

NIH Announces Policy Changes Regarding the Inclusion of Children, Women, and Minorities as Research Subjects

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The National Institutes of Health has announced new policies regarding requirements related to the individuals who participate as research participants in studies funded by NIH.

In one notice ([NOT-OD-18-014](#)), NIH has announced a new requirement affecting grant recipients conducting a Phase III clinical trial. A Phase III clinical trial, as defined by NIH, is a study to determine efficacy of a biomedical or behavioral intervention in large groups of people by comparing the intervention to other standard or experimental interventions. Researchers conducting these kinds of studies will need to ensure that their study has an adequate sample to conduct valid analyses examining sex/gender, race, and/or ethnicity and that these analyses are submitted to Clinicaltrials.gov during the clinical trials research process.

According to NIH, this change ensures “that clinical trials are carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other trial participants.”

In a second notice ([NOT-OD-18-008](#)), NIH has announced that it intends to revise its policy and guidelines on the inclusion of children in research projects. A discussion of this issue is scheduled as a formal agenda item for the upcoming December 14-15, 2017 meeting of the Advisory Committee to the NIH Director.

NIH is undertaking this effort to “address the consideration of age as an inclusion variable in research involving human subjects, to identify the criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies.”