinical trials. The announcement from the National Institutes of Health (NIH) appears to defuse, for now, a yearlong controversy over whether basic research on humans should follow the same rules as studies testing drugs.

Behavioral researchers conducting studies that meet the clinical trials definition will also have to take a training course on clinical practices, but it can be a brief online seminar tailored to the field.

“This delay is progress because it gives them more time to get it right, and in the interim people aren’t going to be in trouble if they get it wrong,” says cognitive psychologist Jeremy Wolfe of Harvard Medical School in Boston. One problem he and others hope NIH will work on is a requirement that all basic researchers studying humans submit a separate form for each experiment, which they say doesn’t make sense for exploratory research.

However, academic and scientific groups are disappointed that NIH hasn’t dropped basic science from the clinical trials definition altogether. “Basic research should not be construed as a clinical trial,” says Sarah Brookhart, executive director of the Association for Psychological Science in Washington, D.C., a point on which “the community stands firm.”