NIH Clinical Trials: Definition and Impacts

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Clinicaltrials.gov Registration

3 Reasons to Register

1. You have an NIH-funded clinical trial [REQUIRED]
2. You have a clinical trial involving an FDA-regulated drug or device (ACT – see slide 9) [REQUIRED]
3. You have a clinical trial (regardless of funding source) and want to be allowed to publish your findings in a journal following ICMJE guidelines [VOLUNTARY]

Studies that are Not Clinical Trials

- Studies that are not clinical trials are not required to be registered, however, they are not prohibited from registration
  - Registration itself can sometimes be a challenge since the required fields were designed for clinical trials

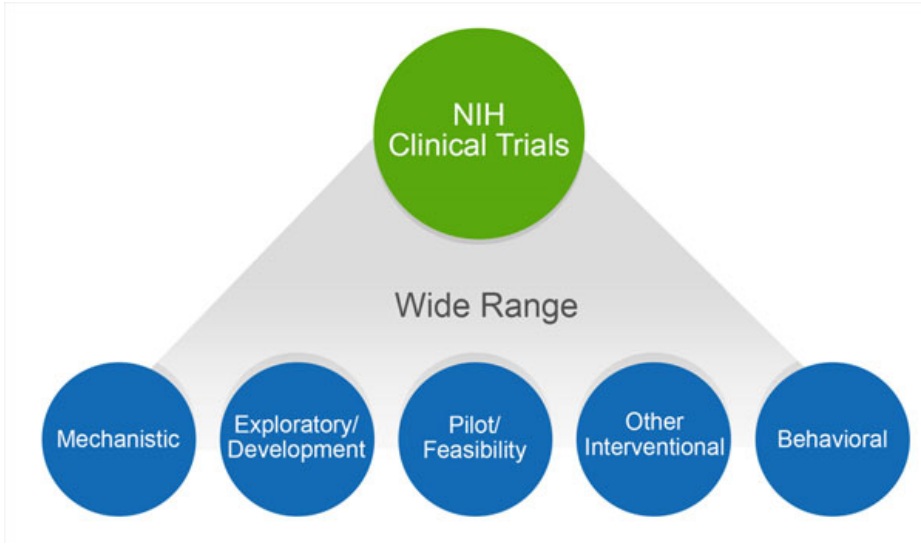
Responsible Party

- Registration responsibility lies with the organization that "owns" the intellectual property
  - Usually determined by who wrote the study protocol
  - Industry-funded research is usually registered by the sponsor, however, every once in awhile we see an industry-funded PI-initiated study. In this case, the PI's organization is responsible for registration

NIH Policy

- All NIH-funded clinical trials are required to be registered as of January 2017
- No information exists on the clinicaltrials.gov website related to this policy
- Information on this policy can be found on NIH's website

#1: NIH-Funded Clinical Trials

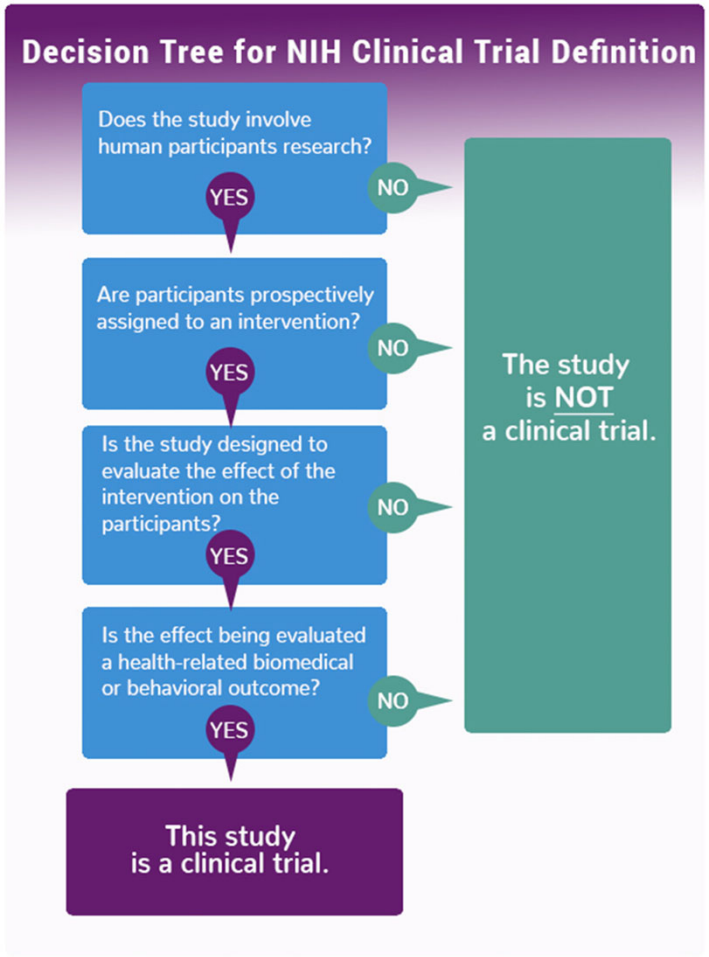


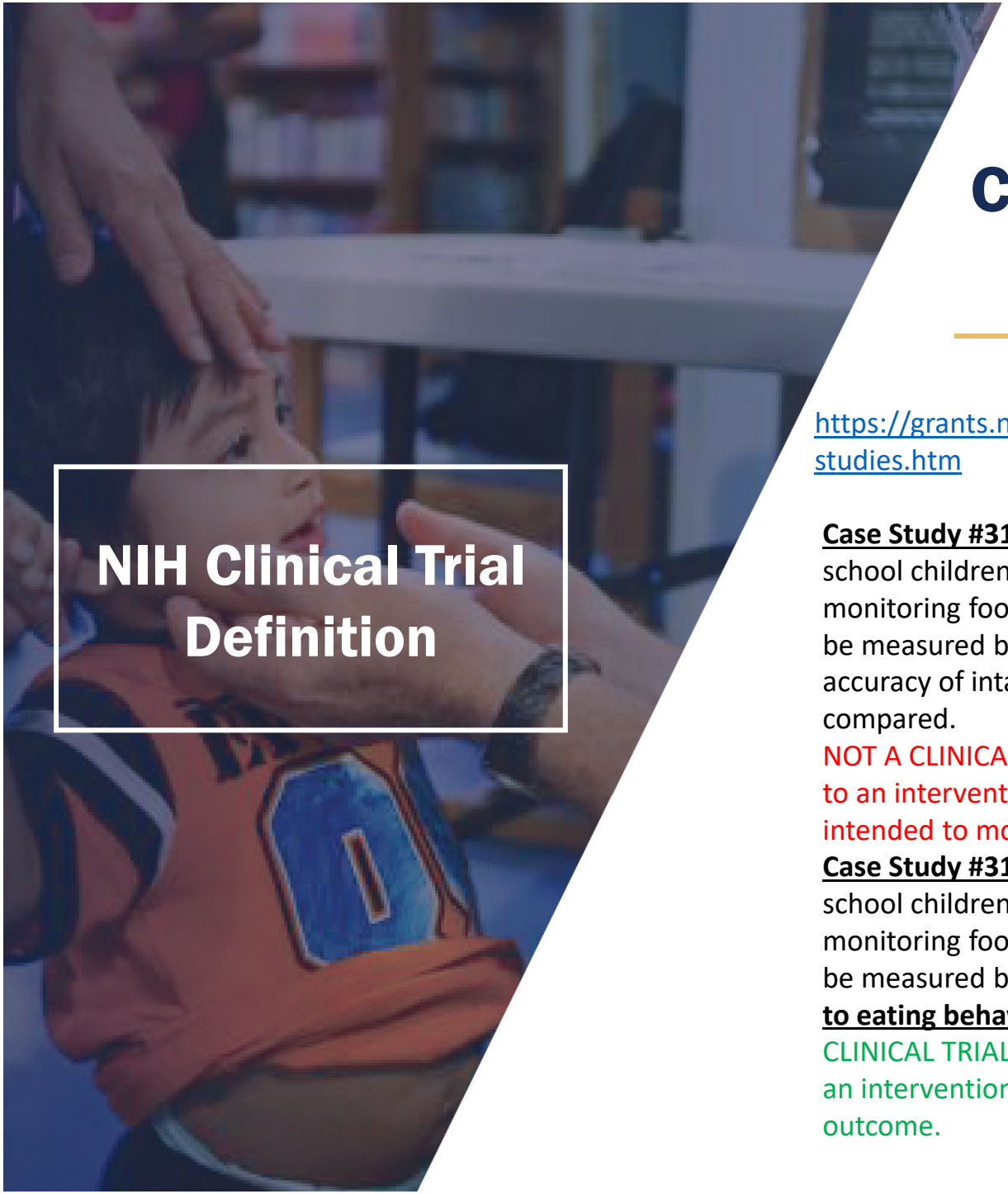
- **Definition – 2014**
- **Guidance – 2017**
- **Policy – 2018**

Must respond yes to all 4 questions

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Decision Tree for NIH Clinical Trial Definition





NIH Clinical Trial Definition

Case Study Review

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

Case Study #31a. A study involves the recruitment of school children to evaluate two different tools for monitoring food intake. Food consumption behavior will be measured by a pocket camera and food diary. The accuracy of intake using the two methods will be compared.

NOT A CLINICAL TRIAL. The participants are not assigned to an intervention. The intake monitoring methods are not intended to modify health outcomes.

Case Study #31b. A study involves the recruitment of school children to evaluate two different tools for monitoring food intake. Food consumption behavior will be measured by a pocket camera and food diary. **Changes to eating behavior will be assessed**.

CLINICAL TRIAL. Participants are prospectively assigned to an intervention and eating behavior is a health-related outcome.

#2: FDAAA 801: Applicable Clinical Trials (ACT)

- **ACT Checklist: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf**
- **Must be a clinical trial, AND**
- **Evaluate at least one drug or device regulated by the FDA, AND**
- **Is other than a Phase 1 drug study or device feasibility study, AND**
- **Must respond yes to at least one:**
  - Is at least one study facility located in the US?
  - Is the study conducted under an IND or IDE?
  - Does the study involve a drug or device that is manufactured in the US but exported for study in another country

#3: ICMJE Guidelines and Publication

- **International Committee of Medical Journal Editors**
- **Broad definition of clinical trial similar to the NIH**
- **Requires registration in publicly available database; minimum number of required fields; clinicaltrials.gov is acceptable**
- **Registrations, results reporting and data sharing plans are required**
- **You must register prior to enrolling subjects**

- Registrations are considered “voluntary”; there are no legal or financial penalties for noncompliance
- Noncompliance will result in a publishing embargo; journals that are part of the consortium will not publish findings from noncompliant trials
- Data collected prior to registration will not be allowed to be included

NIH Clinical Trial Policy

There are two major updates to NIH's Clinical Trial Policy that you need to know

Takeaway # 1

- NIH announced enhanced enforcement of NIH requirement to register trials
- Your grant funds can be withheld for noncompliance

Takeaway #2

- As of January 25, 2018, separate RFA's will be issued for clinical trials
- Most RFA's are silent, meaning clinical trials are allowed; some RFA's will require or disallow clinical trials
- Applicants must use NIH FORMS-E application package, requiring a high level of detail on the study protocol and anticipated enrollment

FSU CLINICALTRIALS.GOV REGISTRATION

FSU Resources

Upcoming FSU Workshop

- October 21st, 2020
- 10:00 – 11:00

Submission Questions?

- OCRA (ocra@fsu.edu)
- CTSA NCRT (ncrt@med.fsu.edu)

Contact OCRA (Office for Clinical Research Advancement) to:

- Create your username, and
- Obtain access to the clinicaltrials.gov portal

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THANK YOU!