

## NIDCD Clinical Trials Definition

Good morning, NIDCD-funded researchers. As you may be aware, many across NIH have heard recently of applications being administratively withdrawn without review. The basis for the withdrawal was misclassification (by the investigator) of the application as “not a clinical trial”; upon receipt of the application, NIH determined that the research proposed met the NIH definition of a clinical trial <https://grants.nih.gov/policy/clinical-trials/definition.htm>. Such applications may have been submitted to a Funding Opportunity Announcement (FOA) such as a Program Announcement, that did not allow clinical trials. Thus, the application was returned. The definition of a clinical trial has evolved at NIH over recent years, which has resulted in the classification of some projects as clinical trials, when previously they were not. In addition, an area of continued confusion for PIs is the NIH definition of an intervention: “a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.”

The guiding determinants for a clinical trial are:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answer is yes to all four, the study is a clinical trial.

The guidance on this has been in place for some time. Then, around early 2018, NIH began segregating FOAs as “Clinical Trial Required” “Clinical Trial Not Allowed” and “Clinical Trial Optional” and requiring that PIs select the appropriate FOA for their science based on the above definition. For the last two years, roughly, **there’s been a period of leniency** in place where applications were allowed to come through even if they selected the wrong FOA (re: CT designation). **That period of leniency recently ended**, and NIH has now started to withdraw applications where the science is determined to be a CT but the FOA does not allow CTs, which is what has been happening recently. The link regarding the notice to end leniency is <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-126.html>.

For applicants submitting an R01, consider this announcement [NIDCD Clinical Trials in Communication Disorders \(R01 - Clinical Trial Required\) PA-18-334](#). Other grant mechanisms, be sure to apply to FOAs that indicate “Clinical Trial Optional” or “Clinical Trial Required”. Finally, check out our resources at <https://www.nidcd.nih.gov/research/clinical-studies/researchers-professionals>.

To those who have had their applications withdrawn or have colleagues who have experienced this problem, my understanding is that NIH central is very aware of this issue and is hoping to find a better way forward. We are very very sorry this has happened.

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