

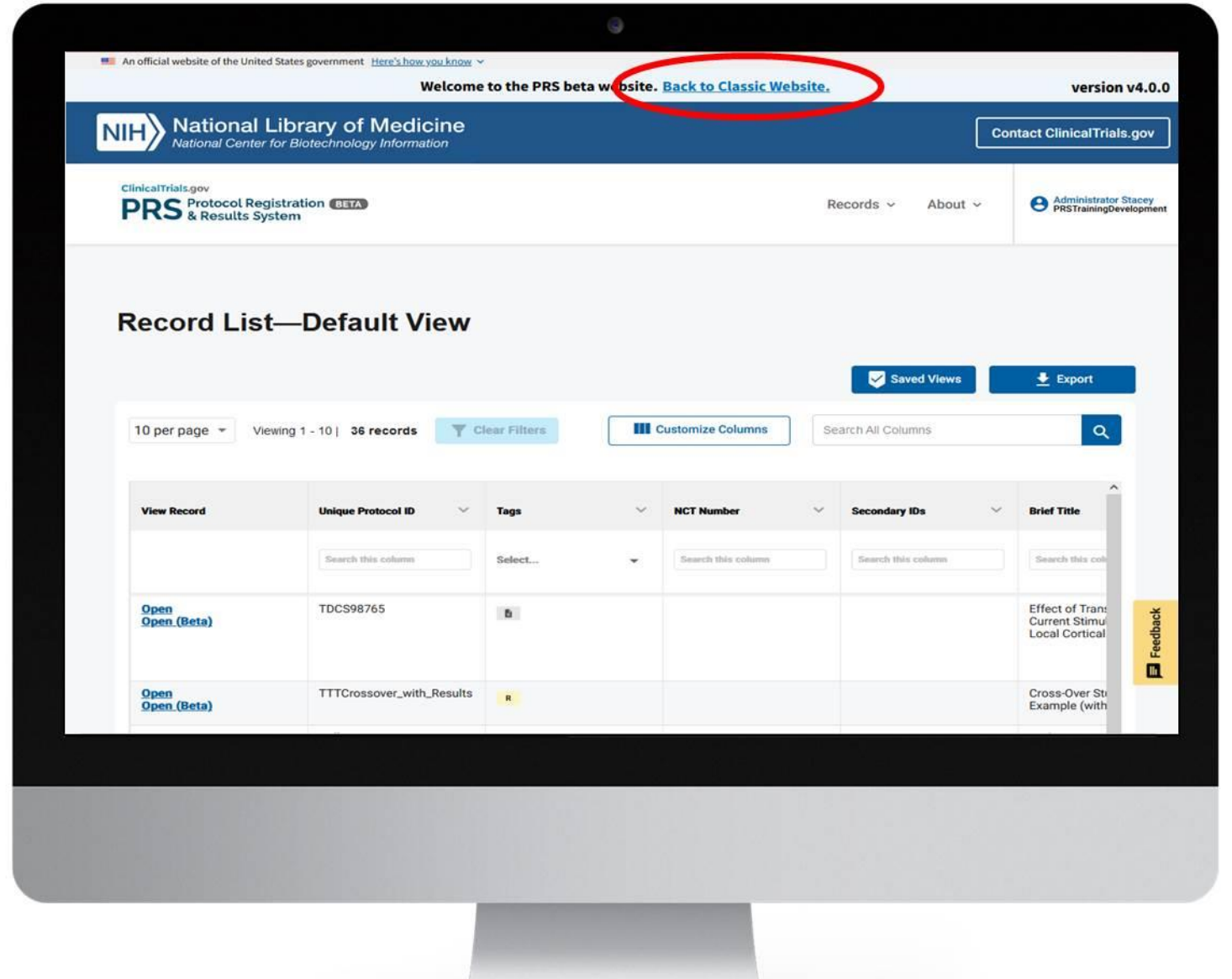
Modernization of the Protocol Registration and Results Database: Development of PRS Beta

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Accessing PRS Beta

Log Into the Classic Site to Access PRS Beta



Access Via PRS Production or PRS Test

PRS Production

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 03/31/2026
[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 a PRS account.
See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.
[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](#) | [HHS Vulnerability Disclosure](#)

PRS Beta resides within the classic version of:

- The PRS production system (left)
- The PRS Test system (right)

PRS Test

ClinicalTrials.gov PRS
Protocol Registration and Results System

PRS TEST SYSTEM

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 03/31/2026
[Burden Statement](#)

This is a test version of the Protocol Registration and Results System (PRS). Creating or modifying records in this system will have no effect on the production (operational) PRS or ClinicalTrials.gov. Data on this system is occasionally replaced entirely with a copy of the latest data from the production system. [Data last copied from production PRS: 4, 2016] If you had an account on the production PRS at that time, the same login information should work on this system. **WARNING: Do not use the PRS Test System to prepare data for the production PRS.** This system sometimes runs a software release that is not fully compatible with that of the production system. If you notice problems or have questions while using this test system, please contact us using the Contact ClinicalTrials.gov PRS link (in the upper right corner, after logging in).

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

Username:

Password:

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for a PRS account.
See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.
[Send email to ClinicalTrials.gov PRS Administration](#).

The PRS Test system is a playground version of the PRS production system.

PRS Beta Deployment

Records created in PRS Beta and updates made to existing records in PRS Beta can be accessed in the classic environment (PRS or PRS Test).

PRS Beta deployed
to PRS Test



PRS Beta deployed
to the PRS
production system

Updates to PRS Beta are first released in PRS Test because:

- PRS Test provides a stable test environment for all types of users; all users with a PRS Test account can provide feedback.
- Testing in PRS Test allows detection of issues (bugs) that can be fixed before PRS Beta is deployed to the production system.

Once major updates to PRS Beta have been tested in PRS Test and necessary fixes have been made, PRS Beta is released to the PRS production system.

Users of the production system can provide feedback about their experience and about any bugs that might not have been detected previously.

PRS Beta: Record List

PRS Beta Record List Page: Top Menu

Welcome to the PRS beta website. [Back to Classic Website.](#) version v4.0.0

NIH National Library of Medicine
National Center for Biotechnology Information

Contact ClinicalTrials.gov

ClinicalTrials.gov
PRS Protocol Registration & Results System **BETA**

Records ▾ About ▲

Administrator Stacey
PRSTrainingDevelopment

User: AdminStacey
Admin.Stacey@prstrainingdev.com

My Profile

My Administrators

Log Out

About PRS Beta

Release Notes

Record List—Default View

10 per page ▾ Viewing 1 - 10 | 36 records [Clear Filters](#) [Customize Columns](#) Search All Columns 🔍

View Record	Unique Protocol ID ▾	Tags ▾	NCT Number ▾	Secondary IDs ▾	Brief Title
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PRS Beta Record List Page: Customizing Views

Record List

Customize Column Display

Select or deselect columns to view in the record list table. Click and drag the labels or use the arrows to reorder the columns in the table.

Select All

01 Group ⓘ

02 Unique Protocol ID ⓘ

03 Tags ⓘ

04 NCT Number ⓘ

05 ClinicalTrials.gov ID ⓘ

24 Last Modifier ⓘ

25 Record Verification Date ⓘ

26 Study Start Date ⓘ

27 Intervention Types ⓘ

28 IND/IDE ⓘ

Selected Columns: (10)

10 per page

[View Record](#)

[Open](#)
[Open \(Beta\)](#)

[Open](#)
[Open \(Beta\)](#)

[Export](#)

Brief Title

Effect of Trans
Current Stimul
Local Cortical

[Feedback](#)

Cross-Over Str
Example (with

[Cancel](#) [Save](#)

Check or uncheck boxes to add or remove columns from view

Drag and drop a column to change its position or use up and down arrows


Hover over an information icon to learn more about the column


PRS Beta Record List Page: Additional Features

Record List—Default View

Export the current view or all columns


Save a customized view or select a different view (e.g., Planning View)

 Saved Views

 Export

10 per page ▾

Viewing 1 - 10 | 36 records

 Clear Filters

 Customize Columns



Search All Columns



Sort columns

Filter columns

Open in classic or PRS Beta

View Record	Unique Protocol ID	Tags	NCT Number	Secondary IDs	Brief Title
Open Open (Beta)	TDCS98765				Effect of Trans Current Stimul Local Cortical
Open Open (Beta)	TTTCrossover_with_Results				Cross-Over Str Example (with

In addition, click on links within rows to:

- Email staff
- Obtain more information about certain fields (e.g., FDAAA status)

 Feedback

Enhancements

From the PRS Beta Record List, users can now:

- Reorder columns
- Access all available columns from a single location
- Save views
- Filter data in **all** columns, not just a select few
- Send emails directly from the Record List

PRS Beta: Protocol Section

Creating a New Record

Review tips for creating a record in easier to understand language

Review a brief description; expand Additional Information and Data Element Definition accordions to obtain more information

Click on information icons to access additional information about each data element

Directly access the relevant Data Element Definition; no need to search through all definitions for the module

Organization's Unique Protocol ID *

Enter the unique string of characters used by the sponsor to identify this study record.

Additional Information

The Unique Protocol ID:

- Can be the study's ethics committee approval number, grant number, institutional review board number, or any similar unique identifier
- Can be used for only one record in the organization's PRS account

Data Element Definition

Unique Protocol Identification Number *

Definition: Any unique identifier assigned to the protocol by the sponsor.
Limit: 30 characters.
[Link to DED](#)

Feedback

Organization's Unique Protocol ID *

30 characters allowed

Review these tips before creating a record. [Cancel record creation](#) **Definitions**

1. Use the PRS account of the study sponsor.
 - a. Verify that the study sponsor (the initiator of the trial) has a PRS account.
 - b. For help, see: [How to Apply for a PRS Account](#)
2. Only the [responsible party](#) can register the study.
 - a. You can create the record even if you are not the responsible party, but a responsible party has been entered.
 - b. For help, see: [How do I determine who is the responsible party for a study?](#)
3. The study should be registered only once.
 - a. A study with multiple collaborators or sites should be registered only once.
 - b. All study sites should be listed in a single study record.

* Required
* **S** Required if Study Start Date is on or after January 1, 2020
† Conditionally required

Creating a New Record – Secondary IDs

Classic PRS Edit Study Identification

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

* Organization's Unique Protocol ID:

* Brief Title:

[*] Acronym: (if any)
If specified, will be included at end of Brief Title in parentheses.

* § Official Title:

[*] Secondary IDs: (if any)

Add one at a time

Examples:
R01DA013131,
U01HL066582,
5R01HL123451-01A2
Tip: Look up the grant/contract number using [NIH RePORTER](#).

Set ID Type ✕ Delete

+ Add Secondary ID

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Secondary IDs [i]

These should be provided if they exist. If the study is funded by a U.S. Federal Government agency, the grant or contract number must be included as a Secondary ID.

Secondary ID Type

- US NIH Grant/Contract Award Number
- Other Grant/Funding Number
- Registry Identifier
- EudraCT Number
- Other Identifier

US NIH Grant/Contract Award Number

R01DA013131, U01HL066582, 5R01HL123451-01A2
Tip: Look up the grant/contract award number using the [NIH RePORTER](#).

30 characters allowed

+ Add US NIH Grant/Contract award number [Remove](#)

Other Grant/Funding Number **Grantor or Funder Organization**

30 characters allowed 119 characters allowed

+ Add Other Grant/Funding Number [Remove](#)

[Cancel record creation](#)

Completing the Protocol Section

Access important notifications at the top of each page, as well as details that identify the current study record

Click on the Record Summary tab to proceed with reviewing and submitting the record for review

Use side panel navigation to enter data for remaining modules in any order

The screenshot displays the ClinicalTrials.gov PRS Beta interface. At the top, there is a navigation bar with the logo, 'Records', and 'About' menus. A blue notice banner at the top states: 'Notice: PRS Beta is under development and is often updated. You may find differences in your study record between this site and the classic PRS. Use the feedback button to report any issues you encounter. Use the classic PRS to review, complete, and submit your study protocol.' Below the notice is a 'Record List' table with columns for 'Brief Title', 'NCT Number', and 'Unique Protocol Id'. The first row is highlighted with a red border: 'Effect of Transcranial Direct Current Stimulation on Local Cortical Processing', 'NCT ID not yet assigned', and 'TDCS98765'. Below the table are four tabs: 'Record Summary', 'Protocol', 'Study Documents', and 'Results'. The 'Record Summary' tab is active, showing a 'Protocol Summary' section with a left-hand navigation menu. The menu items are: 'Study Identification', 'Study Status', 'Sponsors and Collaborators', 'Oversight', 'Study Description', 'Conditions', 'Study Design', and 'Arms and Interventions'. The main content area shows the 'Protocol Summary' details for the selected record, including 'Study Identification', 'Organization's Unique Protocol ID' (TDCS98765), 'Brief Title' (Effect of Transcranial Direct Current Stimulation on Local Cortical Processing), 'Acronym', 'Study Type' (Interventional), and 'Official Title'. A 'Feedback' button is located in the bottom right corner.

Enhancements

- More immediate access to information about data elements
 - Essential information is provided on screen
 - Further information is provided in a pull-out drawer
 - Individual components can be expanded or collapsed for ease of reading
 - The relevant Data Element Definition is directly available
 - Information is easier to understand
- Improved navigation:
 - Ability to add information to modules in any order
 - Fewer clicks to include information, e.g., Secondary IDs
- Modernized look and feel

PRS Beta: Record Summary Page

People and Actions Menus

The screenshot displays the 'Record List' page for a clinical trial. A 'Download Record' dialog box is open, showing options for file type (PDF, RTF, XML) and validation status (With/Without validations). Annotations highlight the 'Search for users' field, the 'Email users' button, and the 'Download' button. The background shows the 'Record Actions' menu with options like 'XML Upload disabled', 'Download Record', and 'Delete Record'. A 'Feedback' button is visible in the bottom right corner.

Download Record

File Type

- PDF
- RTF
- XML

Select PDF to share a draft of the current record version with or without system validations (for example, errors, warnings, notes).

With validations
 Without validations

Select RTF to share a draft of the current record version that can be edited in a word processing program, such as Microsoft Word. Changes will need to be manually entered into the PRS.

Select XML to download and preserve data from the current record version for upload at a later time (for example, if entered results have to be temporarily deleted to allow submission of protocol updates).

Download

Record Actions

- XML Upload disabled
- Download Record
- Delete Record
- Administrator Actions
- Copy Record

Record Status

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

Feedback

Other Features

← [Record List](#) People ▾ Actions ▾

Brief Title: Effect of Transcranial Direct Current Stimulation on Local Cortical Processing
NCT Number: NCT ID not yet assigned
Unique Protocol Id: TDCS98765

Record Summary Protocol Study Documents Results

Record Summary

⚠ Return to the classic PRS to resolve additional issues, review for accuracy, and submit your record. [Complete Next Steps in the Classic PRS](#)

Use this page to see the current status of a record in the PRS and find controls for managing the record. This page also has status information for the modules in the Protocol Section, along with links for editing those modules.

Record Dates, Statuses and More Information

Dates			
Last Updated	Initial Release	Last Release	Initial Delayed Results Release
09/21/2023 13:57	Not yet released	Not yet released	Not yet released

Statuses and More Information			
PRS Review	Public Site	Record Owner	FDAAA
Not yet released	Not yet registered	PIVenka	ACT

Record Status ⓘ

In Progress Entry Completed Approved Released PRS Review Public

Feedback

Dates and other information are reorganized to facilitate ease of review

The Record Status bar is retained to display the current state of the record

Information icons link to drawer content that:

- Describes display options
- Is interactive for some data elements (e.g., FDAAA determination is detailed)

Validation Messages

See total numbers at a glance

The screenshot shows the 'Study Status' section of a ClinicalTrials.gov study page. The left sidebar contains a navigation menu with items: Protocol Summary, Study Identification, Study Status (highlighted), Sponsors and Collaborators, Oversight, Study Description, Conditions, Study Design, Arms and Interventions, Outcome Measures, Eligibility, Contacts and Locations, IPD Sharing Statement, and References. The main content area is for the 'Study Start Date' field, which is set to Jun 01 2023. A warning message is displayed: 'Warning: Start Date 2023-06-01 should not be in the past for studies that are Not yet recruiting.' Below this, two error messages are shown in red: 'Error: Study Start Date Type can only be Anticipated for a study that has not yet started' and 'Error: Anticipated Start Date cannot be in the past.' The 'Type' section has radio buttons for 'Anticipated' (selected) and 'Actual'. A 'Feedback' button is visible in the bottom right corner.

Overall Recruitment Status * ⓘ
If you select "Suspended," "Terminated," or "Withdrawn," an explanation of why the study was stopped is required.
Not yet recruiting

Study Start Date * § ⓘ
Date of enrollment of the first participant.
The Day field is optional for anticipated dates.

Warning: Start Date 2023-06-01 should not be in the past for studies that are Not yet recruiting.

Month	Day	Year
Jun	01	2023

Type

Error: Study Start Date Type can only be Anticipated for a study that has not yet started

Error: Anticipated Start Date cannot be in the past.

Anticipated
 Actual

Primary Completion Date * ⓘ
Final data collection date for the primary outcome measures.
The Day field is optional for anticipated dates.

Messages also appear in line with the relevant part to fix

Releasing the Record

An informative banner explains that the record will have to be reviewed, and possibly revised, in the classic system before it is released to QA staff

← [Record List](#) People ▾ Actions ▾

Brief Title
Effect of Transcranial Direct Current Stimulation on Local Cortical Processing

NCT Number
NCT ID not yet assigned

Unique Protocol Id
TDCS98765

Record Summary | Protocol | Study Documents | Results

Record Summary

⚠ Return to the classic PRS to resolve additional issues, review for accuracy, and submit your record.

[Complete Next Steps in the Classic PRS](#)

Use this page to see the current status of a record in the PRS and find controls for managing the record. This page also has status information for the modules in the Protocol Section, along with links for editing those modules.

Record Dates, Statuses and More Information

Dates			
Last Updated	Initial Release	Last Release	Initial Delayed Results Release
09/21/2023 13:57	Not yet released	Not yet released	Not yet released

Statuses and More Information			
PRS Review	Public Site	Record Owner	FDAAA
Not yet released	Not yet registered	PIVenka	ACT

Record Status ⓘ

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

[Feedback](#)

Click on the button to return to the Record Summary in the classic system.

| Enhancements

- More accessible content with added functionality
- Improved messaging and navigation to fix errors and address warnings prior to submission of the record for review
- Reorganized content to facilitate ease of review

Upcoming Updates to PRS Beta

- QA/QC for Protocol Registration
- Addition of the Results Section
- QA/QC for Results Submission
- Continual improvements based on user feedback – use the “Feedback” button to let us know what is working and what is not

Please Join Us For a Q and A with Our Expert Panel:

- **Nachiket Dharker**
Product Owner
- **Maureen Strange**
PRS Subject Matter Expert
- **Ben Babics**
Technical Lead

Thank
you!