Clinical Trials in NCI Grants

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NIH NATIONAL CANCER INSTITUTE

New Investigator Meeting
November 22, 2019

Agenda

1. *NIH definition of Clinical Trials*
2. *Single IRB requirements*
3. *Clinical trial considerations*
4. *Registering and reporting*

Clinical Trial Reforms & Policy Changes

In 2016, NIH announced initiatives targeted to enhance and improve:

Efficiency

Enhance the efficiency of how research studies involving human participants are conducted

Transparency

Promote a culture of transparency in research in order to advance public health

Accountability

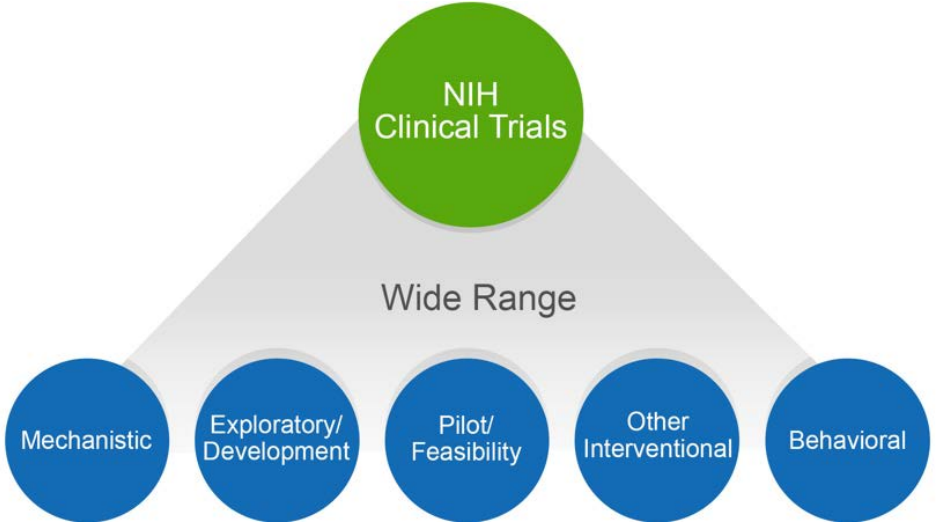
Ensure that NIH can appropriately identify and report on their clinical trials portfolio to ensure proper stewardship

Timely Reporting

Decrease the time it takes investigators to publicly report study results

NIH Definition of a Clinical Trial is Broad

- Encompasses a wide range of types of trials, including:
  - Mechanistic
  - Exploratory
  - Pilot/Feasibility
  - Behavioral



A research study in which one 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

Questions to Ask Yourself

Does your study…

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the **effect of intervention(s)** on the human subject(s)?
- ✓ Have a **health-related biomedical or behavioral outcome?**

If "yes" to ALL of these questions, your study is considered a clinical trial

Unsure how to answer the questions? Resources may be found at https://grants.nih.gov/policy/clinical-trials.

Includes studies involving

- Healthy participants
- Clinicians
- Caregivers
- Single arm interventions
- Behavioral interventions

Clinical Trials: FOAs

All FOAs are designated as one of the following in Section II of the FOA:

- ✓ Clinical Trial **Required**
- ✓ Clinical Trial **Not Allowed**
- ✓ Clinical Trial **Optional**
- ✓ No Independent Clinical Trials: *only for Career Development (K) & Fellowship (F)

Tip: Contact your Program Official or the Scientific/Research contact listed in Section VII of the FOA to ensure you are submitting to the correct announcement

Single Institutional Review Board (sIRB) Policy for Multi-site Research

NIH expects that all multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a *single Institutional Review Board (sIRB)* to conduct the ethical review required for the protection of human subjects

sIRB policy aims to:

- ✓ Streamline IRB review process to enhance research efficiency
- ✓ Reduce unnecessary administrative burdens and inefficiencies

Learn more at https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

Clinical Trial Considerations

- Multi-site trials
  - Delays getting sites open and accruing
- Intervention
  - Delays developing intervention
  - Subcontracts (e.g. IT platforms, apps)
  - Acquisition of agent(s)
- Recruitment
  - Access to populations
  - Change in recruitment strategies
  - Key stakeholders/champion turnover

When in Doubt – Reach Out

- Don’t wait until the Progress Report (RPPR)
- Let your Program Director know if there are delays that you are not able to mitigate
- Not able to meet milestones?
- Strategies you have put in place to resolve the issue
- Budget considerations

Posting and Reporting Requirements

Registering & Reporting Requirements for ClinicalTrials.gov

In order to comply with the NIH Policy on Clinical Trial Dissemination, grantees must:

- ✓ Submit a plan in the application that outlines compliance with the expectations of the policy
- ✓ Register the clinical trial no later than 21 days after enrolling the first participant
- ✓ Submit summary results no later than one year after primary completion date

Posting Clinical Trials Informed Consent Forms

- Revised Common Rule requires clinical trials post one IRB-approved version of a consent form that has been used to enroll participants on a public federal website designated for posting consent forms
- Consent must be posted after recruitment closes, and no later than 60 days after the last study visit
- Can upload an IRB-approved version of the consent to ClinicalTrials.gov study record
  - English version only

Learn more: https://grants.nih.gov/policy/clinical-trials/informedconsent

NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

All grants involving clinical trials must **register** and **report** the results in ClinicalTrials.gov

NIH dissemination policy:

- ✓ Extends previous HHS laws and regulations to apply to **all** NIH-funded clinical trials, including the defined subset of “applicable clinical trials”
- ✓ Increases the availability of information to the public about clinical trials

Learn more at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

www.cancer.gov

www.cancer.gov/espanol