

Guidance for Basic Experimental Studies with Humans (BESH) Funding Opportunities

Need help determining if your study falls within a Basic Experimental Studies with Humans (BESH) funding opportunity announcement? The following key considerations and associated examples may help!

Does the study aim to understand fundamental aspects of phenomena or observable facts without specific applications towards processes or products in mind?

A key factor in determining if research falls under the BESH FOA is if it has the intent to further the understanding of a phenomenon without a specific application in mind. But how “translational” can the study be and still be defined as “basic research” consistent with 32 CFR 272.3?

We define “process or products” as stated in the definition of basic research as the “application of biomedical or behavioral products, procedures, or services intended to affect a health-related outcome of an individual or a group of individuals either by better understanding the mechanism of action of an intervention or a measurable improvement in health.”

If the translational nature of the study is only aspirational and alluded to only in the purpose and public health implications, (i.e., the findings from the study *may* or *could* have potential applications in the future), then the study is not truly “applied” and is not said to have “a process or product in mind”.

Conversely, studies that examine the mechanisms by which an intervention works or the processes that account for an intervention’s effects on a clinical outcome are considered to have a process or product in mind, and thus should submit under a Clinical Trial Required FOA.

Note that any FDA Phase 0 or 1 trial is by default considered to have a process or product in mind and, therefore, should submit under a Clinical Trial Required FOA as well.

Key Consideration: Is the study itself applied (i.e., with a process or product in mind), or is the study looking to gain a fundamental understanding of a process that may have translational potential in the future?

- If the purpose of the study is to gain a fundamental understanding of a phenomenon, even if it is using an intervention or experimental manipulation as a probe to do this = **Basic Experimental Studies with Humans (BESH) Required FOA**
 - Ex. Findings from the study are used to understand a phenomenon, which may eventually be used to improve treatment options
- If the purpose of the study is actually translational/applied with process in mind, and/or is focused on how the intervention or treatment produces its effects = **Clinical Trial (CT) Required FOA**
 - Ex. The findings from the study are designed to study how a treatment target can be modified.

Does the study utilize an experimental manipulation or intervention as a probe to understand a basic phenomenon or process?

Basic research uses a range of probes to perturb a phenomenon or physiological process. Some of these probes are derived from existing treatments. As a result, it is often difficult to determine along the continuum of “basic” to “applied” research if the experimental manipulation is testing the existing treatment or merely using the intervention as a probe to understand a basic phenomenon.

Key consideration: Is the purpose of using the experimental manipulation or intervention primarily to understand a basic phenomenon, or is it to understand more about the intervention or its effects?

- If the purpose of using the experimental manipulation or intervention is to learn more about a basic phenomenon = **Basic Experimental Studies with Humans (BESH) Required FOA**
 - Ex. The primary outcomes of the study measure or assay the basic phenomenon
- If the purpose of using the experimental manipulation or intervention is to learn more about the clinical or health-related outcomes, including mechanisms of action of the intervention = **Clinical Trial (CT) Required FOA**
 - Ex. The primary outcomes of the study are clinical in nature or aim to measure a change in health status of the participant