University at Buffalo
Clinical and Translational Science Institute

ClinicalTrials.gov Registration and Results Guide

ClinicalTrials.gov (CT.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.

Important Notices:

1. Registration and Results Reporting Timelines

If you plan on publishing your study results, it is highly recommended that you register prior to the first subject enrollment (study must have an NCT number) due to ICMJE policy (see page 9 for more information).

	FDAAA Law	NIH Policy	ICMJE Policy	CMS
Scope	Applicable Clinical Trials (ACT)	All NIH-funded Trials	Interventional Clinical Trials (broad scope of "intervention")	Qualifying Clinical Trials
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**	**Prior to first subject enrollment**	**Prior 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**

2. No "Delayed Results Extension" After 1 Year Due Date

As of January 25, 2022, the PRS **no longer permits Responsible Parties to submit Good Cause Extension requests late** for ACTs with a primary completion date on or after January 18, 2017.

A Responsible Party may request to delay the submission of results information for an ACT by submitting a good cause extension request via the ClinicalTrials.gov Protocol Registration and Results System (PRS) **prior to the date (i.e., the day before) that results information would otherwise be due**. The standard submission deadline for results information is no later than 1 year after the ACT's primary completion date.

The extension request **must include a description of the reasons** that the responsible party believes constitute good cause to justify an extension and an estimated date on which the results information will be submitted, with sufficient detail to allow for evaluation of the request.

3. Consequences for Noncompliance

As of August 2021, the FDA started issuing **notices of noncompliance to individual investigators** for failing to report study results. In addition to receipt of a letter from the FDA that outlines the details and time frame for remedying the violation and potential penalties for continued noncompliance, information regarding the violation will be publicly available on the noncompliant study record in ClinicalTrial.gov (see example below).


Study Details | Tabular View | Results Submitted | FDAAA 801 Violations | Disclaimer | How to Read a Study Record

Information on FDAAA 801 Violations — More Information: Notices of Noncompliance [FDA]

Available on ClinicalTrials.gov	Issued by FDA	Study Record Submitted	Notice Type	FDAAA 801 Notice
September 3, 2021	August 31, 2021	December 15, 2018	Violation Identified by FDA	Failure to Submit. The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.

As of July 21, 2022, noncompliance with ClinicalTrials.gov registration and results reporting may result in **fines of $13,237 per study/per day for PIs and institutions**. In addition to civil monetary penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution.

For an NIH funded study for which a grantee is the responsible party, failure to submit required results information could result in **NIH not releasing remaining funding for a grant or funding for a future grant**.

4. Policy for Responsible Party (RP) when leaving the University at Buffalo

Once your study is made public on ClinicalTrials.gov, it will remain on the website permanently. **If you leave the University at Buffalo, you must provide your future contact information to the UB CT.gov administrator** before you leave UB so that the change can be made in the CT.gov study record. If another PI is taking over the study responsibilities for you, you must provide the new information of the new Responsible Party to the UB CT.gov administrator before you leave UB.

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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.

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

The regulations require that, for an applicable clinical trial for which registration information is required to be submitted, the registration information must be submitted within 21 days after the first human subject is enrolled. An NCT number must be provided for the trial to be considered registered. The final rule defines "enrolled" to mean a "human subject's, or their legally authorized representative", agreement to participate in a clinical trial following completion of the informed consent process. Potential subjects who are screened for the purpose of determining eligibility for a trial, but do not participate in the trial, are not considered enrolled.

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

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 must also meet one 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 exclude 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

Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials generally must be submitted not later than one year after the trial's Primary Completion Date.

- 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 (ACTs) 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.

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."

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.

Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials generally must be submitted not later than one year after the trial's Primary Completion Date.

- 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 (ACTs) 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.

Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought.

Results, including adverse events, must be submitted within one year from the date the last patient was evaluated for the primary outcome measure.

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

Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial? For helpful information using NIH decision tree on the definition of a clinical trial, see: https://grants.nih.gov/ct-decision/index.htm

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:
     - Drug or device
     - Surgical techniques
     - Eat a certain diet
     - Exercise
     - Change daily habits
     - Read a book
     - Try mobile app
     - Play video game
     - Stop smoking
     - Participate in new curriculum
     - Complete hand-eye coordination tasks

3. Is the study designed to evaluate the effect of the intervention on the participants?
   Examples include:
     - Mood management for smokers
     - Reading comprehension
     - Adherence to exercise routine
     - 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

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 are 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.

Extension of Some Flexibilities for BESH

NIH is extending the period of delayed enforcement for registration and results reporting, originally announced in NOT-OD-18-212, through **September 24, 2023**. This delayed enforcement is only applicable to BESH studies submitted to funding opportunities designated as "basic experimental studies with humans" in the title.

NIH recognizes that registering and reporting results in ClinicalTrials.gov poses a challenge for some types of BESH projects. NIH remains committed to working with the BESH community and will continue to explore solutions to facilitate the dissemination of information in ways that are useful to other researchers and members of the public, while also maintaining the NIH commitment to stewardship and increasing transparency. During the extension, NIH will continue to assess the needs of the BESH community as solutions are considered for BESH registration and results reporting.

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 Good Clinical Practice (GCP) training in accordance with NOT-OD-16-148 for all personnel involved in the conduct, oversight, or management of prospective basic science studies involving human participants. NIH also continues to expect posting of informed consent forms in accordance with NOT-OD-19-110 and as required by Section 46.116(h) of the Revised Common Rule for all basic science studies involving human participants that obtain informed consent. Additionally, all such applications continue to require completion of the full PHS Human Subjects and Clinical Trials Information form, and will be evaluated using the clinical trial review criteria.

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. Examples of journals that follow ICMJE guidelines:

- New England Journal of Medicine
- The Lancet
- The Journal of the American Medical Association (JAMA)
- American Journal of A-Z
- Health Services Research
- International Journal of Epidemiologic Research
- Advances in Clinical Medical Research (list date 2/3/21)
- Anti-Inflammatory & Anti-Allergy Agents in Medical Chemistry (list date 3/9/21)

ICMJE requires registration of clinical trials in a public trial 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. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

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 prior 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**	**Prior to first subject enrollment**	**Prior 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 (over $13,000/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?

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)

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 by the **Responsible Party (RP)**. **Owners** are often Study Coordinators or study team members, that assist the RP with data entry.

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).

The **Responsible Party** field defaults to "Sponsor". The University at Buffalo usually will require the following:

- 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.
- If your study is not under an IND or IDE, choose "Principal Investigator" from the drop-down menu.
- If you are a student, resident, or fellow: Your Faculty Supervisor should be listed as the Overall Study Official in the Contacts section and should be added and should be given edit rights by adding them to the "Access List" on the Record Summary page.

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

To prevent theft of intellectual property, we advise that the study registration should include basic information written for a non-scientific reader (8th grade level). We advise that primary and secondary objectives should be put in the Brief Summary, and that the Detailed Description is optional and can be left blank. Often investigators include extensive information about protocol design in the Detailed Description, but that is more than basic information. The downside to including all this information is that it is possible for someone else to pirate the design. We also advise that eligibility criteria be a *limited list* (as in the CT.gov Protocol Data Element Definitions). Eligibility criteria also can disclose a great deal about study design, still, many investigators include their complete list of eligibility criteria.

Document upload is not required at registration in the Protocol Section.

Guided Tutorials

The PRS Guided Tutorials provide step-by-step instructions for submitting registration and results information into the ClinicalTrials.gov Protocol Registration and Results System (PRS). The tutorials have new and updated content and features, including examples from materials developed for the behavioral sciences community.

Also, two new sections have been added: Quick Overview Guides are designed to help users get the most from the tutorials, and the PDF Library has all tutorial content in a single place, readily available for download.

The PRS Guided Tutorials are grouped into three sections: Registration Tutorials, Study Documents Tutorial, and Results Tutorials. Each tutorial provides a PRS module overview, ClinicalTrials.gov data element descriptions, step-by-step instructions with images from the PRS for entering information using a Parallel study design example, and tips to identify and prevent the most common issues identified in the ClinicalTrials.gov Results Quality Control (QC) review process. Although the tutorials are designed to be reviewed in order, you can review individual topics as needed, and the tutorials are available on multiple devices (desktop, laptop, tablet, cell phone). Each tutorial features example figures, questions and answers about optional aspects of results data entry, downloadable and printable tutorial PDFs, and links to additional resources such as checklists, templates, and definitions.

For basic help with using PRS, review the Quick Start Guide found in the Help section of the PRS main menu. More detailed instructions are available in the PRS User's Guide, also found on the PRS main menu.

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

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

Considerations for Observational Studies and Expanded Access Records:
https://clinicaltrials.gov/ct2/manage-recs/how-register#Considerations

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.

Data element entries are annotated with symbols to indicate generally what information is required to be submitted (and under which circumstances). For more information about various requirements and definitions of regulatory terms under 42 CFR Part 11, see Support Materials.

*	Required field
*§	Required if Study Start Date is on or after January 18, 2017
[*]	Conditionally required

Note: The term "clinical study" is used to refer to both interventional and observational studies. The term "participant" is used to refer to human subjects.

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.

Important: Once your study is made public on ClinicalTrials.gov, it will remain on the website permanently. If you leave the University at Buffalo at any time, you will need to provide your future contact information to the UB CT.gov administrator so that the change is made in the CT.gov study information.

Institution-Specific Information to Enter:

Study Identification Module

- **Unique protocol ID:** Use the UB IRB study number (StudyXXXXXXXX) or the IRB study number from other IRBs.
- **Secondary IDs:** Enter the grant number, funding agency number or other funding source number, if applicable.

Study Status Module

Record Verification Date: Date that the Responsible Party last reviewed the entire record and confirmed it to be accurate and complete. An update must be submitted **at least once yearly** while the study is active, even if only the Record Verification Date changes.

Overall Recruitment Status: Recruitment status for the study as a whole.

- Recruiting: people seeing the CT.gov record can call to enroll.
- Enrolling by Invitation: people seeing the record cannot call to enroll (potential participants must be invited, e.g., patients already under care).
- Active, not recruiting: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled
- Completed: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant's last visit has occurred)
- Suspended: Study halted prematurely but potentially will resume
- Terminated: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention
- Withdrawn: Study halted prematurely, prior to enrollment of first participant

Study Start Date: Date study enrollment will open (anticipated) or opens for enrollment (actual).

- When the first participant is enrolled, change to the date of first enrollment.
- Enrollment is defined as the date the first informed consent form is signed (unless otherwise defined in the protocol).

Primary Completion Date: Final data collection date (anticipated or actual) for the primary outcome measure (or all primary outcomes if there are more than one). Usually this is the last patient visit or assessment date.

Sponsor/Collaborators Module

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.
- If your study is not under an IND or IDE, choose "Principal Investigator" from the drop-down menu.
- If you are a student, resident, or fellow: Your Faculty Supervisor should be listed as the Overall Study Official in the Contacts section and should be added and should be given edit rights by adding them to the access list on the Record Summary page.

The person identified as the Responsible Party acts as the official contact person for that account and full contact information for that person must be listed in the PRS account.

The Investigator Affiliation should be listed as the **State University of New York at Buffalo**.

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.

Oversight Module

Human Subjects Review Board Information:

If the study was approved by the UB IRB, enter the following information:

- Board Name: University at Buffalo Institutional Review Board (UBIRB)
- Board Affiliation: State University of New York at Buffalo
- Board Contact: Phone: 716-888-4888
- Email: UB-IRB@buffalo.edu
- 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.

Contacts/Locations Module

Central Contact Person * (*or Facility Contact required*)
Definition: The name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the study can be addressed. Include the following information:

- **First Name**
- **Middle Initial**
- **Last Name or Official Title** *
- **Degree**
- **Phone**: * Toll free phone number of the Central Contact Person. Use the format 800-555-5555 within the United States and Canada. If outside the United States and Canada, provide the full phone number, including the country code.
- **Ext**: phone extension, if needed
- **Email**: * electronic mail address of the central contact person

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.

Important:
Once all required information is entered in the record, remember to look for the **"Next Step"** box at top of record page with instructions for the next steps to complete. You will see a blue/green button with either **Entry Complete** or **Approve** or **Release**. When all required information is entered into the record, select the **Entry Complete** button. The PI must then review the record for accuracy and completeness, assessing whether any corrections need to be made. If information is complete, PI can select the **Approve** button. Select **Release** to submit the record to ClinicalTrials.gov for quality assurance review. If you do not click on the buttons until you see **"Released"**, the record is not complete and it will not be released to ClinicalTrials.gov PRS for review. These steps are required every time a change is made to the record.

After study record Release, registration record reviews take 2-5 business days to be returned. If the study record is a review of study records with results, it may 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.

Requests for email assistance or for a teleconference should be submitted to register@clinicaltrials.gov.

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.

PRS Comment Types

Type	Explanation
ERROR	Serious issues that must be addressed. (e.g., missing required* content, internal inconsistency)
WARNING	Potentially serious issues that should be reviewed and addressed as needed. (e.g., Study Start Date data element)
NOTE	Potential issues that should be reviewed and addressed, as needed (if not possible, then may ignore)

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

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

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

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 and non-compliance.

4. Entering Results Data

Results for ACTs and NIH-funded clinical trials are due within 1 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).

Notice: Published results in a manuscript are not sufficient to meet the requirements for submission of clinical trial results information to the ClinicalTrials.gov data bank.

Study Results Guided Tutorial

The PRS Guided Tutorials provide step-by-step instructions for submitting Results information into the ClinicalTrials.gov Protocol Registration and Results System (PRS). The tutorials have new and updated content and features, including examples from materials developed for the behavioral sciences community.

Also, two new sections have been added: Quick Overview Guides are designed to help users get the most from the tutorials, and the PDF Library has all tutorial content in a single place, readily available for download.

Example Studies for Results Data Entry

The following example study records and study papers are fictional and were created to illustrate key concepts for results data entry in PRS.

- **Parallel Study Design**: Example ClinicalTrials.gov record and fictional table and figures
- **Cross-over Study Design**: Example ClinicalTrials.gov record and fictional manuscript
- **Dose Escalation Study Design**: Example ClinicalTrials.gov record and fictional manuscript
- **Factorial Study Design**: Example ClinicalTrials.gov record and fictional manuscript
- **Multiple Period Study Design**: Example ClinicalTrials.gov record and fictional manuscript
- **Units Other Than Participants**: Example ClinicalTrials.gov record and fictional manuscript
- **Cluster Randomized Design**: Example ClinicalTrials.gov record and fictional manuscript
- **Fractional Factorial Design**: Example ClinicalTrials.gov record and fictional manuscript
- **Micro-Randomized Design**: Example ClinicalTrials.gov record and fictional manuscript

- **SMART Design**: Example ClinicalTrials.gov record and fictional manuscript

Notice: The FDA and NIH may take action against Responsible Parties (RP) if they do not submit required results information. Failure to submit required results information is a prohibited act under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(jj)(2), for which FDA could pursue civil monetary penalties of up to $10,000 a day under 21 U.S.C. 333(f)(3) against the ACT's responsible party. For an ACT for which a grantee is the responsible party, failure to submit required results information could result in NIH or FDA, as applicable, not releasing remaining funding for a grant or funding for a future grant in accordance with section 402(j)(5)(A) of the PHS Act.

Delayed Results and Results Expected Dates
As of January 25, 2022, the PRS no longer permits Responsible Parties to submit Good Cause Extension requests late for ACTs with a primary completion date on or after January 18, 2017.

A Responsible Party may request to delay the submission of results information for an ACT by submitting a good cause extension request via the ClinicalTrials.gov Protocol Registration and Results System (PRS) prior to the date (i.e., the day before) that results information would otherwise be due. The standard submission deadline for results information is no later than 1 year after the ACT's primary completion date.

The extension request **must include a description of the reasons** that the responsible party believes constitute good cause to justify an extension and an estimated date on which the results information will be submitted, with sufficient detail to allow for evaluation of the request.

Inclusion of Protocol and Statistical Analysis Plan
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.

Beginning in January 2020, ClinicalTrials.gov is expecting to update posting procedures for submitted results information for applicable clinical trials with a study start date on or after January 18, 2017 and results information first submitted after the implementation date for the updated procedures. These study records will be posted publicly after each NLM quality control (QC) review (within 30 days of each submission). If major issues are identified, a general notice that the QC review process has not concluded will be noted on the public study record and *only* the brief standard *major* comment(s) will be shown with the relevant section(s). PRS advisory comments will not be publicly displayed on the study record. Responsible parties will be notified via email when their record has been QC reviewed and if major issues were identified.

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. Allow adequate time to enter results (can take over 20 hours).

The process of submitting results information to ClinicalTrials.gov is conceptually similar to preparing a manuscript for publication in a journal. An individual familiar with the study design and data analysis (such as the clinical investigator or study statistician) will need to be involved in order to accurately summarize the results information in the tabular format required by law and to ensure that the results are consistent with the ClinicalTrials.gov review criteria.

General resources to help you prepare:

- PRS Guided Tutorials for assistance with entering registration and results information in the PRS: https://prsinfo.clinicaltrials.gov/tutorial/content4/index.html#/
- 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 CT.gov
- Helpful Hints (with common study design examples): https://prsinfo.clinicaltrials.gov/ResultsExamples.pdf
- Registration or Results Quality Control Review Criteria

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

Uploading Study Documents

You may upload study documents, including the study protocol, statistical analysis plan, and informed consent form, to your study record to make them accessible to the public. Prior to uploading, ensure that the document is appropriate for public posting and that any information that may identify participants has been redacted.

For studies with a Primary Completion Date on or after **January 18, 2017**, the full study protocol and statistical analysis plan (SAP) must be uploaded as part of results information submission. However, an option is now provided to indicate when there was not an SAP for a study, which will remove the ERROR message for a missing SAP. If that option is chosen, a statement that the SAP does not exist will also be shown on the ClinicalTrials.gov public website.

Uploading study documents for public posting at the time of registration is optional. Studies with a Primary Completion Date on or after January 18, 2017, must include the study protocol and statistical analysis plan (SAP) as part of results information submission.

Uploading the informed consent form (ICF) is optional, but it may be required if your study is conducted or supported by a Common Rule (45 CFR 46) department or agency (see information on the Office for Human Research Protections Clinical Trial Informed Consent Form Posting (45 CFR 46.116(h)) page).
Examples of Agencies (20 Total):

- Homeland Security
- Department of Defense
- Department of Veterans Affairs
- Department of Health and Human Services (Includes NIH, AHRQ, CDC)
- National Science Foundation

New versions of study documents may be uploaded as needed. The most recent version will be available on the ClinicalTrials.gov study record page, and all previously posted versions of documents will remain publicly available on the Archive site through the History of Changes link on a record.

Documents can be submitted in separate files or as one file. For example, if the statistical analysis plan (or statistical considerations for analyzing results) is included in the study protocol, the document can be submitted as one file.

Uploading New Study Documents

Before submitting, include a cover page with the official title of the study, the NCT number (if available), and the date of the document. The files you plan to upload must also be in the Portable Document Format Archive (PDF/A) file format. PDF/A is a version of the Portable Document Format (PDF) specifically developed for long-term preservation of electronic documents.

Word processors (such as Microsoft Word) and PDF editors (such as Adobe Acrobat Pro) provide the option to save or convert to the PDF/A file format. Note that PDF readers do not usually offer a function to convert to PDF/A format.

As of September 18, 2018, when uploading a document, if it is determined not to be in valid PDF/A format, the PRS now attempts to automatically convert the document to valid PDF/A. If the conversion is successful, a message appears indicating that the conversion has taken place and requests that the changed document be reviewed carefully before the study record is Released. The conversion to valid PDF/A is automatically noted in the Record Log. All documents should still be converted to PDF/A format prior to uploading. That is, this mechanism should not be relied upon to convert PDF to PDF/A.

Document Formatting

When using the "Save as PDF" function in Word, the format is regular PDF by default. To save as PDF/A, save as PDF, click "Options," and check the "ISO 19005-1 compliant (PDF/A)" box.

To save as PDF/A in Acrobat PRO, in the "Save as document type" drop-down menu, select PDF/A. Click settings to choose the type of PDF/A, but default (PDF/A-2b) should be fine.

Prematurely Terminated Trials

Records that have an NCT number cannot be deleted.

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.

Applicable Clinical Trials (ACTs) that terminate prematurely but have enrolled participants and collected data during the trial must report results on ClinicalTrials.gov. For a trial that was terminated after participants were enrolled, provide any available data.

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).

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.

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).

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

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

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 do I add a Co-PI or Sub-I to the CT.gov listing?

Answer: In "Contacts/Locations," edit location and click the "Add Investigator" button. You can add sub-investigators that way. Do not list them as collaborators, as that is for listing entities assisting with results, providing funding, etc.

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 that be recorded 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 study record 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.

Question: Are "pilot" drug or device studies considered to be an "applicable drug clinical trial" or "applicable device clinical trial," respectively, under the regulation?

Answer: It depends. The terms "pilot" drug or device study are not interchangeable with the terms "phase 1" drug study or "feasibility" device study, respectively. The regulation does not identify "pilot" studies in defining "applicable drug clinical trial" and "applicable device clinical trial" in 42 CFR 11.10(a) and 42 CFR 11.22(b). Therefore, the characteristics of each individual clinical trial of a drug, biological, or device product must be evaluated to determine whether it meets the applicable clinical trial definition, independent of whether the responsible party considers the trial to be a "pilot" study. We note that the definition of applicable drug clinical trial in 42 CFR 11.10(a) excludes phase 1 clinical investigations and the definition of applicable device clinical trial excludes certain types of small clinical trials to determine the feasibility of a device product. Please see https://clinicaltrials.gov/ct2/manage-recs/faq#fr_36.

Question: Is a protocol and statistical analysis plan (SAP) required to be submitted?

Answer: The regulations at 42 CFR 11.48(a)(5) require a copy of the protocol and SAP (if not included in the protocol) 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 regulations at 42 CFR 11.48(a)(5) also state that a "responsible party may redact names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the protocol or statistical analysis plan prior to submission, unless such information is otherwise required to be submitted under this part."

Question: Are appendices required to be included in the uploaded study protocol?

Answer: Clinicaltrials.gov considers the protocol appendices that contain a "description of the clinical trial, including objective(s), design, and methods," and any "relevant scientific background and statistical considerations," to be part of the full protocol and as such they must be included with the uploaded protocol. Please note that before including any appendices with the study protocol for posting, responsible parties may redact information in a protocol appendix consistent with 42 CFR 11.48(a)(5), which permits the responsible party to redact, among other things, trade secret and/or confidential commercial information from the protocol and statistical analysis plan prior to submission, unless such information is otherwise required to be submitted by the regulation. Please see https://clinicaltrials.gov/ct2/manage-recs/faq#fr_38.

Question: When does my obligation to update clinical trial information end?

Answer: The regulation in 42 CFR 11.64(a)(3) specifies when a responsible party is no longer required to update a clinical trial record. To determine when a study record for an applicable clinical trial (ACT) that is required by 42 CFR 11.22(a) to be registered or a clinical trial that is submitted voluntarily no longer needs to be updated under 42 CFR 11.64(a), the type of clinical trial information and the primary completion date must be considered. Please see https://clinicaltrials.gov/ct2/manage-recs/faq#fr_37.

Websites

- ClinicalTrials.gov (public website): https://clinicaltrials.gov/
- ClinicalTrials.gov PRS Protocol Registration and Results System (for record creation and editing): https://register.clinicaltrials.gov/

Additional Resources

- PRS Guided Tutorials for assistance with entering registration and results information in the PRS.
- 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

Sample Cover Page for Protocol, Statistical Plan and ICF

Official Title:	Official Title of Study
NCT number:	
Document Type:	[Indicate one of the following: Study Protocol; Statistical Analysis Plan; Study Protocol and Statistical Analysis Plan; Informed Consent Form (Indicate type: Main, Parent/Guardian, Assent, etc.)] **DELETE non-applicable text**
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