

Description

Clinical trials in the research community are subject to strict ethical and regulatory requirements. For instance, in the U.S., researchers must register clinical trials and report the results on ClinicalTrials.gov. Recently, National Institutes of Health (NIH), the largest funding agency of clinical trials in the U.S., changed the “clinical trial” definition. The policies that were initially implemented only in biomedical clinical trials will now be equally applicable to social sciences and behavioral sciences intervention trial. This expanded definition of a clinical trial is the subject of a recent controversy.

These requirements intend to distinguish clearly between a clinical trial and a clinical research study. This change will promote scientific transparency and accountability in data collection, tracking, and reporting results. Nevertheless, why these new policies are unacceptable to some of the researchers?

The New NIH Definition of Clinical Trials

The NIH published its new clinical trial definition on October 23, 2014. A Clinical trial is defined as:

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. [1]

This might seem like a basic definition, but many social and behavioral scientists see this as a major change in the NIH policy. The revised NIH definition of clinical trial is very broad. For instance, *intervention* can also include “strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits)”.

Additionally, “behavioral outcome” will fall under the purview of the new definition of clinical trials. Behavioral outcomes could include any measured result involving human behavior. For example, behavioral science researchers could study whether looking at images makes participants quicker to respond to test questions. In the past, this type of study was not part of the NIH clinical trial definition. Under the new NIH clinical trial policies, behavioral science researchers might be required to register and report the results of this type of study at ClinicalTrials.gov.

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Backlash from the Social Science Research Community

According to some researchers, the expanded NIH clinical trial definition is a problem. Some researchers believe that the definition is too broad and may encompass studies that do not relate to medicine or treatment interventions. Therefore, researchers may have to utilize more resources to follow and complete related paperwork and regulations, making it more difficult for them to do their work efficiently.

Another potential problem is that it requires registering and reporting more studies. The website clinicaltrials.gov contains a database of clinical trials that is accessible to the public. The Federation of Associations in Behavioral & Brain Sciences (FABBS) shared a concern that that including more trials in the database might confuse the public. Users visit this site to find information in trials that they could participate. However, with more behavioral and non-medical studies in the database, patients may have a harder time to find relevant information. [2]

Assessment: Transparency is a Good Thing

The clinical trials process is more complicated than that of the basic sciences research. However, with a growing population, more complicated medical and behavioral treatments, advanced technology, and other challenges of the modern medical era increased transparency will improve help both researchers and the patients.

NIH is trying to clarify the scope of the new definition and providing information in form of case studies to help behavioral and social scientists identify if their research is a clinical trial. Overall, the broader definition of clinical trials will benefit the public and the research community. However, there may be a period of adjustment to new requirements and increased availability of information.

References

1. National Institutes of Health, “Notice of Revised NIH Definition of ‘Clinical Trial’,” 23 October 2014, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html
2. Jocelyn Kaiser, “Some scientists hate NIH’s new definition of a clinical trial. Here’s why,” 19 July 2017, https://www.sciencemag.org/news/2017/07/some-scientists-hate-nih-s-new-definition-clinical-trial-heres-why

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Author
daveishan

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