Mentimeter

What does the term *clinical trial* mean to you?

125 responses

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NIH-Defined Clinical Trials in NCI Grants

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NIH NATIONAL CANCER INSTITUTE

New Investigator Meeting

October 30, 2023

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

NIH Clinical Trial Policy

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 to advance public health

Accountability

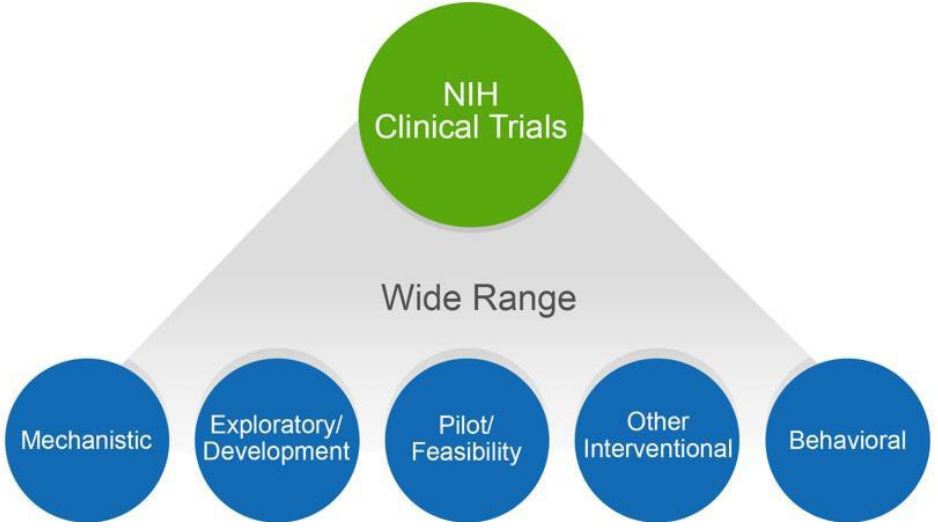
Ensure that NIH can appropriately identify and report on their clinical trials portfolio to ensure proper stewardship

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.htm

Includes studies involving

- Healthy participants
- Clinicians
- Informal caregivers
- Single arm interventions
- Behavioral interventions
- Randomized and non-randomized study designs

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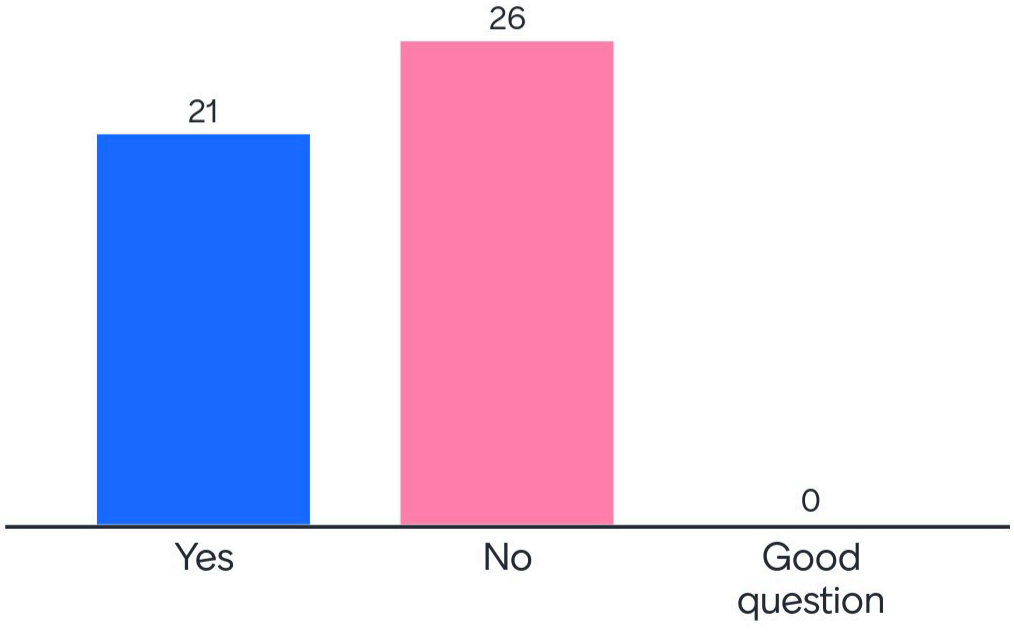
Do you have a clinical trial in your grant?



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Clinical Trials: NOFO

All NOFOs are designated as one of the following in Section II of the Notice of Funding Opportunity (NOFO):

- ✓ 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 NOFO 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 conducting the same research protocol, 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/humansubjects/single-irb-policy-multi-site-research.htm

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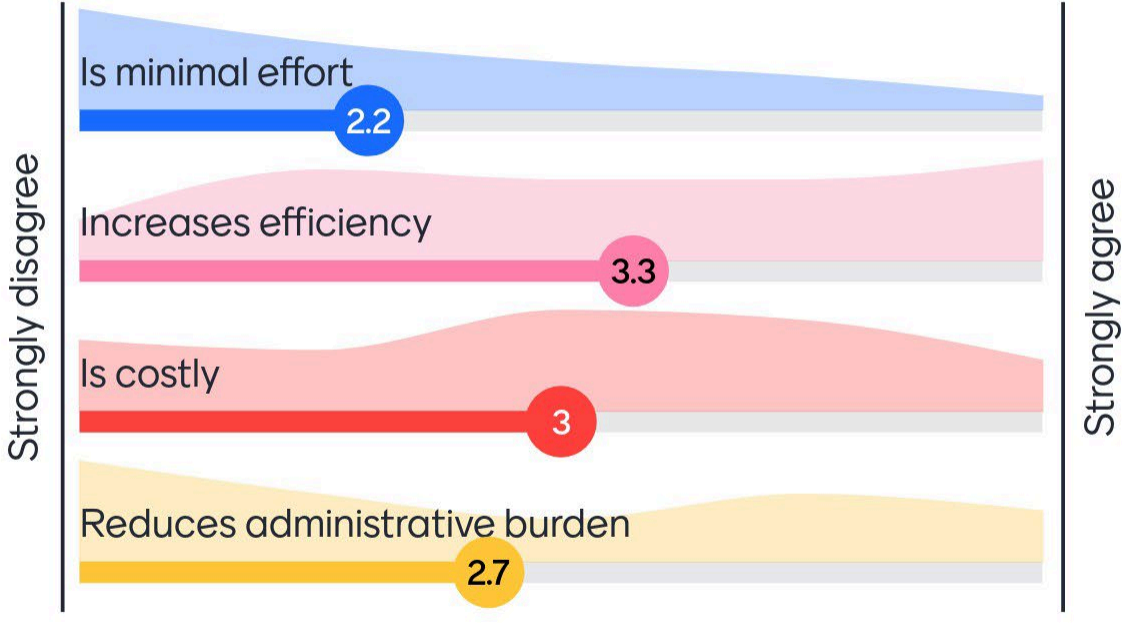
Implementing the single IRB policy



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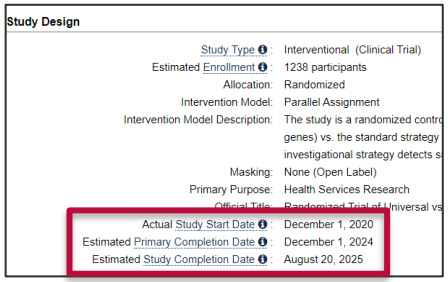
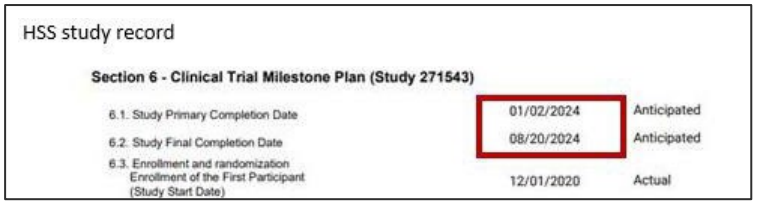
Registering & Reporting Requirements for ClinicalTrials.gov

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
- ✓ The dates in the grant, Human Subjects System, and ClinicalTrials.gov must match:
  - ✓ Study start date
  - ✓ Primary completion date
    - The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure.
  - ✓ Study completion date
    - The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome, secondary outcome, and adverse events. The last participants last visit is the study 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.htm

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

NIH Policy on Inclusion Across the Lifespan

To ensure individuals are included in clinical research in a manner appropriate to the scientific question under study so that the knowledge gained from NIH-funded research is applicable to all those affected by the researched diseases/conditions.

Reporting Requirement:

- ✓ Progress reports much include individual-level data on participate age at enrollment, sex/gender, race and ethnicity.

Age Enrollment Report

Age Categories	0-1	2-5	6-12	13-17	18-25	26-45	46-64	65-75	76+	Unknown/ Not Reported	Total
Total	*	*	*	*	*	46	30	*	*	11	93

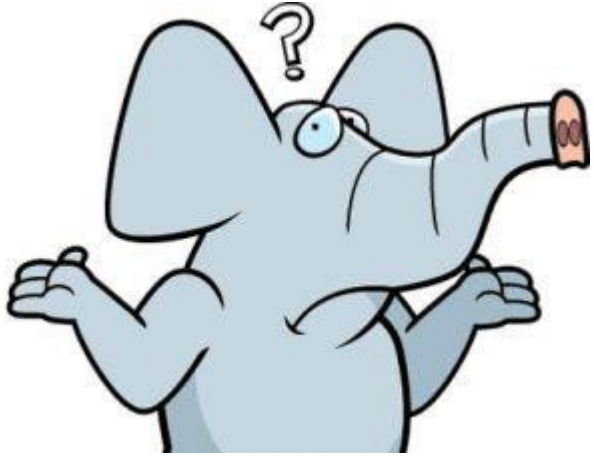
https://grants.nih.gov/policy/inclusion/lifespan.htm

Clinical Trial Considerations

- **Multi-site trials**
  - Delays getting sites open and accruing
- **Intervention**
  - Development delays
  - Subcontracts (e.g., IT platforms, apps)
  - Acquisition of agent(s) and equipment
- **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
- Changing Institutions



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What challenges have you experienced with your clinical trial?

52 responses

Slower then anticipated accrual	Slower than expected accrual	Hiring staff
Multiple IRB reviews	subcontracts being delayed	Hiring staff
Changing institutions	App company went out of business	Meeting recruitment goals

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What challenges have you experienced with your clinical trial?

52 responses

Recruitment and retention	IRB, staffing,	Slow accrual
Recruitment	Slow recruitment	Single IRB startup
Slower accrual	Regulatory	sIRB taking long time when only 2 sites

What challenges have you experienced with your clinical trial?

52 responses

Technology development delays

Recruitment

regulatory

Concordance with single IRB plan

Not done before (lack of experience)

Recruitment difficulty

None?

Definition of clinical trial is very unclear!!!

Irb staffing

What challenges have you experienced with your clinical trial?

52 responses

Coordinating regulatory approvals, both within my own institution and across partnering institutions

Single irb takes forever and adds work

Dealing with budget cuts

AccrualStaffing IRB approval

Administrative challenges with subaward

Lower participation from rural practices

Enrollment & CITI training requirements

Technology changes

Additional reviews by the NCI cancer center at my institution, in addition to IRB reviews.

What challenges have you experienced with your clinical trial?

52 responses

sIRB being approved at sites

IRB modifications to get approval

International conflict has prevented collaborators from working

Many layers of IRB and cancer center reviews for startup and amendments

Management plan for conflict of interest

Including DUAs in Subcontracts taking forever

Coordinating across sites

Budget cut = short staffed for recruitment

Budget cuts = lack of funds for coordinators

What challenges have you experienced with your clinical trial?

52 responses

New institutional policy prohibitingRecruitment at a planned site

Unclear if behavioral intentions or perceptions constitute a health outcome

Budget cuts

IRB and Cancer Center reviews

Regulatory/ IRB/ DUA/BAA

Managing human subjects when one aim is a trial but another isn't

Legal agreements between institutions --for data sharing etc

Resources

- NIH Office of Extramural Research
  https://grants.nih.gov/policy/clinical-trials
  - Definitions
  - Case studies
  - Registering and reporting
  - Training slides & videos
  - Decision tools