

Clinical Trial Reporting Requirements

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Introduction

This page helps sponsors and investigators understand the key legal and policy requirements for clinical trial registration and results submission to ClinicalTrials.gov. The description of each requirement on this page includes an overview for quick reference, description, and links to supporting materials.

The 2 main reasons to register clinical trials and submit summary results are:

- Registration for certain clinical trials is required by laws and policies such as:
 - Final Rule for FDAAA 801, 42 CFR Part 11
 - NIH Policy on Dissemination of NIH-funded Clinical Trial Information
 - WHO International Clinical Trials Registry Platform
- The International Committee of Medical Journal Editors (ICMJE) Policy requires prospective registration to publish results from a clinical trial in medical journals

Read more about key laws, regulations, and policies on this page.

Final Rule (42 CFR Part 11) for the Food and Drug Administration Amendments Act of 2007 (FDAAA)

Overview

- What is it? U.S. Federal regulation implementing FDAAA 801 effective in 2017
- Which clinical trials must follow it? Clinical trials of FDA-regulated drug, biological, or device products other than Phase 1 trials of drug/biological products or small feasibility studies of device products
- Does it require registration? Yes
- Does it require results submission? Yes

Description

In September 2016, the U.S. Department of Health and Human Services issued a [Final Rule for Clinical Trials Registration and Results Information Submission](#) (42 CFR Part 11) that clarifies and expands the regulatory requirements and procedures for submitting registration and summary results information of clinical trials on ClinicalTrials.gov, in accordance with [FDAAA 801](#). The final rule is intended to make it clear to sponsors, investigators, and the public which trials must be submitted, when they must be submitted, and whether compliance has been achieved. The final rule also expands the FDAAA 801 requirements by requiring the submission of results information for trials of unapproved products. The regulation became effective on January 18, 2017.

Supporting materials

- NLM: [Frequently Asked Questions \(FAQs\)](#): View FAQs about the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11).
- NIH: [Checklist and Elaboration for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial](#) (PDF) (June 2018)
- NIH OER: [ClinicalTrials.gov and FDAAA FAQs](#) - Further Resources for NIH Grantees: Information for NIH applicants and grantees about registering a study, submitting results, and certifying compliance in NIH grants and progress reports.
- FDA: [FDA's Role: ClinicalTrials.gov Information](#): Information about the certification form required to accompany certain applications/submissions to FDA and the statement required to be included in informed consent regarding the availability of clinical trial information on ClinicalTrials.gov for Applicable Clinical Trials.
- FDA: [Guidance for Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank](#) (August 2020)

NIH Policy on Dissemination of NIH-funded Clinical Trial Information

Overview

- What is it? National Institutes of Health (NIH) policy effective in 2017
- Which clinical trials must follow it? Clinical trials funded in whole or in part by NIH of any intervention (includes drug, biological, and device products, as well as surgical procedures, and behavioral interventions)
- Does it require registration? Yes
- Does it require results submission? Yes

Description

In September 2016, NIH issued a [final policy](#) to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Under this [policy](#), every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to [FDAAA 801](#) or not. This policy is effective for applications for funding, including grants, other transactions, and contracts submitted on or after January 18, 2017. For the NIH intramural program, the policy applies to clinical trials initiated on or after January 18, 2017.



Supporting materials

- NIH: [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#) [↗](#) (September 2016)
- NIH Office of Extramural Research (OER): [Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov](#) [↗](#)
 - [Electronic Research Administration \(eRA\) Research Performance Progress Report \(RPPR\) Submission Validations for Clinical Trial Registration and Results Reporting](#) [↗](#)
 - The Open Mike blog post [NIH Clinical Trials Reporting Compliance: A Shared Commitment](#) [↗](#) (March 24, 2023) describes progress with results information submission to ClinicalTrials.gov through FY 2022 and reaffirms NIH's ongoing commitment to improve with help from investigators and institutional leaders.
- NIH OER: [Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies With Human Participants](#) [↗](#) (May 2024)
- NIH: [NIH Scientific Data Sharing Website](#) [↗](#) (April 2022) describes NIH's data sharing policies that require researchers to make their research results available to the public if NIH supported the research. Sharing data increases transparency, allows others to use the data, and helps efforts to reproduce the research results.

International Committee of Medical Journal Editors (ICMJE) Policy

Overview

- What is it?** Publication policy initiated by the ICMJE in 2004
- Which clinical trials must follow it?** Any (includes drugs, biological, and device products, as well as surgical procedures, and behavioral treatments)
- Does it require registration?** Yes, for all interventional studies, including Phase 1 studies, and defines criteria for "acceptable registries"
- Does it require results submission?** No, but the ICMJE expects authors to meet results information submission requirements "of their funding and regulatory agencies" and "encourages... results reporting even when not required"

Description

In 2005, the [ICMJE](#) [↗](#) began requiring trial registration as a condition of publication. ICMJE issued a [clinical trial registration](#) [↗](#) policy as part of the ICMJE [Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](#) [↗](#), which is followed by more than 1,000 journals. The ICMJE Recommendations encourage journal editors to require that all clinical trials be entered in a public registry before the start of participant enrollment for the trials to be considered for publication. The ICMJE expects authors to meet all results reporting requirements of their funding and regulatory agencies. If there are no such reporting requirements, the ICMJE encourages authors to submit results information to the same database on which their trials are registered. In June 2017, ICMJE [amended its recommendations](#) [↗](#) (PDF) to include registration of an individual participant data (IPD) sharing statement (see [IPD Sharing Statement data element](#) on ClinicalTrials.gov) as an additional consideration for publication of reports for clinical trials that begin enrolling participants on or after January 1, 2019.

Supporting materials

- NLM: [WHO \(ICMJE\) - ClinicalTrials.gov Cross Reference \(PDF\)](#), which is a table that maps the WHO Trial Registration Data Set, required by the ICMJE registration policy, to the corresponding data elements in ClinicalTrials.gov
- ICMJE: [Frequently Asked Questions About Clinical Trials Registration](#)
- ICMJE Journals Stating that They Follow the ICMJE Recommendations: [Journals that have asked ICMJE to include them on the list of journals that follows the ICMJE's recommendations](#)

World Health Organization (WHO) International Clinical Trials Registry Platform

Overview

- What is it?** International policy initiated by WHO in 2006 and affirmed by the signatories of the Joint Statement on Public Disclosure of Results from Clinical Trials(PDF)
- Which clinical trials must follow it?** Any (includes drugs, biological, and device products, as well as surgical procedures, and behavioral treatments)
- Does it require registration?** Yes, "The registration of all interventional trials is a scientific, ethical and moral responsibility"
- Does it require results submission?** Yes, the 2015 WHO Statement on the Public Disclosure of Clinical Trials Results specifies that "[t]here is an ethical imperative to report the results of all clinical trials, including those of unreported trials conducted in the past"

Description

In 2006, WHO stated that all clinical trials should be registered, and it identified a [minimum trial registration dataset](#) [↗](#). In 2007, WHO launched the International Clinical Trials Registry Platform (ICTRP), which includes a [search portal](#) [↗](#) providing a single point of access to studies registered in various international registries. The ICTRP Search Portal includes data available on ClinicalTrials.gov.

The WHO [International Clinical Trials Registry Platform \(ICTRP\)](#) [↗](#) policy specifies that "the registration of all interventional trials is a scientific, ethical and moral responsibility." Accordingly, ICTRP provides a global forum for trial registries to share best practices and promotes the development of specific criteria for primary registries in the WHO Registry Network. In addition, the [WHO Statement on Public Disclosure of Clinical Trials Results](#) [↗](#) specifies that "[t]here is an ethical imperative to report the results of all clinical trials, including those of unreported trials conducted in the past."

Supporting materials

- WHO ICTRP [Trial Registration Data Set](#) [↗](#): Describes the minimum amount of trial information that must appear in a clinical study registry in order for a given trial to be considered fully registered by the WHO

- **WHO ICTRP Search Portal** [↗](#): Provides a single point of access to studies registered in various international registries, including data available on ClinicalTrials.gov

Other U.S. Laws, Policies, and Guidance

Revised Common Rule (45 CFR Part 46) and Posting of Clinical Trial Consent Forms

Overview

- **What is it?** Regulations from U.S. federal agencies for the protection of human subjects involved in research
- **Which clinical trials must follow it?** Any clinical trial conducted or supported by most U.S. departments or agencies
- **Does it require registration?** No, but if a trial is registered, its informed consent form can be uploaded on ClinicalTrials.gov to meet the posting requirements
- **Does it require results submission?** No

Description

In January 2017, [nearly 20 Federal department and agencies](#) [↗](#) issued a [revised Federal Policy for the Protection of Human Subjects](#) [↗](#) (also known as subpart A of 45 CFR part 46, or the "Common Rule"). The regulation became effective on July 19, 2018, [as amended](#) [↗](#).

The [revised Common Rule \(45 CFR 46.116\(h\)\)](#) [↗](#) requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form used in enrolling participants be posted on a publicly available Federal website within a specific time frame. In an [August 2018 announcement](#) [↗](#), ClinicalTrials.gov and Regulations.gov were identified as the publicly available federal websites that will satisfy the consent form posting requirement.

Supporting materials

- NIH: [Appendix A.1](#) of the ClinicalTrials.gov Results Data Elements Definitions document
- OHRP: [Informed Consent Posting](#) [↗](#)
- NIH OER: [Guidance on Posting Informed Consent Forms for NIH-Funded Clinical Trials](#) [↗](#) (May 2019)

Food and Drug Administration Modernization Act of 1997 (FDAMA)

Overview

- **What is it?** U.S. Federal law enacted in 1997
- **Which clinical trials must follow it?** Efficacy trials of FDA-regulated investigational new drugs for "serious or life-threatening diseases and conditions"
- **Does it require registration?** Yes
- **Does it require results submission?** No

Description

The first U.S. Federal law to require trial registration on ClinicalTrials.gov was the [Food and Drug Administration Modernization Act of 1997 \(FDAMA\)](#) [↗](#) (PDF). Section 113 of FDAMA (FDAMA 113) required the National Institutes of Health (NIH) to create a public information resource on certain clinical trials regulated by the FDA. Specifically, FDAMA 113 required that the registry include information about federally or privately funded clinical trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions.

The information in the registry was intended for a wide audience, including individuals with serious or life-threatening diseases or conditions, members of the public, health care providers, and researchers.

NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

Overview

- **What is it?** Policy and guidelines on reporting sex/gender and race/ethnicity in NIH-funded research
- **Which clinical trials must follow it?** Applicable NIH-defined Phase III clinical trials, complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11
- **Does it require registration?** Yes, as per 42 CFR Part 11
- **Does it require results submission?** Yes, as per 42 CFR Part 11

Description

For NIH-funded research meeting the definitions of an applicable clinical trial and an [NIH-defined Phase III clinical trial](#) [↗](#), NIH requires reporting of results of valid analyses by sex/gender and race/ethnicity in ClinicalTrials.gov. This policy implements provisions in the 21st Century Cures Act (Public Law 115-255), enacted on December 13, 2016.

Supporting materials

- NIH: [Guidance for reporting valid analysis as required by the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research \(NOT-OD-18-014\)](#) [↗](#) (PDF)
- NIH: [Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research](#) [↗](#) (November 2017)

Department of Veterans Affairs (VA) Clinical Trial Registration and Results Submission Policy

Overview

- **What is it?** Policy and guidelines on registration and results for clinical trials funded by VA Office of Research and Development (ORD)
- **Which clinical trials must follow it?** VA-funded clinical trials
- **Does it require registration?** Yes
- **Does it require results submission?** Yes

Description

The [VA policy on clinical trial registration and submission of summary results](#) requires principal investigators (PIs) of VA Office of Research and Development (ORD)-funded clinical trials to register their trials and submit summary results to ClinicalTrials.gov as a condition of funding. This policy uses the same definition of clinical trial as the [International Committee of Medical Journal Editors](#) and the [World Health Organization](#). PIs must register their VA ORD-funded clinical trial on ClinicalTrials.gov in order for study funds to be distributed. They must also update the study record in a timely manner and submit summary results information within 1 year of the Completion Date (see [Primary Completion Date data element](#) on ClinicalTrials.gov).

Supporting materials

- VA: [ORD Sponsored Clinical Trials: Registration and Submission of Summary Results](#)

**Patient-Centered Outcomes Research Institute (PCORI)
Process for Peer Review and Public Release of Results**

Overview

- **What is it?** Policy and guidance on PCORI-funded research
- **Which clinical studies must follow it?** Comparative clinical effectiveness clinical trials and observational studies funded by PCORI
- **Does it require registration?** Yes
- **Does it require results submission?** Yes

Description

PCORI adopted a [process for peer review and public release of the research findings](#) of the comparative clinical effectiveness research studies that it funds. This process includes registering and submitting summary results information to ClinicalTrials.gov for relevant clinical trials and observational studies.

Supporting materials

- [PCORI's Process for Peer Review of Primary Research and Public Release of Research Findings](#) (PDF) (February 2015)
- PCORI Recorded Webinar: [New Peer Review Requirements for all PCORI Awards](#) (60:37) (June 2015)

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