Keeping Up with ClinicalTrials.gov: A Systematic Approach in Maintaining Compliance

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Office of Research and Economic Development
Research Regulatory Affairs
Human Subjects Protection Program (HSPP)

2019 SRAI Annual Meeting
San Francisco, CA
October 21, 2019
Getting to Know You!
Fun Facts about Rutgers
Learning Objectives

1. Describe why clinical trials disclosure matters; list resources to assist investigators in maintaining compliance

2. Identify how to establish a system in your organization to facilitate and monitor clinical trials registration and results reporting
Roadmap

• Why Do We Care?
• What ..... 
  ❖ is ClinicalTrials.gov?
  ❖ is a “Clinical Trial”?
  ❖ are the Regulatory Bodies?
• Who’s Watching?
• Reporting Responsibilities
• Establish a System in Your Organization
• Resources
  1. NIH
  2. CONSORT (Consolidated Standards of Reporting Trials)
  3. ClinicalTrials.gov website, Protocol Registration System (PRS) email
  4. Clinical Trials Registration and Results Reporting Taskforce
Why Do We Care?
Results reporting should not be considered a burden. Reporting results is an essential part of the scientific process; it is an integral component of the scientific method.

--- Michael S. Lauer, MD, Extramural Research, NIH
Three Pivotal Cases

- **Paxil**
  - GSK suppressed evidence on harms and lack of efficacy in children

- **Vioxx**
  - Merck failed to report heart attacks

- **Celebrex**
  - Pfizer reported misleading results
Kaplan-Meier estimates for ulcer complications according to traditional definition. Results are truncated after 12 months, no ulcer complications occurred after this period. (Adapted from Lu 2001.)
Takeaway

It is scientifically and ethically imperative for researchers to understand that clinical trial registration and results reporting is a key commitment to our research participants.

We all need the results of clinical trials to advance knowledge and inform our medical decisions.
Benefits to Register & Report Results

• **Human Subject Protections**
  - Allows potential participants to find studies
  - Assists ethical review boards and others to determine appropriateness of studies being reviewed
  - Promotes fulfillment of ethical responsibility to human volunteers – research contributes to medical knowledge

• **Research Integrity**
  - Facilitates tracking of protocol changes
  - Mitigates information bias (e.g. non publication)
  - Increases transparency of research enterprise

• **Evidence Based Medicine**
  - Facilitates tracking of studies and outcome measures
  - Allows for more complete identification of relevant studies
  - Provides data to support evidence-based medicine

• **Allocation of Resources**
  - Promotes more efficient allocation of resources

**All Contribute to Increased Public Trust in Clinical Research**
WHAT ....

.... is a Clinical Trial?

.... is ClinicalTrials.gov?

.... are the Regulatory Bodies?
Overview of ClinicalTrials.gov

- 300,000+ registrations
- 38,000+ posted results
- 215 million page views per month
- 145,000 unique visitors daily

[Image of ClinicalTrials.gov diagram]

First Things First: ClinicalTrials.gov

• There are two different systems:
  ❑ Public site: https://www.clinicaltrials.gov/
  ❑ User site: Protocol Registration and Results System (PRS) https://register.clinicaltrials.gov/

• There are two basic functions of ClinicalTrials.gov:
  ❑ Registration (creating and updating the record)
  ❑ Results Reporting (to be completed within 12 months of “Primary Completion”)
Applicable Clinical Trial (ACT): Clinical trial include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices.

Clinical Trial (NIH): 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.

Clinical Trial (ICMJE): A research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
Determination of NIH “Clinical Trial”

The following questions should be used to determine whether a study meets the NIH clinical trial definition:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

- If the answers are all “yes,” the study is a clinical trial.
- If any answers are “no,” the study is not a clinical trial.

FAQ: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5220
Case studies: https://grants.nih.gov/policy/clinical-trials/case-studies.htm
<table>
<thead>
<tr>
<th>Year</th>
<th>Entity</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>Congress</td>
<td>The 1st U.S. law to require trial registration (FDAMA)</td>
</tr>
<tr>
<td>2000</td>
<td>NIH</td>
<td>Launch ClinicalTrials.gov website</td>
</tr>
<tr>
<td>2005</td>
<td>ICMJE</td>
<td>Requires registration prior to enrollment</td>
</tr>
<tr>
<td>2006</td>
<td>WHO</td>
<td>All clinical trials should be registered</td>
</tr>
<tr>
<td>2007</td>
<td>CMS</td>
<td>PI must enroll qualifying clinical trials in ClinicalTrials.gov</td>
</tr>
<tr>
<td>2007</td>
<td>Congress</td>
<td>Expanded registration, results reporting and civil penalties (FDAAA)</td>
</tr>
<tr>
<td>2008</td>
<td>NIH</td>
<td>Release results database in ClinicalTrials.gov</td>
</tr>
<tr>
<td>2013</td>
<td>WMA</td>
<td>Declaration of Helsinki requires registration &amp; results reporting</td>
</tr>
<tr>
<td>2015</td>
<td>CMS</td>
<td>Mandatory reporting of clinical trial number on claims</td>
</tr>
<tr>
<td>2017</td>
<td>FDA</td>
<td>Final Rule compliance date (April 18, 2017)</td>
</tr>
<tr>
<td>2017</td>
<td>20 Federal Agencies</td>
<td>Revised Common Rule (45 CFR 46) Issued</td>
</tr>
<tr>
<td>2017</td>
<td>WHO</td>
<td>Signatories of international agencies to require registration and results reporting</td>
</tr>
</tbody>
</table>
## Selected Trial Registration Laws & Policies

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Intervention Type</th>
<th>Registration Policy Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDAAA 801 U.S. Federal Law (2007)</td>
<td>Drugs, biologics, and devices</td>
<td>Controlled clinical investigations of a FDA-regulated drug, biologic, or device, except Phase 1 or small feasibility studies</td>
<td></td>
</tr>
<tr>
<td>WMA 2013 Declaration of Helsinki</td>
<td>International policy, adopted by the WMA (1964, 2013)</td>
<td>Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)</td>
<td>&quot;Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.&quot; (Para 35)</td>
</tr>
<tr>
<td>Clinical Trials Directive 2001/20/EC, Article 11</td>
<td>European Union directive (2001)</td>
<td>Drugs and biologics</td>
<td>Phase 2–4 adult trials and Phase 1–4 pediatric trials</td>
</tr>
<tr>
<td>WHO Int'l Clinical Trials Registry Platform</td>
<td>International policy initiated by WHO (2006)</td>
<td>Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)</td>
<td>&quot;The registration of all interventional trials is a scientific, ethical and moral responsibility.&quot;</td>
</tr>
<tr>
<td>ICMJE Policy Publication policy by ICMJE (2004)</td>
<td>Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)</td>
<td>All interventional studies, including Phase 1 studies; defines criteria for &quot;acceptable registries&quot;</td>
<td></td>
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</table>
# US Clinical Trials Reporting Requirements

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>Registration</td>
<td>Registration &amp; Results Reporting</td>
<td>Registration &amp; Results Reporting</td>
</tr>
<tr>
<td><strong>Phase</strong></td>
<td>All</td>
<td>Not Phase 1</td>
<td>All</td>
</tr>
<tr>
<td><strong>Intervention Type</strong></td>
<td>All</td>
<td>Drug, biologic, &amp; device products regulated by the FDA</td>
<td>All (e.g., including behavioral intervention)</td>
</tr>
<tr>
<td><strong>Funding Source</strong></td>
<td>All</td>
<td>All</td>
<td>NIH</td>
</tr>
<tr>
<td><strong>Enforcement</strong></td>
<td>Refusal to publish</td>
<td>Criminal proceedings and civil penalties (up to $11,805* $11,569*/ day); Loss of HHS funding</td>
<td>Loss of NIH funding</td>
</tr>
</tbody>
</table>

**Effective**
- 2005
- January 18, 2017
- January 18, 2017

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International Committee of Medical Journal Editors (ICMJE)


[19]
Requirements for Registration

- **FDAAA**: The Principal Investigator must register and input required clinical trial information through the Protocol Registration System (PRS) at the ClinicalTrials.gov website **no later than 21 days after enrollment of the first participant** (https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa).

- **NIH**: The Principal Investigator must register and input required clinical trial information at the ClinicalTrials.gov website **no later than 21 days after enrollment of the first participant** (https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information).

- **CMS**: The Principal Investigator must register and input required clinical trial information and obtain an NCT# at the ClinicalTrials.gov website **before submitting claims for such services to CMS**.

- **ICMJE**: The Principal Investigator must register with an ICMJE qualified publicly-accessible registry **at or before the first patient is enrolled in the study** as a condition for publication in a participating journal (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration).
Who’s Watching?
Cumulative Number of Registered Clinical Trials with at Least One U.S. Site from October 2008 to September 2014

STAT article: Faced with public pressure, research institutions step up reporting of clinical trial results

In this visualization, you can explore 12,821 clinical trials that failed to report required results to ClinicalTrials.gov or reported them after the legal deadline, as of Sept. 11, 2017. Reporting violations also were recorded as of Sept. 11, 2015. The violations are grouped by the parties responsible for reporting trial results (the larger the circle, the more violations), and by category of research organization. Click or tap on any of the circles to zoom in or out. Click or tap on the small circles, which represent individual clinical trials, to open the related ClinicalTrials.gov page in a new window. Use the search box to find a particular responsible party.

Clinical trial legend:
- □ Results missing in 2015 and 2017
- □ Results missing in 2015; posted late as of 2017
- □ Results not required in 2015; missing in 2017
- □ Results not required in 2015; posted late as of 2017
- □ Results posted late before Sept. 11, 2015

Percentage of each responsible party’s clinical trials that had results reported late or not at all.

AllTrials FDAAA Trials Tracker

Who’s sharing their clinical trial results?
FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively came into force for all trials due after January 2018. The FDA are not publicly tracking compliance. So we are, here.

- Trials reported: 2839 out of 4218
- Percent reported: 67.3%
- US Govt could have imposed fines of at least: $4,754,720,172
- Fines claimed by US Govt: $0

Filter trials by status:
- On
- Overdue
- On (overdue or cancelled results)
- Off (ongoing)
- Off (reported)
- On (reported late)

Search

Showing 1 to 100 of 2,332 entries

Status, Sponsor, Trial ID, Title, Completion date, Days overdue

http://fdaaa.trialstracker.net/
How’s Rutgers Doing on TrialsTracker?

All individual trials at Rutgers, The State University of New Jersey

- Trials reported: 2 out of 2
- Percent reported: 100.0%
- US Govt could have imposed fines of at least: $647,864
- Fines claimed by US Govt: $0

Filter trials by status:
- Off
- Ongoing
- Reported
- Reported (late)

<table>
<thead>
<tr>
<th>Status</th>
<th>Trial ID</th>
<th>Title</th>
<th>Completion date</th>
<th>Days overdue</th>
</tr>
</thead>
<tbody>
<tr>
<td>reported-late</td>
<td>NCT01753099</td>
<td>Obstructive Sleep Apnea in WTC Responders: Role of Nasal Pathology [pACT]</td>
<td>2017-03-31</td>
<td>86</td>
</tr>
<tr>
<td>reported</td>
<td>NCT02632838</td>
<td>Utilizing a Mobile Health (mHealth) Application to Improve Hypertension Monitoring and Self-management in an Underserved Community: A Pilot Study [pACT]</td>
<td>2017-09-30</td>
<td></td>
</tr>
</tbody>
</table>
• Health Canada will begin posting reports from pharmacological clinical trials within 120 days of approving or rejecting applications.

• Canada's move follows a similar policy enacted four years ago by the European Medicines Agency of the European Union. The U.S. Food and Drug Administration, on the other hand, continues to treat this information as confidential to companies and rarely makes it public.
Top US institutes still aren’t reporting clinical-trial results on time

US law requires researchers to post study findings on a public registry within a year of completion – or face heavy fines.

Many leading US universities are breaking the law by failing to make public the results of their clinical trials.

A report published on 25 March found that 25 of the 40 universities that sponsor the most trials in the United States did not post study results on a public, government

https://www.nature.com/articles/d41586-019-00994-1#correction-0
Not Reporting Results of a Clinical Trial Is Academic Misconduct

Joshua D. Wallach, MS, PhD; Harlan M. Krumholz, MD, SM

Article, Author, and Disclosure Information

Failure to report the results of clinical trials threatens the public’s trust in research and the integrity of the medical literature, and should be considered academic misconduct at the individual and institutional levels. According to the ethical principles for research outlined in the Declaration of Helsinki, researchers “have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports” (1). When participants volunteer to take part in clinical trials, and expose themselves to interventions with unknown safety and efficacy profiles, they have a tacit assumption, based on trust, that the evidence generated will inform clinical science (2). Health care providers and medical societies, who are responsible for evaluating and synthesizing evidence and filling the gap between research and practice, need
Reporting Responsibilities
Key Concepts

- Responsible Party (i.e. PI per RU policy) must submit scientific and administrative information
- PI and statistician(s) are strongly encouraged to be involved
- Summarize results information in tabular format
- Conceptually similar to prepare for journal manuscript
- The intended audience is “readers of the medical literature.”
- The Basic Results Database requires the reporting of what was done; it does not require a change in study design or study procedures;
- Quality Assurance is designed to ensure that results are complete and meaningful; it does not ensure that studies are valid, useful, or interesting!
Overview - Results Database

**ClinicalTrials.gov Results Database**

**Scientific info**
- Participant Flow
  - Study design
  - Arms/Groups
  - Period/Stage (& title)
  - # of start and completed
- Baseline Characteristics
  - Age
  - Gender
  - Race, Ethnicity, Region
- Specific Measure
- Outcome Measures/Statistical Analyses
  - Type (1°, 2°..)
  - Title & description
  - Time frame
  - Arm/group title & description
  - # participants

**Administrative Info**
- Adverse Events
  - Time frame
  - Source name
  - Arms/groups (title & description)
- Point of Contact, agreement btw Sponsor and PI

Upload Documents

Human Subjects Protection Program
Summary of Updated Federal Requirements

Final Rule

• Requires registration & results submission for “applicable clinical trials” (ACTs)
• Requires submission of Protocol and Statistical Analysis Plan (SAP) at time of results information submission
• Expands scope of results reporting requirements to include trials of unapproved products

2018 Common Rule

• Requires posting of an IRB-approved version of the consent form to a federal website/registry, such as ClinicalTrials.gov.
Data Sharing Policies


- ICMJE requirements

Clinical trials that begin enrolling participants on or after 1 January 2019 **must** include a data sharing plan in the trial's **registration**. 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.
Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank

Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice (OGCP)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health(CDRH)
Office of Regulatory Affairs (ORA)

September 2018

Record Status

In progress → Entry Completed → Approved → Released → PRS Review → Public

1. **In progress** – initial data entry or update ongoing
2. **Entry Completed** – ready for internal review by administrator/investigator
3. **Approved** – record passed internal review
4. **Released** – submitted to ClinicalTrials.gov
5. **PRS Review** – under review by ClinicalTrials.gov
6. **Public** – posted on ClinicalTrials.gov public web site

Blue = what Investigators need to do
Establish a System in Your Organization
Establish a System in Your Organization

A. Identify a point person to assist investigators
B. Establish a mechanism to identify clinical trials in your organizations
C. Create a user-friendly website
D. Work with Research Administration to create policy and procedures for registration and results reporting. Update as necessary.
E. Provide active outreach to investigators and staff, offering education and timely information
F. Support investigators to communicate with ClinicalTrials.gov Team in NIH
A. Identify a Point Person to Assist Investigators in Your Organization

1. Who does this position(s) fall under at your institution?

2. How are you funding this position(s)?

3. Consider the following to explore options on the ClinicalTrials.gov Protocol Registration System (PRS) Administrator support:
   - Full Time Employee (FTE)
   - Funding Source
   - Chain of Command
Rational and Key Elements for Housing the PRS Administrator in an Organization

It is recommended that the PRS Administrator ....

1. Has access to IRB study database which enables internal monitoring and management
2. Conducts quality assurance review of protocols newly registered on ClinicalTrials.gov
3. Has ability to monitor non-compliance with federal regulations

WHY?

1. Clinical trials registration and results reporting is a Human Subjects Protection issue.
2. The approach aligns with the Declaration of Helsinki paragraph 35 and 36 (updated October 2013) "All study results inconclusive, negative or positive be made public".
B. Initiate a Mechanism to Identify Clinical Trials and Facilitate Registration

*Mechanisms in place at Institutional Review Board (IRB)*
- eIRB application questions on investigators to self report
- IRB provided the protocol templates to distinguish “interventional studies” and “non-interventional studies”

*Mechanisms in place at Human Subjects Protection Program (HSPP)*
- PRS Administrator generates a monthly report from eIRB of newly IRB-approved studies to capture interventional studies required to register on ClinicalTrials.gov

*Mechanisms that are utilized to check on progress of results reporting*
- Planning Report at ClinicalTrials.gov PRS
C. Create a User-Friendly Website

- Establish a website of clinical trials registration and results reporting
- Provide information and resources
- Conduct trainings on how to navigate the website
- Regularly update it
D. Work with Research Administration to Create Policy and Procedures for Registration and Results Reporting. Update as necessary.

Ad hoc committee meet with the Institutional Official to discuss details of policy and procedures, including enforcement for registration and results reporting.
OFFICE OF RESEARCH REGULATORY AFFAIRS POLICY

Policy Name: Clinical Trials Registration and Results Reporting
Approval Authority: Institutional Official
Originally Issued: June 1, 2017
Adopted: June 1, 2017
Amended: February 25, 2019
Amended Approved: March 19, 2019
Responsible Executive: Associate Vice President, Office of Research Regulatory Affairs
Responsible Office: Office of Research Regulatory Affairs
Contact: Human Subjects Protection Program
https://orra.rutgers.edu/hssp
(973) 972-1149

1. Policy Statement
The University requires registration and results reporting of certain clinical trials (as defined in Section 5 below) at ClinicalTrials.gov, a publicly-accessible registry, to promote responsible dissemination of information about clinical trials to the public. Ensure compliance with pertinent Federal and State law and funding agency requirements, and to meet professional publication standards.

2. Reason for the Policy
Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA) established legal requirements for sponsors and designated principal investigators responsible for certain clinical trials to register and report results information to ClinicalTrials.gov. To comply with FDAAA, the National Institutes of Health (NIH) and the Center for Medicare and Medicaid Services (CMS) obliges grantees to follow registration and reporting requirements to qualify for funding. Further, the International
E. Provide Active Outreach and Education

Customized, extensive opportunities for training to meet individual and/or group needs are offered:

- **Rollout Sessions** were given at all campuses.
- **All IRB Executive Committees** received an introductory session, and continuous updates.
- **Department or Group Meetings** are encouraged to include a presentation of ClinicalTrials.gov on the agenda.
- **Personalized Tutoring/Meetings** are conducted with individual faculty and their staff.
- **Individual Phone Consultations** are available upon request.
- **IRB Open House** had a ClinicalTrials.gov information table, next to our ClinicalTrials.gov poster.
F. Institutional PRS Administrator’s Expanded Role in Maintaining Compliance

- Participate in ClinicalTrials.gov Taskforce, a nation-wide group joined by institutional PRS administrators. Activities include monthly conference calls and various subcommittees to collaborate on projects and issues.
- Open communication with ClinicalTrials.gov PRS Team at National Institutes of Health. Act as a liaison between investigators and the ClinicalTrials.gov PRS Reviewers.
- Identify and share best practices with other institutions
- Develop solutions and tools for regulatory support
- Respond to requested consultations with from around the country
- Expand institutional knowledge with the Taskforce update on a regular basis.
RESULTS

1. Developed and implemented an Institutional Policy
2. Initiated collaboration with other departments to develop in-house procedures to maintain compliance (e.g. investigators separation procedure)
3. Increased the knowledge on disclosure requirements – in both investigators and institution
4. HSPP being viewed as more than a compliance overseer
5. Gaining IRB’s buy-in for this compliance endeavor
6. Initiate a ClinicalTrials.gov-focused QA Program to bring stakeholders together and regularly share the findings with senior management to enhance infrastructure support of institutional research enterprise.

GOAL: enhancing institutional compliance with federal regulations FDAAA 801 to uphold protection of human subjects in clinical research
Our ultimate goal is to be a resource to our research faculty, so that they know that they can always come back for support at any given time.
Resources

1. NIH
2. CONSORT
3. ClinicalTrials.gov official website, and its Protocol Registration System (PRS) Website & PRS email
4. Clinical Trials Registration and Results Reporting Taskforce (CTRRT)
How will NIH educate researchers? NIH will continue to update case studies, FAQs, tools, and resources to clarify guidance around the NIH clinical trial definition. See resources at: [https://grants.nih.gov/policy/clinical-trials.htm](https://grants.nih.gov/policy/clinical-trials.htm)

Additionally, NIH staff are prepared to help researchers determine whether their studies meet the NIH clinical trial definition.
CONSORT 2010 Flow Diagram

**Enrollment**
- Assessed for eligibility (n= )
  - Excluded (n= )
    - Not meeting inclusion criteria (n= )
    - Declined to participate (n= )
    - Other reasons (n= )

**Randomized** (n= )

**Allocation**
- Intervention (n= )
  - Received allocated intervention (n= )
  - Did not receive allocated intervention (give reasons) (n= )
  - Intervention (n= )
    - Received allocated intervention (n= )
    - Did not receive allocated intervention (give reasons) (n= )

**Follow-Up**
- Lost to follow-up (n= )
- Discontinued (n= )
  - Lost to follow-up (n= )
  - Discontinued (n= )

**Analysis**
- Analysed (n= )
  - Excluded from analysis (give reasons) (n= )
  - Analysed (n= )
    - Excluded from analysis (give reasons) (n= )
CONSORT checklist: Six Sections/Topics, 25 items

<table>
<thead>
<tr>
<th>Sections/Topics</th>
<th>Checklist Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>Trial title; Structured summary of design, methods, results &amp; conclusion</td>
</tr>
<tr>
<td>Introduction</td>
<td>Background and objectives</td>
</tr>
<tr>
<td>Methods</td>
<td>Design, participants, interventions, outcomes, sample size, randomization, blinding, statistical methods</td>
</tr>
<tr>
<td>Results</td>
<td>Participant flow, baseline data, number analyzed, outcomes and estimation, harms, ancillary analyses,</td>
</tr>
<tr>
<td>Discussion</td>
<td>Limitations, generalizability, interpretation</td>
</tr>
<tr>
<td>Other Information</td>
<td>Registration, protocol, funding</td>
</tr>
</tbody>
</table>

http://www.consort-statement.org/
ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 316,464 research studies in all 50 states and in 209 countries.

Find a study

Patients and Families
Search for actively recruiting studies that you may be able to participate in or learn about new interventions/treatments that are being considered.

Researchers
Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.

Study Record Managers
Learn about registering studies and about submitting their results after study completion.
**Free Train-the-Trainer Workshop**

- **Location:** NIH campus in Bethesda, MD.
- **Dates:** **November 4-5, 2019, and May 18-19, 2020.**
- **Contents:** It consists of interactive presentations and hands-on results data entry exercises with the Protocol Registration and Results System (PRS).
  - 1) the basic organizational principles of the PRS results modules, step-by-step data entry instructions for common study designs, Results Review Criteria, and navigating the ClinicalTrials.gov website help resources; 2) an overview of key laws and policies, including the registration and results submission requirements of **FDAAA 801** and its implementing regulations (**42 CFR Part 11**).
- **Who should attend:** personnel responsible for providing ClinicalTrials.gov training and support to others at their academic institution/organization.
ClinicalTrials.gov: Hot Off the PRS!

- Provides timely updates for submitters & PRS users
- Proactive communication
- Other ways to stay informed: What’s New - ClinicalTrials.gov & PRS
- Sign up: https://bit.ly/33qcZBb
Message to ClinicalTrials.gov Staff

Before sending a message to ClinicalTrials.gov, try the following alternatives:

- Check the Frequently Asked Questions page for answers to common inquiries to ClinicalTrials.gov.
- Contact your organization's PRS Administrator for assistance.

* Your Email Address: chennr@ored.rutgers.edu

* Message:

Send  Cancel

* Required fields

Contact ClinicalTrials.gov PRS
Objectives:

- Understanding and applying the requirements;
- Identifying best practices in managing the requirements;
- Developing tools to assist both regulatory support and investigators in meeting the requirements;
- Serving as a communication forum to support academia in meeting clinical trials registration/reporting requirements.
This group focuses on the requirements for clinical trials registration and results reporting that affect US academic health centers.

**Examples of our work:**

- Template presentation slides
- Template questions to identify Applicable Clinical Trials and trials triggering NIH policy (in eIRB application)
- Administration and oversight benchmark survey
- Guidance: manage relocation of the Responsible Party
- Sample job descriptions
- Manual of considerations for protocol redaction prior to posting
- Forum for feedback to ClinicalTrials.gov staff at NIH

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“Medical advances would not be possible without participants in clinical trials,” said NIH Director Francis S. Collins, M.D., Ph.D. “We owe it to every participant and the public at large to support the maximal use of this knowledge for the greatest benefit to human health. This important commitment from researchers to research participants must always be upheld.”
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