



NIH Extends Policy for Clinical Trial Registration and Results Reporting for NIH-Funded Basic Experimental Studies with Humans (BESH)

Scope of Notice (NOT-OD-19-126)

On July 24, 2019, the National Institutes of Health (NIH) published a notice that the requirement for *clinical trial registration and results reporting* for a subset of NIH-supported research whose primary purpose is basic experimental studies with humans (BESH) has been **further extended to September 24, 2021**. BESH studies meet both the [NIH definition of a clinical trial](#), and also the [NIH definition of basic research](#).

During this extension period, *clinical trial registration and results reporting* is still required, however, there is flexibility on the platform for registration and results submission.

- The use of an alternative platform will be described at the *time of application* in the *Dissemination Plan*.
- Funded awardees for applications submitted to BESH-specific Funding Opportunity Announcements (FOAs) who are not using ClinicalTrials.gov to meet the policy expectation will *provide in their annual progress reports the unique identifier assigned by the alternative platform, if available, and a link to the report (i.e., page or record)* in the alternative platform.
- This delayed enforcement is *only applicable to BESH studies submitted to **funding opportunities** designated as “basic experimental studies with humans”* in the title.
- Good Clinical Practice (GCP) training is still required ([NOT-OD-16-148](#)).
- The [PHS Human Subjects and Clinical Trials Information form](#) is also still required ([criteria](#)).

This policy does ***not*** apply to *NIH applications* submitted to the *incorrect FOA based on the study-type designation*.

- Starting for *due dates on or after September 25, 2019*, NIH applications submitted to an *incorrect FOA based on study-type designation* (i.e., a clinical trial submitted to a “clinical trial not allowed” FOA) may be *withdrawn*.

Additional guidance:

- [NOT-OD-19-024](#)
- [Table of FOA Types by Clinical Trial Allowability](#)
- [NOT-OD-18-212](#)
- [BESH FAQs](#)
- Inquiries: grantsinfo@od.nih.gov