



ClinicalTrials.gov Registration User's Guide

For questions, please contact your institution's Protocol and Registration/Results System (PRS) Admin for institution specific guidance, or Rachael.Massey@UHhospitals.org for general CT.gov questions. If unsure who the PRS admin is please check the CTSC website.



CLINICAL AND
TRANSLATIONAL
SCIENCE COLLABORATIVE



Veterans Health Administration
VA Northeast Ohio Healthcare System

CT ClinicalTrials.gov PRS: Login

register.clinicaltrials.gov/

Use this address to enter registration information

My Access | Employ... CT ClinicalTrials.gov-Pu... CT ClinicalTrials.gov Pr... eCFR :: 42 CFR Part... For Employees | Uni... Clinical Research &... Airwatch for Mobile... IRB

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

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

If you are unsure who your PRS admin is email: register@clinicaltrials.gov for assistance or check the CTSC website

Organization is case sensitive and site specific- contact your organizations PRS admin with questions

Organization:

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

Username:

Password: [Forgot password](#)

Contact your PRS admin to find out your username

Login

CT.gov will email a generated password, you will be prompted to change it the first time logging in

Help

ClinicalTrials.gov PRS *Protocol Registration and Results System*

Quick Links

[New Record](#)

Records ▾ Accounts ▾ Help ▾

- From the Help menu choose “Protocol Data Entry”
- The PRS Guided Tutorials are helpful in providing examples

Help: Protocol Data Entry

Need help understanding protocol data entry? For introductory information on the process, see the [PRS Guided Tutorials](#).

Additional resources for protocol registration:

- [Protocol Registration Data Element Definitions](#) - describes the registration data items (required and optional) that are entered via PRS
- Protocol Registration Templates: Each template is a formatted summary of the data elements for each registration module, specific to the relevant study type. The templates are intended to help investigators understand and gather the data needed to complete each registration module.
 - [Interventional Study Protocol Registration Template \(PDF\)](#)
 - [Observational Study Protocol Registration Template \(PDF\)](#)
 - [Expanded Access Protocol Registration Template \(PDF\)](#)
- [Expanded Access Data Element Definitions](#) - describes the expanded access data items (required and optional) that are entered via PRS
- [Protocol Review Criteria \(PDF\)](#) - review criteria for submitted study records
- [Frequently Asked Questions \(FAQ\)](#)

U.S. Laws: Clinical trial registration and results submission

- [Final Rule for Clinical Trials Registration and Results Information Submission \(42 CFR Part 11\)](#) - clarifies and expands requirements for submitting clinical trial registration and results information to ClinicalTrials.gov in accordance with Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801)
- [FDAAA 801 Requirements](#) - clinical trial registration and results submission requirements from Section 801 of the Food and Drug Administration (FDA) Amendments Act of 2007
- [FDAMA 113 Requirements](#) - clinical trial registration requirements under Section 113 of the Food and Drug Administration Modernization Act of 1997

Getting Started.....

- You will need to contact the PRS Administrator at your institution for specific institutional policies regarding CT.gov registration. Please email register@clinicaltrials.gov to find out who the PRS admin is for your institution. You can also view a list of PRS admins on the CTSC website.
- If you would like to set up a one on one to walk through the registration please email Rachael.Massey@UHhospitals.org . Rachael will not be able to provide institution specific guidance, but rather general CT.gov help.
- Registration can take ~2 hours to complete
- Can be saved as a draft and finished later. Make sure to always hit the “Save” button on the bottom of each page



- Once you have entered all the required data, hit the green “Entry Complete” button, it will then go to the Responsible Party to be Approved and Released, then to ClinicalTrials.gov for PRS review (can take up to 10 days so don’t wait till the last minute to submit)
- After CT.gov reviews, the record owner will get an email with the NCT# or with PRS comments, which are required to be addressed within **15 calendar day**
- Records are required to be updated annually, or more frequently as changes occur
 - Each time you are in the record make sure to update the Record Verification to current month/year

Creating a New Record

To create a new record, click the New Record link or use the Records drop down menu

Quick Links

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

Records ▾ Accounts ▾ Help ▾

Email: Rachael.Massey@UHhospitals.org [[Update](#)]

To try out the new PRS system click here. PRS will switch over in July 2023

Try out the new PRS beta home page, part of the ongoing ClinicalTrials.gov modernization.

[New PRS Beta Home Page](#)

To edit an existing record click on the Open link

The system flags records with problems that need to be fixed

Record List

Showing: 1 record

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Responsible Party	Problems
Open	1258 RM Test		Muscle O2 Saturation	In Progress	04/26/2022 10:25	Rachael Massey Rachael.Massey@UHhospitals.org	<ul style="list-style-type: none">• Entry Not Completed• Never Released

Show/Hide Columns ▾

Record Status Page

The Record Owner defaults to who starts the record and is the primary contact for ClinicalTrials.gov. If you need to change the Record Owner please email your PRS admin

Add anyone who needs edit rights. Record Owner can do this.

Record Status

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

Next Step: Confirm data entry complete

Entry Complete ?

Record Owner: RMassey 

Last Update: 04/28/2022 10:20 by RMassey 

Initial Release: [Not yet released]

Access List: [Edit](#)

Upload: Allowed [Edit](#)

PRS Review: [Not yet released]

Public Site: [Not yet registered]

FDAAA: ACT ?

Initial Release date displays on the public site. This is important for ACTs and ICMJE

Click **Entry Complete** once all edits are complete. This will send the record to the Responsible Party for Approval and Release

Record Summary Page

Click the **Spelling** link to review spelling errors

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

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

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: STUDY20221234 RM

Brief Title: Remuverol in Adults With Disc Herniation

Module Status:

Study Identification: ✓

Study Status: **1 Error** | [1 Note](#)

Sponsor/Collaborators: ✓

Oversight: **1 Warning**

Study Description: ✓

Conditions: ✓

Study Design: ✓

Arms and Interventions: **3 Notes**

Outcome Measures: ✓

Eligibility: ✓

Contacts/Locations: **Information is required**

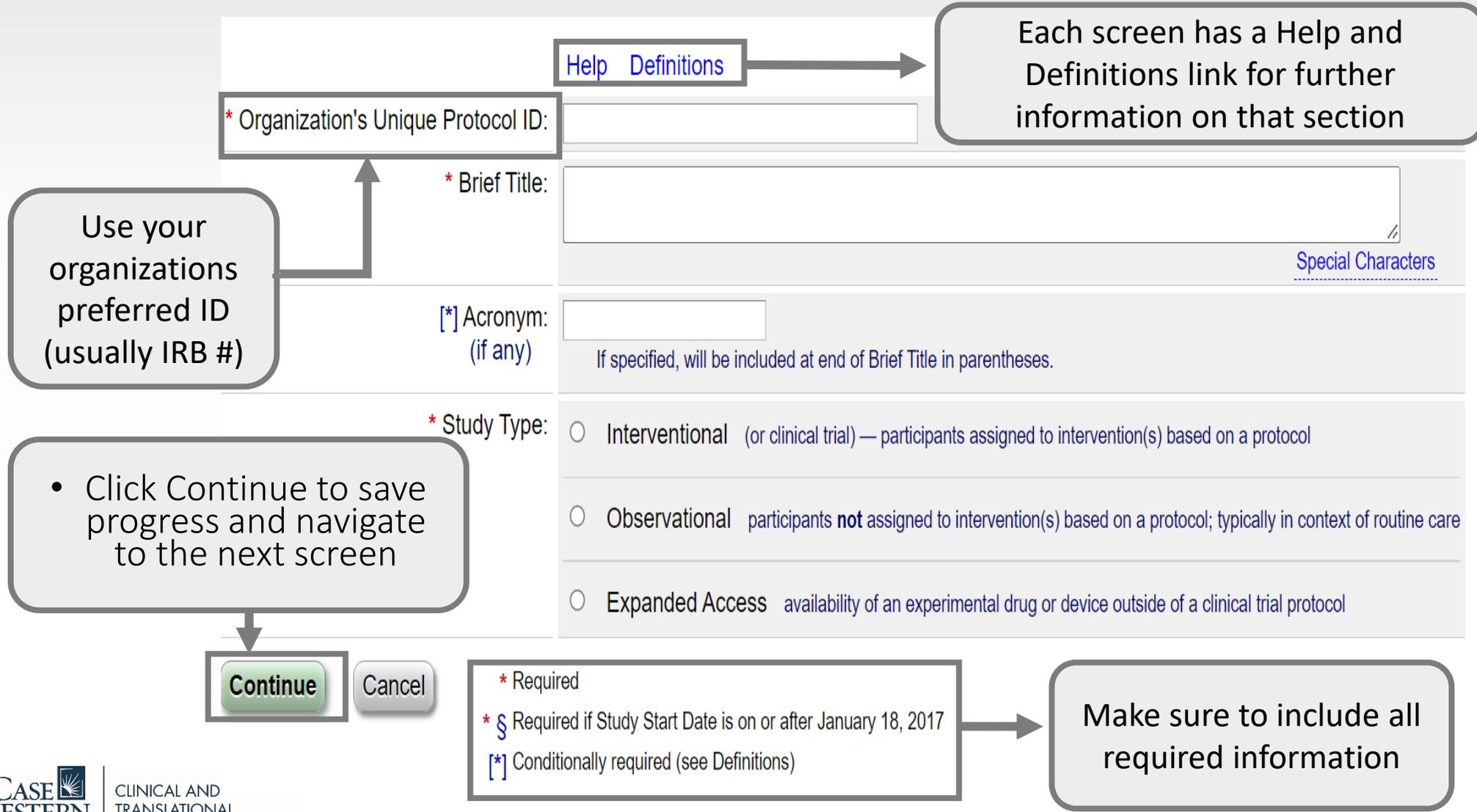
IPD Sharing Statement:

References:

Click the **Open** link to make edits to the different sections of the record

Error: must be addressed before submitting the record
Warning: not required to be addressed, but should try and address if possible
Note: potential issues, should be reviewed and addressed as needed

Study Description Page



Once you enter the brief title and study type this page will display. It is letting you know the different sections of the record. Hit **OK** after you review.

The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Arms and Interventions
- Outcome Measures
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.

On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.

OK

Study Identification Page

[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)

* Required
* § Required if Study Start Date is on or after January 18, 2017

This title will be displayed in search results on the public site

Needs to match title submitted to IRB

For NIH funded studies, add the Grant Number. If you get an error, leave blank and try adding later. It can take a few weeks for numbers to show in the system

Record Verification/Study Status

Update RVD **every time** the record is updated. Records are required to be verified annually, this is how they track.

* Record Verification Date:

Month: Year:

* Overall Recruitment Status:

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

Only use “Active, not recruiting” if data is still being **collected**. If data collection is complete, the status should be Completed or Terminated.

Recruitment Status Definitions

Overall Recruitment Status *

Definition: The recruitment status for the clinical study as a whole, based upon the status of the individual sites. If **at least one** facility in a multi-site clinical study has an Individual Site Status of “Recruiting”, then the Overall Recruitment Status for the study must be “Recruiting”. Select one:

- **Not yet recruiting:** Participants are not being recruited
- **Recruiting:** Participants are currently being recruited, whether or not any participants have yet been enrolled
- **Enrolling by invitation:** Participants are being (or will be) selected from a predetermined population
- **Active, not recruiting:** Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled
- **Completed:** The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant’s last visit has occurred)
- **Suspended:** Study halted prematurely but potentially will resume
- **Terminated:** Study halted prematurely and will not resume, participants are no longer being examined or receiving intervention
- **Withdrawn:** Study halted prematurely, prior to enrollment of first participant

Study Start Date

Please note:
Day is required for actual dates

Tip: Day is not required for Anticipated dates.

* § Study Start Date:

Month: Day: Year: Type:

Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

Study Start Date is either:
Anticipated- estimated date which the study will be open for recruitment

Actual- date of enrollment of first participant

Primary and Study Completion Dates

* Primary Completion Date: Month: Day: Year: Type:

* § Study Completion Date: Month: Day: Year: Type:

Completion Dates are based on **data collection!**

They are **NOT** based on:

- data analysis
- database lock
- publication
- IRB closure

Final data collection for the primary **and** secondary outcome measures **and** adverse events (for example, last participant's last visit)

Examples on next slide

Primary and Study Completion Dates

Remember: If required, results for the primary outcome measure(s) are due within one year of the Primary Completion Date. Results for the secondary outcome measures are due one year after the completion date **for that outcome**.

* Primary Completion Date:	Month: <input type="text" value="September"/> Day: <input type="text" value="01"/> Year: <input type="text" value="2023"/> Type: <input type="text" value="Anticipated"/>
	<i>Final data collection date for primary outcome measure.</i>
* § Study Completion Date:	Month: <input type="text" value="December"/> Day: <input type="text" value="01"/> Year: <input type="text" value="2023"/> Type: <input type="text" value="Anticipated"/>
	<i>Final data collection date for study.</i>

In the example above, Primary Outcome results are due by **September 01, 2024**. All study results must be entered by **December 01, 2024**. Some secondary results may be due earlier depending on data collection time frames for that outcome.

Completion Dates Examples

Primary Outcome Measure:

1. Change in Pain as measured by the Visual Analogue Scale (VAS)
[Time Frame: Baseline, 12 weeks]

Secondary Outcome Measures:

2. Change in the Beck Depression Inventory (BDI-II)
[Time Frame: Baseline, 16 weeks]

The **Primary Completion Date** is when the last subject completes the VAS (i.e. the subject's 12 week visit).

The **Study Completion Date** is when the last subject completes the DBI-II (i.e. the last subject's 16 week visit)*

*If AE collection extends beyond 16 weeks then the study completion date would be the date of final AE collection.

Sponsor/Collaborators Page

For Responsible Party ask your PRS admin which to use:

- Sponsor
- Principal Investigator
- Sponsor/Investigator

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

*** Responsible Party:** ←

Because UHCaseMC has no Administrator, either Principal Investigator or Sponsor-Investigator must be selected.

Investigator Information

Investigator Name [Username]: ↓
Select the investigator's PRS account.
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.
[Investigator not in list?](#) [Incorrect name format?](#)

Investigator Official Title:

Investigator Affiliation:

*** Sponsor:** ←

Primary organization conducting study and associated data analysis (not necessarily a funding source).

Collaborators: ←

Organization(s) providing support: funding, design, implementation, data analysis or reporting.
Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)
Enter **only the organization name**.

Should pre-populate as organization used for log-in

If the study is NIH funded, include the NIH office here

Oversight Page

	Help Definitions
* § U.S. FDA-regulated Drug:	Yes <input type="button" value="v"/> Studying one or more U.S. FDA-regulated drug or biologic products? For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF) .
* § U.S. FDA-regulated Device:	No <input type="button" value="v"/> Studying one or more U.S. FDA-regulated device products? For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF) .
* U.S. FDA IND/IDE: (Not public)	No <input type="button" value="v"/> Studying drug/device product or Investigational Device Exemption (IDE)?
[*] Product Exported from U.S.:	--Select-- <input type="button" value="v"/> Studying a drug or device product that is manufactured in and exported from the U.S.?
Human Subjects Protection Review:	Board Status: --Select-- <input type="button" value="v"/>
Data Monitoring Committee:	Yes <input type="button" value="v"/>
FDA Regulated Intervention:	Yes <input type="button" value="v"/>
Section 801 Clinical Trial:	Yes <input type="button" value="v"/>

Refer to definitions and ACT Checklist for help with this section

If this is marked "Yes" the IND/IDE information is required

Enter IRB information, what is required detailed on next slide

Section 801 = Applicable Clinical Trial

Human Subjects Protection Review

* Human Subjects Protection Review:

Board Status: ▼

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.]

Approval Number:

Board Name:

Board Affiliation:

Board Contact: Phone: Extension:

Email:

Address:

These fields are required. Check with PRS admin for more information

Study Description Page

TIP: Do not use first or second person. Replace “I” and “we” with “the investigator”; replace “you” with “subjects”

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

* Brief Summary:

The purpose of this study is to assess the safety and efficacy of Remuverol on treatment of Condition A.

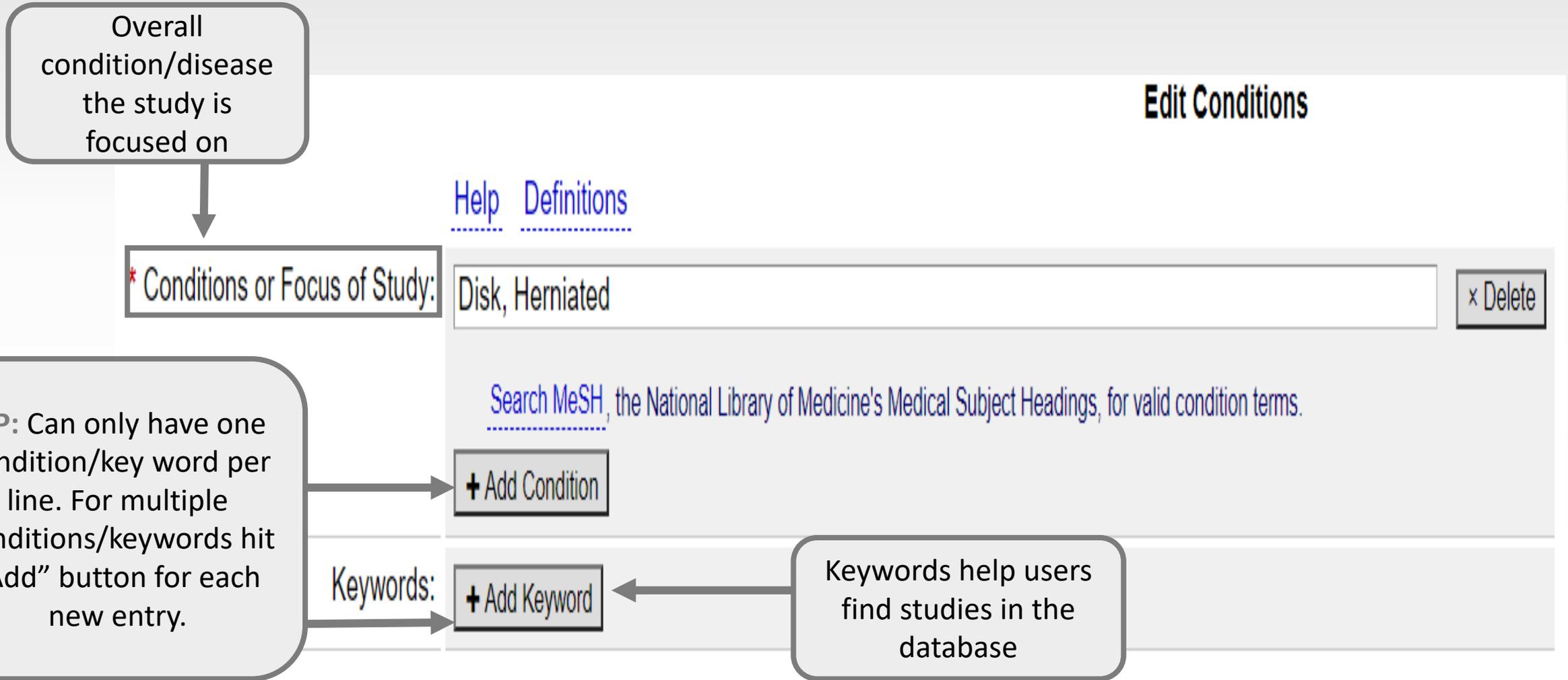
Describe the study in terms understandable to the lay public. **TIP:** Consider using the consent form since this is already written in lay terms

Detailed Description:

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

This field is optional and can be left blank. **Do not** include the entire protocol.

Conditions Page



Interventional Study Design Page

Edit Interventional Study Design

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

* Study Type: Interventional

* § Primary Purpose: Treatment

* Study Phase: Phase 3

Use "N/A" for trials that do not involve drug or biologic products.

* § Interventional Study Model: Parallel

Model Description:

* § Number of Arms: 2

* § Masking:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor

None (Open Label)

Check all roles that are masked or check None (Open Label).

Masking Description:

* § Allocation: Randomized

Select N/A for single-arm studies.

* § Enrollment: Number of Participants: 75

Type: Anticipated

Use the definitions link to view definition of "enrolled"

Number enrolled should be changed to actual when a study has completed data collection.

Arms Page

Edit Arms

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

Arms:

* Arm Title: Remuverol
Formerly Arm Label: Brief, descriptive label to be used as row or column heading in tables.

* Arm Type: Experimental

[*] Arm Description: Participants will receive 15 mg tablet Remuverol orally, twice daily for 12 weeks.
Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.

* Arm Title: Placebo

* Arm Type: No Intervention

[*] Arm Description: Participants will receive 15 mg Remuverol Placebo orally, twice daily for 12 weeks.

For Arm Type you must choose from drop down. Use definitions link for more info

Use to add additional arms

Arm description needs to describe intervention administered. This is not a required filed, but it is best to include for clarity.

Interventions Page

TIP: Record should include ALL interventions pre-specified in the protocol, even if it is not a intervention “of interest”

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

Arms: Experimental: Remuverol
No Intervention: Placebo

Interventions:

* Intervention Type: Drug

* Intervention Name: Remuverol

For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).

[*] Other Intervention Names: (if any)

+ Add Other Name

Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

* § Intervention Description: 15 mg tablet

Do not repeat information already included in arm/group descriptions.

NOTE: Intervention Other Names have not been specified

* Intervention Type: Drug

* Intervention Name: Placebo

[*] Other Intervention Names: (if any)

+ Add Other Name

* § Intervention Description: Remuverol placebo tablet

Placebo should be listed as a Drug intervention

Add each intervention administered separately

Cross Reference

Each intervention has to be assigned to an arm. Hit **edit** here to do that.

[Edit](#)

Cross-Reference

Arms	Interventions	
	Drug: Remuverol	Drug: Placebo
Experimental: Remuverol	✓	
Placebo Comparator: Placebo		✓

✓ - Intervention is administered to patients in this Arm.

* Cross-Reference:

Arms	Interventions	
	Drug: Remuverol	Drug: Placebo
Experimental Remuverol	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Placebo Comparator: Placebo	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Check boxes for Interventions associated with each Arm in the study.

Outcome Measure: Tips

- Protocol/statistical analysis plan must be submitted with results and will be made public. There are some redactions that are allowed, but are limited. This is required for all results submissions, even voluntary submissions.
- Must include ALL Primary and Secondary outcomes listed in protocol (tertiary/exploratory are optional)
- Label outcomes as “primary” or “secondary” in the record the same as they are labeled in the protocol
 - May have more than one primary outcome if needed

Outcome Measure: Title

Should include what you are measuring and how

- Include the metric (ie. scale, score, number, percentage)
 - Ex: Pain as measured by the Visual Analogue Scale
 - Ex: Number of AEs as measured by patient report
- Be clear and concise, no verbs
 - Ex: “Maximum tolerated dose of Drug A” is preferable over “To determine the maximum tolerated dose of Drug A in patients with breast cancer”. Only include what is being measured and how in the title.
- Only one measure per outcome
 - Ex: All-cause mortality, hospitalizations, and ER visits should be 3 separate outcomes
 - *Exception-** if you are measuring a composite score, but must explain how you are measuring
 - Ex: Composite score of all-cause mortality, hospitalizations, and ER visits. In the description make sure to explain how you will combine all measures to get one overall raw score.

Outcome Measure: Time Frame

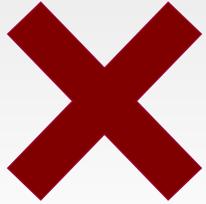
Should include specific time point data was collected

- Specific time point of data collection for that outcome measure (e.g. # of minutes, hours, weeks, months, years)
 - Ex: During hospitalization, approximately 5 days
 - Ex: End of study, up to 12 weeks
 - Should only have one time point in the time frame, unless you are measuring a change. If you are measuring a change must have “change” in the title
 - Ex: Change in pain score as measured by the VAS, Time Frame: Baseline, 3 months, 6 months (Make sure to include all time points you are measuring the change)
- *NOTE*** If you are not measuring a change, each time point would be its own outcome measure
- Pain as measured by the VAS, Time Frame: Baseline
 - Pain as measured by the VAS, Time Frame: 3 months
 - Pain as measured by the VAS, Time Frame: 6 months

Outcome Measure: Description

- Make sure to include the range and meaning of any scores used in a scale
 - Ex: The Visual Analog Scale is a 10 item questionnaire ranking the severity of pain. Scores are measured on a 5 point likert scale, with 5 being extreme pain and 1 being no pain at all.
- Descriptions are not required, but should be used to clarify what is measured and how

Outcome Measure: Example



Title:

Description:

Time Frame:



Title:

Description:

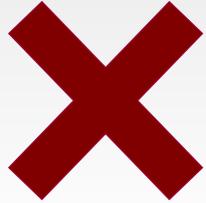
Time Frame:

There are multiple time points, so “change” is included in the title

The Title includes the scale that is used to asses the change in pain

The Description includes what the scale means and the range

Outcome Measures: Example



Title:

Description:

Time Frame:



Title:

Description:

Time Frame:

They will not just accept “safety”, they want to know how you are measuring safety.

“End of study” is not descriptive enough, need to add actual length of time

Since no change is being measured only one time point is needed

Eligibility Page

* Sex:	All <input type="text"/>	* Denotes required field
	Biological sex of eligible participants.	
[*] Gender Based:	No <input type="text"/>	
	If applicable, indicate if participant eligibility is based on self-representation of gender identity.	
* Age Limits:	Minimum: 18 <input type="text"/> Years <input type="text"/>	Maximum: N/A (No limit) <input type="text"/>
* § Accepts Healthy Volunteers:	No <input type="text"/>	
* Eligibility Criteria:	<p>Inclusion Criteria: - <input type="text"/></p> <p>Exclusion Criteria: - <input type="text"/></p> <p>Make sure to put a – before each inclusion/ Exclusion Criteria so it formats correctly</p> <p>Special Characters</p>	

Contacts/Locations Page

Name, phone number, and email are required

* Central Contact Person:

First Name: MI: Last Name: Degree:

Phone: Ext: Email:

Either Central Contact or Facility Contacts are required.
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Central Contact Backup:

First Name: MI: Last Name:

Phone: Ext: Email:

Not required, but if you want to add someone- must include name, phone number and email

Overall Study Officials:

First Name: MI: Last Name: Degree:

Organizational Affiliation:

Official's Role:

Must include PI listed with IRB

Can add any Co-I's here

IPD Sharing Statement Page

This is sharing individual participant level data, not aggregate data sets. If you plan to share this level of data you must present your plan and have it IRB approved.

ICMJE requires this question be answered, so do not leave as “Undecided”. Either mark “Yes” if you have already submitted and had your plan approved, or “No” if you have not yet submitted the plan to IRB.

If you mark “Yes” the following information is required:

- Must check all information that will be shared: Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF), Clinical Study Report (CSR), Analytic Code
- Must provide a time frame which should include how the data will become available and for how long
- Must provide Access Criteria

References Page

▼ Citations:

Links:

Available IPD/Information:

Here you made
include any citations
or links.

NOTE: CT.gov does
not like the use of
foot notes in the
record.