ClinicalTrials.gov

Registration and Results Reporting

NIH POLICY (2016)
Definition
Scope and Applicability
Responsible Party

DHHS FINAL RULE (2016)
Definition
Responsible Party

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The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information covers all applications for funding (including grants, contracts, and other transactions) submitted on or after January 18, 2017 that request support for the conduct of any clinical trial. The policy does not apply to clinical trials in ongoing, non-competing awards, but will apply if the grantee submits a competing renewal application that includes a new clinical trial. The policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, NIH encourages all ongoing NIH-funded clinical trials to follow this policy. Investigators conducting NIH-funded applicable clinical trials that are subject to the statute* and rule** also need to be in compliance with those requirements.

The policy does not apply to:
- clinical trials in ongoing, non-competing awards
- a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct
- NIH-funded clinical trials initiated before the effective date

The policy applies:
- to all applications for funding (including grants, contracts, and other transactions) submitted on or after January 18, 2017 that request support (in whole or in part) for the conduct of any clinical trial
- if the grantee submits a competing renewal application that includes a new clinical trial
- to an “applicable clinical trial”, as defined by FDAAA, for existing studies initiated prior to 2017

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2 https://grants.nih.gov/policy/clinical-trials/reporting/faq.htm#5053
5 HHS Agencies (includes NIH): https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html
* FDAAA, ** Final Rule / 42 CFR Part 11
Specific to a funding opportunity announcement (FOA) / Review the Notice of Award document, in Section III (Terms and Conditions, R&D paragraph)
NIH POLICY

Definition of a Clinical Trial 1, 2

A research study in which one or more human subjects are prospectively assigned interventions to one or more health-related biomedical or behavioral outcomes.

1 https://www.federalregister.gov/d/2016-22379/p-70
2 https://grants.nih.gov/policy/clinical-trials/definition.htm

Unpacking the definition (slides 5 & 6): https://grants.nih.gov/sites/default/files/Clinical-Trials-Changes-full%20length_v5.pptx


FAQs: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm

March 2018 - possible update to definition for basic behavioral research:
NIH POLICY

Responsible Party 1, 2, 3

NIH-Funded Clinical Trial is subject only to the NIH Policy:
- The recipient or investigator

NIH-Funded Clinical Trial is subject to the DHHS Final Rule:
- The Sponsor, or
- The Principal Investigator, if designated by the sponsor, grantee, contractor, or awardee

Registration at ClinicalTrials.gov: within 21 days after enrollment of the first research participant 4

Results Submission at ClinicalTrials.gov: within 12 months after primary completion date 5

2 https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm#
3 https://www.federalregister.gov/d/2016-22379/p-74
4 https://clinicaltrials.gov/ct2/manage-recs/faq#fr_5
5 https://clinicaltrials.gov/ct2/manage-recs/faq#fr_7


Noncompliance (page 6), 2016 NEJM article: The FDAAA and the NIH policy hold all parties responsible for clinical trials (not just the individual investigators) accountable. [DOI: 10.1056/NEJMsrg1611785]
Applicable Device Clinical Trial
1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric postmarket surveillance required by FDA

Applicable Drug Clinical Trial
Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation

A note about Expanded Access
Information on the availability of investigational drug products (including biological drug products) for expanded access will continue to be required to be submitted to the Clinical Trials.gov database.

FAQs: https://clinicaltrials.gov/ct2/manage-recs/faq

References:
2. https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered
DHHS FINAL RULE

Responsible Party ¹, ²

- The Sponsor, or
- The Principal Investigator, if designated by the sponsor, grantee, contractor, or awardee

**Final Rule: effective January 18, 2017 / compliance date of April 18, 2017**

**Registration at ClinicalTrials.gov:** within 21 days after enrollment of the first research participant ³, ⁴

**Results Submission at ClinicalTrials.gov:** within 12 months after primary completion date ⁵, ⁶

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² https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhoIsResponsibleForRegistering
⁴ https://clinicaltrials.gov/ct2/manage-recs/faq#fr_5
⁶ https://clinicaltrials.gov/ct2/manage-recs/faq#fr_7

FAQs: https://clinicaltrials.gov/ct2/manage-recs/faq

Registration & Results submission - table (prior to 2007, and on/after effective date of final rule): https://www.federalregister.gov/d/2016-22129/p-961


Noncompliance (page 6), 2016 NEJM article: The FDAAA and the NIH policy hold all parties responsible for clinical trials (not just the individual investigators) accountable. [DOI: 10.1056/NEJMsr1611785]
Human Research meets conditions of the **NIH Policy**

Register at ClinicalTrials.gov within **21 days** of enrollment of first research subject

Submit **Study Results** at ClinicalTrials.gov within **12 months** after completion of research study

Human Research meets conditions of the **DHHS Final Rule**

Register at ClinicalTrials.gov within **21 days** of enrollment of first research subject

Submit **Study Results** at ClinicalTrials.gov within **12 months** after completion of research study

**REGISTRATION**
- How to Register
- Tutorial (page 13/slide 25)
- Data Elements Defined
- Criteria for the review of your submission

**EDITING / UPDATING**
- How to Edit / When to Update Your Record

**RESULTS SUBMISSION**
- How to Submit Results
- Criteria for the review of your results
### NIH POLICY

*Review the Notice of Award document, in Section III (Terms and Conditions - R&D paragraph)*

**Applies:**
- to all applications for NIH funding (including grants, contracts, and other transactions) submitted **on or after January 18, 2017** that request support *(in whole or in part)* for the conduct of any clinical trial
- if the grantee submits a competing renewal application that includes a new clinical trial
- to an “applicable clinical trial”, as defined by FDAAA, for existing studies initiated prior to 2017

**Does not apply to:**
- clinical trials in ongoing, non-competing awards
- a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct
- NIH-funded clinical trials initiated before the effective date

### DEFINITION

A research study in which one or 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.

### RESPONSIBLE PARTY

**NIH-Funded Clinical Trial is subject only to the NIH Policy:**
- The recipient or investigator

**NIH-Funded Clinical Trial is subject to the DHHS Final Rule:**
- The Sponsor, or
- The Principal Investigator, if designated by the sponsor, grantee, contractor, or awardee

### REGISTRATION & RESULTS SUBMISSION

**Registration at ClinicalTrials.gov:** within **21 days** after enrollment of the first research participant

**Results Submission at ClinicalTrials.gov:** within **12 months** after primary completion date

### DHHS FINAL RULE

**Effective January 18, 2017**  
**[Table: study initiated before 2007, after 2007, on/after Final Rule]**

**Applicable Device Clinical Trial**

1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric postmarket surveillance required by FDA

**Applicable Drug Clinical Trial**

Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation

**A note about Expanded Access**

Information on the availability of investigational drug products (including biological drug products) for expanded access will continue to be required to be submitted to the ClinicalTrials.gov database.

### REQUIRE GCP TRAINING

**NONCOMPLIANCE**

- The Sponsor, or
- The Principal Investigator, if designated by the sponsor, grantee, contractor, or awardee

### EDITING / UPDATING

**NONCOMPLIANCE**

- How to Edit / When to Update Your Record

### RESULTS SUBMISSION

**NONCOMPLIANCE**

- How to Submit Results
- Criteria for the review of your results

### Guidance:


*Blue texts have hyperlinks*
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