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FOA based on study-type designation (i.e., a clinical trial submitted to a “clinical trial not allowed” FOA) may be withdrawn.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