

Sharing Access to A Study Team Member in ClinicalTrials.gov

Before you start

- Both the record creator (owner) and the study team member need ClinicalTrials.gov accounts. IF the study team member does not have an account, s/he should create one following the tip sheet linked [here](#) (Level 2 password required, or email UMMS-RegAffairs@med.umich.edu)

Enter ClinicalTrials.gov through Submit Studies (clinicaltrials.gov)

https://clinicaltrials.gov

Most Visited Getting Started MCommunity ITS eResearch Wolverine Access Compliance: Universit... U-M Medical School I...

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 **192,475 studies** with locations in all 50 States and in **189 countries**. Text Size ▾

Search for Studies

Example: "Heart attack" AND "Los Angeles"

Search Help

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

Locations of Recruiting Studies

Location	Percentage
Non-U.S. Only	53%
U.S. Only	41%
Both U.S. and Non-U.S.	6%

Total N = 35,662 studies
(Data as of June 14, 2015)

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

For Patients and 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 your study](#)
- [FDAAA 801 requirements](#)
- [Learn more...](#)

Learn More

- [Tutorials for using ClinicalTrials.gov](#)
- [Glossary of common site terms](#)
- [For the Press](#)
- [Using our RSS Feeds](#)

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

Choose PRS System

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

Example: "Heart attack" AND "Los Angeles"
Search for studies:
[Advanced Search](#) | [Help](#) | [Studies by Topic](#) | [Glossary](#)

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

Home > [Submit Studies](#) Text Size ▾

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.

Related Pages

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

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" and contains the following 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. 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](#)." 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." followed by the word "Wednesday" in a text input field. The word "Wednesday" is highlighted in blue, and a blue arrow points from the "Wednesday" link in the sidebar to this input field. Below the input field is a "Continue" button. At the bottom right of the main content area, it says "This page last reviewed in September 2014" and a green "TO TOP" link. The footer contains navigation links for "For Patients & Families", "For Researchers", and "For Study Record Managers", and a row of links: "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; Organization is UMichigan (or UMichiganCC)

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 R	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 R	1R21AG031951 - 01A1	NCT01046643	Early Menopause Hormone Treatment and Cognition (R21)	Public	05/16/2014 08:45	
Open R	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

- Pick the study to which you want to give your team member access. Select Edit.

Record List - Edit

[Home](#) [Download XML](#) [Contact Information](#)

KEY: PR Pending PRS Review R Contains Results DR Has Delayed Results U Last modified via XML Upload NP No longer public

Sort by Protocol ID	ClinicalTrials.gov ID	Sort by Brief Title	Overall Status	Sort by Owner	Responsible Party	Sort by Updater	Sort by Updated	Record Status
Edit 234567						DWilson	10/19/2014 23:05	In Progress
Edit						DWilson	10/07/2014 12:09	In Progress
Edit						DWilson	07/11/2014 10:49	In Progress

- Once you see the study, you'll see the owner and the words Access List. Click on Access List and a pull down menu of everyone in UMichigan's system will open.

ID: [redacted] [redacted] t

Record Summary

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

Record Status

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

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

Record Owner: DWilson	Access List: []
Last Updated: 10/07/2014 12:09 by DWilson	Upload: Allowed
Initial Release: [Not yet released]	PRS Review: [Not yet released]
	Public Site: [Not yet registered]

Step Seven

- Select the person/s to whom you want to give access by checking the box next to their name. Note they are largely alphabetical by first name. Make sure you click Save at the bottom of the page.

ABCdouble Test

Record Access List

Select one or more users from the list below to allow those users to access this record. A user granted access to a record in this manner can perform all of the same actions on the record as if he were the record owner, with the exception of modifying the Record Access List.

Record Owner: DWilson

Current Access List:

- Allow access to:
- ANA BAYLIN (ABAYLIN)
 - Adam Dorfman (ADorfman)
 - Adam Eickmeyer (AEickmeyer)
 - Aditya S. Pandey, MD (APandey)
 - Aidin Pour (APour)
 - Aimee K. Armstrong (AArmstrong)
 - Aine Kelly, MD (AKelly)
 - Alan Baptist (ABaptist)
 - Alexandre DaSilva, DDS, MS (ADaSilva)
 - Alexis V. Nees M.D. (ANees)
 - Alicia Cohen (ACohen)
 - Alison Berent-Spillson (ASpillson)
 - Allison Aiello (AAiello)
 - Alon Weizer (AWeizer)
 - Amanda Dempsey (ADempsey)
 - Amanda Kingsley (AKingsley)
 - Amanda Pennington (APennington)
 - Amir Alexander (AAlexander)
 - Amy E Rothberg (ARothberg)
 - Amy J. Sebitz (ASebitz)

Save

Cancel

Verify Success

You should now see that person's name in your Access List for that record.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record List > Record Summary

Send message to ClinicalTrials.gov PRS
Org: UMichigan User: DWilson **Logout**

ID: 13579 ABCdouble Test [NCT ID not yet assigned]

Record Summary

Record Access List changes:
added EBeene

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

Record Status

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

Next Step: Finish Protocol section

Record Owner: DWilson
Last Updated: 10/07/2014 12:09 by DWilson
Initial Release: [Not yet released]

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

Don't forget to Log out!

Remember Your Responsibilities

- If you are the Responsible Party, you will still have to Approve and Release changes that the study team member makes to the record. Please proofread seriously, as all records in ClinicalTrials.gov are permanently archived and publicly accessible in each version. This is definitely a case of an ounce of prevention being worth a pound of cure.

Questions?

- Contact the Office of Regulatory Affairs.
- UMMS-RegAffairs@med.umich.edu
- [http://msa.med.umich.edu/
regulatory_affairs/research/human/clinical-
trials](http://msa.med.umich.edu/regulatory_affairs/research/human/clinical-trials)
- 734 764-0634