Baystate Health

Did You Know? NIH Ends Clinical Trial Classification for BESH Studies

The National Institutes of Health (NIH) has issued a new policy titled Basic Experimental Studies in Humans (BESH) Will No Longer Be Considered Clinical Trials by the NIH (NOT-OD-26-032).

What has changed?

Effective for applications submitted on or after May 25, 2026, Basic Experimental Studies Involving Human Subjects (BESH) will no longer fall under the NIH Clinical Trial Definition:

> **"Clinical Trial"** – a 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.
>
> **"Basic Experimental Studies Involving Humans" (BESH)** – studies in humans that have the purpose of understanding fundamental aspects of phenomena without a direct application towards clinical processes or products. We define "process or products" as the application of biomedical or behavioral research to affect a health-related outcome. Accordingly, the NIH does not consider BESH to be clinical trials (NOT-OD-26-032).
>
> **"Observational Studies Involving Humans" –** these are studies in which data are gathered from or about human participants, but the researchers do not perform an intervention. Observational studies can be conducted with human participants in real time or can be performed retrospectively using previously gathered data or information. Observational studies involving humans are not clinical trials or BESH.

WHAT HAS CHANGED?

BESH studies:

- Will no longer be considered clinical trials by NIH
- Will not be subject to NIH clinical trial requirements
- Will not require registration or results reporting to ClinicalTrials.gov
    - In certain circumstances, your project may qualify under BESH but require registration on ClinicalTrials.gov. An example would be if the journal you plan to submit your article to requires it. Please work with SPA and the IRB to determine this.
- NIH Definitions of Clinical Trial vs BESH vs Observational Studies involving Humans

WHAT STILL APPLIES?

Although BESH will no longer be treated as clinical trials, these studies must continue to comply with:

- Human subjects protections
- All applicable clinical research laws and regulations
- The NIH Data Management and Sharing Policy
- Any other relevant policies.

- For BESH study NIH Grant applications **submitted on or before May 24, 2026**, and contract solicitations issued prior to that date, BESH projects much continue to be treated as a clinical trial and need to follow the clinical trial requirements.

WHY DOES THIS MATTER?

This update reduces administrative burden for investigators conducting BESH studies, while maintaining critical compliance requirements related to human subjects protections and data management.

Departments supporting NIH-funded research should review proposal development and compliance workflows to ensure alignment with this updated classification that began May 25, 2026.

WHAT YOU SHOULD DO:

- Human subjects protections still fully apply, including IRB review, informed consent, and the NIH Data Management and Sharing Policy.
- For new applications, work with the IRB and SPA to confirm whether a study qualifies as BESH under the updated NIH policy and definitions.
- Do not assume a project is exempt from human subjects requirements – this change only affects clinical trial classification, not participant protections.
- Continue to follow current award terms for active projects until NIH guidance or award conditions change.
- You can find additional NIH guidance here: Is My Project a Clinical Trial, Basic Experimental Study Involving Humans (BESH), or an Observational Study Involving Humans?

Human Participants?	Prospectively Assigned Intervention?	Evaluate Effect of Intervention?	Health-Related Outcome?	Study Type
Yes	Yes	Yes	Yes	Clinical Trial
Yes	Yes	Yes	No	BESH
Yes	Yes	No	No	Observational
Yes	No	No	Yes	Observational
Yes	No	No	No	Observational

National Institutes of Health, Policy & Compliance: Is My Project a Clinical Trial, Basic Experimental Study Involving Humans (BESH), or an Observational Study Involving Humans?