

ClinicalTrials.gov PRS – How to Register and Maintain a Record



IRB Compliance Program
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Overview



- Purpose
- Rules and Regulations
- PRS and IRB
- Record Owner vs Responsible Party
- Registration
- Creating a Record
- Review
- Updating a Record
- Questions



Purpose



Trial Registry Purposes for Various Groups

Registry Purpose	Group That Benefits
Fulfill ethical obligations to participants and the research community	Patients, the general public, the research community
Provide information to potential participants and referring clinicians	Patients, clinicians
Reduce publication bias	Users of the medical literature
Help editors and others understand the context of study results	Journal editors, users of the medical literature
Promote more efficient allocation of research funds	Granting agencies, the research community
Help institutional review boards (IRBs) determine the appropriateness of a research study	IRBs, ethicists

Source: Zarin DA, Keselman A. Registering a clinical trial in ClinicalTrials.gov. *Chest*. 2007;131(3):909-12. [Full Text]

Results Database Purposes for Various Groups

Results Database Purpose	Group That Benefits
Provide a public record of basic study results in a standardized format	Researchers, journal editors, IRBs, ethicists
Promote the fulfillment of ethical obligations to participants and the overall contribution of research results to medical knowledge	Patients, the general public, the research community
Reduce publication and outcome reporting biases	Users of the medical literature
Facilitate systematic reviews and other analyses of the research literature	Researchers, policymakers

Source: Tse T, Williams RJ, Zarin DA. Reporting "basic results" in ClinicalTrials.gov. *Chest*. 2009;136(1):295-303. [Full Text]

Rules and Regulations



- Federal Regulations

- FDAMA, FDAAA 801, 42 CFR 11

IT'S THE LAW!!

Penalties –

- Fines of up to \$11,383/day
- Withholding of funding to the PI and the institution
- Potential criminal penalties

- NIH regulations

- Revised definition of a clinical trial (includes behavioral interventions)
- Required for all NIH-funded clinical trials

- International Committee of Medical Journal Editors (ICMJE)

- Similar to NIH definition.
- Must register prior to enrolling the first subject
- Must include IPD (Individual Participant Data) sharing statement

Protocol Registration and Results System (PRS) and IRB



- register.clinicaltrials.gov
- Online system for entering data to be published on the public site
- PRS training
- IRB reviews
- hso.research.uiowa.edu

ClinicalTrials.gov PRS
Protocol Registration and Results System

Record Owner vs Responsible Party



Record Owner – Person responsible for entering data in record

- Not legally responsible for the content of the record





Responsible Party (Sponsor) – Person or entity initiating the clinical trial and responsible for the contents of the ClinicalTrials.gov record

- Is required by law to create, maintain, and monitor from beginning to end
- Significant penalties if found in non-compliance

Record Owner Responsibilities



- You are responsible for maintaining the study records associated with your account
- When you enter information about the study, please ensure the information is correct, readily understood by the public, and updated in a timely manner
- Only one owner can be assigned to a study record, but the owner can also allow other users to edit the study record
- Use the Access List

Record Owner:	Test User 	Access List:	 Edit
Last Updated:	12/17/2014 14:08 by Test User 	Upload:	Allowed Edit
Initial Release:	[Not yet released]	PRS Review:	[Not yet released]
Results Expected:	January 2015 	Public Site:	[Not yet registered]

Responsible Party Responsibilities



- Responsible for 'Approving' and 'Releasing' the record
- Assure that deadlines are met
- Verify that content is complete and accurate
- May also be the Record Owner

Registration Information



- Description of study
 - Study type, Phase, Design, Outcome measures
- Recruitment information
 - Eligibility criteria, locations, recruitment status
- Administrative and other information
 - Key dates and contact information
- Helpful links to add
 - MEDLINE publications, consumer health information, FDA information

Creating a Record



- Email PRS adminster to create an account ct-gov@uiowa.edu
- Login
 - Organization: uiowa
 - Username: hawkid
 - Password: you set, but PRS admin can reset, if needed
- Help and User Guides

The screenshot shows the ClinicalTrials.gov interface. A red circle highlights the "New Record" link in the "Quick Links" section. Another red circle highlights the "Records" dropdown menu in the top navigation bar. A third red circle highlights the "Open" link in the first row of the "Record List" table.

Quick Links

- [New Record](#)
- [Quick Start Guide](#)
- [Problem Resolution Guide](#)

Records Accounts Help

Record List

Showing: 6 records [Show/Hide Columns](#)

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Problems
Open	Protocol123		A 24-Week Double-Blind Trial of Remuverol in Adults With Condition A	In Progress	05/21/2015 14:26	<ul style="list-style-type: none">• Entry Not Completed• Never Released

Getting Started



- The 'Unique Protocol ID' must list the HawkIRB number (digits only)
- Brief title – Layman's terms

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:

* Brief Title:

[Special Characters](#)

Acronym:

If specified, will be included at end of Brief Title in parentheses.

* ‡ Study Type:

☐ Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol

☐ Observational participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care

☐ Patient Registry [\[About Patient Registries\]](#)

☐ Expanded Access [\[About Expanded Access Records\]](#)

[Continue](#) [Cancel](#)

* Required by ClinicalTrials.gov

‡ = FDAAA Required to comply with US FDA Amendments Act

(‡) = (FDAAA) May be required to comply with US FDA Amendments Act

IRB Board Approval



- Contacts should list research investigators, not IRB or administrative contacts unrelated to the trial
- University of Iowa IRB 01, irb@uiowa.edu, 319-335-6564

[Help](#) [Definitions](#)

(*) FDA Regulated Intervention?:	--Select--	Does this trial involve a drug, biologic or device subject to US Food and Drug Administration (FDA) regulations?
(*) IND/IDE Protocol?: (Not public)	--Select--	FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?
* Board Approval:	Status: --Select--	
* Board Name:	<input type="text"/>	
* Board Affiliation:	<input type="text"/>	
* Board Contact: (Not public)	Business Phone: <input type="text"/> Extension: <input type="text"/> Business Email: <input type="text"/> Business Address: <input type="text"/>	
Data Monitoring Committee?:	--Select--	
* Oversight Authorities:	<input type="text"/> x Delete	
+ Add Oversight Authority List of oversight authorities		
Format (in English) as Country: Organization Name		
Examples: United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medicinal Devices		

Sponsor/Collaborators



- The Sponsor/Collaborators section must list 'Sponsor-Investigator' as the responsible party type, and the PI's name should be selected from the drop down menu

* Responsible Party:	<div>Sponsor-investigator</div> <div>Select Sponsor unless the Investigator has been designated as Responsible Party per FDAAA.</div> <div>For Principal Investigator or Sponsor-Investigator only, provide:</div> <div>Investigator Name [Username]: <div>--Select--</div><div>Select the investigator's PRS account.</div><div>The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.</div><div>Investigator not in list? Incorrect name format?</div><div>Investigator Official Title: <input type="text"/></div><div>Investigator Affiliation: <input type="text"/></div></div>
* Sponsor:	<div><input type="text"/></div> <div>Primary organization conducting study and associated data analysis (not necessarily a funding source).</div>
Collaborators:	<div><div><input type="text"/></div><div>x Delete</div></div> <div><div>+ Add Collaborator</div><div>Organization(s) providing support: funding, design, implementation, data analysis or reporting. Enter only the organization name.</div></div>

Study Description/Status



- Brief Title and Summary should be in lay language
- Overall Recruiting Status and Recruiting Status in 'Contacts/Locations' must match
- Dates are needed for Study Start Date, and Primary and Study Completion Dates
- Change the Verification Date to the current month and year (this updates the record)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record List > Record Summary > Protocol Section > Study Description

D: 1234567 ABC Study

Edit Study Description

[Help](#) [Definitions](#)

* ‡ Brief Summary:

[Special Characters](#)

Detailed Description:

Edit Study Status

[Help](#) [Definitions](#)

* ‡ Record Verification Date: Year:

* ‡ Overall Recruitment Status:
Tip: Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

* ‡ Study Start Date: Year:

* ‡ Primary Completion Date: Year: Type:
Final data collection date for primary outcome measure.

Study Completion Date: Year: Type:
Final data collection date for study.

* Required by ClinicalTrials.gov
‡ = FDAAA Required to comply with US FDA Amendments Act
(‡) = (FDAAA) May be required to comply with US FDA Amendments Act

Outcome Measures



Outcome measure information: Please be as specific as possible.


- **Title:** include the name of the specific measure. Avoid using verbs, that is, do not put "To determine..."
- **Time Frame:** must have a time point at which the outcome is assessed for the specific metric used (hours, days, weeks, years) Hint: specify which study day it is measured - do not use "until the end of study or death"
- **Description:** describes what will be measured, not why it is measured. If the outcome measure is a questionnaire or scale, provide the range and what low or high scores mean
- **Safety Issue:**
Is this outcome measure assessing a safety issue?

A screenshot of a web form titled "Edit Outcome Measures". The form has two tabs: "Help" and "Definitions". Under the "Definitions" tab, there is a section for "Primary Outcome Measure" labeled "Outcome 1". This section contains fields for "Title", "Time Frame", and "Description", each with a text input box. There is also a "Safety Issue?" dropdown menu with "--Select--" as the current selection. A "Delete Outcome" button is located to the right of the "Safety Issue?" dropdown. Below the "Primary Outcome Measure" section, there are three sections for "Secondary Outcome Measures", "Other Pre-specified Outcomes", and "Add Other Outcome", each with an "Add" button.

Outcome Measure Example 1

Edit Outcome Measures


[Help](#) [Definitions](#)


*  Primary Outcome Measure: *Outcome 1*


* Title: Nausea

* Time Frame: During scheduled treatment period

Description: Nausea Scale

 Safety Issue? No

 Delete Outcome


 Add Primary Outcome

Outcome Measure Example 2

Edit Outcome Measures

[Help](#) [Definitions](#)

* ‡ Primary Outcome Measure:



Outcome 1

* Title:

* Time Frame:

Description:

(‡) Safety Issue?

Arms and Interventions

- Arms = Rows
- Interventions = Columns
- Examples of different study designs can be found on [ClinicalTrials.gov](https://clinicaltrials.gov) and PRS

Arms and Interventions

[Protocol Section](#) [Help](#) [Definitions](#)

[Edit](#) **Arms**

Arm: Experimental: Acetaminophen & Tramadol
Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth every 6 hours for 7 days.

Arm: Active Comparator: Acetaminophen & Placebo
Acetaminophen 325 mg tablet and Placebo (for Tramadol) 50 mg tablet by mouth every 6 hours for 7 days.

[Edit](#) **Interventions**

Intervention: Drug: Acetaminophen
Other Names:
Tylenol
Anacin-3
NOTE: Intervention Description: data not entered.

Intervention: Drug: Tramadol
Other Names:
Ultram
Rybix
NOTE: Intervention Description: data not entered.

Intervention: Drug: Placebo (for Tramadol)
Sugar pill manufactured to mimic Tramadol 50 mg tablet.
NOTE: Intervention Other Names have not been specified

[Edit](#) **Cross-Reference**

Arms	Interventions		
	Drug: Acetaminophen	Drug: Tramadol	Drug: Placebo (for Tramadol)
Experimental: Acetaminophen & Tramadol Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth every 6 hours for 7 days.	✓	✓	
Active Comparator: Acetaminophen & Placebo Acetaminophen 325 mg tablet and Placebo (for Tramadol) 50 mg tablet by mouth every 6 hours for 7 days.	✓		✓

✓ - Intervention is administered to patients in this Arm.

Central Contacts/Locations



- List information from the research team, not the IRB
- Information can be copied from records, or manually entered
- Locations should list all study sites involved in research, including data analysis

[Edit](#) **Overall Contacts**

Central Contact: John Smith, RN 123-456-7890 john.smith@xyz.com
Central Contact Backup: Sue Jones, RN 123-456-7890 sue.jones@xyz.com
Overall Study Officials: Principal Investigator Tom Jones, MD XYZ Medical Center

[Copy locations...](#) from a master list, extracted from this organization's records.

United States, New York

[Edit](#) **Location**

XYZ Medical Center
New York, New York, United States, 12345
Contact: Tom Jones, MD [x Delete Location](#)

[+ Add Location](#)

Before Submitting a record



Please ensure you have thoroughly reviewed your study record...

- All fields should be completely filled out and in lay language (where possible)
- All **red** errors must be corrected
- Any misspelled words should be corrected (Use Spelling Tool)
- Acronyms and abbreviations spelled out

A screenshot of the ClinicalTrials.gov PRS (Protocol Registration and Results System) Record Summary page. The page shows the record status as "In Progress" and lists various details such as Record Owner, Last Update, Initial Release, Last Release, Access List, Upload, PRS Review, Public Site, and FDAAA. A red circle highlights the "Spelling" link in the bottom left corner of the page.

ClinicalTrials.gov PRS
Protocol Registration and Results System

[Home](#) > Record Summary

D: 20160211 Candy and Games for Awesome People

Record Summary

[Home](#) [Help](#)

Record Status

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

Next Step: Finish Results section [Entry Complete](#)

Record Owner: bbrotzma
Last Update: 04/25/2017 15:26 by bbrotzma
Initial Release: 02/03/2017
Last Release: 02/03/2017 [Receipt \(PDF\)](#)

Access List: [Edit](#)
Upload: Allowed [Edit](#)
PRS Review: [Review History](#)
Public Site: [Not yet registered]
FDAAA: ACT

[Spelling](#) [Preview](#) [Draft Receipt \(PDF\)](#) [RTF](#) [Download XML](#) [Admin Only: Copy Protocol](#) [Change Owner](#)

Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: 20160211

Approve AND Release



Complete: The person updating or owner of the record will click on "Complete" to indicate that the study is ready for the "Approve" and "Release" actions

Approve and Release: The Responsible Party (PI, if Sponsor-Investigator) of the study needs to click on "Approve" and "Release" for the study to go through PRS review and be published on ClinicalTrials.gov website

Record Summary

[Record List](#) [Help](#)

Record Status

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

Next Step: Confirm data entry complete **Entry Complete** ?

Record Owner:	Test User	Access List:	
Last Updated:	12/08/2014 10:04 by Test User	Upload:	Allowed
Initial Release:	[Not yet released]	PRS Review:	[Not yet released]
Results Expected:	January 2018	Public Site:	[Not yet registered]

PRS Review



ClinicalTrials.gov does a manual review

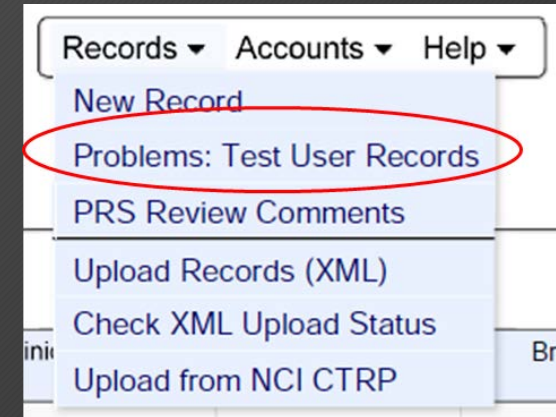
- If there are QA issues, the record owner and RP will receive notification from ClinicalTrials.gov with comments
- The study will be reset to "In Progress"
- Study Owner/RP will correct the issues and re-release it
- If there are no QA issues, the study is assigned an NCT number and published on the "public" side of the database
- This process takes about 2-5 business days

Check the Record for Problems



PRS System identifies current 'Problem Records'

- Records that have not been marked as completed.
- Active studies that have not been updated in the past 6 months
- Records missing one or more data elements required by FDAAA, such as: Responsible Party, Study Start Date, Primary Completion Date and Primary Outcome Measure
- Records that appear to be overdue for registration of results per FDAAA



General Updating Tips



- Complete all fields
- Use **spelling tool** for spelling errors
- Spell out acronyms and abbreviations
- Use the EDIT links to make changes or “Edit All” link at top
- Check for errors and warnings
- Check for notes (optional to address)

[Edit](#) **Sponsor/Collaborators**

Sponsor:
Responsible Party:
Collaborators:

Information is required

[Edit](#) **Oversight**

FDA Regulated?:
⚠ WARNING: FDA Regulated Intervention? has not been entered.
❌ ERROR: All Section 801 clinical trials are FDA regulated.

Applicable Trial?: Section 801 Clinical Trial? Yes
Delayed Posting? No [Only for trials of uncleared devices or unapproved

IND/IDE Protocol?:
⚠ WARNING: IND Protocol? has not been entered.

Review Board: Approval Status: Approval Number: 12/01/2014
Board Name:
Board Affiliation:
Phone: Email:
⚠ WARNING: Approval Status has not been entered.

Data Monitoring?:
💡 NOTE: Data Monitoring Committee?: data not entered.

Oversight Authorities:
⚠ ALERT: Oversight Authorities not entered.

[Edit](#) **Study Description**

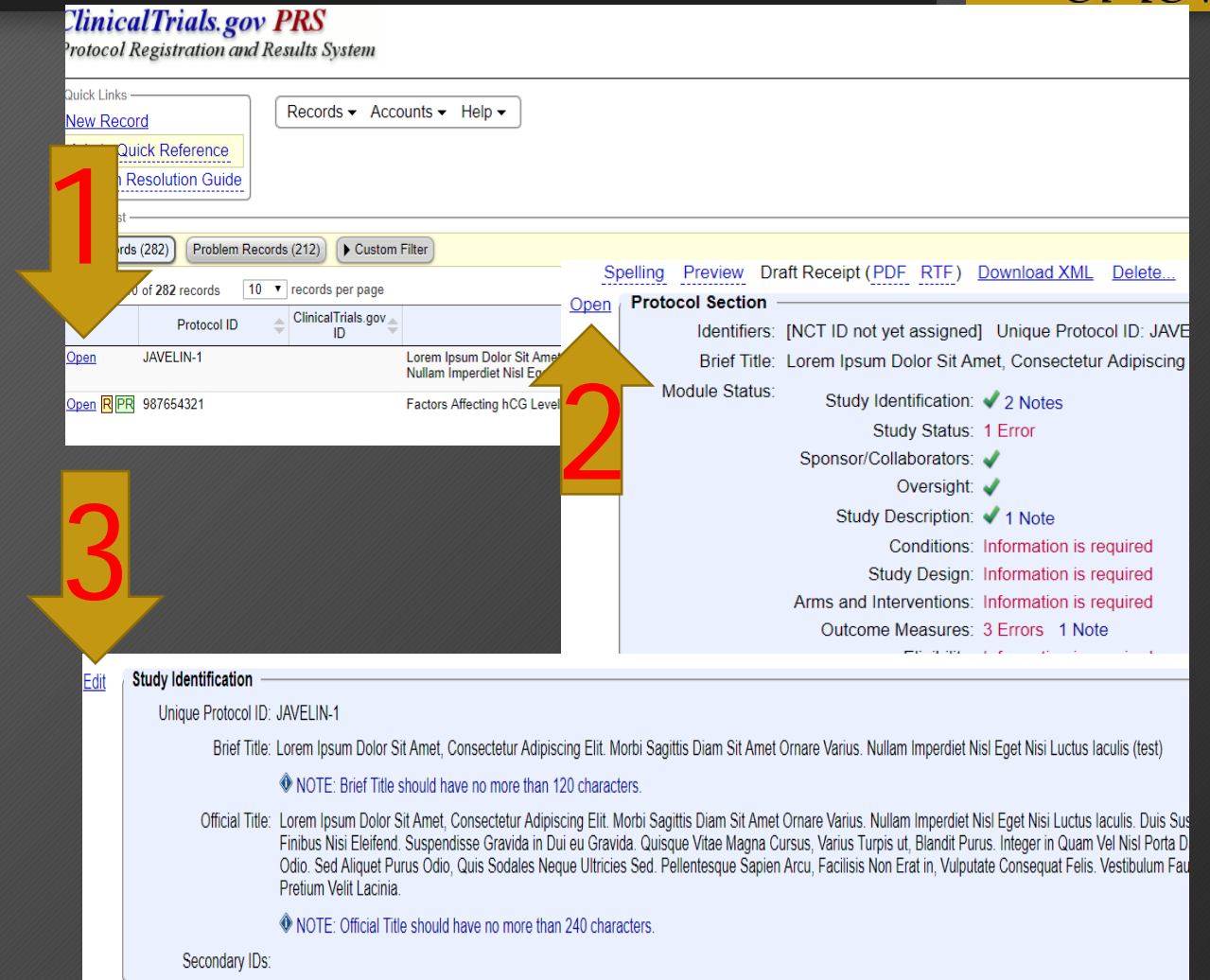
Brief Summary: The purpose of this study is to assess the safety and efficacy of Ren

Detailed Description:
💡 NOTE: Detailed Description: data not entered.

Updating Your Record

1. Click on "Open" next to the record
2. Click on "Open" next to the Protocol Section
3. Make appropriate changes by clicking on "Edit" along the side in the study record

- If no changes have occurred in the year, update the Record Verification Date
- Click on the "Save" button at the bottom of the page
- Be sure to click on "Complete" when finished updating
- Know who is responsible for "Approval" and "Release"



The screenshot displays the ClinicalTrials.gov PRS (Protocol Registration and Results System) interface. It shows a list of records with columns for Protocol ID, ClinicalTrials.gov ID, and a brief title. A table lists records, including JAVELIN-1 and 987654321. A red arrow labeled '1' points to the 'Open' link next to the record. A second red arrow labeled '2' points to the 'Open' link next to the 'Protocol Section' for the selected record. A third red arrow labeled '3' points to the 'Edit' link at the bottom of the page. The right side of the interface shows the 'Protocol Section' details, including Identifiers, Brief Title, Module Status, and Study Identification. The 'Study Identification' section shows the Unique Protocol ID (JAVELIN-1), Brief Title, Official Title, and Secondary IDs, along with notes about character limits.

What Else Do We Need to Know



- Results
- Training
- Departmental liaisons
- hso.research.uiowa.edu

Summary



- Fill out Registration ("Create" a record)
- Actions:
 - In Progress: Fields to be completed
 - Entry Completed: Ready for Approval and Release
 - Approved/Released:
 - RP is sole party that can "Approve & Release"
- ClinicalTrials.gov PRS Review
- NCT number assigned
- Posted on ClinicalTrials.gov 2-5 business days

Questions?



Contact Information



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