Clinical Trials:
Information To Help You Plan Your Next Steps

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Agenda

- NIH Definition of a Clinical Trial
- Clinical Trial Allowed Funding Opportunity Announcements (FOA)
- Registration and Reporting
- Explain Why the Changes
- Single IRB
- Take Away

NIH Definition of a Clinical Trial

- Use the following four questions to determine the difference between a clinical study and a clinical trial:
  - Does the study involve human participants?
  - Are the participants prospectively assigned to an intervention?
  - Is the study designed to evaluate the effect of the intervention on the participants?
  - Is the effect being evaluated a health-related biomedical or behavioral outcome?
- Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…
  - You are studying healthy participants
  - Your study does not have a comparison group (e.g., placebo or control)
  - Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
  - Your study is utilizing a behavioral intervention
- Studies intended solely to refine measures are not considered clinical trials.
- Studies that involve secondary research with biological specimens or health information are not clinical trials.

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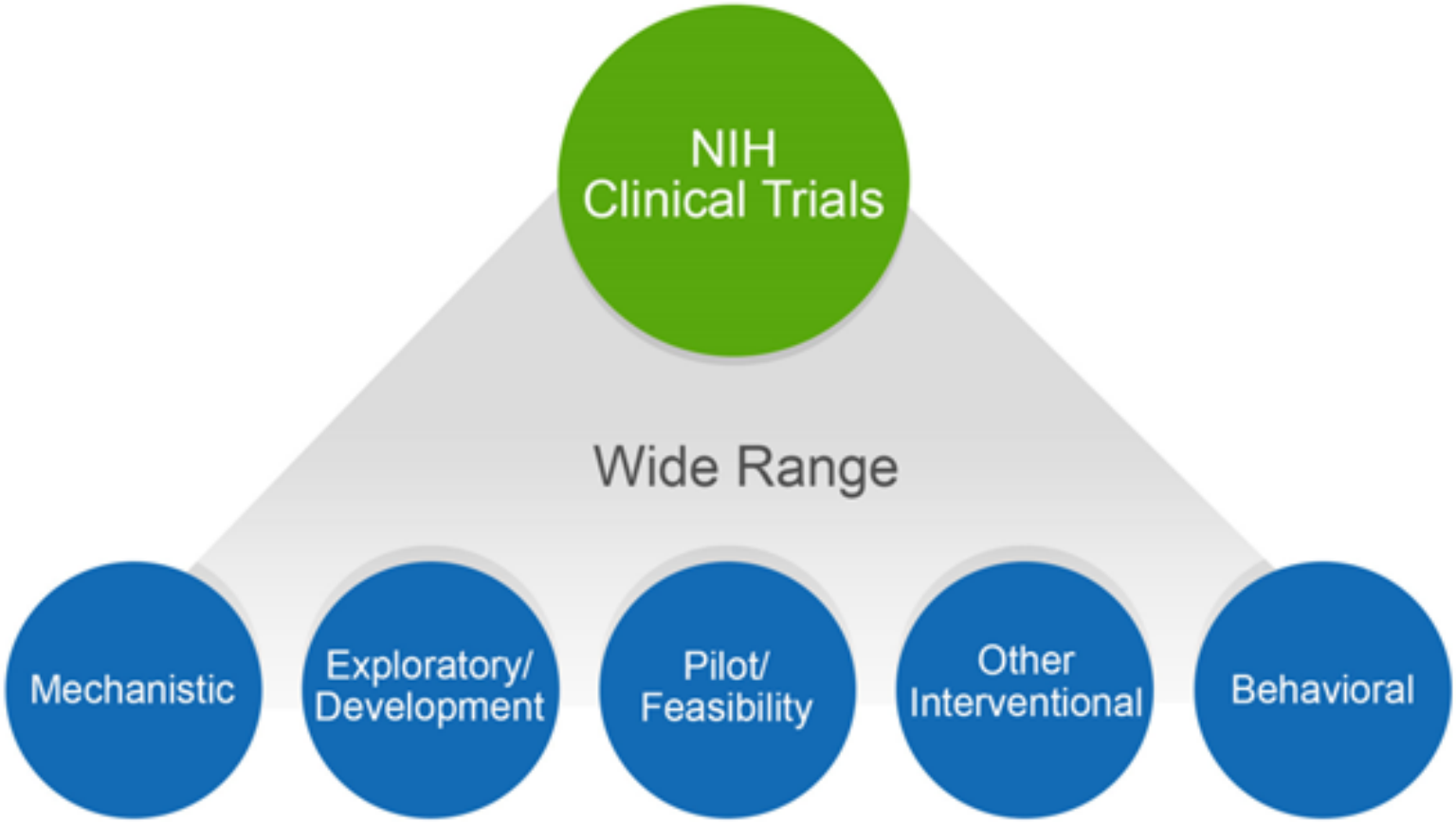
NOT-OD-15-015 Notice of Revised NIH Definition of "Clinical Trial"

NIH Clinical Trials – Wide Range



https://grants.nih.gov/policy/clinical-trials/definition.htm

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Allowability of Clinical Trials in the FOA Title: The Grace Period Is Over

Clinical Trial Not Allowed	Only accepts applications that do not propose clinical trial(s)
Clinical Trial Required	Only accepts applications that propose clinical trial(s)
Clinical Trial Optional	Accepts applications that either propose or do not propose clinical trial(s)
Basic Experimental Studies with Humans (BESH) Required	Only accepts applications that propose clinical trial(s) that also meet the definition of basic research

- **Basic Experimental Studies with Humans (BESH)**
- These studies fall within the NIH definition of a clinical trial and also meet the definition of basic research.
- All FOAs for Basic Experimental Studies with Humans (BESH) are designated as "Required - Basic Experimental Studies with Humans: Only accepting applications that propose clinical trial(s) that also meet the definition of basic research" in *Section II. Award Information*.
- Participation in funding opportunities for Basic Experimental Studies with Humans will vary by NIH Institute and Center (IC). Many ICs will continue to accept Basic Experimental Studies with Humans through existing FOAs that accept clinical trials. It is important to check with a Program Officer to determine the most appropriate FOA for your application.

https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm

Registration and Reporting

- **Step 1** Determine if the competing application, contract proposal, funded grant, or awarded contract supports a clinical trial.
- **Step 2**
- Determine which regulations and/or policies apply to your NIH-funded clinical trial.
- **Step 3**
- Certify compliance in NIH grant applications, contract proposals and progress reports.
- **Step 4**
- Determine who is responsible for clinical trial registration and results reporting.
- **Step 5**
- Ensure the responsible entity registers the clinical trial no later than 21 days after enrolling the first subject.
- **Step 6**
- Ensure the responsible entity updates information in the clinical trial record at least once every 12 months.
- **Step 7**
- Ensure the responsible entity reports summary results not later than a year after clinical trial completion date.

Registration and Reporting

Determine if the competing application, contract proposal, funded grant, or awarded contract supports a clinical trial.

If yes, then your study is subject to **both** FDAAA 801 as implemented by 42 CFR Part 11 (the Final Rule), and the NIH Policy on Dissemination of NIH Funded Clinical Trial Information.

If no, then your study is subject to the NIH Policy on Dissemination of NIH Funded Clinical Trial Information.

https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm

Why Changes to Clinical Trial Policies?

- The success of the clinical trial enterprise relies on the public trust in scientific rigor, transparency, and ethical oversight. NIH is the largest federal funder of clinical trials in the United States, with a $3 billion annual investment.

- It is essential that the NIH:
  - Support trials investigating high priority questions
  - Avoid needlessly duplicating previously conducted trials
  - Exercise proper stewardship over precious public resources, in part by developing and maintaining robust data about the trials we support
  - Respect ethical obligations to participants who give their time and sometimes put themselves at risk for the sake of advancing science
  - Promote broad, transparent, timely, and responsible dissemination of information from NIH-funded clinical trials

https://grants.nih.gov/policy/clinical-trials/why-changes.htm

Why Changes to Clinical Trial Policies?

Historically, NIH has had difficulty reporting how many clinical trials it has funded and results from many NIH-funded clinical trials are never published or reported in a public database.

Consequently, the Government Accountability Office (GAO) recommended NIH improve clinical trial data collection and establish and implement a process for using this data effectively. Regulations have been incorporated into policies that aim to:

Enhance the application and award processes to increase NIH's ability to assess the merits and feasibility of clinical trial applications

Improve oversight and transparency

Increase the sharing of clinical trial results

https://grants.nih.gov/policy/clinical-trials/why-changes.htm

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Single IRB Policy for Multi-site Research

Purpose

- Historically, in many multi-site studies, each site has its own IRB which conducts an independent review of studies involving human research participants. The use of a single IRB of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites.

- The goal of this policy is to enhance and streamline the IRB review process for multi-site research so that research can proceed as quickly as possible without compromising ethical principles and protections for human research participants.

- Applicants are expected to include a plan for the use of a sIRB in the grant applications and contract proposals they submit to the NIH

Take Away

- Communicate with your Program Officer early and often.
- Read the FOA thoroughly since each one is different especially regarding clinical trials.
- Keep up with policy changes.
- Seek information from more than one person (e.g., Program Officer, Grant Specialist, Scientific Review Officer, others).

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