

How to Withdraw or Terminate a Record from ClinicalTrials.gov

Enter ClinicalTrials.gov through Submit Studies

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

[Find Studies](#) [About Clinical Studies](#) [Submit Studies](#) [Resources](#) [About This Site](#)

ClinicalTrials.gov currently lists 187,388 studies with locations in all 50 states and in 188 countries.

Text Size ▾

Search for Studies

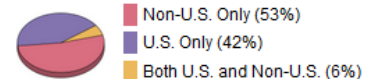
Example: "Heart attack" AND "Los Angeles"

[Advanced Search](#) | [See Studies by Topic](#)
[See Studies on a Map](#)

Search Help

- [How to search](#)
- [How to find results of studies](#)
- [How to read a study record](#)

Locations of Recruiting Studies



Total N = 35,023 studies
Data as of March 31, 2015

- [See more trends, charts, and maps](#)

Learn More

- [ClinicalTrials.gov Online Training](#)
- [Glossary of common site terms](#)

[For the Press](#)

[Using our RSS Feeds](#)

For Patients & Families

- [How to find studies](#)
- [See studies by topic](#)
- [Learn about clinical studies](#)
- [Learn more...](#)

For Researchers

- [How to submit studies](#)
- [Download content for analysis](#)
- [About the results database](#)
- [Learn more...](#)

For Study Record Managers

- [Why register?](#)
- [How to register study records](#)
- [FDAAA 801 Requirements](#)
- [Learn more...](#)

[HOME](#) [RSS FEEDS](#) [SITE MAP](#) [TERMS AND CONDITIONS](#) [DISCLAIMER](#) [CONTACT NLM HELP DESK](#)

Copyright | Privacy | Accessibility | Viewers & Players | Freedom of Information Act | USA.gov
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Choose PRS System

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"

Search for studies:

Search

[Advanced Search](#) | [Help](#) | [Studies by Topic](#) | [Glossary](#)

[Find Studies](#) ▾ | [About Clinical Studies](#) ▾ | [Submit Studies](#) ▾ | [Resources](#) ▾ | [About This Site](#) ▾

[Home](#) > [Submit Studies](#)

Text Size ▾

SUBMIT STUDIES

[Why Should I Register and Submit Results?](#)

[FDAAA 801 Requirements](#)

[How to Apply for an Account](#)

[How to Register Your Study](#)

[How to Edit Your Study Record](#)

[How to Submit Your Results](#)

[Frequently Asked Questions](#)

[Support Materials](#)

[Training Materials](#)

Related Pages

- [Protocol Registration and Results System \(PRS\)](#)

Do you or someone you know want to participate in a clinical study? See [information for patients and families](#).

Submit Studies

ClinicalTrials.gov allows the registration of clinical studies with human subjects that assess biomedical and/or health outcomes and that conform to:

- Any applicable human subject or ethics review regulations (or equivalent)
- Any applicable regulations of the national or regional health authority (or equivalent)

New to registering studies? See [For Study Record Managers](#).

[Why Should I Register and Submit Results?](#)

Learn about the purpose of study registration and results submission. Includes an overview of applicable laws and policies.

[FDAAA 801 Requirements](#)

Learn about Section 801 of the Food and Drug Administration Amendments Act and the basic requirements for registering clinical trials and submitting summary results, including information about the Responsible Party, Applicable Clinical Trials, deadlines, and penalties.

Show them you're human by typing in the day name; hit continue

The screenshot shows the ClinicalTrials.gov website interface. At the top left is the logo "ClinicalTrials.gov" and the text "A service of the U.S. National Institutes of Health". To the right is a search bar with the placeholder text "Example: 'Heart attack' AND 'Los Angeles'", a "Search" button, and links for "Advanced Search", "Help", "Studies by Topic", and "Glossary". Below this is a navigation bar with dropdown menus for "Find Studies", "About Clinical Studies", "Submit Studies", "Resources", and "About This Site". The breadcrumb trail reads "Home > Submit Studies > Go to PRS". On the right side of the breadcrumb trail is a "Text Size" dropdown. A left-hand sidebar titled "SUBMIT STUDIES" contains links such as "Why Should I Register and Submit Results?", "FDAAA 801 Requirements", "How to Apply for an Account", "How to Register Your Study", "How to Edit Your Study Record", "How to Submit Your Results", "Frequently Asked Questions", "Support Materials", and "Training Materials". The main content area is titled "Go to PRS" in red. It contains the text: "Data providers use a Web-based data entry system called the Protocol Registration and Results System (PRS) to register a clinical study or submit results information for a registered study." followed by "You must have a PRS account to register study information on ClinicalTrials.gov." and "If you do not have an account, see [How to Apply for an Account](#)." Below this is a yellow highlighted box with the instruction "To proceed to PRS, enter the day of week exactly as it appears below and continue." and a form field containing "Wednesday" with a "Continue" button. A blue arrow points from the "Wednesday" text in the form field to the word "Wednesday" in the instruction above it. At the bottom right of the yellow box is the text "This page last reviewed in September 2014". At the very bottom of the page are links for "HOME", "RSS FEEDS", "SITE MAP", "TERMS AND CONDITIONS", "DISCLAIMER", and "CONTACT NLM HELP DESK".

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Search for studies:
[Advanced Search](#) | [Help](#) | [Studies by Topic](#) | [Glossary](#)

[Find Studies](#) | [About Clinical Studies](#) | [Submit Studies](#) | [Resources](#) | [About This Site](#)

Home > Submit Studies > Go to PRS Text Size ▾

SUBMIT STUDIES

- [Why Should I Register and Submit Results?](#)
- [FDAAA 801 Requirements](#)
- [How to Apply for an Account](#)
- [How to Register Your Study](#)
- [How to Edit Your Study Record](#)
- [How to Submit Your Results](#)
- [Frequently Asked Questions](#)
- [Support Materials](#)
- [Training Materials](#)

Go to PRS

Data providers use a Web-based data entry system called the Protocol Registration and Results System (PRS) to register a clinical study or submit results information for a registered study.

You must have a PRS account to register study information on ClinicalTrials.gov.

If you do not have an account, see [How to Apply for an Account](#).

To proceed to PRS, enter the day of week exactly as it appears below and continue.

Wednesday

This page last reviewed in September 2014

[^ TO TOP](#)

[For Patients & Families](#) | [For Researchers](#) | [For Study Record Managers](#)

[HOME](#) | [RSS FEEDS](#) | [SITE MAP](#) | [TERMS AND CONDITIONS](#) | [DISCLAIMER](#) | [CONTACT NLM HELP DESK](#)

Login

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 08/31/2015
[Burden Statement](#)

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
[Send email to ClinicalTrials.gov PRS Administration](#)

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

IF you forgot your password, click [Forgot password](#), and the email will come to you with a temporary one almost instantaneously. Don't forget then to change your password later to something you'll remember. One easy option is 5 -6 characters from a password you use a lot followed by "4CT.gov"

Choose your study and open it

IF you need to change your password, do it with Accounts here

ClinicalTrials.gov PRS
Protocol Registration and Results System

[Contact ClinicalTrials.gov PRS](#)
Org: UMichigan User: DWilson [Logout](#)

Email: dlehman@med.umich.edu [\[Update\]](#)

Help us improve: [PRS Survey](#)

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

Records Accounts Help

Record List

Showing: 1-14 of 14 records 25 records per page Show/Hide Columns

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Problems
Open	HUM00091388		Neurocircuit Mechanisms of OCD Across the Lifespan	Entry Completed	02/26/2015 12:25	<ul style="list-style-type: none"> • Ready for Review and Approval • Never Released
Open	U036889	NCT02366611	Pain Control Using Neuromodulation in Patients Undergoing Definitive Chemoradiotherapy for Head and Neck Cancer	Public	02/18/2015 14:35	
Open	Test study for DWilson		Practice Purposes Only	In Progress	01/28/2015 16:08	<ul style="list-style-type: none"> • Entry Not Completed • Never Released • Missing FDAAA Information
Open	HUM00085489	NCT02340663	Nocturnal Mouth Guards, SOVA vs. Standard Acrylic Orthotic; Phase IV (SISU-SOVA)	Public	01/16/2015 23:27	
Open	HUM00041349	NCT01279200	Use of High Cost Monitoring During Letrozole Ovulation Induction	Public	01/05/2015 07:20	
Open	1R01MH093486-01A1	NCT01673087	Stress Biomarkers-Attaching Biological Meaning to Field Friendly Salivary Measures	Public	12/03/2014 11:50	
Open	HUM00068360	NCT01894074	The Effects of an Intensive Lifestyle Intervention on Reproductive Outcomes	Public	12/02/2014 16:10	
Open	HUM00079230	NCT02055794	Promoting Optimal Healing After Laceration Repair Study (PALS)	Public	12/02/2014 08:18	
Open	F029661-00	NCT01554527	Continuous Positive Airway Pressure (CPAP) After Adenotonsillectomy in Children	Public	12/01/2014 11:31	
Open	HUM00053677	NCT01900314	Imaging Biomarkers for TMS Treatment of Depression	Public	10/27/2014 10:36	
Open	HUM00076630		Evaluating Use of Double Up Food Bucks (DUFB) Among Families at an Ypsilanti Community Health Center	In Progress	09/23/2014 10:38	<ul style="list-style-type: none"> • Entry Not Completed • Never Released
Open	1R21AG031951 - 01A1	NCT01046643	Early Menopause Hormone Treatment and Cognition (R21)	Public	05/16/2014 08:45	
Open	2276	NCT00670800	Study of Brain Function in Women With Insulin Resistant Polycystic Ovary Syndrome	Public	05/15/2014 14:33	
Open	HUM00075628	NCT02068703	Sleep Enhancing Tools: Pilot Study	Public	02/19/2014 09:51	<ul style="list-style-type: none"> • Not Recently Updated - Not Recruiting

IF the study was never given an NCT #, then you can choose Delete; it will then ask you to verify on the next screen and you should be done; Otherwise, chose Edit for Protocol section to open study status

The screenshot displays a web interface for managing clinical trial records. At the top, there are navigation links for 'Home' and 'Help'. Below this is a 'Record Status' section with a progress bar showing stages: 'In Progress' (highlighted), 'Entry Completed', 'Approved', 'Released', 'PRS Review', and 'Public'. A 'Next Step' box indicates 'Finish Protocol section' with an 'Entry Complete' button. The record details include: Record Owner: DWilson; Last Updated: 01/28/2015 16:08 by DWilson; Initial Release: [Not yet released]; Results Expected: [Unknown -- unspecified or invalid Primary Completion Date]; Access List: []; Upload: Allowed; PRS Review: [Not yet released]; Public Site: [Not yet registered]. A 'Delete' button is circled in red. Below the record details is the 'Protocol Section' section, which includes an 'Edit' link and a list of module statuses with associated error and warning counts.

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

Record Status

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

Next Step: Finish Protocol section **Entry Complete**

Record Owner: DWilson
Last Updated: 01/28/2015 16:08 by DWilson
Initial Release: [Not yet released]
Results Expected: [Unknown -- unspecified or invalid Primary Completion Date]

Access List: []
Upload: Allowed
PRS Review: [Not yet released]
Public Site: [Not yet registered]

[Spelling](#) [Preview](#) [Draft Receipt \(PDF RTF\)](#) [Download XML](#) **Delete**

[Edit](#) **Protocol Section**

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Test study for DWilson
Brief Title: Practice Purposes Only

Module Status:

- Study Identification: ✓ 2 Notes
- Study Status: 2 Errors 1 Warning 1 Note
- Sponsor/Collaborators: 1 Error
- Oversight: 2 Errors 1 Note
- Study Description: Information is required
- Conditions: Information is required
- Study Design: Information is required
- Arms and Interventions: Information is required
- Outcome Measures: ✓
- Eligibility: Information is required
- Contacts/Locations: Information is required
- References:

Edit Study Status to Change Overall Recruitment Status and Update Record Verification Date

Protocol Section

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#)

[Edit](#) Study Identification

Unique Protocol ID: F029661-00

Brief Title: Continuous Positive Airway Pressure (CPAP) After Adenotonsillectomy in Children

Official Title: Sleep-Disordered Breathing and CPAP After Adenotonsillectomy in Children

Secondary IDs: 1R01HL105999-01A1 [US NIH Grant/Contract Award Number]

[Edit](#) Study Status

Record Verification: December 2014

Overall Status: Recruiting

Study Start: March 2012

Primary Completion: December 2016 [Anticipated]

Study Completion: December 2017 [Anticipated]

[Edit](#) Sponsor/Collaborators

Sponsor: University of Michigan

Responsible Party: Principal Investigator

Investigator: Ronald D. Chervin, M.D., M.S. [rchervin]

Official Title: Professor of Neurology

Affiliation: University of Michigan

Collaborators: National Heart, Lung, and Blood Institute (NHLBI)
Michigan Technological University

Edit Study Status, Record Verification Date

Edit Study Status

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

* ‡ Record Verification Date:	December ▾	Year: 2014	
* ‡ Overall Recruitment Status:	Recruiting ▾ <small>Tip: Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.</small>		
‡ Study Start Date:	March ▾	Year: 2012	
* ‡ Primary Completion Date:	December ▾	Year: 2016	Type: Anticipated ▾ <small>Final data collection date for primary outcome measure.</small>
Study Completion Date:	December ▾	Year: 2017	Type: Anticipated ▾ <small>Final data collection date for study.</small>

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

Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated
Withdrawn: study halted prematurely, prior to enrollment of first participant

DO review the entire record. You can do this with Preview. The RP is legally on the hook for all the contents.

- Don't forget to review record's registration information, and Change Record Verification Date in Protocol section.

The screenshot displays a record management interface. At the top, a 'Record Status' section shows a progress bar with stages: In Progress (selected), Entry Completed, Approved, Released, PRS Review, and Public. Below this, a 'Next Step: Finish Protocol section' is shown with an 'Entry Complete' button. The record details include: Record Owner: DWilson, Last Updated: 01/28/2015 16:08 by DWilson, Initial Release: [Not yet released], Results Expected: [Unknown -- unspecified or invalid Primary Completion Date], Access List, Upload: Allowed, PRS Review: [Not yet released], and Public Site: [Not yet registered]. A navigation bar contains links for Spelling, Preview (circled in red), Draft Receipt (PDF, RTF), Download XML, and Delete... Below this, the 'Protocol Section' is visible, with an 'Edit' link circled in red. The protocol details include: Identifiers: [NCT ID not yet assigned], Unique Protocol ID: Test study for DWilson, Brief Title: Practice Purposes Only, Module Status: Study Identification: 2 Notes, Study Status: 2 Errors 1 Warning 1 Note, Sponsor/Collaborators: 1 Error, Oversight: 2 Errors 1 Note, Study Description: Information is required, Conditions: Information is required, Study Design: Information is required, Arms and Interventions: Information is required, Outcome Measures: 1 Note, Eligibility: Information is required, Contacts/Locations: Information is required, and References.

Return out to Record Summary

Protocol Section

ERROR(S) in Protocol Section. See ERROR or information required messages below.
Additional information may be required per FDA. See WARNING messages below.

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#)

[Edit](#) Study Identification

Unique Protocol ID: Test study for DWilson

Brief Title: Practice Purposes Only

NOTE: A title this short is probably not sufficiently descriptive.

Official Title: Device Sample Trial

NOTE: A title this short is probably not sufficiently descriptive.

Secondary IDs:

[Edit](#) Study Status

Record Verification: January 2015

Overall Status:

ERROR: Overall Status is a required field.

Study Start:

WARNING: Study Start Date has not been entered.

Primary Completion:

ERROR: Primary Completion Date has not been entered.

Study Completion:

NOTE: Study Completion Date has not been entered.

[Edit](#) Sponsor/Collaborators

Click Next Step Entry Complete;
Then if you are the RP,
Click Next step Approve,
and Next Step Release

Record Summary

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

Record Status

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

Next Step: Finish Protocol section **Entry Complete** ?

Record Owner: DWilson

Last Updated: 01/28/2015 16:08 by DWilson

Initial Release: [Not yet released]

Results Expected: [Unknown -- unspecified or invalid Primary Completion Date]

Access List: []

Upload: Allowed

PRS Review: [Not yet released]

Public Site: [Not yet registered]

[Spelling](#) [Preview](#) [Draft Receipt \(PDF RTF\)](#) [Download XML](#) [Delete...](#)

Edit Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Test study for DWilson

Brief Title: Practice Purposes Only

Module Status: Study Identification: ✔ 2 Notes

Study Status: 2 Errors 1 Warning 1 Note

Sponsor/Collaborators: 1 Error

Oversight: 2 Errors 1 Note

At that point you should be able to download a PDF “receipt” to say you completed the submission

- DO stay aware of emails from their system.
- If the trial’s information doesn’t pass their Quality Assurance, it will bump back to “In Progress”. You, or anyone with access to the NCT record, can see if that has happened, or if they are still reviewing it. It’s generally good to check in 3 days for protocol/registration changes, in 2 weeks or so for results reporting.