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.

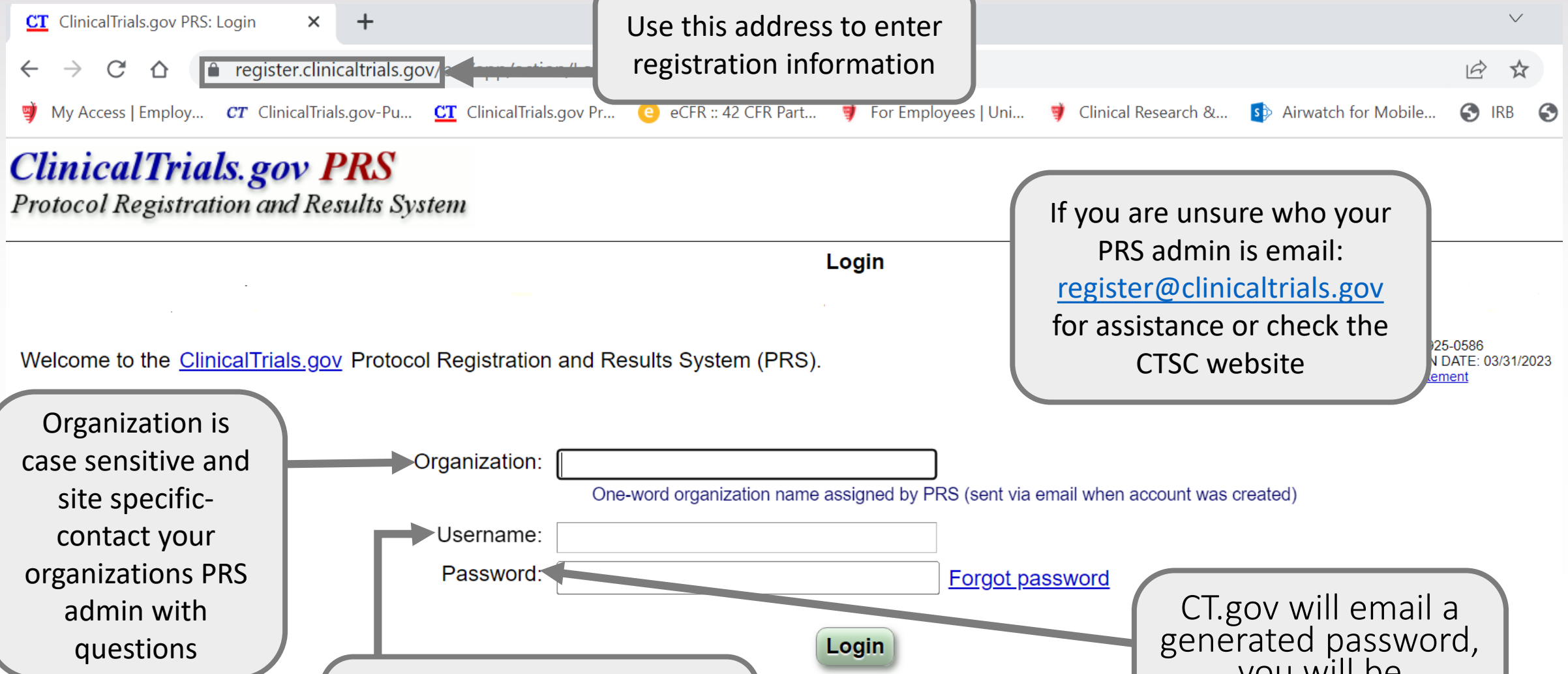
Case Western Reserve University | Clinical and Translational Science Collaborative

Cleveland Clinic

University Hospitals Cleveland Medical Center

MetroHealth

VA | U.S. Department of Veterans Affairs | Veterans Health Administration | VA Northeast Ohio Healthcare System



Use this address to enter registration information

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

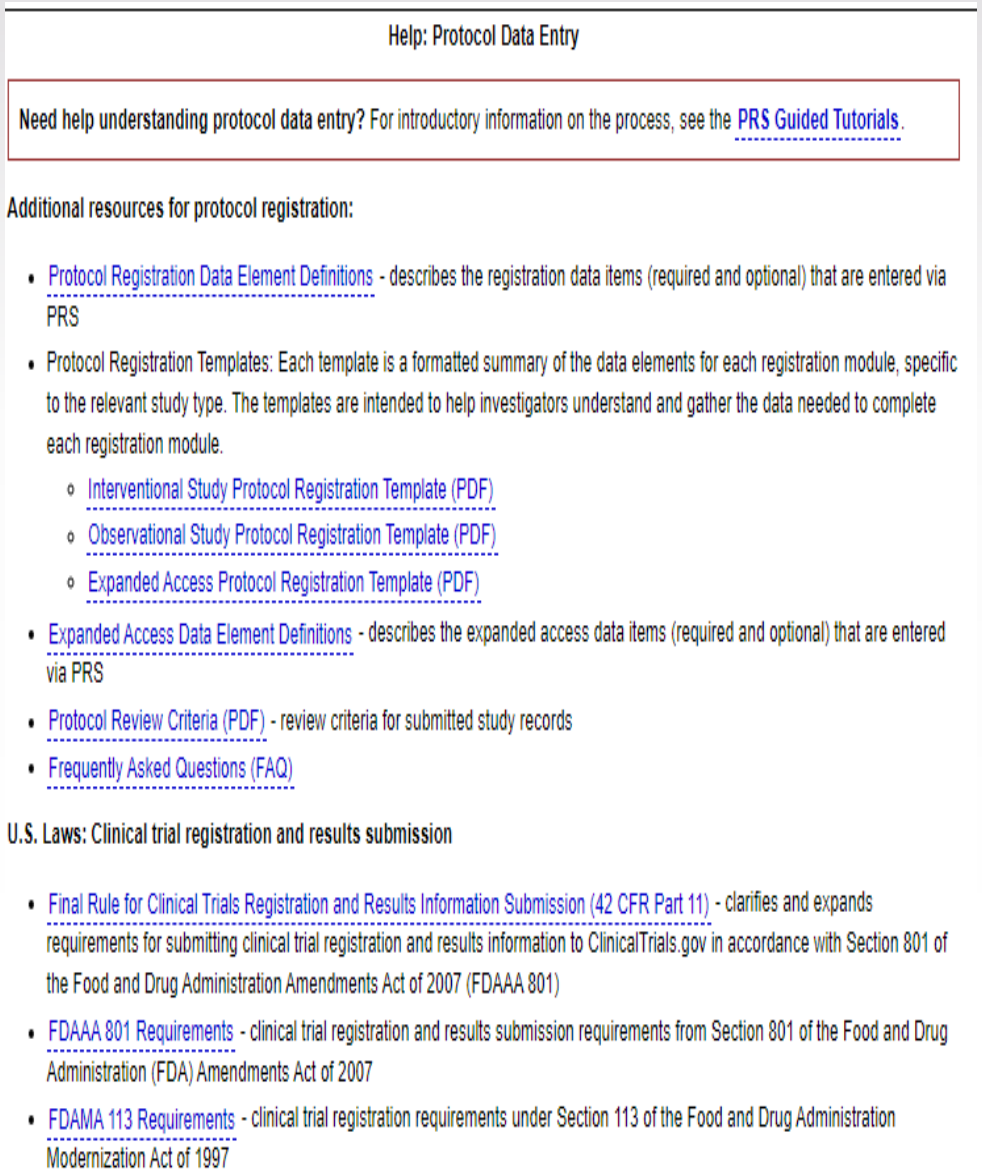
Organization is case sensitive and site specific- contact your organizations PRS admin with questions

Contact your PRS admin to find out your username

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

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

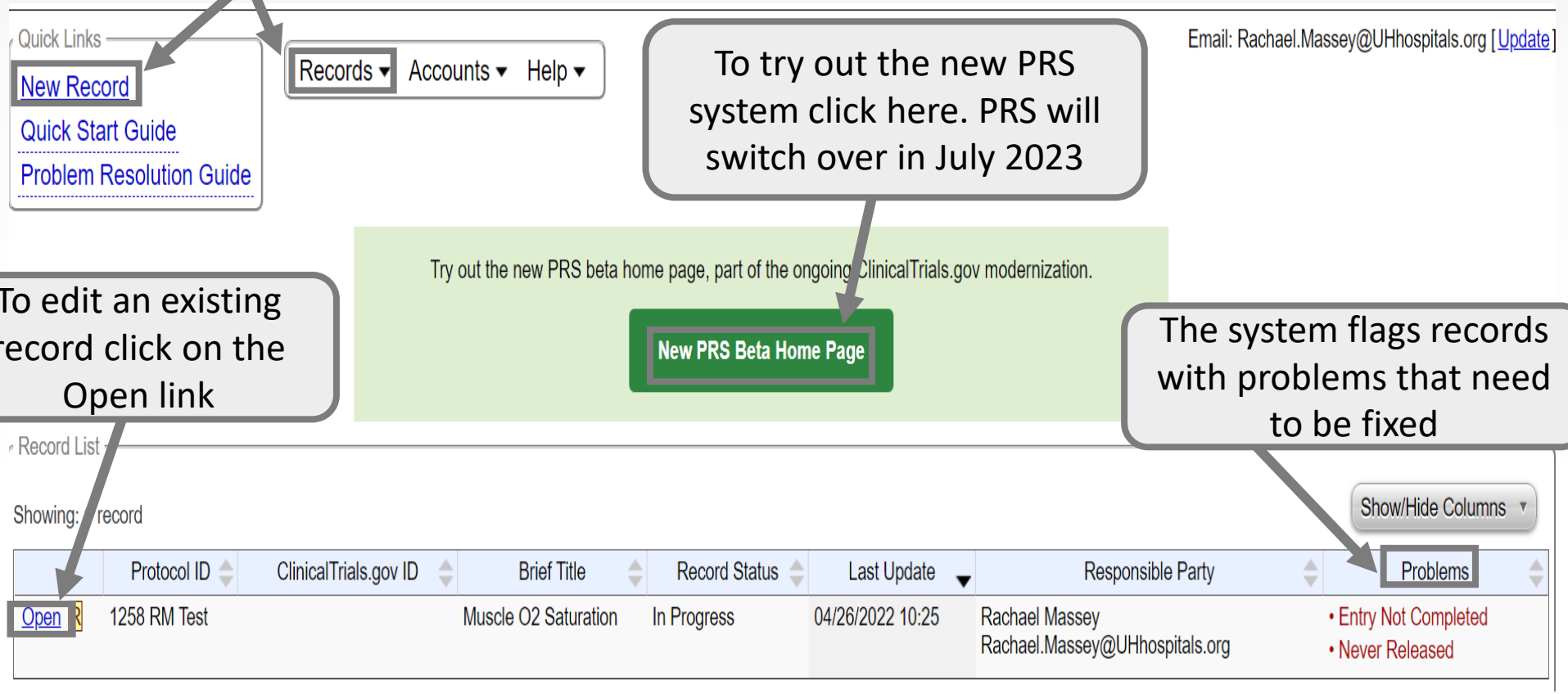
Getting Started…..

- 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



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

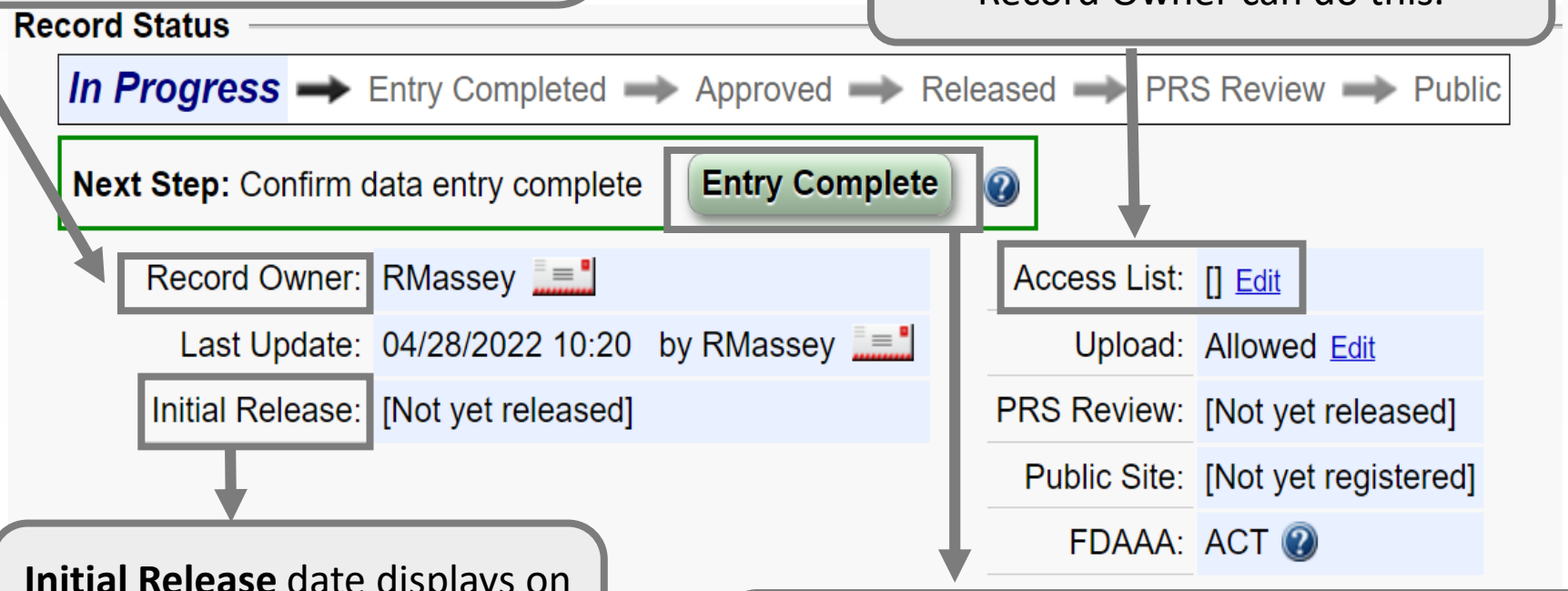
To edit an existing record click on the Open link

The system flags records with problems that need to be fixed

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.

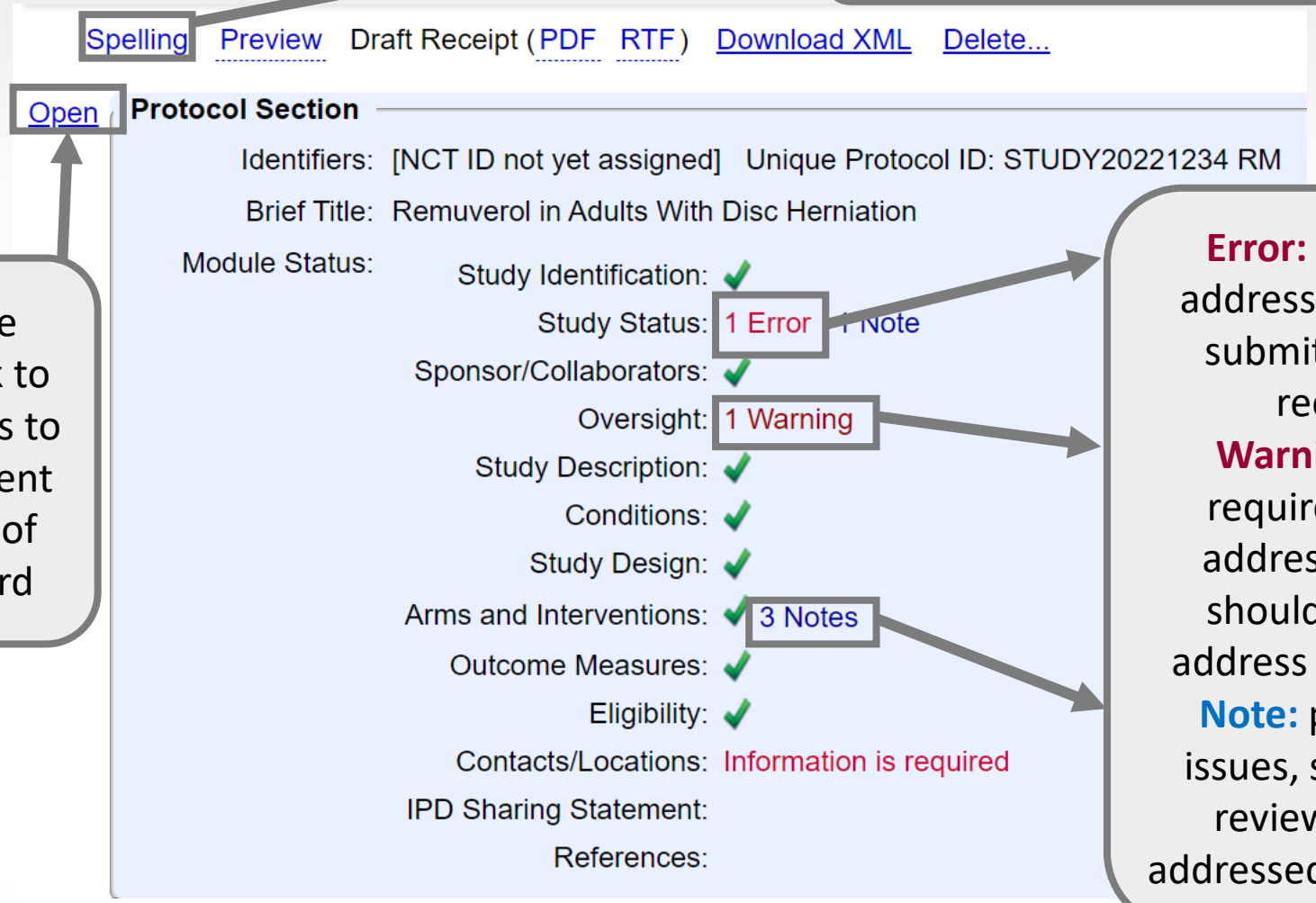


Initial Release date displays on the public site. This is important for ACTs and ICMJE

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



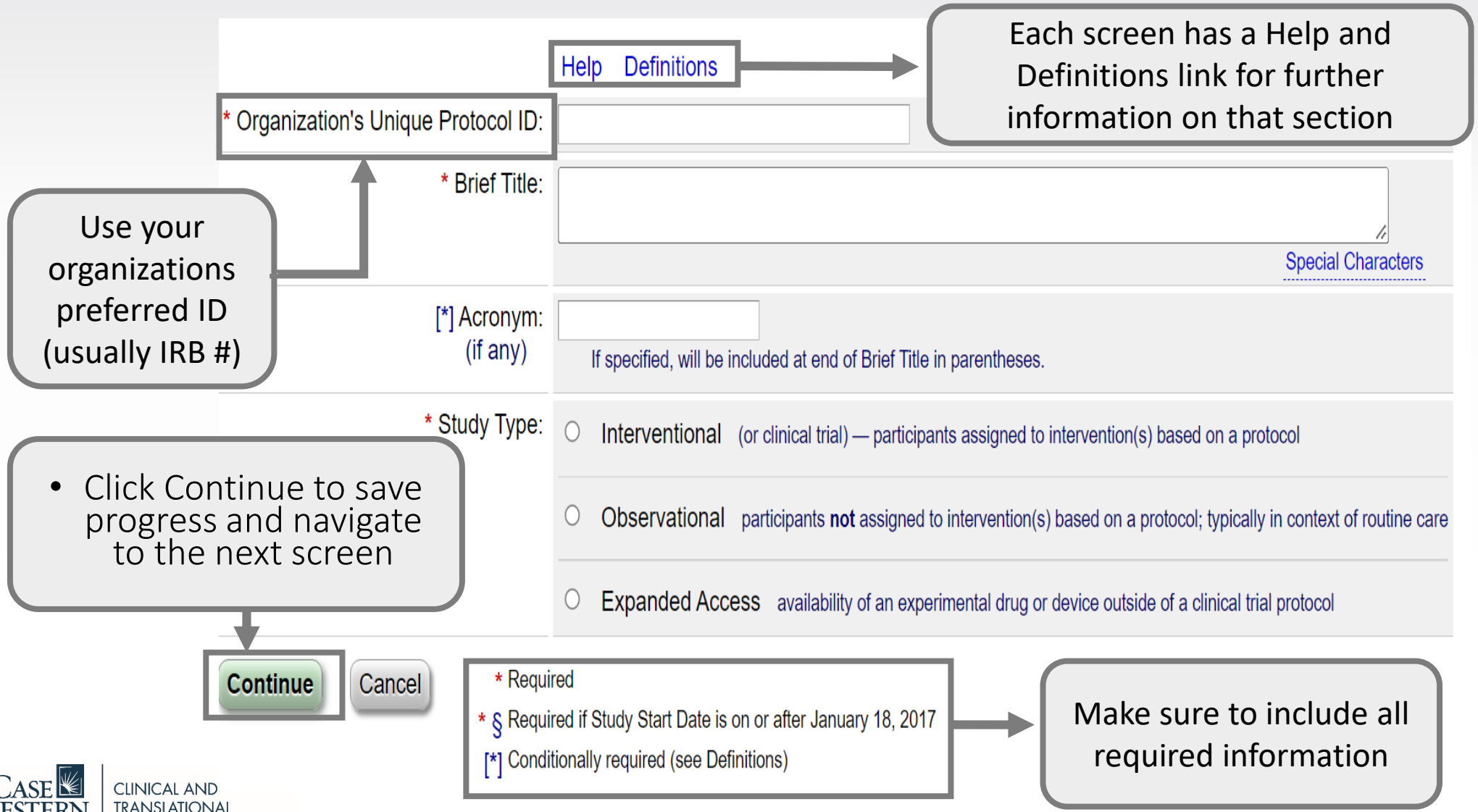
Click the **Open** link to make edits to the different sections of the record

Error: must be addressed before submitting the record

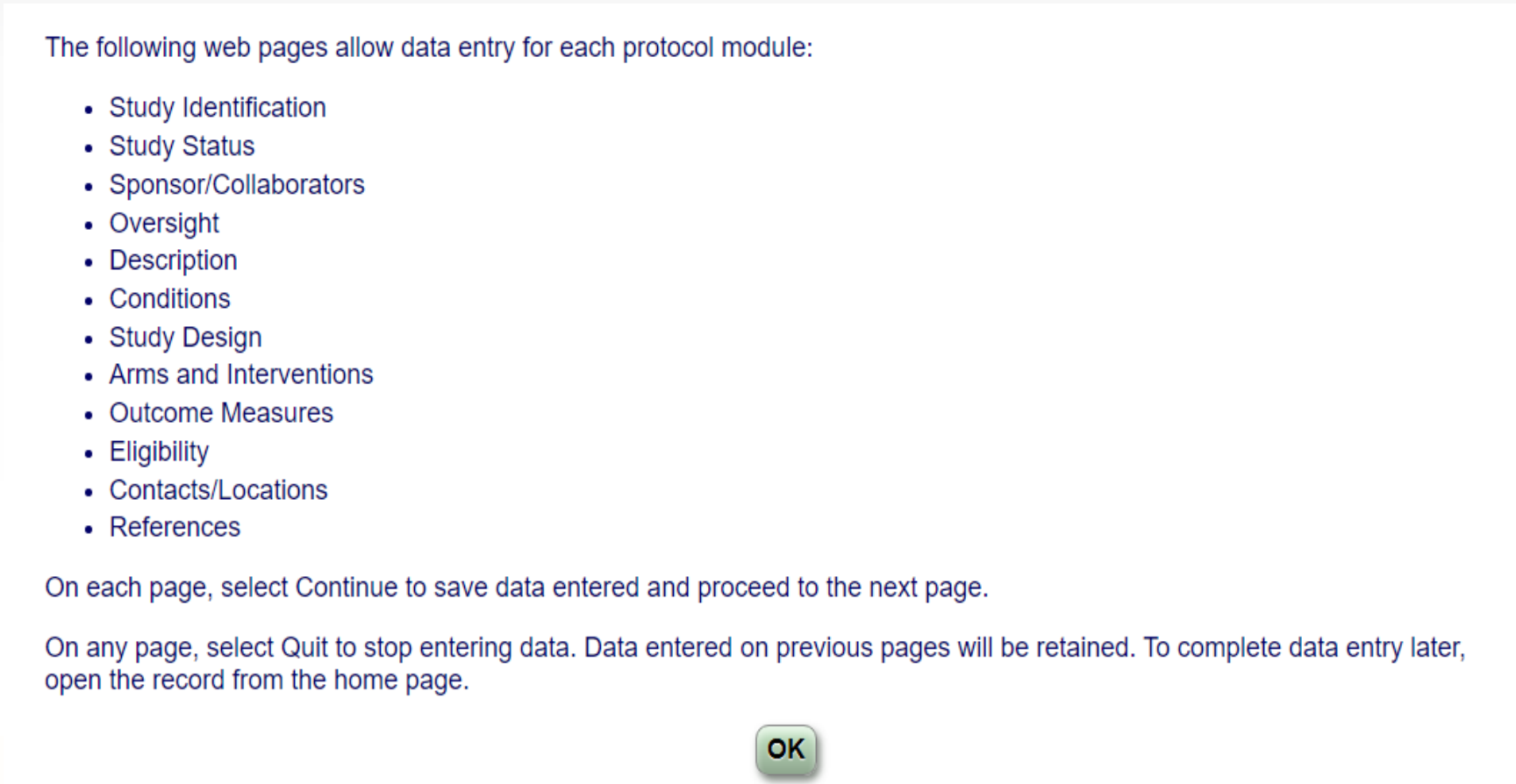
Warning: not required to be addressed, but should try and address if possible

Note: potential issues, should be reviewed and addressed as needed

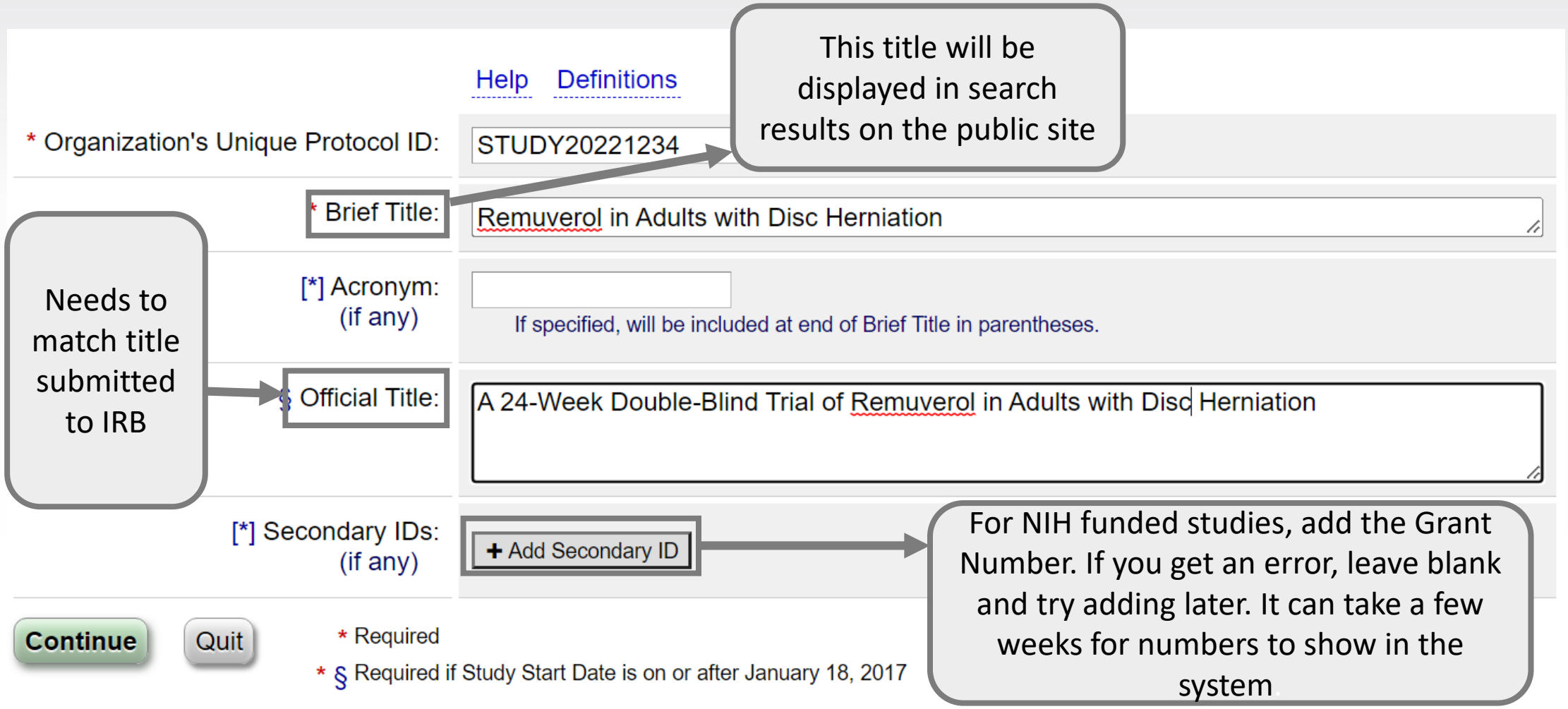
Study Description Page



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.

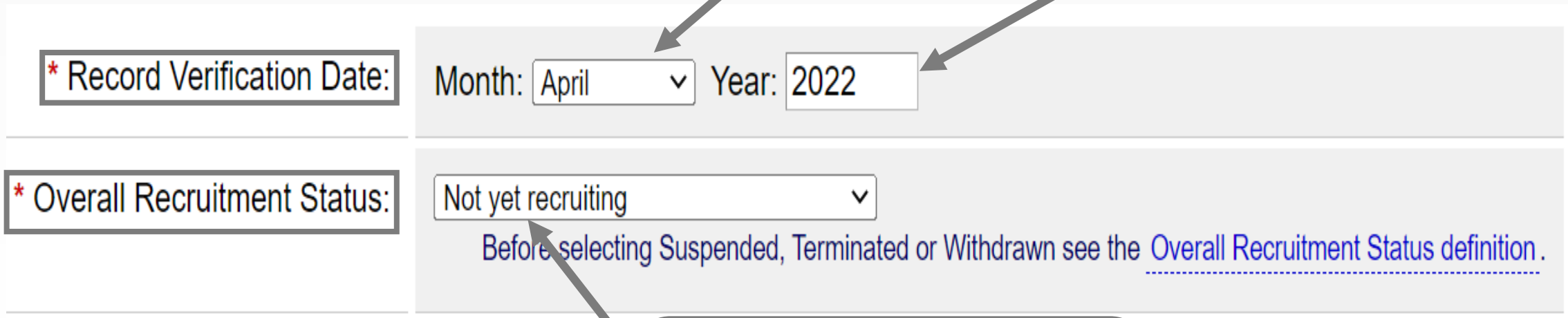


Study Identification Page



Record Verification/Study Status

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



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

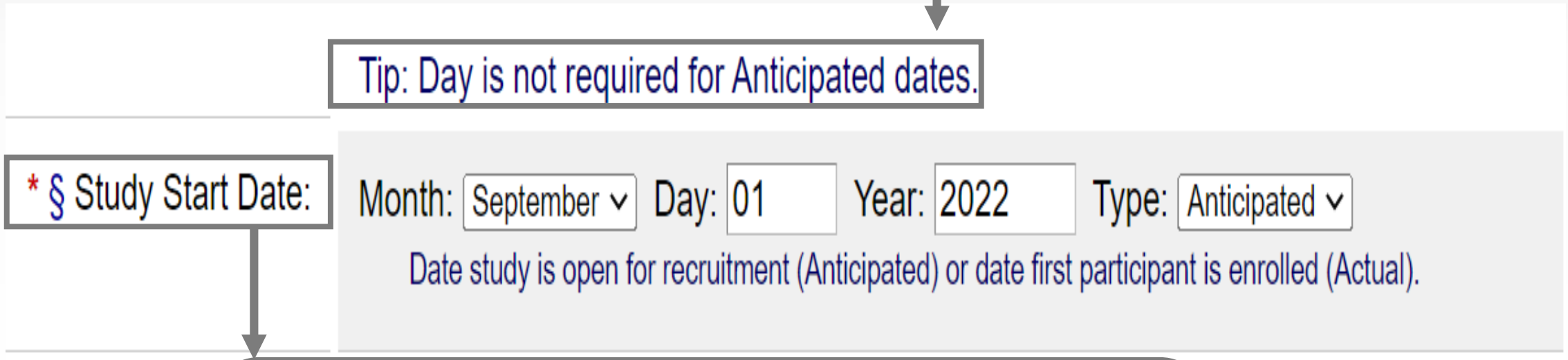
Overall Recruitment Status *

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

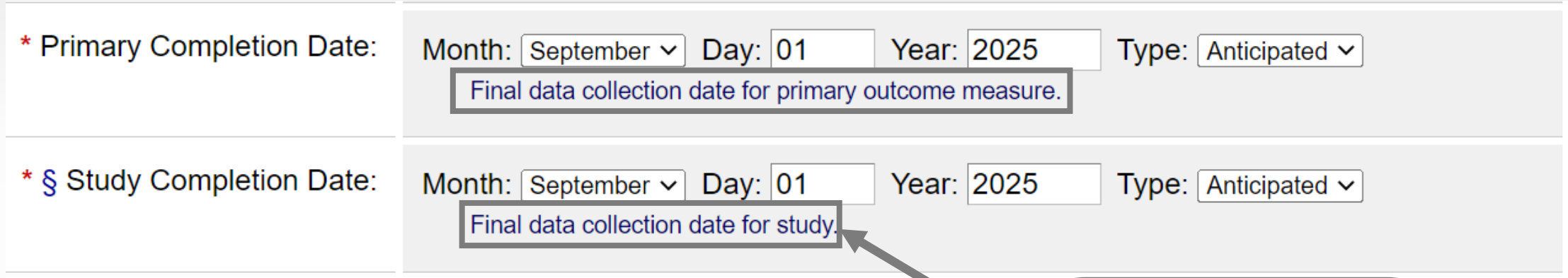
Study Start Date

Please note:
Day is required for actual dates



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



Completion Dates are based on data collection!
They are NOT based on:

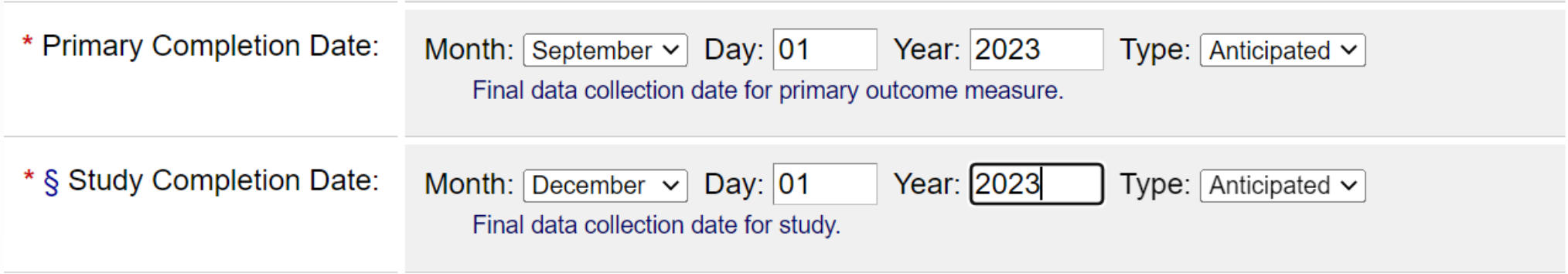
- data analysis
- database lock
- publication
- IRB closure

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**.



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).

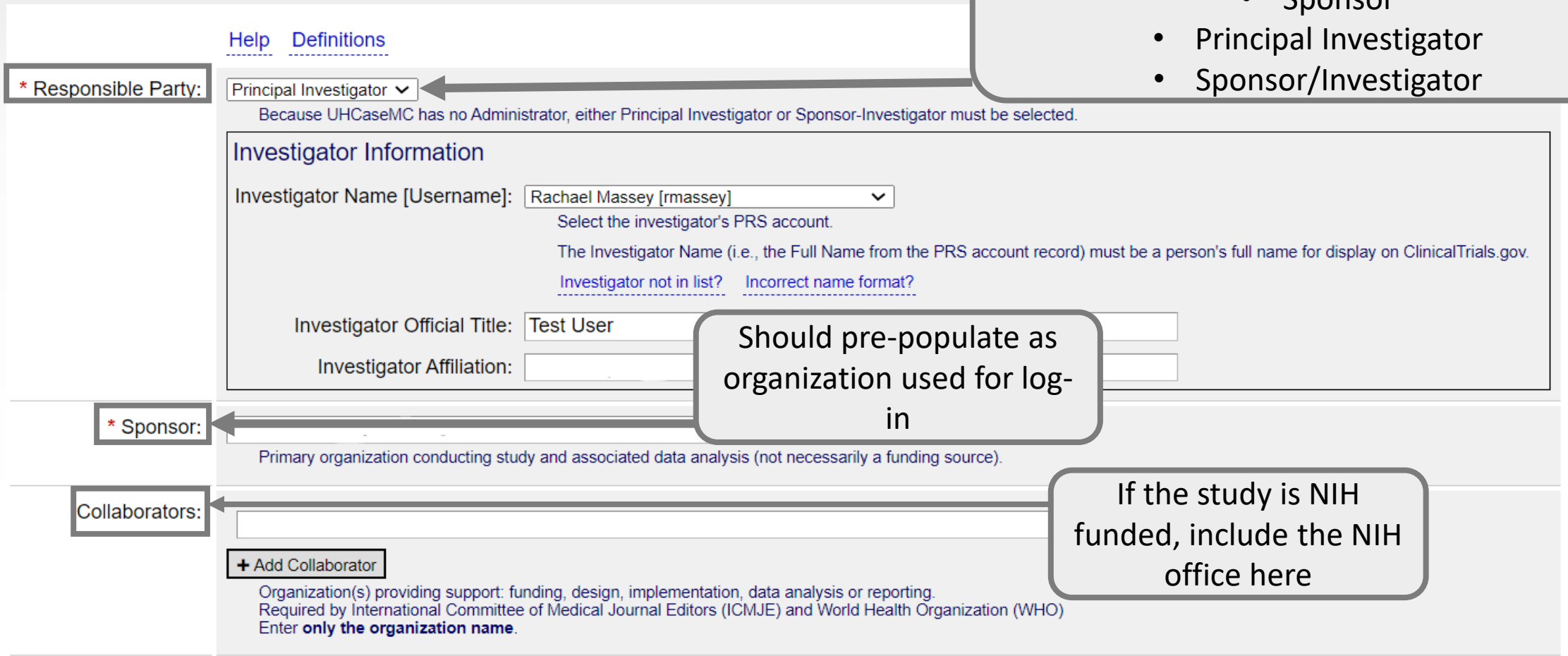
The Study Completion Date is when the last subject completes the DBI-II (i.e. the last subject's 16 week visit)*

*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:

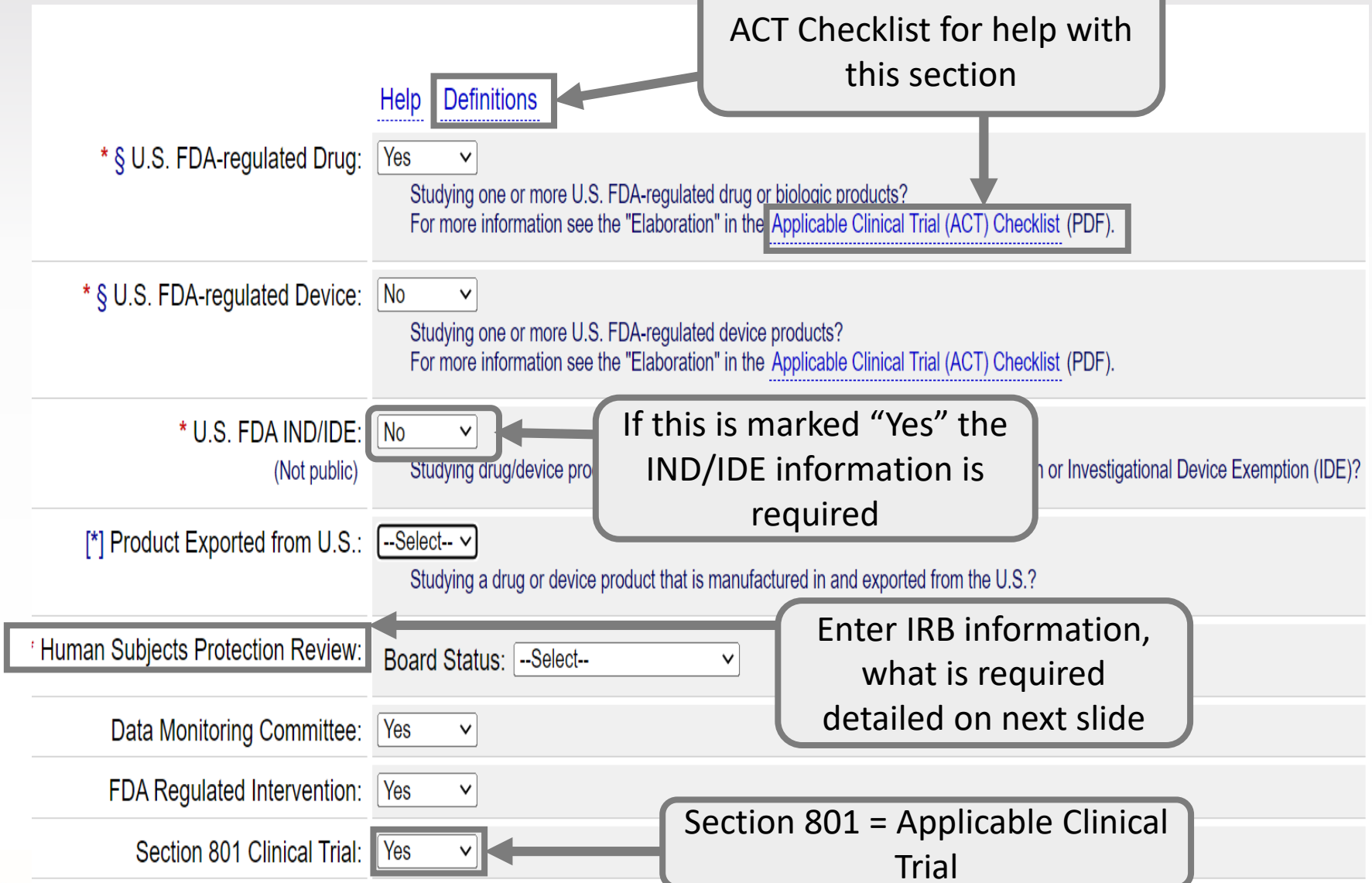
- Sponsor
- Principal Investigator
- Sponsor/Investigator



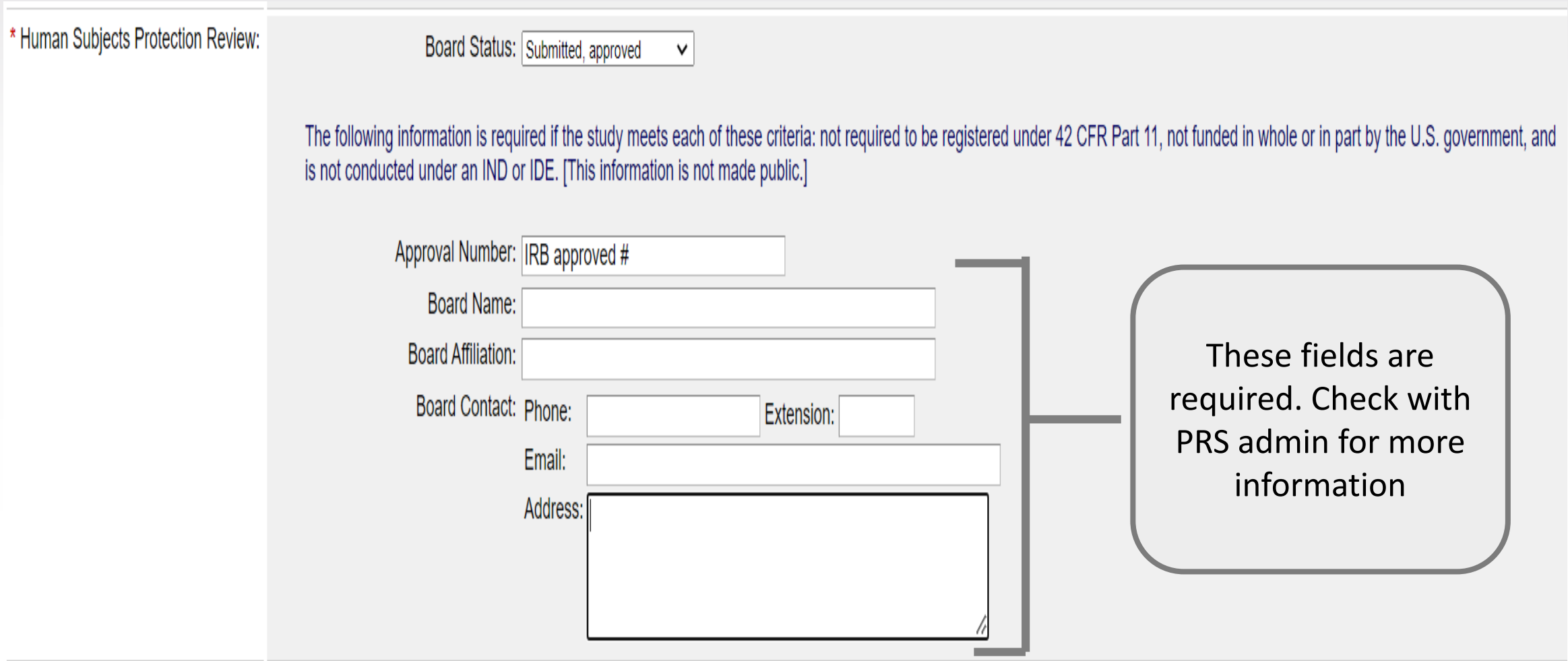
Should pre-populate as organization used for log-in

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

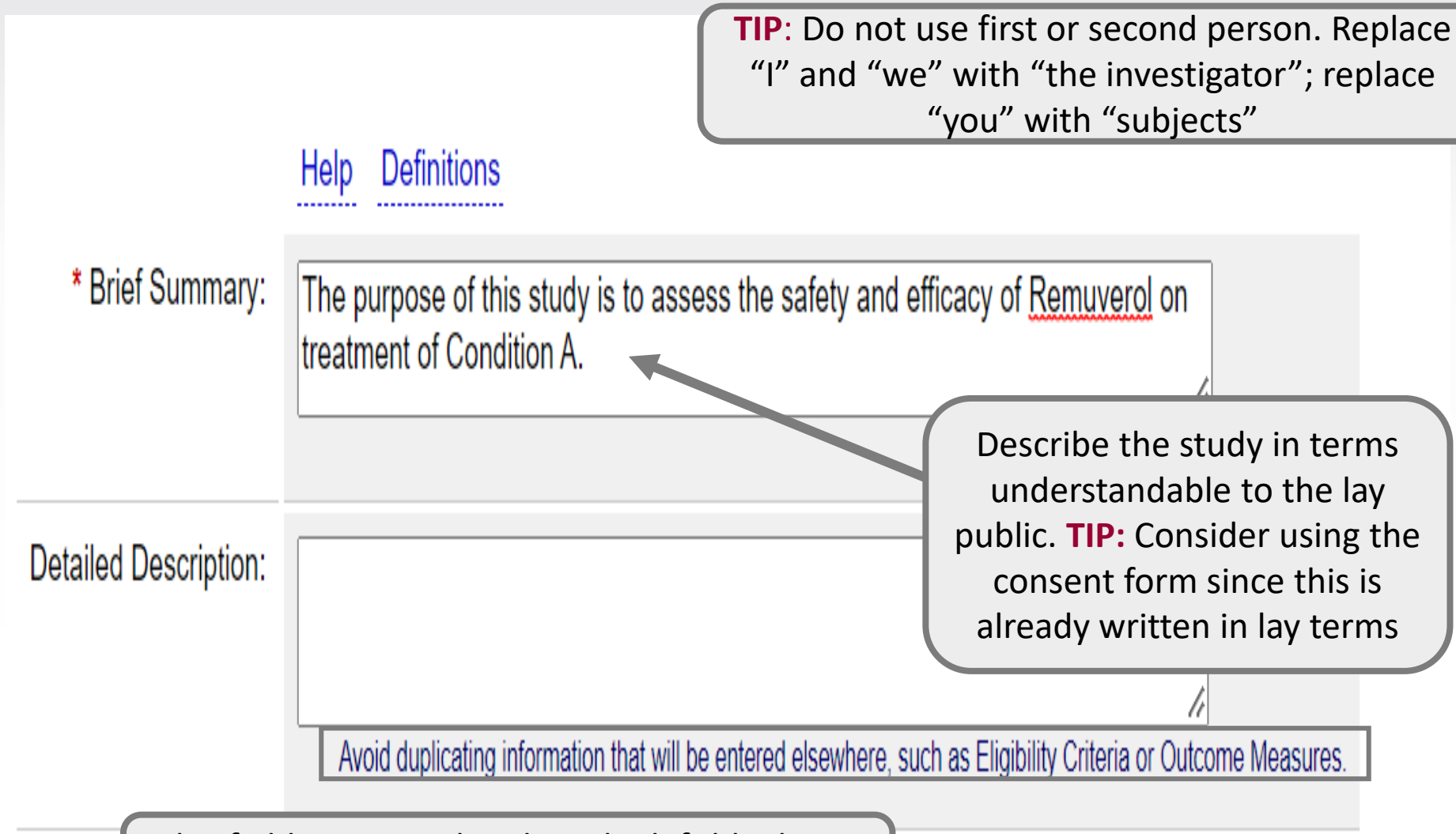
Oversight Page



Human Subjects Protection Review

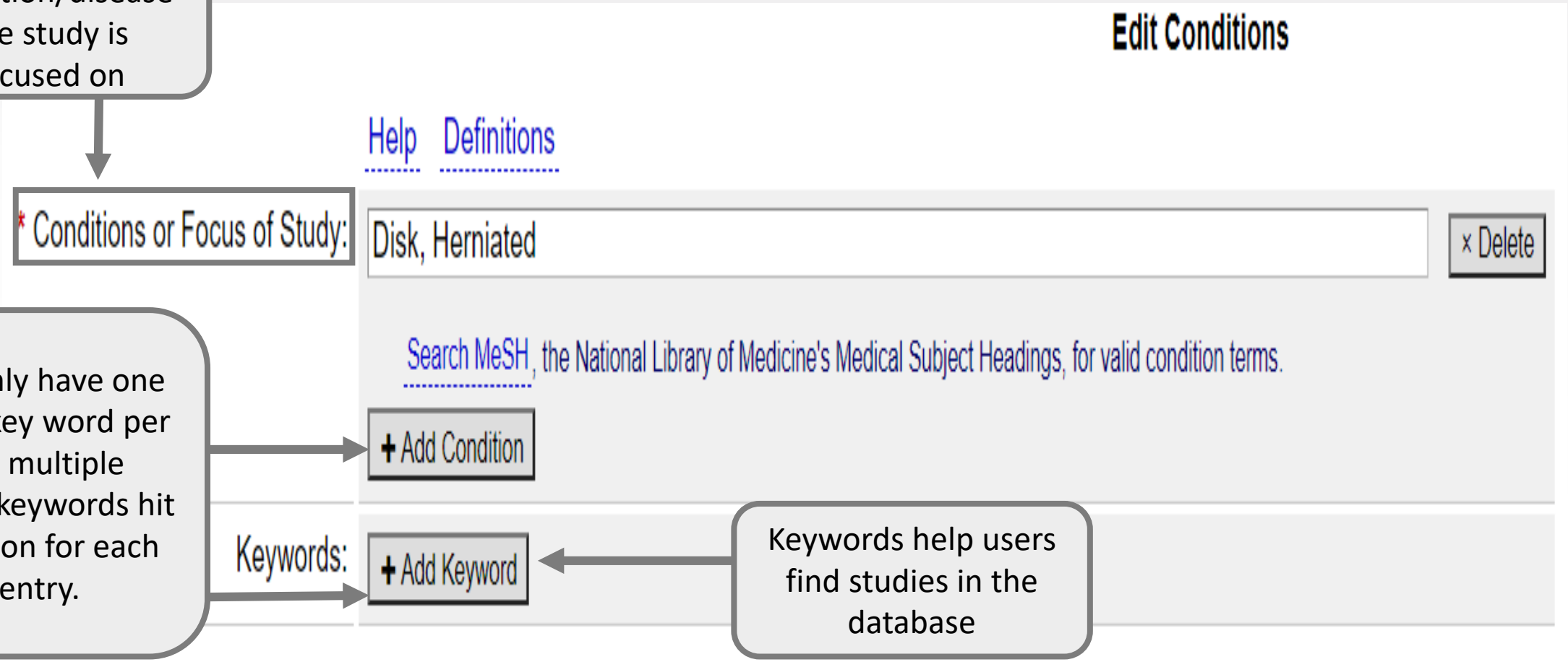


Study Description Page



Conditions Page

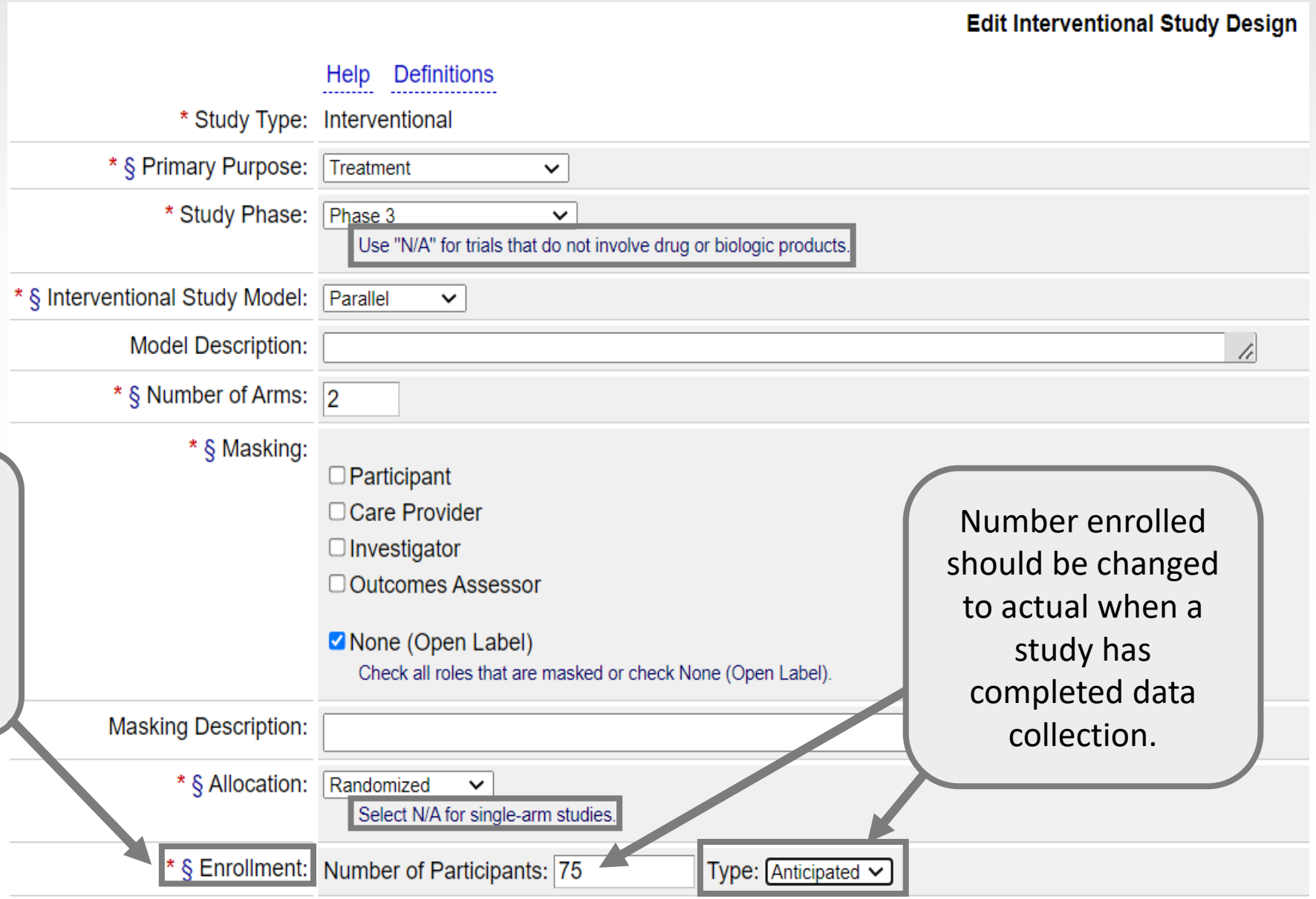
Overall condition/disease the study is focused on



TIP: Can only have one condition/key word per line. For multiple conditions/keywords hit "Add" button for each new entry.

Keywords help users find studies in the database

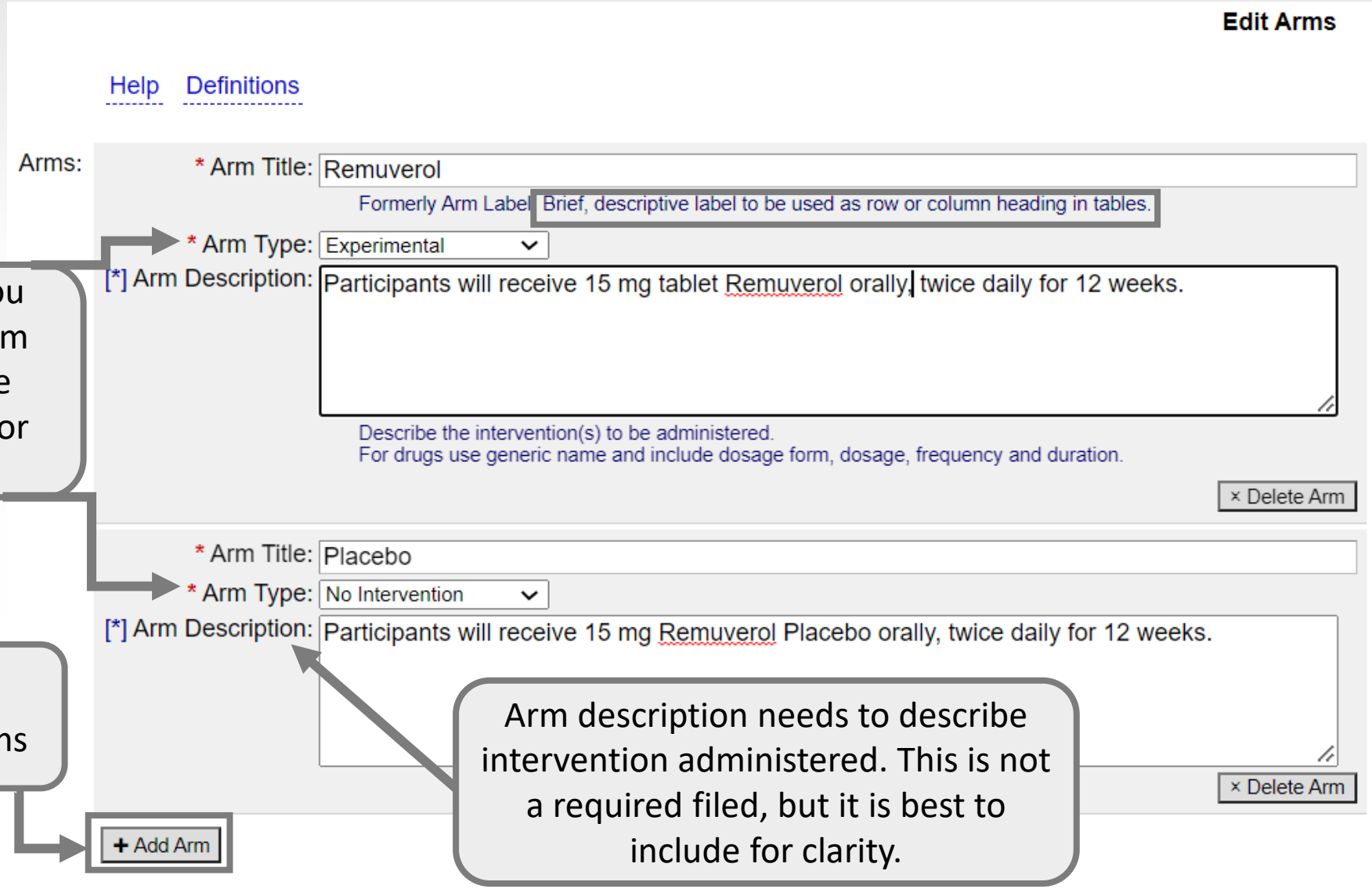
Interventional Study Design Page



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



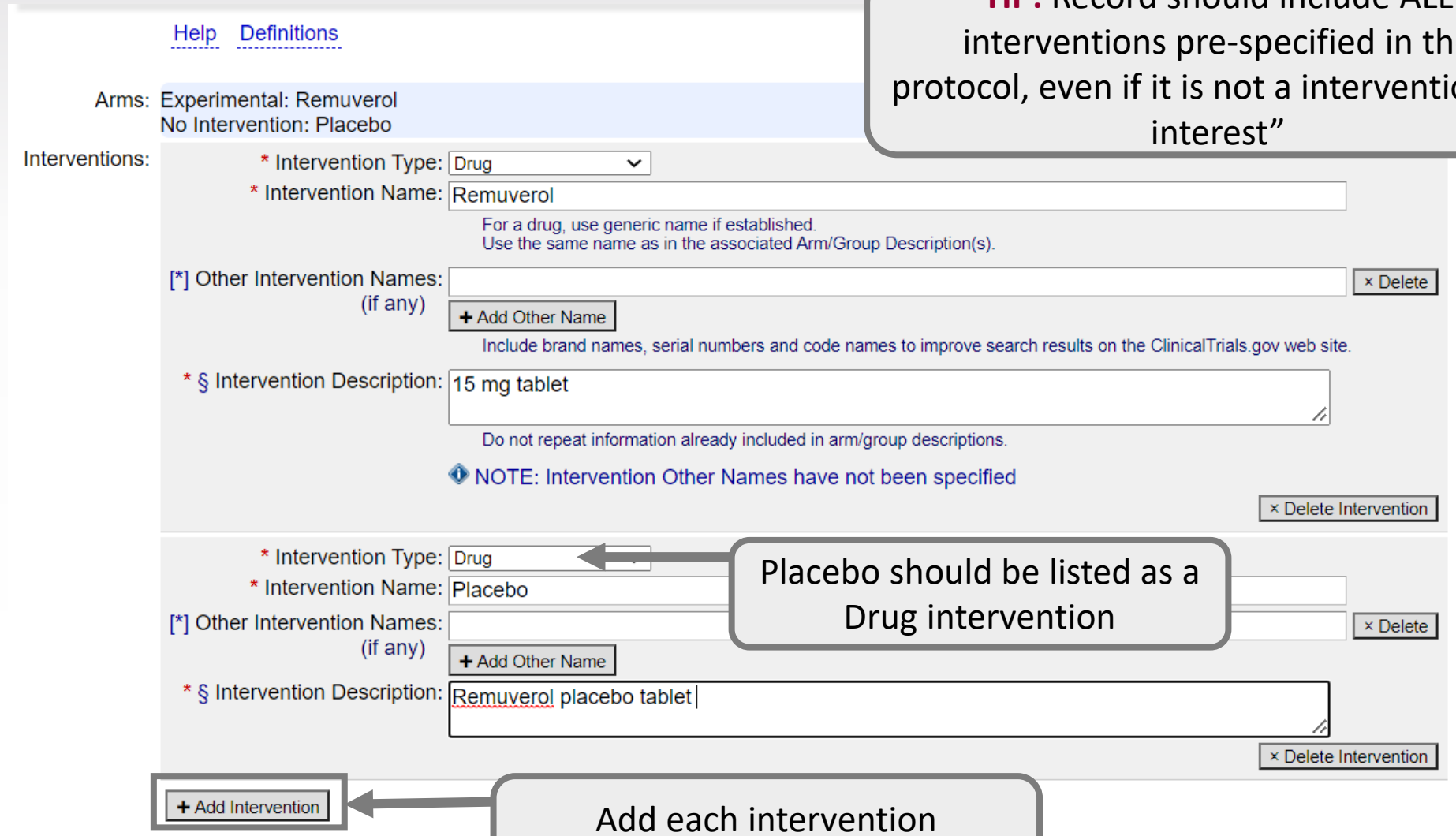
For Arm Type you must choose from drop down. Use definitions link for more info

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"



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	☑	☐
Placebo Comparator: Placebo	☐	☑

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:	To determine the effect of Remuverol on pain in adults
Description:	
Time Frame:	Baseline, 12 weeks

Title:	Change in pain as measured by the Visual Analogue Scale (VAS)
Description:	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.
Time Frame:	Baseline, 12 weeks

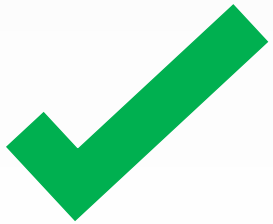
There are multiple time points, so "change" is included in the title

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:	To assess the safety of Remuverol
Description:	
Time Frame:	End of study



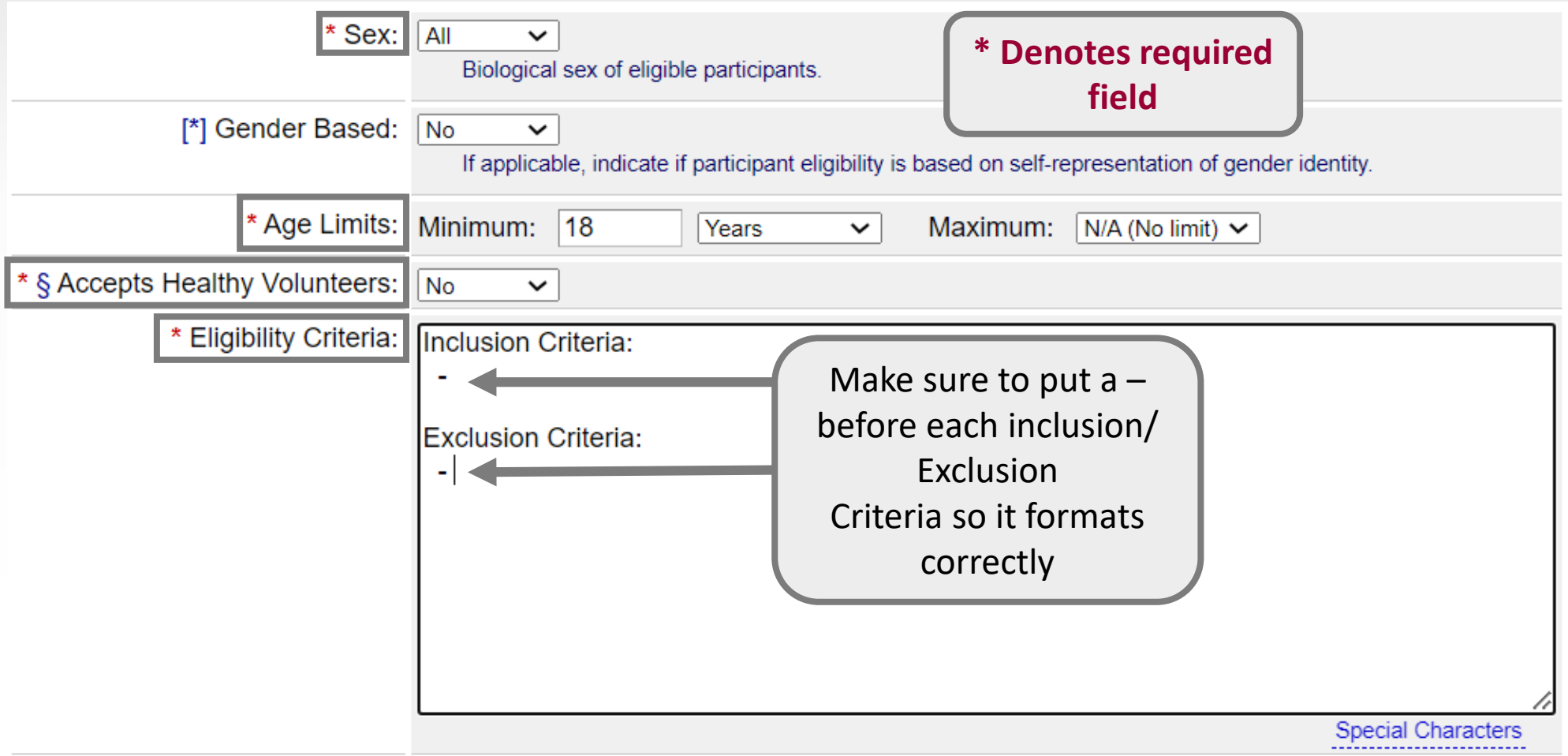
Title:	Number of participants with at least one adverse event as measured by patient report
Description:	Adverse events will include any AE related to study drug.
Time Frame:	End of study, up to 24 weeks

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

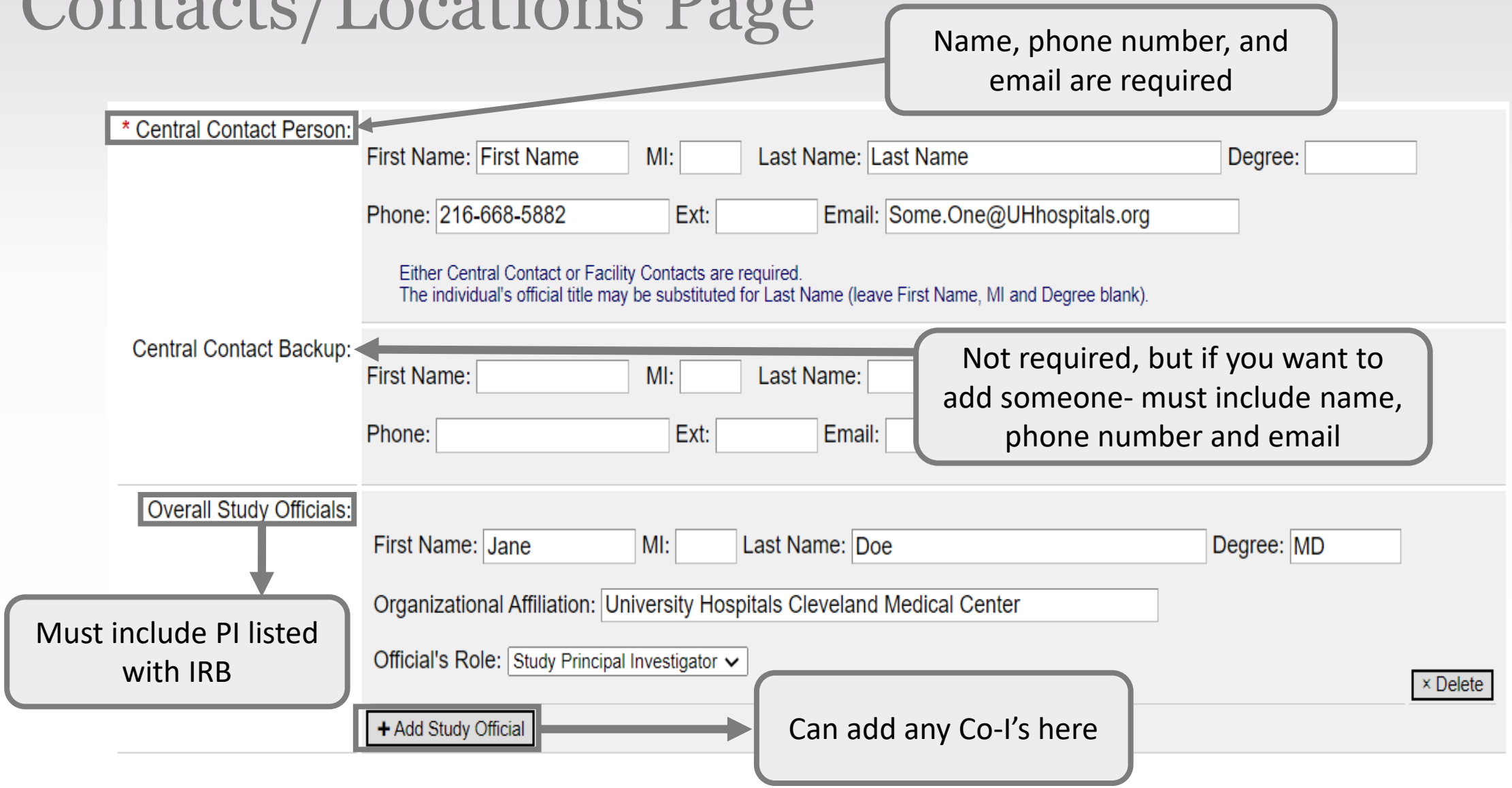
“End of study” is not descriptive enough, need to add actual length of time

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

Eligibility Page



Contacts/Locations Page



IPD Sharing Statement Page

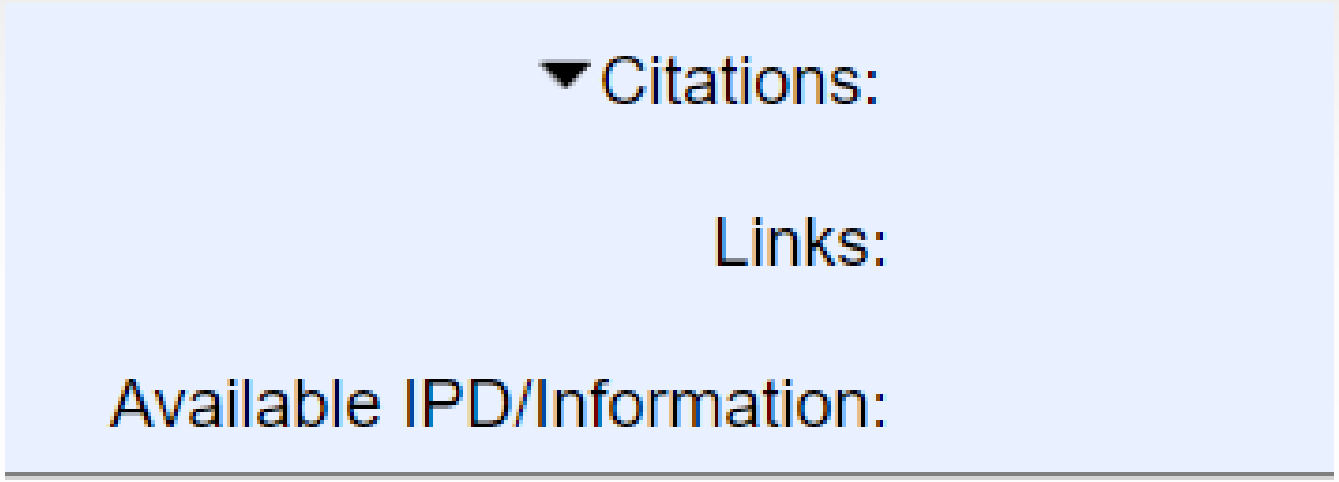
This is sharing individual participant level data, not aggregate data sets. If you plan to share this level of data you must present your plan and have it IRB approved.

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



Here you made include any citations or links.

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