

## ClinicalTrials.gov Registration and Results 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.

### Noncompliance with ClinicalTrials.gov Regulations

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 public noncompliant study record at 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.

**Noncompliance with ClinicalTrials.gov registration and results reporting may result in fines over \$10,000 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.**

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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://prsinformo.clinicaltrials.gov/ACT\\_Checklist.pdf](https://prsinformo.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

**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](http://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.

**Helpful NIH Clinical Trials 10 Minute Overview presented by Penn State University:** [What NIH's Definition Means for Researchers](#)

### 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 ClinicalTrials.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

### 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

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 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.

### 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 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](http://www.who.int/ictrp/network/primary/en/index.html)) or in [ClinicalTrials.gov](http://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](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?

	<b>FDAAA Law</b>	<b>NIH Policy</b>	<b>ICMJE Policy</b>	<b>CMS</b>
<b>Scope</b>	Applicable Clinical Trials (ACT) per FDAAA	All NIH-funded clinical trials	Interventional clinical trials (broad scope of "intervention")	Qualifying clinical trials
<b>Intervention Type</b>	<p>All FDA regulated drugs, biologics, and devices</p> <p>Excludes:</p> <ul style="list-style-type: none"> <li>• phase I drug trials</li> <li>• small device feasibility trials</li> <li>• observational</li> <li>• behavioral interventions</li> </ul>	<p>All</p> <p>Includes:</p> <ul style="list-style-type: none"> <li>• basic science</li> <li>• behavioral</li> <li>• mechanistic</li> <li>• educational</li> <li>• surgical</li> <li>• social science</li> <li>• phase 1 drug</li> <li>• device feasibility</li> <li>• diagnostics</li> <li>• dietary supplements</li> </ul> <p>Excludes:</p> <ul style="list-style-type: none"> <li>• observational</li> <li>• pre-existing data</li> <li>• focus groups</li> </ul>	<p>All</p> <p>Includes:</p> <ul style="list-style-type: none"> <li>• behavioral</li> <li>• diagnostics</li> <li>• dietary</li> <li>• supplements</li> <li>• process of care</li> <li>• surgical procedures</li> <li>• educational programs</li> </ul> <p>Excludes:</p> <ul style="list-style-type: none"> <li>• observational</li> </ul> <p>Note: Some journals require registration of observational studies</p>	Clinical trials that are qualified for coverage
<b>When to Register</b>	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
<b>Results Reporting</b>	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
<b>Phase of the Trial</b>	Excludes Phase 1 (drug) and Feasibility (device)	All	All	Qualified clinical trials
<b>Enforcement if Non-Compliant</b>	<ul style="list-style-type: none"> <li>• Public notice</li> <li>• FDA sanctions</li> <li>• Civil monetary penalties (up to \$10,000/day)</li> <li>• Loss of HHS funding to study and/or institution</li> </ul>	<p>Loss of NIH funding:</p> <ul style="list-style-type: none"> <li>• For the PI</li> <li>• For the Institution</li> </ul>	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 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).

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.

**ClinicalTrials.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](mailto: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](mailto:lynnjago@buffalo.edu)  
716-888-4843

## 2. How to Register a Study

### PRS 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.

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](mailto:lynnjago@buffalo.edu).

Institution-Specific Information to Enter:

- **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.
- **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.

- **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](mailto: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.

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.

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.

Requests for email assistance or for a teleconference should be submitted to [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov).

**Helpful Tip:**

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 will 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 for review. These steps are required every time a change is made to the record.

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](mailto: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 field every 12 months until all required registration and results information has been submitted, even if no other updates are required.

#### **Helpful Tip:**

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**

**Notice:** The FDA and NIH may take action against responsible parties 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.

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).

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.

### **Delayed Results and Results Expected Dates**

As of February 1, 2021, responsible parties may only submit certifications for delayed submission of results information prior to the date (i.e., the day before) the standard submission deadline for the results information. The standard submission deadline for results information is no later than 1 year after the ACT's primary completion date.

### **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**

#### PRS Guided Tutorials

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.

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 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](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](#)).

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](mailto: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](https://clinicaltrials.gov) and a docket folder on Regulations.gov ([Docket ID: HHS-OPHS-2018-0021](https://www.regulations.gov/docket/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](mailto: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](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](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](https://clinicaltrials.gov/ct2/manage-recs/faq#fr_37).

## Websites

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

## 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](#)