University at Buffalo

ClinicalTrials.gov Registration Guide

ClinicalTrials.gov is a publicly available registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. It is maintained by the National Library of Medicine (NLM) of the National Institutes of Health (NIH). Clinicaltrials.gov captures significant summary protocol information before and during the trial as well as summary results and adverse event information of a completed trial. The website helps patients find trials, enhances the design of clinical trials and prevents duplication of unsuccessful or unsafe trials, improves the evidence base that informs clinical care, increases the efficiency of drug and device development processes, improves clinical research practice, and builds public trust in clinical research. Federal laws and regulations as well as editors of prominent medical journals require registration of a clinical trial, as described below.

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Which studies need to be registered in Clinicaltrials.gov?

1. Registration is Required by Law for Applicable Clinical Trials (ACT) (FDAAA Law)

ClinicalTrials.gov was mandated by the Food and Drug Administration Modernization Act of 1997 (FDAMA) and expanded under the Food and Drug Administration Amendments Act of 2007 (FDAAA). Final Rule regulations became effective as of **January 18, 2017**. All "Applicable Clinical Trials" are required to be registered and have results entered on ClinicalTrials.gov.

For a full checklist to determine whether a study or trial is an Applicable Clinical Trial (ACT): https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

Applicable Clinical Trials (ACT) per FDAAA
Definition of Applicable Clinical Trial under FDAAA (see helpful flow chart):

> **Trials of Drugs/Biologics:**
> Controlled, clinical investigations of a product subject to FDA regulations, other than Phase 1. This may include interventional studies with dietary supplements.

> **Trials of Devices:**
> Prospective controlled trials with health outcomes, which compares an intervention with a device against a control, other than small feasibility studies. Including pediatric post-market surveillance studies.

Applicable Clinical Trials under FDAAA <u>must also meet one</u> of the following conditions:

- The trial has one or more sites in the U.S.
- The trial is conducted under an FDA Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) application
- The trial involves a drug, biologic, or device that is manufactured in the U.S. or its territories and is exported for research

FDAAA requirements for registration <u>exclude</u> the following (unless funded either in whole or in part by NIH):

- Phase 1 drug trials, including studies in which drugs are used as research tools to explore biological phenomena or disease processes
- Small clinical trials to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes
- Trials that do not include drugs, biologics, or devices (e.g., behavioral interventions)
- Non-interventional (observational) clinical research, such as cohort or case control studies

Principal Investigators (PI) should consult with commercial sponsors to assure that posting of a trial is in accord with terms of the study contract. A sponsor providing drug only, generally does not accept the registration and results reporting responsibilities. Generally, for IND or IDE studies, the responsibility rests with the local investigator.

ClinicalTrials.gov Language in the Consent Form

By federal regulation, ACTs must include the following language in the consent form. The language cannot be altered in any way.

"A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

Non-compliance with ClinicalTrials.gov registration and results reporting may result in fines over $10,000 per day for PIs and institutions.

2. Registration is required for NIH-funded Clinical Trials (NIH Policy)

The NIH issued policy NOT-OD-16-149 (effective **January 18, 2017**), requiring that all NIH-funded interventional clinical trials must be registered and have results submitted in ClinicalTrials.gov. All interventional trials are included in this policy, even those that are not considered to be Applicable Clinical Trials (ACTs), such as behavioral, surgical, phase 1 drug, and feasibility device studies. This policy applies to studies that are funded in part or whole by the NIH, and are submitted on or after the effective date. Results, including adverse events, must be submitted within one year from the date the last patient was evaluated for the primary outcome measure.

NIH Definition of a Clinical Trial
NIH defines a clinical trial as "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". The definition includes basic science, mechanistic studies, social/behavioral, and educational research.

The NIH definition is intentionally broad, covering a wide range of research not traditionally considered a clinical trial. Though not comprehensive, the NIH provides FAQS and a number of case examples that are useful in interpreting their definition of a clinical trial.

Use the following four questions to determine if your study is a clinical trial:
1. Does the study involve human participants?
   - Includes healthy participants
   - Not biological specimens or health information

2. Are the participants prospectively assigned to an intervention by the investigator?
   - Prospective means expected or in future

- Intervention is a manipulation on subject or subject's environment
  Examples:
    o Drug or device
    o Surgical techniques
    o Eat a certain diet
    o Exercise
    o Change daily habits
    o Read a book
    o Try mobile app
    o Play video game
    o Stop smoking
    o Participate in new curriculum
    o Complete hand-eye coordination tasks

3. Is the study designed to evaluate the effect of the intervention on the participants?
   Examples include:
     o Mood management for smokers
     o Reading comprehension
     o Adherence to exercise routine
     o Positive or negative changes to quality of life

4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Note that if the answers to the 4 questions above are yes, your study meets the NIH definition of a clinical trial, even if…
- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

NOT clinical trials:
- Studies intended solely to refine measures
- Studies that involve secondary research with biological specimens or health information

Helpful NIH Clinical Trials 10 Minute Overview presented by Penn State University: What NIH's Definition Means for Researchers

For further information on the NIH definition of clinical trial, see:
https://grants.nih.gov/ct-decision/index.htm

If your study is considered a clinical trial:
1. Submit to an FOA that is "Clinical Trial Required" or "Clinical Trial Optional"
2. Answer the four questions and fill out an extra section in FORMS-E
3. All study staff need to complete GCP training (social/behavioral GCP training is now available on CITI)
4. Register on ClinicalTrials.gov within 21 days of IRB approval and report results 12 months after you're done collecting data

Steps to Compliance for NIH Awardees

NIH awardees must take specific steps to ensure compliance with NIH implementation of the NIH Policy on Dissemination of Clinical Trials Research and Section 801 of FDAAA, as implemented by 42 CFR Part 11. For further information, see: https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm

Delayed Enforcement and Short-Term Flexibilities for Basic Science Studies

Based on the 2018 Appropriations Bill and community feedback, NIH is delaying enforcement of registration and reporting policies only for prospective basic science studies involving human participants (including behavioral research) under policy NOT-OD-16-149 through September 24, 2019. These studies do not include those for which there are specific applications towards products or processes in mind, such as phase 0 or phase 1 studies of candidate interventions.

The NIH will provide leniency for applications submitted to the incorrect FOA based on the study type designation (please review NOT-OD-18-212 for additional details), in these areas outlined below:

- Registration and Reporting
- Study-Type Specific FOAs
- Good Clinical Practice (GCP)
- Review Criteria
- Human Subjects and Clinical Trial Information Form

Extension of Flexibilities for Prospective Basic Experimental Studies with Human Participants (BESH)

On July 24, 2019, the NIH extended the interim policy flexibilities regarding registration and results reporting for a subset of NIH-funded research whose primary purpose is Basic Experimental Studies with Humans (BESH). These studies, referred to in NOT-OD-18-212 as "prospective basic science studies involving human participants," meet both the NIH definition of a "clinical trial" and also the definition of basic research. This extension will last through September 24, 2021.

During this time, NIH continues to expect registration and results reporting, but with the additional flexibility to register and report results on alternative publicly available platforms. Plans for meeting the NIH reporting expectations using an alternative platform should be described at the time of application in the Dissemination Plan attachment. Funded awardees for applications submitted to BESH-specific FOAs who are not using ClinicalTrials.gov to meet the policy expectation should provide in their annual progress reports the unique identifier assigned by the alternative platform, if available, and a link to the report (e.g., page or record) in the alternative platform. NIH continues to expect that BESH summary results will eventually be transferred into ClinicalTrials.gov. This delayed enforcement is only applicable to BESH studies submitted to funding opportunities designated as "basic experimental studies with humans" in the title.

NIH Cost Reimbursement

There is a section in the NIH Policy that expressly refers to how researchers may recover some of the costs incurred due to compliance activities, such as registration on ClincalTrials.gov. The NIH Policy states that grantees are permitted to:

- Charge the salaries of administrative and clerical staff as outlined in the relevant section of the NIH Grants Policy Statement

- Recover administrative costs through indirect cost recovery

3. Registration is Required for Publication (ICMJE Policy)

The International Committee of Medical Journal Editors (ICMJE) requires that all clinical trials be entered into a public registry as a condition of consideration for publication. Many journals follow ICMJE guidelines. ICMJE requires registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Trials registering purely to satisfy ICMJE requirements are not required to post results.

ICMJE defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. However, several investigators have encountered journal editors who insisted on registration of studies that were observational (e.g., the American Journal of Clinical Nutrition (AJCN) and BMC Urology (part of Springer Nature). There is a growing trend in the direction of registering observational studies so please inquire about whether the journal requires observational studies to be registered prospectively.

Some trials assign health care providers, rather than patients, to intervention and comparison/control groups. If the purpose of the trial is to examine the effect of the provider intervention on the health outcomes of the providers' patients, then investigators should register the trial. If the purpose is to examine the effect only on the providers (for example, provider knowledge or attitudes); registration is not necessary.

The ICMJE accepts publicly accessible registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/network/primary/en/index.html) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP.

As of **July 1, 2018**, manuscripts submitted to ICMJE journals that report the results of a clinical trial must contain a data sharing statement.

Clinical trials that begin enrolling participants on or after **January 1, 2019** must include a data sharing plan in the trial's registration. As a reminder, ICMJE does not require data sharing, and individual participant data are not uploaded to CT.gov.

Data sharing statements must indicate the following:
- whether individual de-identified participant data (including data dictionaries) will be shared (does not refer to collaborators working on data for the study);

- what data in particular will be shared;
- whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.);
- when the data will become available and for how long;
- by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

Examples of Data Sharing Elements can be found in the ICMJE helpful table.

4. Registration is Required When Billing Centers for Medicare and Medicaid Services (CMS)

Registration in ClinicalTrials.gov is required for all "Qualifying Trials", meaning clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1. The National Clinical Trial (NCT) Number that is assigned by ClinicalTrials.gov must be included on all hospital and professional claims for related items/services. ClinicalTrials.gov help on Medicare and Medicaid Services (CMS) billing requirements.

5. Registration is Required for National Cancer Institute (NCI) Supported Clinical Trials

NCI Reporting Policy

"Covered Trials" means all initiated or commenced NCI-Supported Interventional Clinical Trials whether extramural or intramural. Extramural trials include research grants, cooperative agreements, and contracts to conduct Interventional Clinical Trials in all phases and disciplines (e.g., treatment, prevention, supportive care, diagnosis). "Covered Trials" excludes Observational Studies and any NCI-Supported Interventional Clinical Trial in which no subjects are enrolled, but includes any NCI-Supported Interventional Clinical Trial in which at least one subject is enrolled even if the trial is not completed.

"Interventional Clinical Trials" means studies involving human beings (subjects) in which the investigator assigns study subjects (randomly or not randomly) to receive a specific intervention based on the applicable protocol. Such subjects may receive diagnostic, therapeutic, behavioral, and/or another type of intervention. These interventions may, but need not, be investigational or involve an investigational agent (e.g., clinical trials involving surgery, radiation, or screening tests). The subjects are then followed and biomedical and/or health outcomes are assessed. "Interventional Clinical Trials" encompasses all types of trials in all phases including pilot trials, phase zero trials, and normal (or healthy) volunteer trials.

6. Registration is Required for Patient-Centered Outcomes Research Institute (PCORI) Funded Research Projects

PCORI Reporting Policy

Registration is a step in making the public aware of the study and the anticipated questions addressed by the study. PCORI research projects must be registered at the site appropriate to the study design. The registration should be completed using the following naming convention (or similar convention as directed by the site) as a

secondary identifier: "PCORI-PCORI application number" (e.g., PCORI-XXXX-XXXXX). The research project must be registered at one of the following publicly available databases where the research project meets the eligibility requirements:

A. Clinical trial or observational comparative effectiveness study of human participants must be registered <u>prior</u> to enrollment of the first patient. ClinicalTrials.gov must be used for registration of such studies. Results must be submitted to ClinicalTrials.gov as early as possible (in order to address any review comments), but no less than 30 days prior to the draft final research report due date to PCORI.

B. Patient registries must be registered in the Registry of Patient Registries (RoPR) (https://patientregistry.ahrq.gov), which is a repository of patient registries designed and deployed by the Agency for Healthcare Research and Quality (AHRQ) to complement ClinicalTrials.gov. In order for a Patient Registry Profile to exist within the RoPR, a corresponding record must be entered in ClinicalTrials.gov first. The Patient Registry Profile includes a display of the ClinicalTrials.gov Identifier (NCT Number), a hyperlink which will open the record on ClinicalTrials.gov. Results must be submitted to ClinicalTrials.gov as early as possible (in order to address any review comments), but no less than 30 days prior to the draft final research report due date to PCORI.

C. Methodological projects and others that are not appropriate for ClinicalTrials.gov or RoPR must be registered in the Health Services Research Projects in Progress database (HSRProj) (http://wwwcf.nlm.nih.gov/hsr_project/home_proj.cfm). A results draft final research report must be submitted to PCORI on a date established and recorded as a milestone in the contract with PCORI. The date may not exceed 13 months from the primary completion date.

What is required?

	FDAAA Law	NIH Policy	ICMJE Policy	CMS
Scope	Applicable Clinical Trials (ACT) per FDAAA	All NIH-funded clinical trials	Interventional clinical trials (broad scope of "intervention")	Qualifying clinical trials
Intervention Type	All FDA regulated drugs, biologics, and devices Excludes: • phase I drug trials • small device feasibility trials • observational • behavioral interventions	All Includes: • basic science • behavioral • mechanistic • educational • surgical • social science • phase 1 drug • device feasibility • diagnostics • dietary supplements Excludes: • observational • pre-existing data • focus groups	All Includes: • behavioral • diagnostics • dietary • supplements • process of care • surgical procedures • educational programs Excludes: • observational Note: Some journals require registration of observational studies	Clinical trials that are qualified for coverage
When to Register	No later than 21 days of enrollment of the first subject	No later than 21 days of enrollment of the first subject	<u>Prior</u> to first subject enrollment	<u>Prior</u> to claims submitted to Medicare
Results Reporting	No later than 12 months after the Primary Completion Date (the last subject last visit)	No later than 12 months after the Primary Completion Date (the last subject last visit)	Not required	Not required
Phase of the Trial	Excludes Phase 1 (drug) and Feasibility (device)	All	All	Qualified clinical trials

Enforcement if Non-Compliant	• Public notice • FDA sanctions • Civil monetary penalties (up to $10,000/day) • Loss of HHS funding to study and/or institution	Loss of NIH funding: • For the PI • For the Institution	Rejection of the publication	Denial of claims

How do I get started with registering my study?

ClinicalTrials.gov offers targeted assistance to help investigators with specific issues and one-on-one assistance for investigators new to submitting results information.

For example, if an investigator would like a brief overview of the required information before beginning data entry, assistance with learning how to enter results information, would like to discuss strategies for entering a complex study design or unique outcome measure or analysis, ClinicalTrials.gov staff can provide email assistance or schedule a teleconference. In addition, they can also provide assistance in addressing QC Review Comments when there are questions. Requests for email assistance or for a teleconference should be submitted to register@clinicaltrials.gov.

To understand the criteria that ClinicalTrials.gov staff use for QC review, they recommend consulting the review criteria for both registration and results information (included below). These are intended to assist investigators with improving data quality and avoiding major issues.
- ClinicalTrials.gov Protocol Review Criteria (PDF): Describes review criteria for study records submitted to the registry (June 2018)
- ClinicalTrials.gov Results Review Criteria (PDF): Describes review criteria for each scientific module in the results section of the study record submitted to the results database (June 2018)

After study record Release, registration record reviews take 2-5 business days and review of study records with results take up to 30 days if the study appears to be an applicable clinical trial or is NIH-funded. Other types of study records with results will take longer.

1. Protocol Registration and Results System (PRS)

The site uses a Web-based data entry system called the Protocol Registration and Results System (PRS) to register clinical studies and to submit results information for registered studies. You must have a PRS account to register study information on ClinicalTrials.gov.

Before applying for a PRS account, you should ensure that you are the appropriate individual to submit clinical study information to ClinicalTrials.gov. To avoid duplicate registration, studies should be registered only by the Responsible Party. To help you determine who is responsible for registering a study and submitting results, see the Elaboration of Definitions of Responsible Party and Applicable Clinical Trial (PDF).

Clicinaltrials.gov PRS Users Guide: https://register.clinicaltrials.gov/prs/html/prs-users-guide.html

ClinicalTrials.gov establishes one PRS account for an organization (such as a company, university, or medical center). All investigators from that organization who are conducting studies are designated as users of this single PRS account. UB's PRS account is **SUNYBuffalo**.

You can contact the UB PRS Administrator, Lynn Jagodzinski, to request a user login at lynnjago@buffalo.edu. Please provide the following information for account set up:
- Full Name
- Department
- Login Name
- Email Address (email that you use frequently)
- Phone (phone that you use frequently)

Within 2 business days, you will receive an email containing your login name, and a message directly from ClinicalTrials.gov containing your temporary password. Log on to the Protocol Registration and Results System using your login name and password. The Organization name is **SUNYBuffalo**. From the Accounts drop down menu, select "Change Password." The temporary one should be updated to a unique password of your choosing as soon as possible.

ClinicalTrials.gov Training Materials: https://clinicaltrials.gov/ct2/manage-recs/present

To contact the University at Buffalo ClinicalTrials.gov PRS Administrator:
     Lynn Jagodzinski
     Clinical and Translational Science Institute (CTSI)
     lynnjago@buffalo.edu
     716-888-4843

2. How to Register a Study

Registration How-To-Guide: https://clinicaltrials.gov/ct2/manage-recs/how-register.

Protocol Registration Templates: Each template is a formatted summary of the data elements for each registration module, specific to the relevant study type. The templates are intended to help investigators understand and gather the data needed to complete each registration module.
- Interventional Study Protocol Registration Template
- Observational Study Protocol Registration Template
- Expanded Access Protocol Registration Template

PRS Test to Practice Entering Data
PRS Test serves as a test for new PRS software releases, but is frequently used by novice users to practice data entry. Learners who are new to PRS may initially find it helpful to practice entering data into PRS Test.

Protocol Registration Data Element Definitions:
https://clinicaltrials.gov/ct2/manage-recs/resources/#DataElement.

It takes approximately 1 hour to enter registration information. The system offers the option to save data as you go, in case you do not have time to complete the entire process. It is possible to copy and paste information from the protocol into the data fields.

1. Log in to the ClinicalTrials.gov Protocol Registration and Results System using your login name and password. The Organization name is **SUNYBuffalo**.

2. To create a new record, select "New Record" from the Quick Links section at the upper-left corner of the page. The person who creates the new record will be designated as the Record Owner and is responsible for maintaining the registration. To change the Record Owner, contact the PRS Administrator at lynnjago@buffalo.edu.

   Institution-Specific Information to Enter:

   - **Unique protocol ID:** Use the UB IRB study number (StudyXXXXXXXX).
   - **Secondary IDs:** Enter the grant number, funding agency number or other funding source number, if applicable.
   - **Responsible Party:** Defaults to "Sponsor".
     If the study is under an IND or IDE, choose "Sponsor-Investigator" from the drop down menu and choose the IND/IDE holder as the Sponsor-Investigator.
   - **Investigator Name:** Displays only if "Sponsor-Investigator" is chosen as the Responsible Party. If the IND/IDE holder's name is not displayed in the drop down menu, contact the PRS Administrator team to create an account for the IND/IDE holder.
   - **Board Information:**
     o Board Name: University at Buffalo Institutional Review Board (UBIRB)
     o Board Affiliation: State University of New York at Buffalo
     o Board Contact: Phone: 716-888-4888
     o Email: UB-IRB@buffalo.edu
     o Address: Clinical and Translational Research Center
        875 Ellicott Street, Room 5018
        Buffalo, NY 14203
   - **Oversight Authorities:** Always include "United States: Institutional Review Board".
     Only include "United States: Food and Drug Administration" if the study is under an IND or IDE.

3. When entry is complete, click the green "Entry Complete" button on the Record Summary page. The template will be forwarded to the Responsible Party, who will review it and release the approved content to ClinicalTrials.gov for quality assurance review. If ClinicalTrials.gov PRS reviewers find problems with the record, it will be returned to the Record Owner with PRS Comments. The issues will need to be addressed and the record re-released to ClinicalTrials.gov within 15 days for QA and subsequent posting. If you have questions on the content of comments email register@clinicaltrials.gov. Include NCT Number (or Unique Protocol ID prior to posting) and description of question with any supporting information. You may also request a teleconference.

When ClinicalTrials.gov has accepted the record, the Record Owner will receive an email with the NCT#.

Records that have an NCT number cannot be deleted.

Problems with Records and How to Resolve (Section 8 in PRS User's Guide)

Several kinds of issues can trigger a record being identified as having problems. This section describes possible problems with study records and how to resolve them. Click on the **Problem Resolution Guide** using the Quick Links section at the upper-left corner of the page or
Problem Resolution Guide: https://register.clinicaltrials.gov/prs/html/prs-users-guide.html#section8

3. Maintaining the Record

The study team must review the record and update the Record Verification Date every 12 months until all required registration and results information has been submitted, even if no other updates are required.

The following fields must be updated within 30 days of a change, unless otherwise noted:
- Overall Recruitment Status
- Primary Completion Date
- Study Start Date
- Intervention names (must update to a non-proprietary name within 30 days after a non-proprietary name is established)
- Availability of Expanded Access
- Expanded Access Status and Expanded Access Type
- Individual Site Status
- Human Subjects Protection Review Board Status
- Study Completion Date
- Responsible Party and RP Contact Information
- Changes in the protocol that are communicated to subjects
- Device Product Not Approved or Cleared by U.S. FDA (update within 15 days after change in approval or clearance status)

Errors in the Study Status section are the most frequently seen comments on the ClinicalTrials.gov Problem Reports. Updating Completion Date fields in a timely manner can prevent records from being flagged with errors.

4. Entering Results

Results for ACTs and NIH-funded clinical trials are due within one year of the Primary Completion Date (the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome).

A copy of the protocol and statistical analysis plan (SAP), if not included in the protocol, is required to be submitted as part of clinical trial results information for those applicable clinical trials with a Primary Completion Date on or after January 18, 2017. The responsible party may redact names, addresses, and other personally

identifiable information, as well as any trade secret and/or confidential commercial information contained in the protocol or statistical analysis plan prior to submission.

Preparing for Results Reporting

Before you begin, it is recommended that you review the Simple Results Templates and Results Data Preparation Checklists to ensure that you have the information needed to complete the Results Section. The results data needed are similar to the components needed for a journal publication. Preparing data for the Results Section should similarly involve individuals who are familiar with the study design and analysis (such as an investigator or statistician).
General resources to help you prepare:

- How to Submit Your Results homepage: https://clinicaltrials.gov/ct2/manage-recs/how-report

- Basic Results Data Elements Definitions: https://prsinfo.clinicaltrials.gov/results_definitions.html

- PRS User Guide: Located on Main Menu in database

- 10 minute webinars for each results module: https://clinicaltrials.gov/ct2/manage-recs/present

- Helpful Hints (with common study design examples): https://prsinfo.clinicaltrials.gov/ResultsExamples.pdf

Need help with Results? Contact ClinicalTrials.gov PRS to request one-on-one assistance from one of the PRS experts.

Prematurely Terminated Trials

Applicable Clinical Trials (ACTs) that terminate prematurely but have enrolled participants and collected data during the trial must report results on ClinicalTrials.gov.

Indicate that the trial is closed via the "Enrollment Status" field. Enter a brief explanation of the reason(s) why such clinical study was stopped (for a clinical study that is "Suspended," "Terminated," or "Withdrawn" prior to its planned completion as anticipated by the protocol).

For a trial that was terminated after participants were enrolled, provide any available data.

If no data are available for any of the Outcome Measures, specify zero ("0") for the Number of Participants Analyzed in each Arm/Group, and leave the data fields blank. In this case, provide an explanation in the Analysis Population Description for why zero participants were analyzed and, if appropriate, provide information in the Limitations and Caveats module. Even if data are not entered for Outcome Measures, submit the available data for the enrolled participants in the Participant Flow, Baseline Characteristics, and Adverse Events modules.

A good example is NCT00004500, which was terminated early.

If no participants were ever enrolled in the trial, set the "Overall Recruitment Status" to Withdrawn, and no further results information will need to be submitted.

Deleting the Results Section

The Results Section should not be deleted if results are required to be submitted. If the Results Section has been Released, contact Register@ClinicalTrials.gov for assistance with deleting the Results Section.

5. Consent Form Posting

Effective **January 21, 2019**, the revised Common Rule requires that any clinical trial (initially approved or exempt by an IRB on or after 1/21/2019) conducted or supported by a Common Rule department or agency, one consent form be posted on a publicly available federal website after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject. The consent form must have been used in enrolling participants in order to satisfy this new provision. You can read more information about the revised Common Rule on the OHRP website (https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html).

At this time, two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been identified: ClinicalTrials.gov and a docket folder on Regulations.gov ([Docket ID: HHS-OPHS-2018-0021](https://Regulations.gov)).

Additional federal websites that would satisfy the revised Common Rule's clinical trial consent form posting requirement might be identified in the future.

Specific instructions on how to register with ClinicalTrials.gov and upload documents (including clinical trial informed consent forms) to that site may be found at https://clinicaltrials.gov/ct2/manage-recs.

Tips for Success

- Always return to the Record Summary page and click the green Entry Complete button to submit the registration.
- "Errors" must be resolved before you can submit.   "Notes" should be reviewed; however, revisions are not required for submission.
- Do not use first or second person (i.e. replace "we" and "you" with "the investigator" and "subjects").
- Check for spelling errors by clicking the spelling link on the Record Summary page before selecting the "Entry Complete" button.
- The most common reason ClinicalTrials.gov returns a record for revisions is issues with the Outcome Measures section. Review the Protocol Review Criteria, starting on

page 6 for helpful hints:
https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf

- Compliance is tracked through the Record Verification Date so update this field every time the record is updated.

- The Primary Completion Date is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.

- The Study Completion Date is the final date on which data was collected.

- For Applicable Clinical Trials and NIH-funded clinical trials, results must be entered one year after the Primary Completion Date. If there are 2 or more Primary Outcome Measures, results are due one year from the latest Primary Completion date.

- The study does not need to be closed in the IRB to be complete in ClinicalTrials.gov. However, if the IRB is closed, the ClinicalTrials.gov record should be finished also. You may need to reopen a study in order to review PHI for results entry.

Frequently Asked Questions

Question: **Who can enter the registration information into ClinicalTrials.gov?**

Answer: Anyone listed as study key personnel may enter the registration information into ClinicalTrials.gov. You must have a ClinicalTrials.gov account to register a study. The person who creates the registration is designated as the Record Owner, or the main contact for the record. To change the Record Owner, contact the PRS Administrator at lynnjago@buffalo.edu . The Record Owner can give edit rights to additional study personnel by adding them to the access list on the Record Summary page.

Question: Who is the Responsible Party?

Answer: The Responsible Party (RP) is responsible for registering the trial on ClinicalTrials.gov, ensuring accuracy, and making sure the content is up-to-date. For trials run under an IND or IDE, the IND/IDE holder is the Responsible Party and will be required to approve and release the record to ClinicalTrials.gov. For studies without an IND or IDE, the PI is the Responsible Party. The PI is ultimately responsible for the accuracy of the data that is entered in ClinicalTrials.gov.

Question: How can I check the status of my study in ClinicalTrials.gov?

Answer: Check the Record Summary page for an overview of a trial's current status, actions required for finishing the registration or results submission, and a summary of the status of each module within the sections.

Question: How do I get access to a study in ClinicalTrials.gov?

Answer: The person listed as the "Record Owner" can add you to the access list on the Record Summary Page if you have an account. If you don't have an account or the Record Owner is no longer at UB, contact the PRS Administrator.

Question: Is the Primary Completion Date the same as the Study Completion Date?

Answer: Not necessarily. The Primary Completion Date is defined as "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome [measure], whether the clinical trial concluded according to the pre-specified protocol or was terminated."   The Study Completion Date is the "final date on which data was collected."

Question: Do results need to be entered for all studies?

Answer: No, only Applicable Clinical Trials and NIH-funded clinical trials need results entered within 12 months of the Primary Completion Date. However, investigators are encouraged to enter results for all trials. Results must be entered within 12 months of the Primary Completion Date.

Question: How long does the QC review process take?

Answer: After record Release, registration record reviews take 2-5 business days and review of records with results take up to 30 days if the study appears to be an applicable clinical trial or is NIH-funded. Other types of study records with results will take longer.

Question: How often do I need to update my registration?

Answer: Certain data elements need to be updated within 30 days of a change (e.g. Overall Study Status, Completion Dates, Study Start Date, individual site status).

Review and update your record at least annually until all required registration and results information has been submitted. Compliance is tracked by ClinicalTrials.gov using the Record Verification Date field in the Study Status section. Change this date each time you update your record.

Question: Must clinical studies with no external sources of funding ("unfunded" studies) be registered on ClinicalTrials.gov?

Answer: The registration requirements of FDAAA 801 and the International Committee of Medical Journal Editors (ICMJE) policy do not exclude clinical studies with no external sources of funding ("unfunded" studies). See FDAAA 801 and the Final Rule for more information on which trials must be registered under FDAAA 801.

In general, an unfunded study should be registered via the PRS account of the Sponsor. When an investigator is considered the Sponsor (a Sponsor-Investigator), the study should be registered using the PRS account of the investigator's affiliated institution with the Responsible Party indicated as Sponsor-Investigator. ClinicalTrials.gov will then display the investigator as the Sponsor instead of the investigator's institution.

Question: If a study is prematurely closed (for any number of reasons) and an analysis is not done, how should we record that in ClinicalTrials.gov?

Answer: Trials that terminate prematurely must still indicate that the trial is closed via the "Enrollment Status" field and a brief explanation of why the study was terminated should be provided. If you collected data during the trial and the trial meets the definition of an Applicable Clinical Trial (ACT), results must be reported.

For a trial that was terminated after participants were enrolled, provide any available data.

If no data are available for any of the Outcome Measures, specify zero ("0") for the Number of Participants Analyzed in each Arm/Group, and leave the data fields blank. In this case, provide an explanation in the Analysis Population Description for why zero participants were analyzed and, if appropriate, provide information in the Limitations and Caveats module. Even if data are not entered for Outcome Measures, submit the available data for the enrolled participants in the Participant Flow, Baseline Characteristics, and Adverse Events modules.

A good example is NCT00004500, which was terminated early.

Question: How do I submit results information if the trial is terminated (that is, stopped prematurely) and no data were collected for one or more Outcome Measures?

Answer: If no participants were ever enrolled in the trial, set the "Overall Recruitment Status" to Withdrawn, and no further results information will need to be submitted.

Question: When speaking of Individual Participant Data (IPD) sharing, who are they sharing the data with?

Answer: The IPD sharing statement refers to sharing datasets with researchers for additional analyses. It does not refer to collaborators working on data for a particular study.

Question: Who should submit an Expanded Access record?

Answer: The final rule clarifies that expanded access (EA) use of a drug, biological, or device product is not considered an "applicable clinical trial" (ACT) under the definition in 42 CFR 11.10 (81 FR 65009-10). Thus, the submission of clinical trial registration and results information for EA use would not be required.

Websites

- ClinicalTrials.gov (public website)

- ClinicalTrials.gov PRS Protocol Registration and Results System (for record creation and editing)

Additional Resources

- ClinicalTrials.Gov Training Materials

- ClinicalTrials.Gov Support Materials

- Registration How-To Guide

- Results Reporting Guide

- ICJME Clinical Trials Registration Policy

- NIH Resources and News Releases

- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

- [Complementary NIH Policy](#)

- [Clinical Trials Registration and Results Information Submission, Final Rule](#)

- [Summary Table of Final Rule and NIH Policy](#)

- [FDA Amendments Act Final Rule](#)

- [FDAAA 801 Requirements](#)