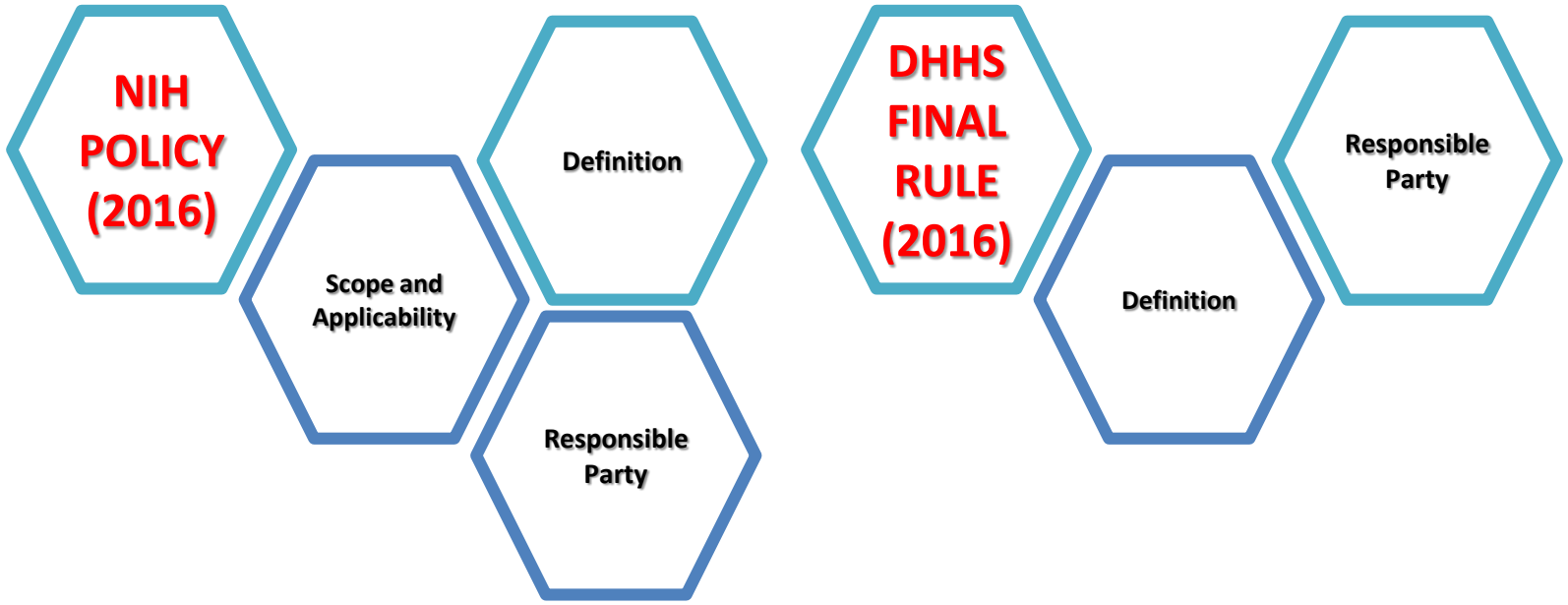
ClinicalTrials.gov

Registration and Results Reporting



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NIH POLICY

Scope and Applicability [1]

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. [2] 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. [2] The policy **does not apply** to a clinical trial that *uses NIH-supported infrastructure* but *does not receive NIH funds to support its conduct.* [3]

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*. [4] Investigators *conducting NIH-funded applicable clinical trials that are subject to the statute* and rule*** also need to be in compliance with those requirements. [4, 5]

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**:

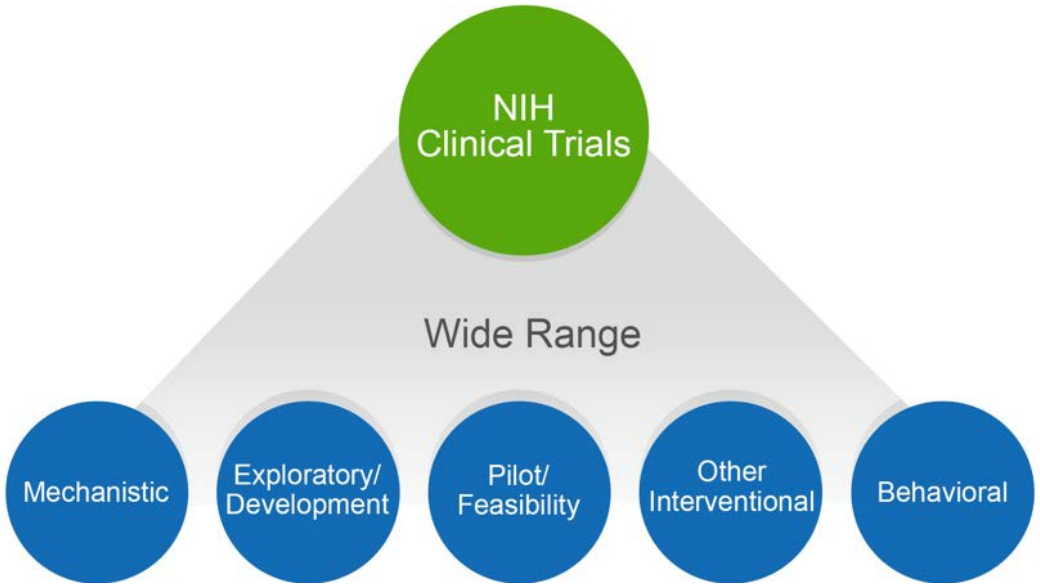
- to all applications for funding (including grants, contracts, and other transactions) submitted **on or after January 18, 2017** that request support (***in whole or in part***) for the conduct of any clinical trial
- if the grantee submits a competing renewal application that includes a new clinical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

1 https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information
2 https://grants.nih.gov/policy/clinical-trials/reporting/faq.htm#5053
3 https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information#p-61
4 https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22379.pdf
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** 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**.



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

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

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

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

- http://www.sciencemag.org/news/2018/03/final-2018-budget-bill-eases-biomedical-researchers-policy-worries

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]

1 https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information#p-62
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

REQUIRED GCP TRAINING: https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

NONCOMPLIANCE: https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information#p-82

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]

DHHS FINAL RULE

Definition of an Applicable Clinical Trial [1, 2, 3]

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. [4]

1 https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-1297
2 https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered
3 https://grants.nih.gov/clinicaltrials_fdaaa/docs/Flow_chart-ACT_only.pdf
4 https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-335

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

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

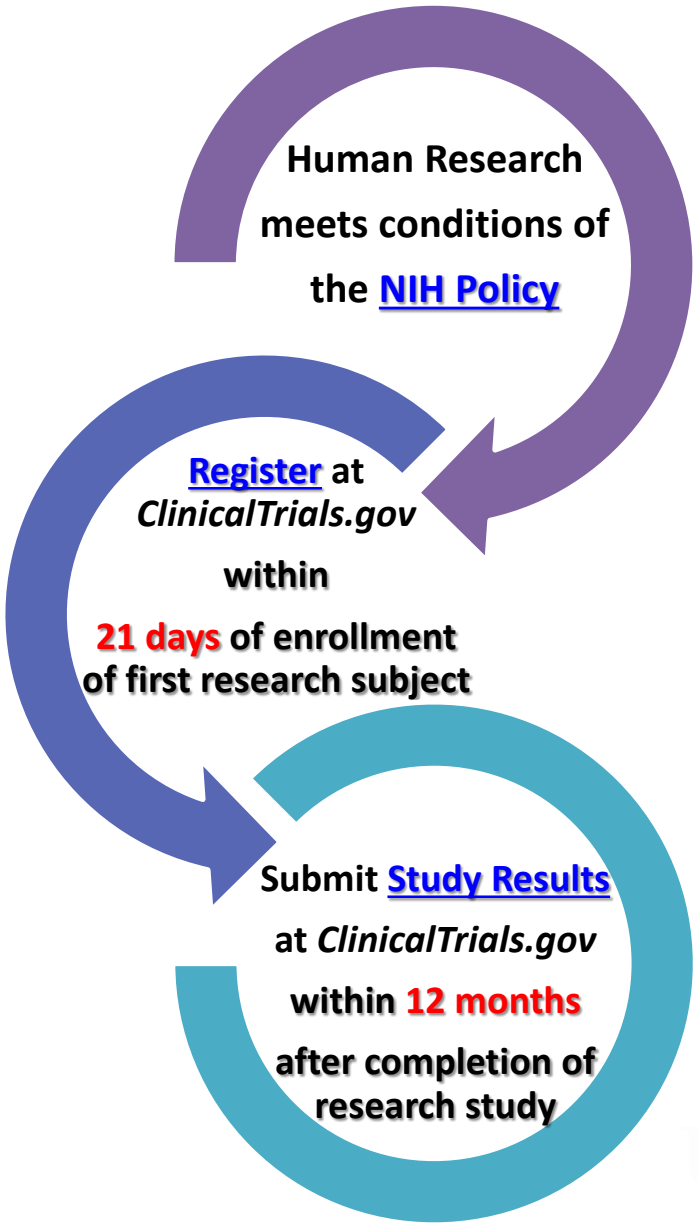
Registration at ClinicalTrials.gov: within 21 days after enrollment of the first research participant [3, 4]

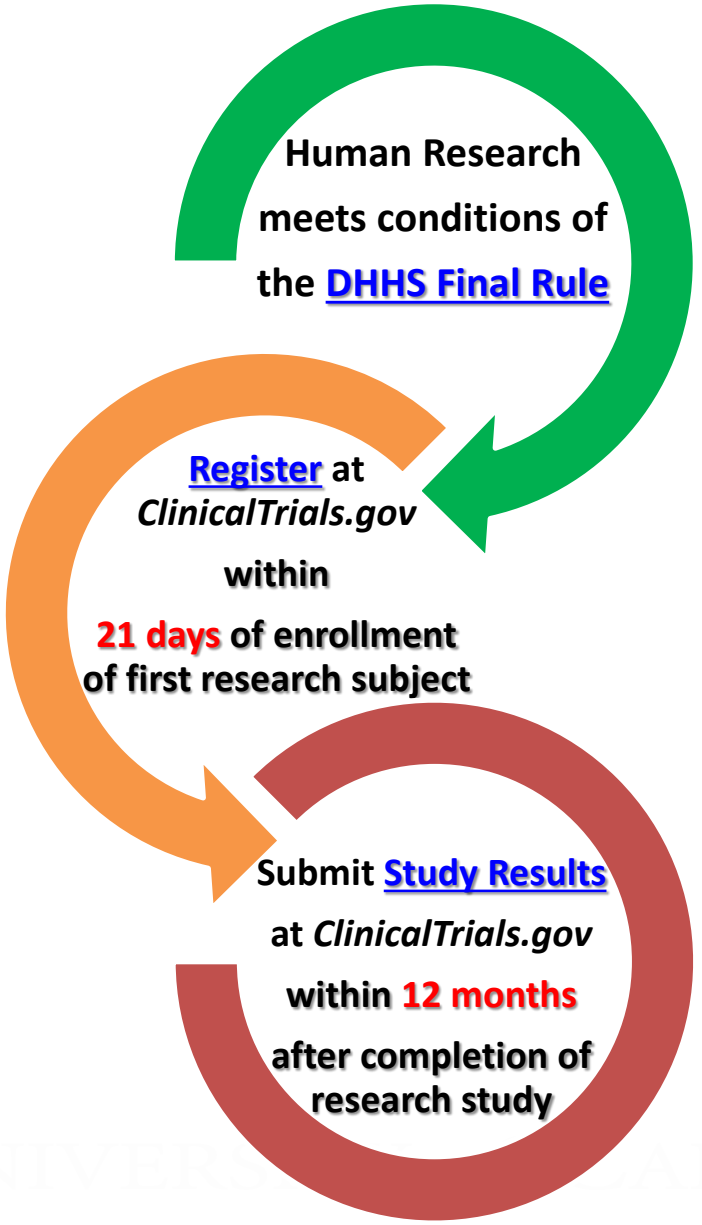
Results Submission at ClinicalTrials.gov: within 12 months after primary completion date [5, 6]

1 https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-1167
2 https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhoIsResponsibleForRegistering
3 https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-1319
4 https://clinicaltrials.gov/ct2/manage-recs/faq#fr_5
5 https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-1440
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
NOTE: Being **unfunded** does **not** exclude applicable clinical trials (ACTs) from the requirement to register.

NONCOMPLIANCE: https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-1682
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]





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

UCI Office of Research
Research Administration

	SCOPE	DEFINITION	RESPONSIBLE PARTY	REGISTRATION & RESULTS SUBMISSION
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	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**.	**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 ***REQUIRED GCP TRAINING*** ***NONCOMPLIANCE***	**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** **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 **VOLUNTARY SUBMISSION** ▪ FAQs ▪ Flowchart and Checklist
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 *Clinical Trials.gov* database.		▪ The Sponsor, or ▪ The Principal Investigator, if designated by the sponsor, grantee, contractor, or awardee **NOTE:** Being **unfunded** does **not** exclude applicable clinical trials (ACTs) from the requirement to register. ***NONCOMPLIANCE***	

Guidance: https://www.research.uci.edu/compliance/human-research-protections/researchers/guidelines-for-registering-in-a-clinicaltrialsgov-registry.html

Blue texts have hyperlinks

UCI CONTACTS

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https://www.research.uci.edu/compliance/human-research-protections/researchers/guidelines-for-registering-in-a-clinicaltrialsgov-registry.html