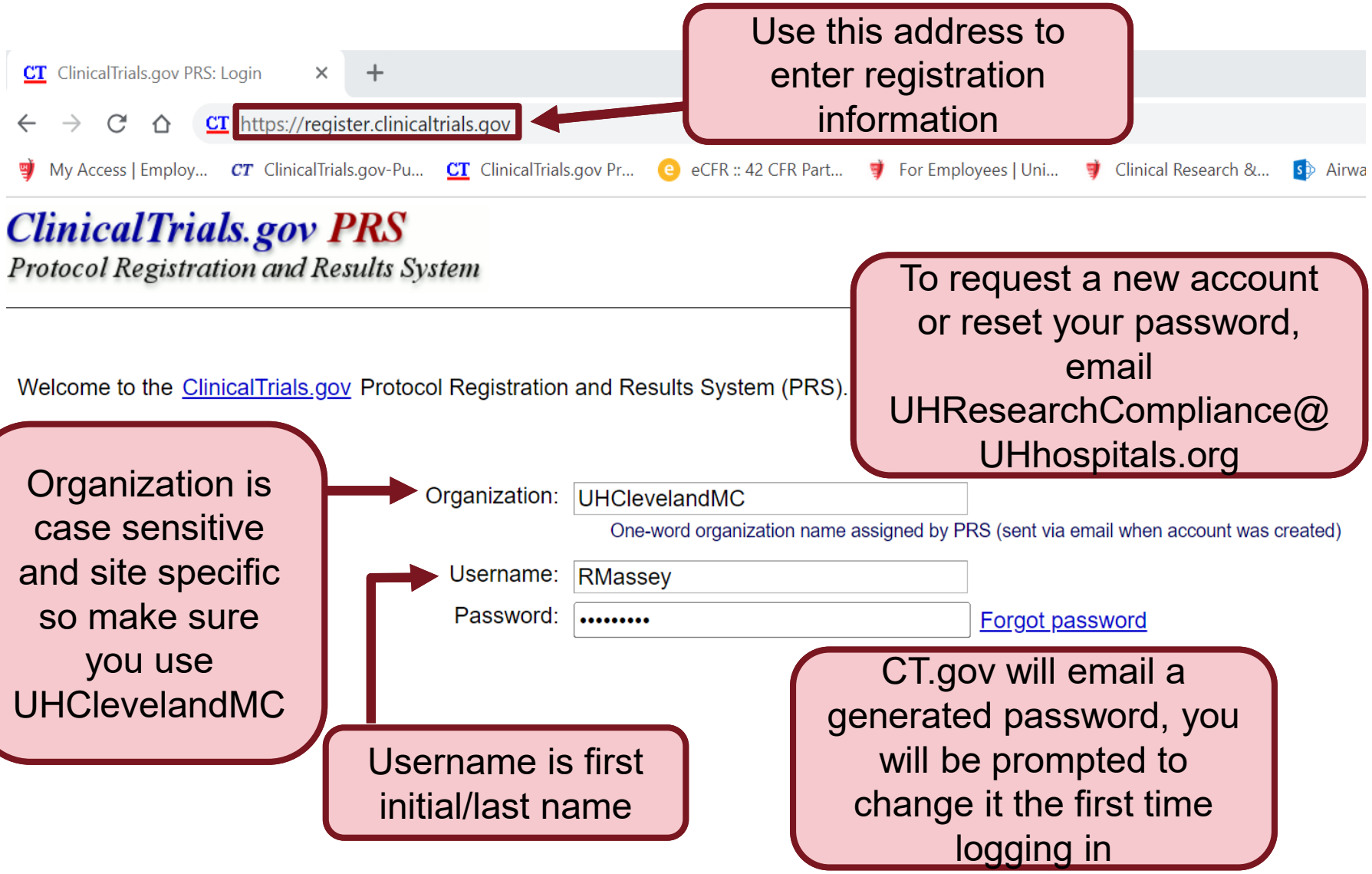
ClinicalTrials.gov Registration User's Guide

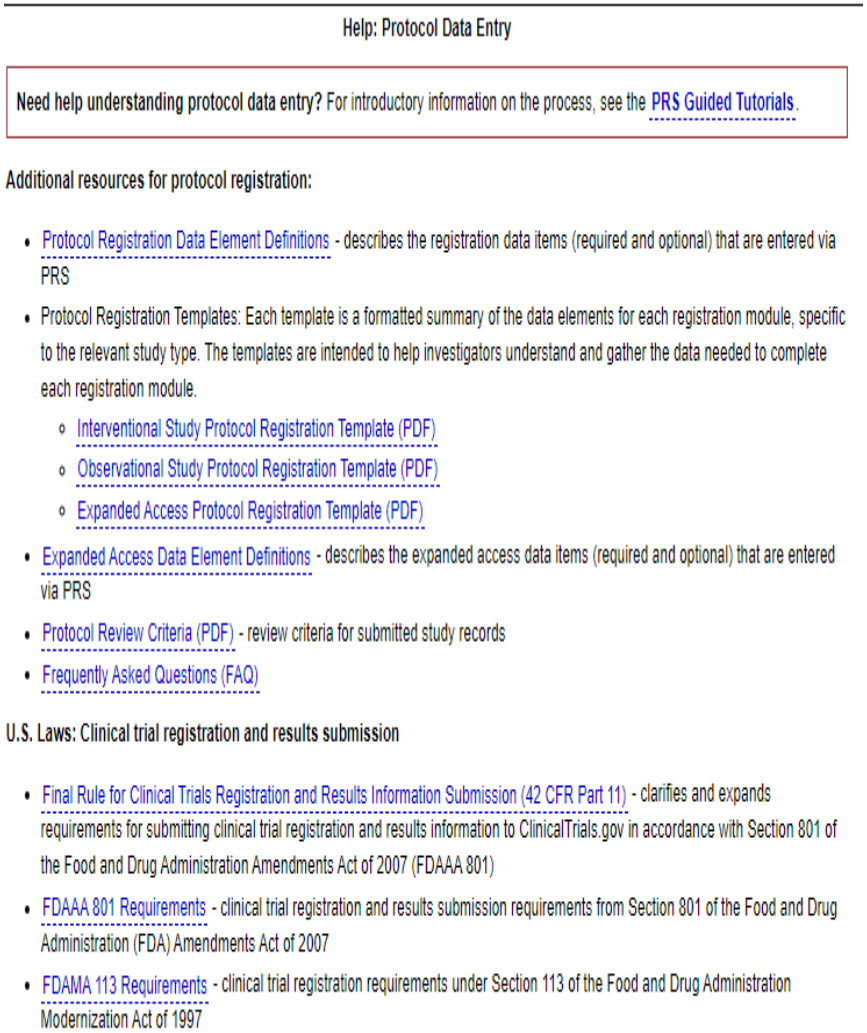
For questions please contact UHResearchCompliance@UHhospitals.org

University Hospitals
Cleveland | Ohio



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

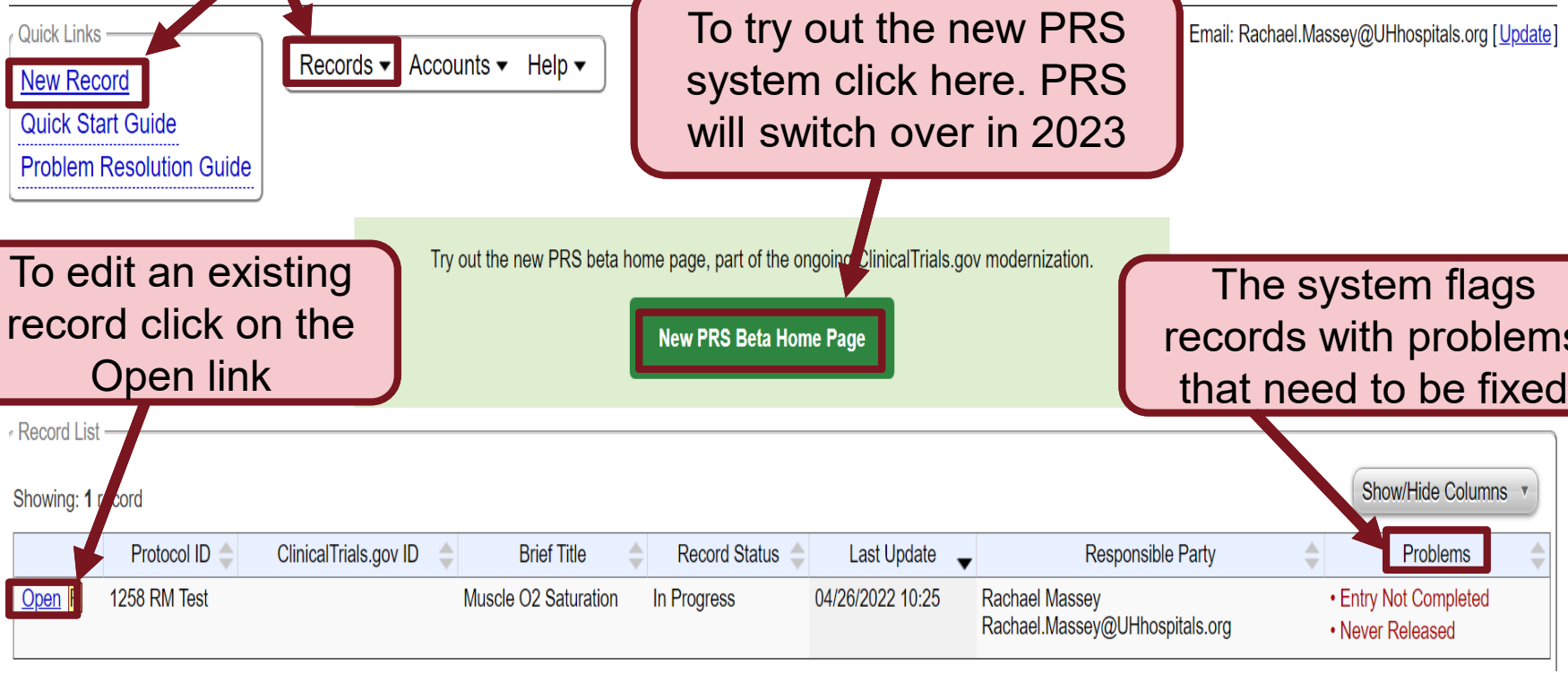
- Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) - clarifies and expands requirements for submitting clinical trial registration and results information to ClinicalTrials.gov in accordance with Section 801 of the Food and Drug Administration Amendments 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…..

- Link to SOPs for ClinicalTrials.gov:
  - https://www.uhhospitals.org/-/media/Files/For-Clinicians/Research/clinical-research-sop-manual.pdf?la=en&hash=90B17F1B80AA9FCD754ED989B53222F557613696
- If you would like to set up a one on one to walk through the registration please email UHResearchCompliance@UHhospitals.org
- 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 a week)
- After CT.gov reviews, the record owner will get an email with the NCT# or with PRS comments, which should 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

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 2023

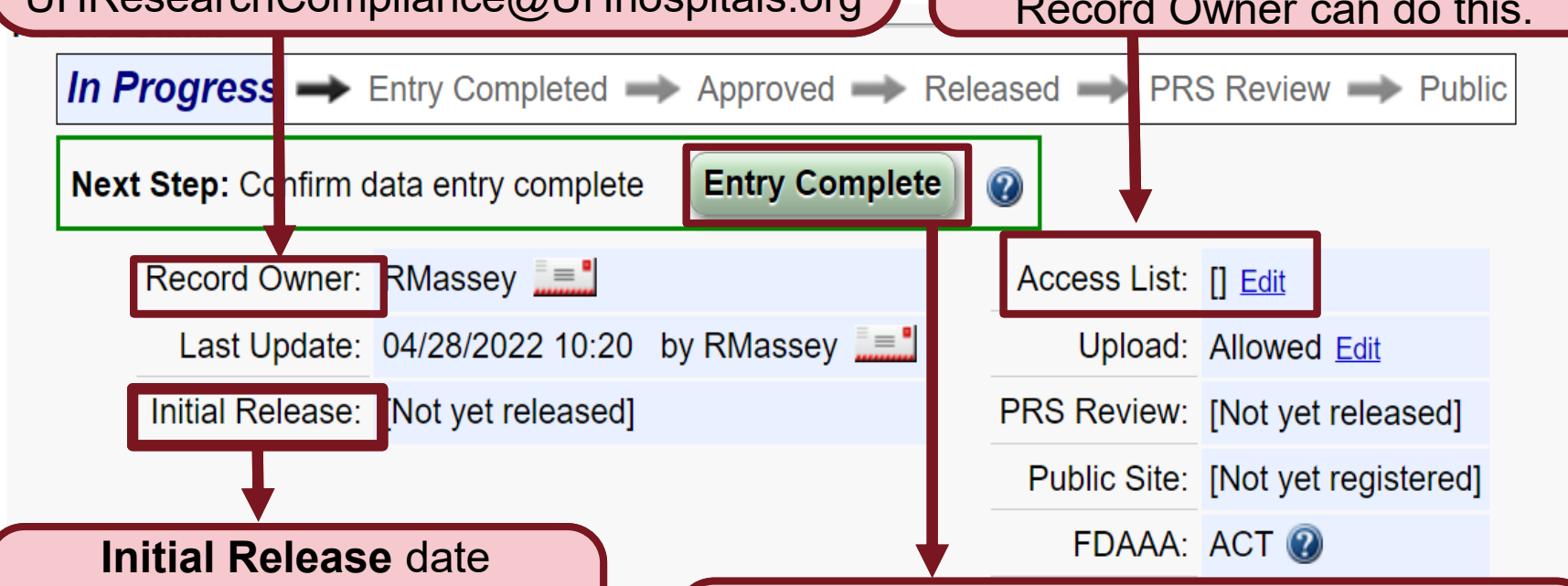
To edit an existing record click on the Open link

The system flags records with problems that need to be fixed

Record Summary 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: UHResearchCompliance@UHhospitals.org

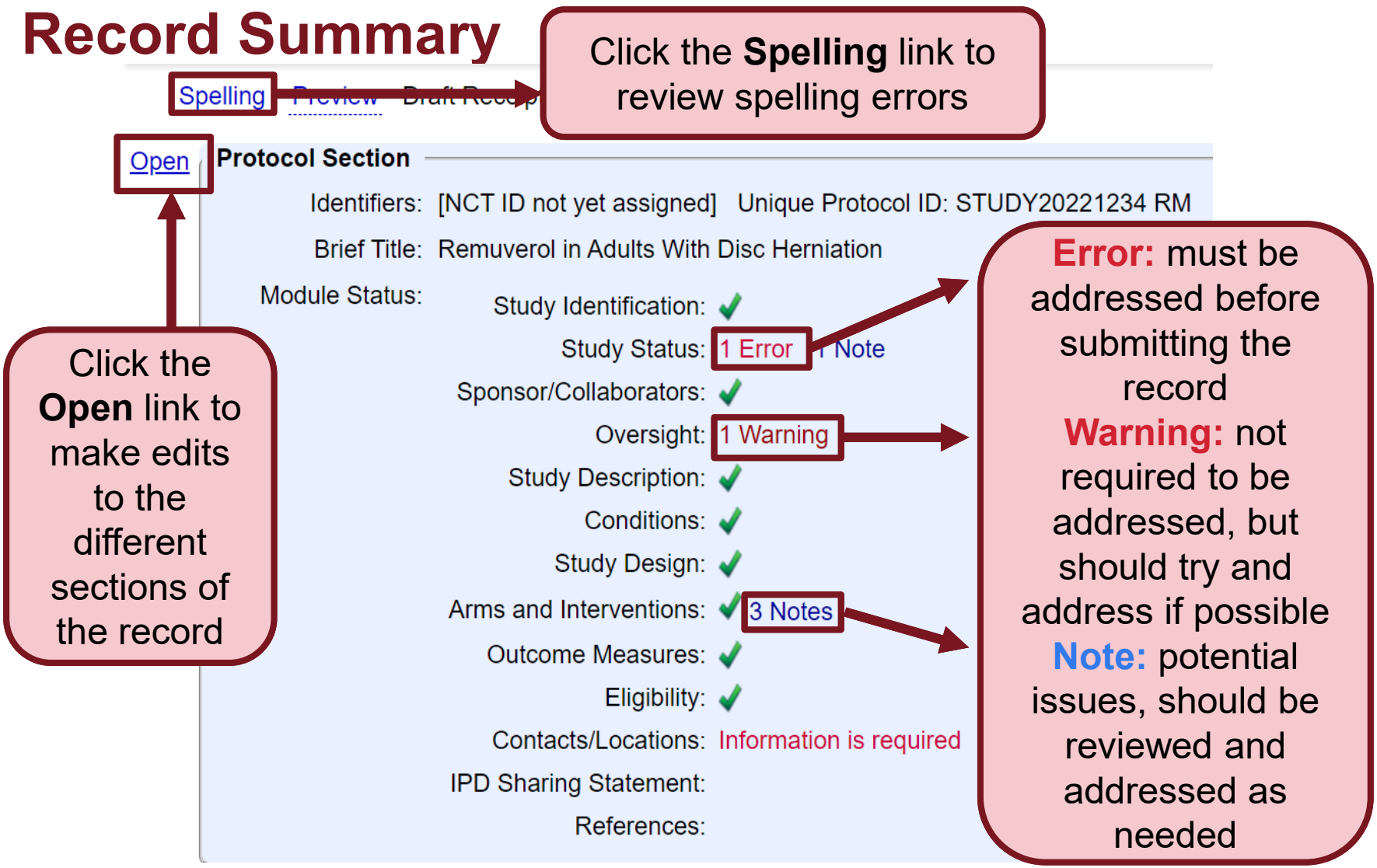
Add anyone who needs edit rights.
Record Owner can do this.

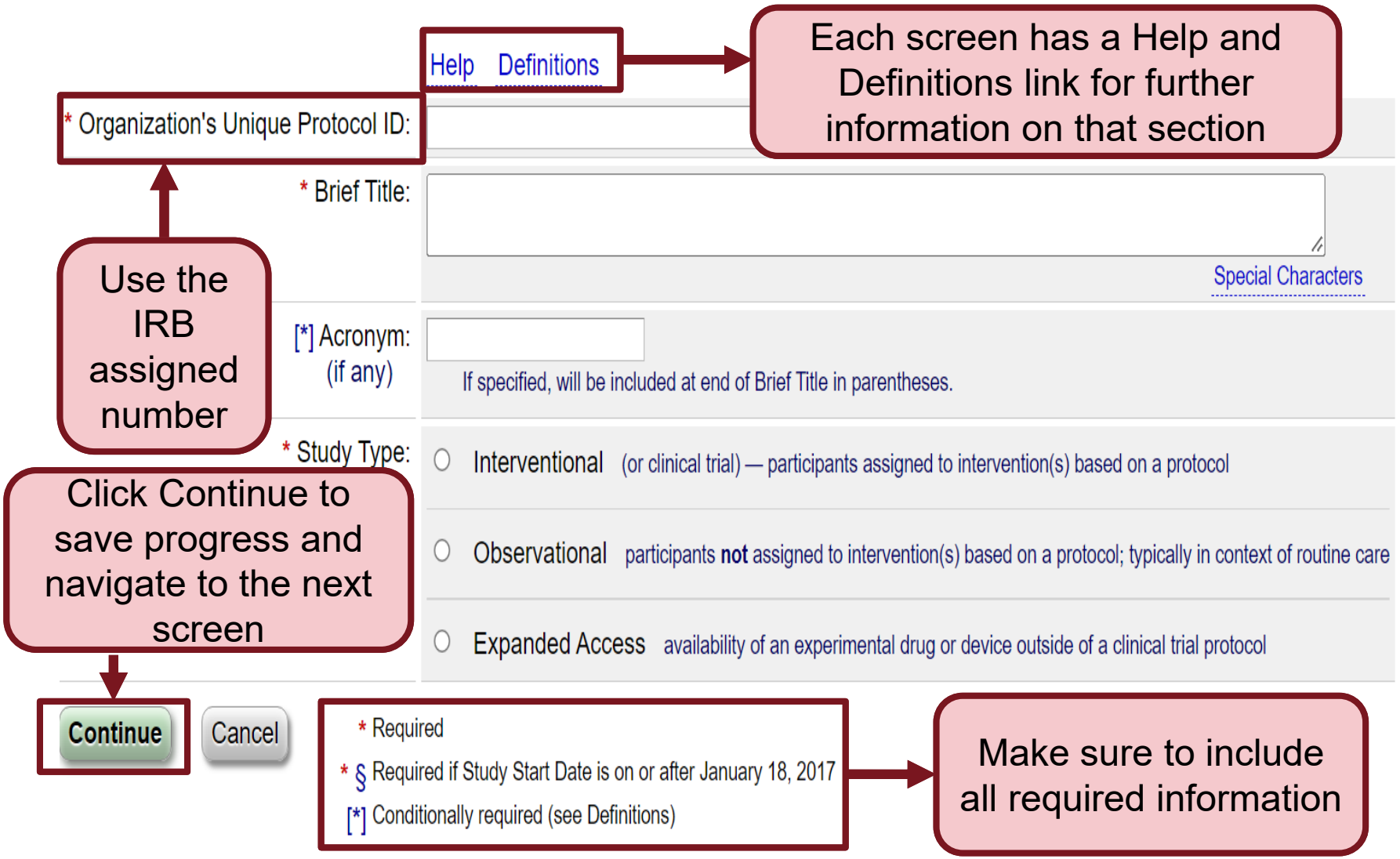


Initial Release date displays on the public site. This is important for ACTs and ICMJE

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

Record Summary





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.

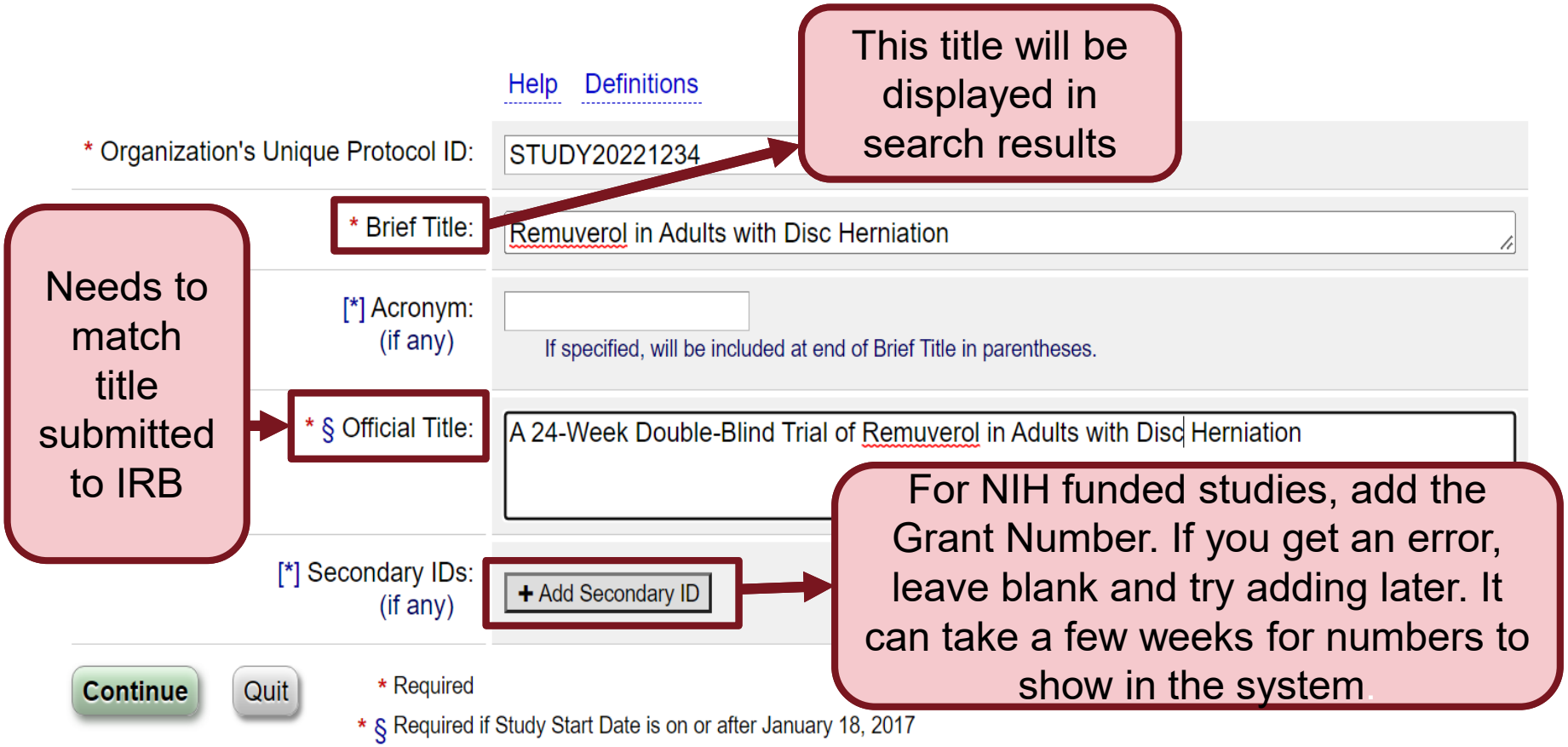
The following web pages allow data entry for each protocol module:

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

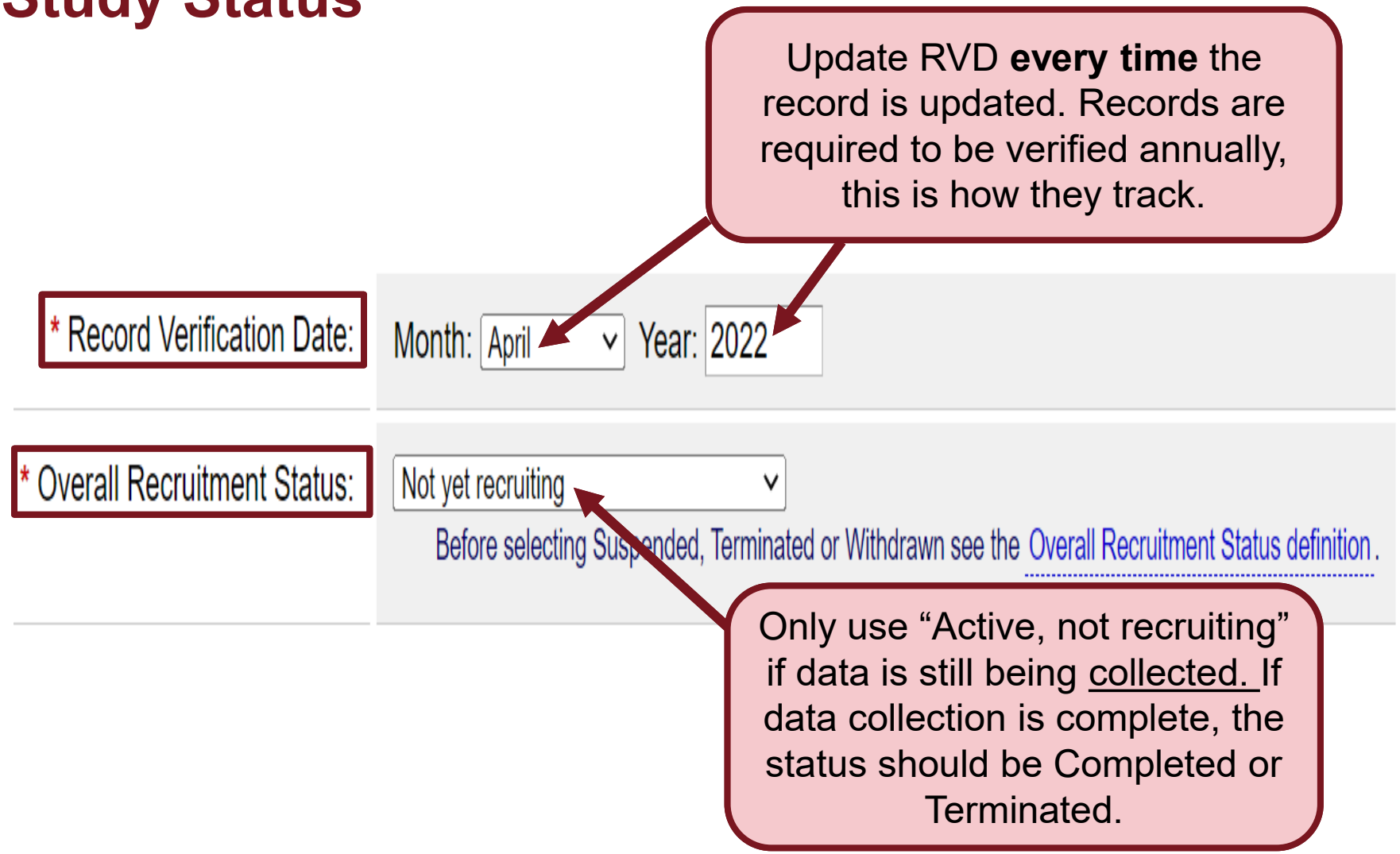
On each page, select Continue to save data entered and proceed to the next page.

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 Status



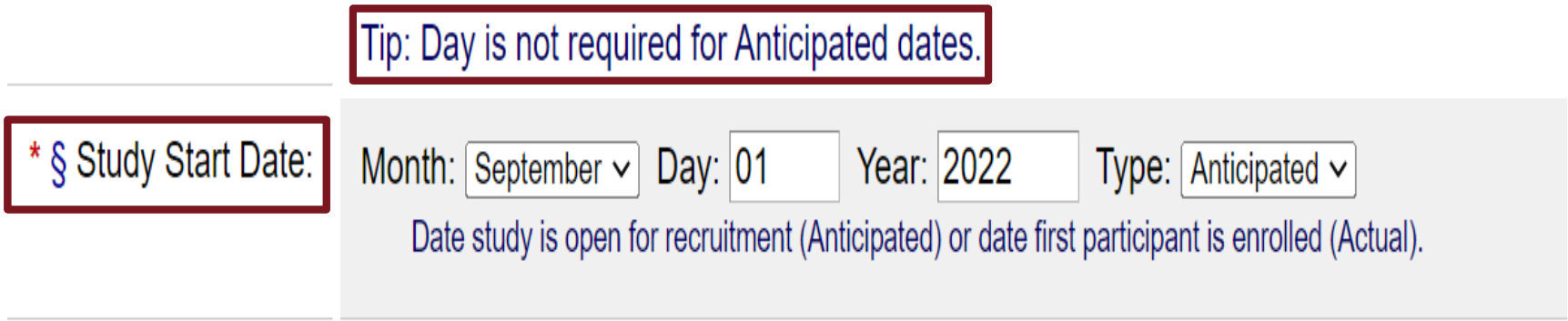
Overall Recruitment Status *

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

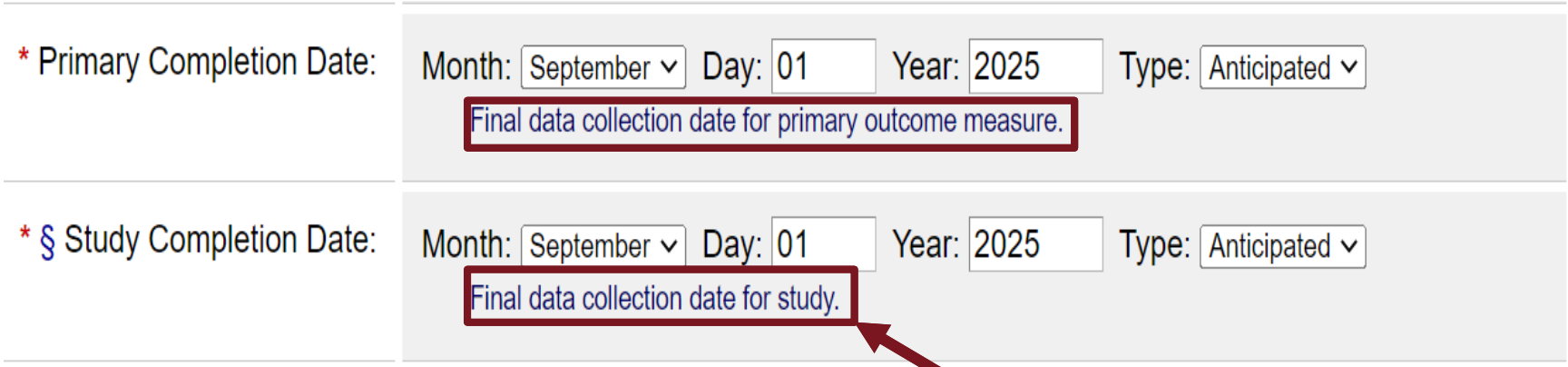
Study Start Date

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.**

* Primary Completion Date:	Month: September Day: 01 Year: 2023 Type: Anticipated Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: December Day: 01 Year: 2023 Type: Anticipated Final data collection date for study.

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:

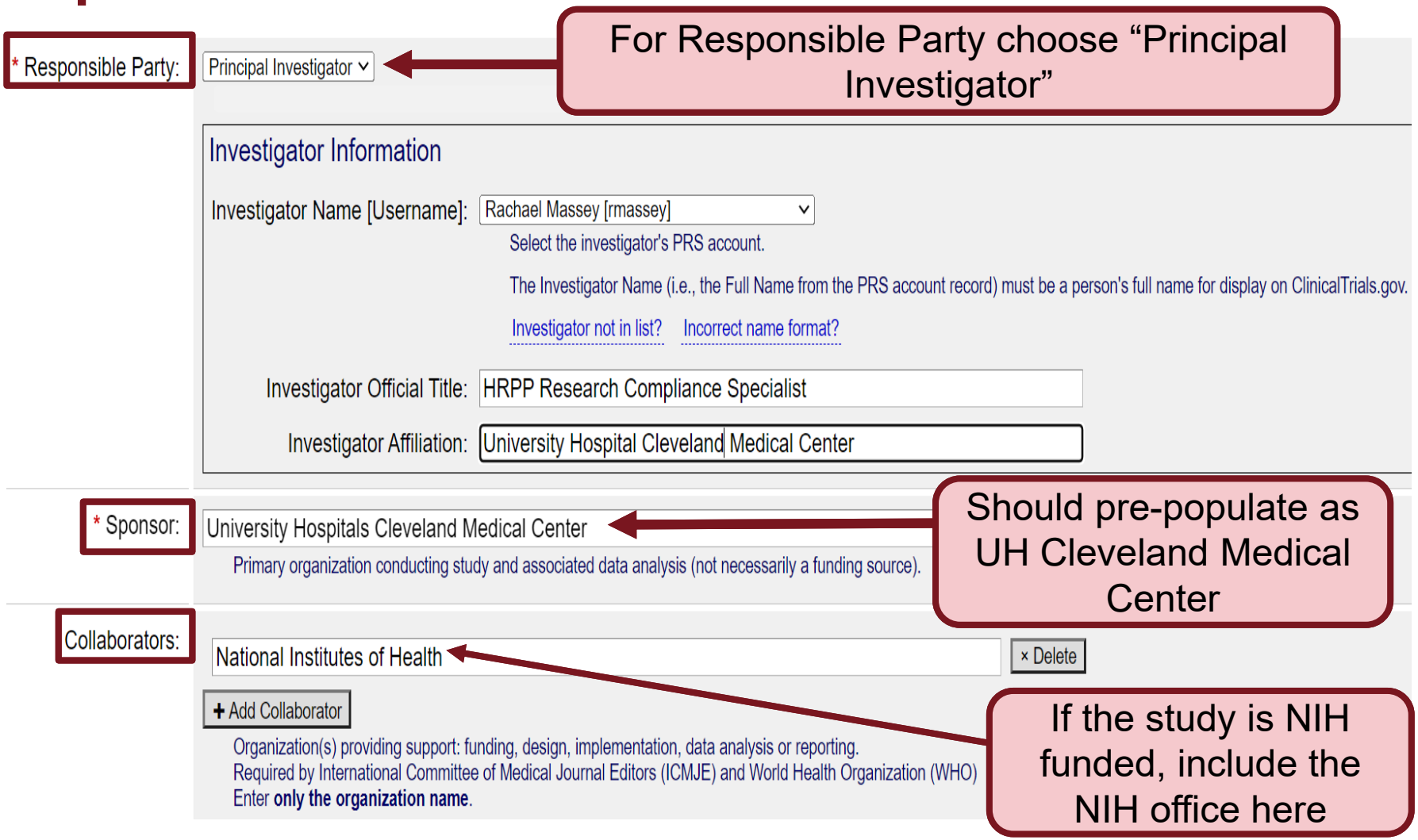
2. Change in the Beck Depression Inventory (BDI-II)
   [Time Frame: Baseline, 16 weeks]

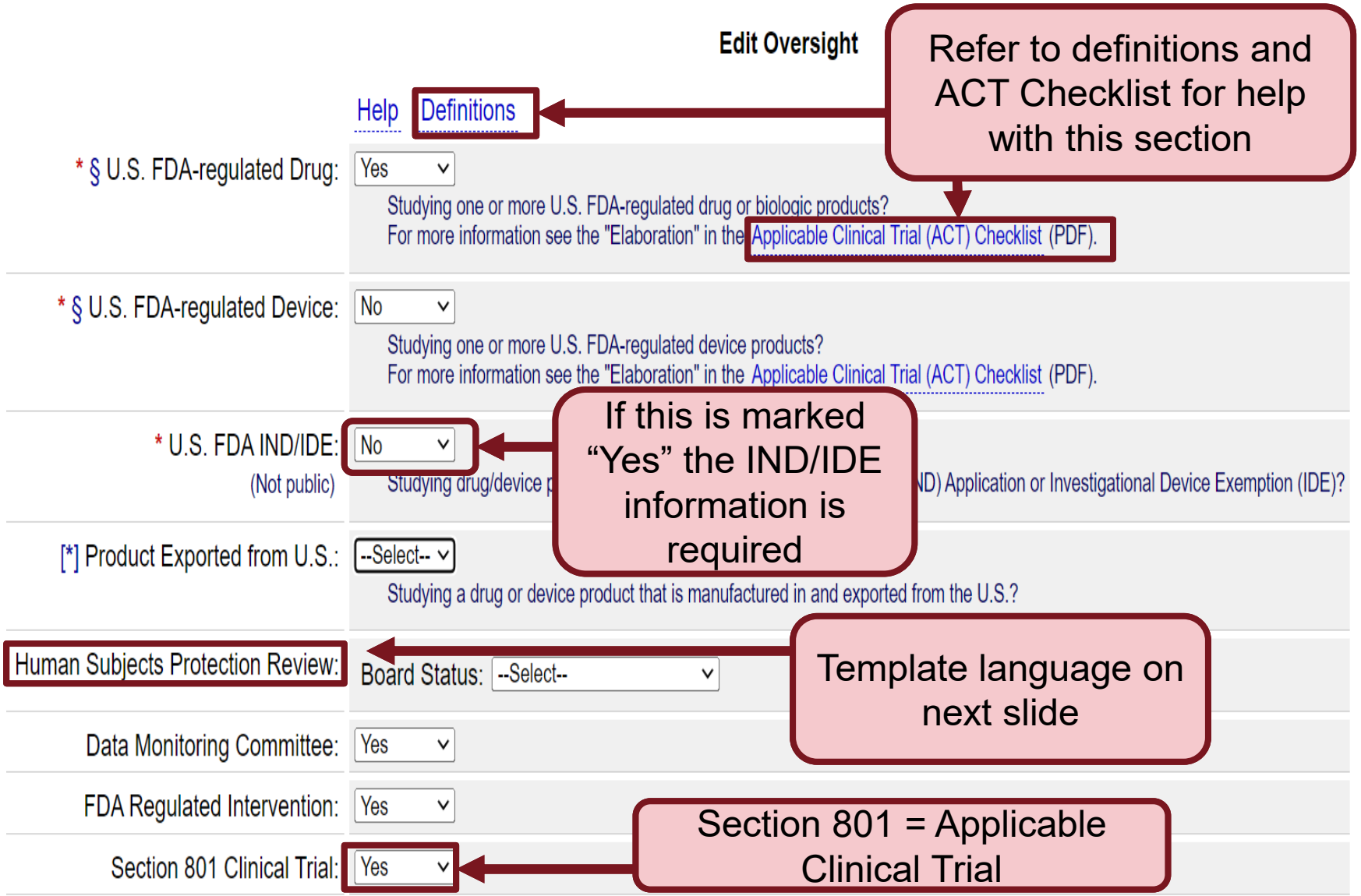
The **Primary Completion Date** is when the last subject completes the VAS (i.e. the subject's 12 week visit).

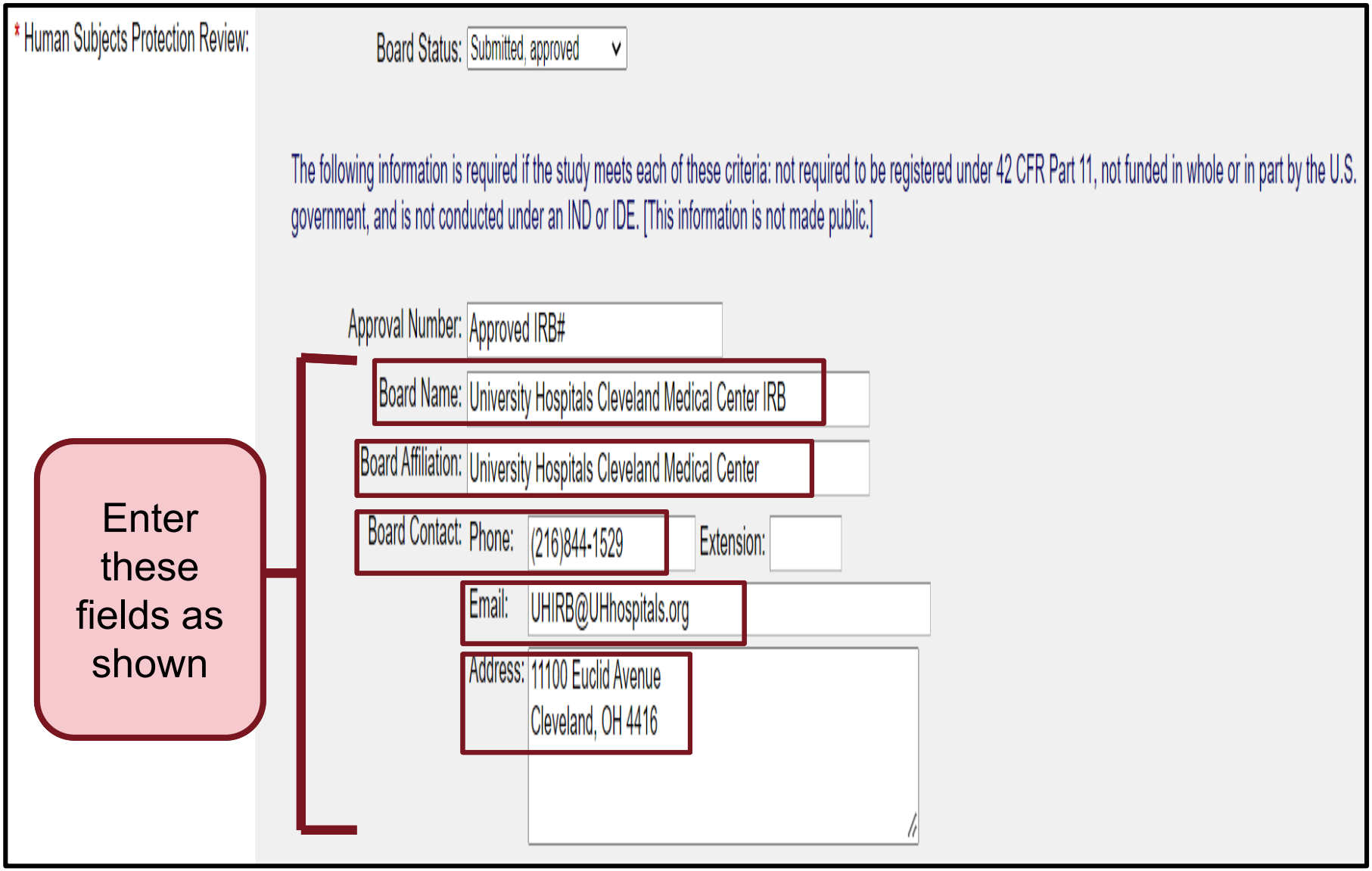
The **Study Completion Date** is when the last subject completes the DBI-II (i.e. the last subject's 16 week visit)*

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

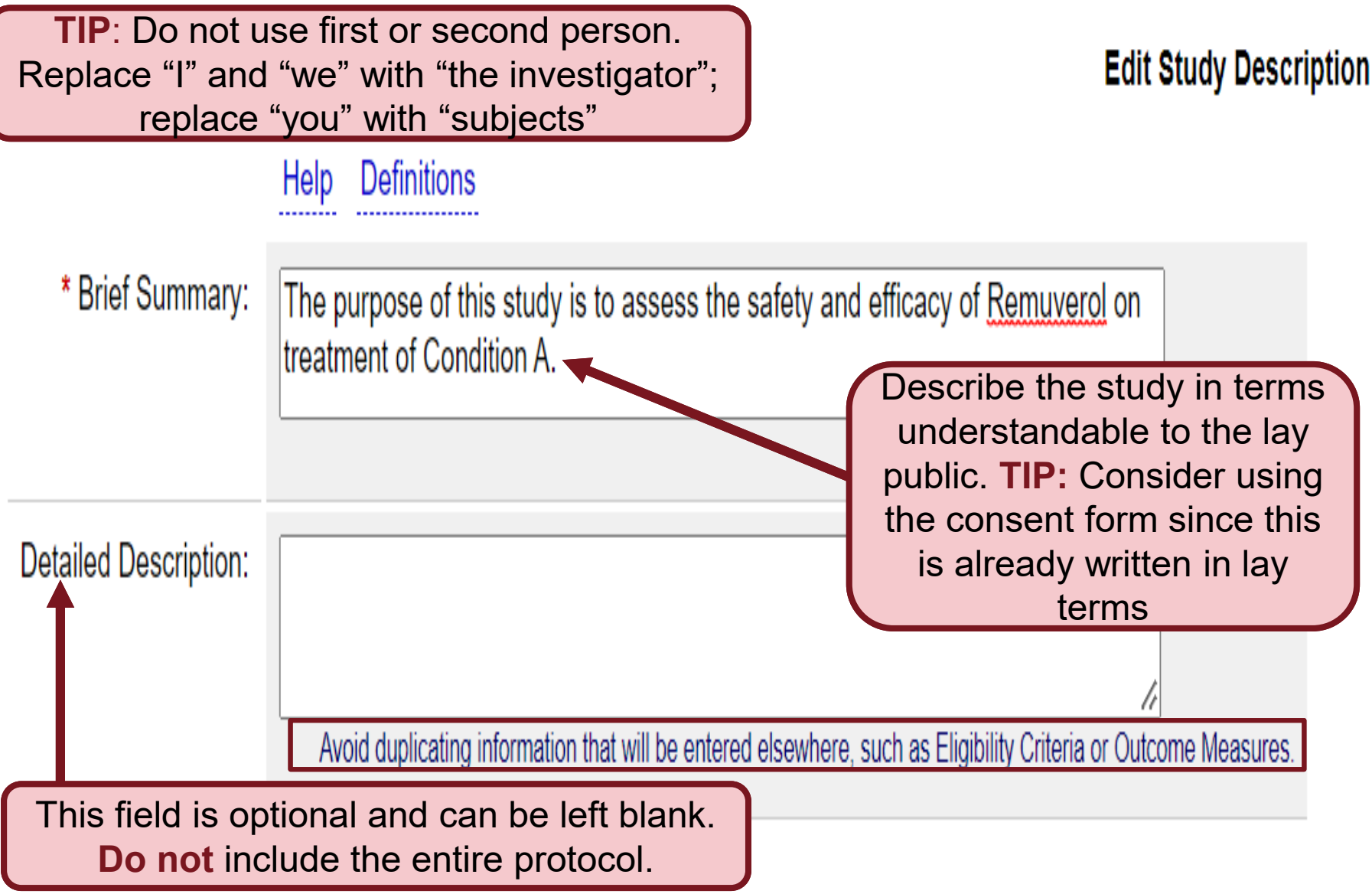
Sponsor/Collaborators



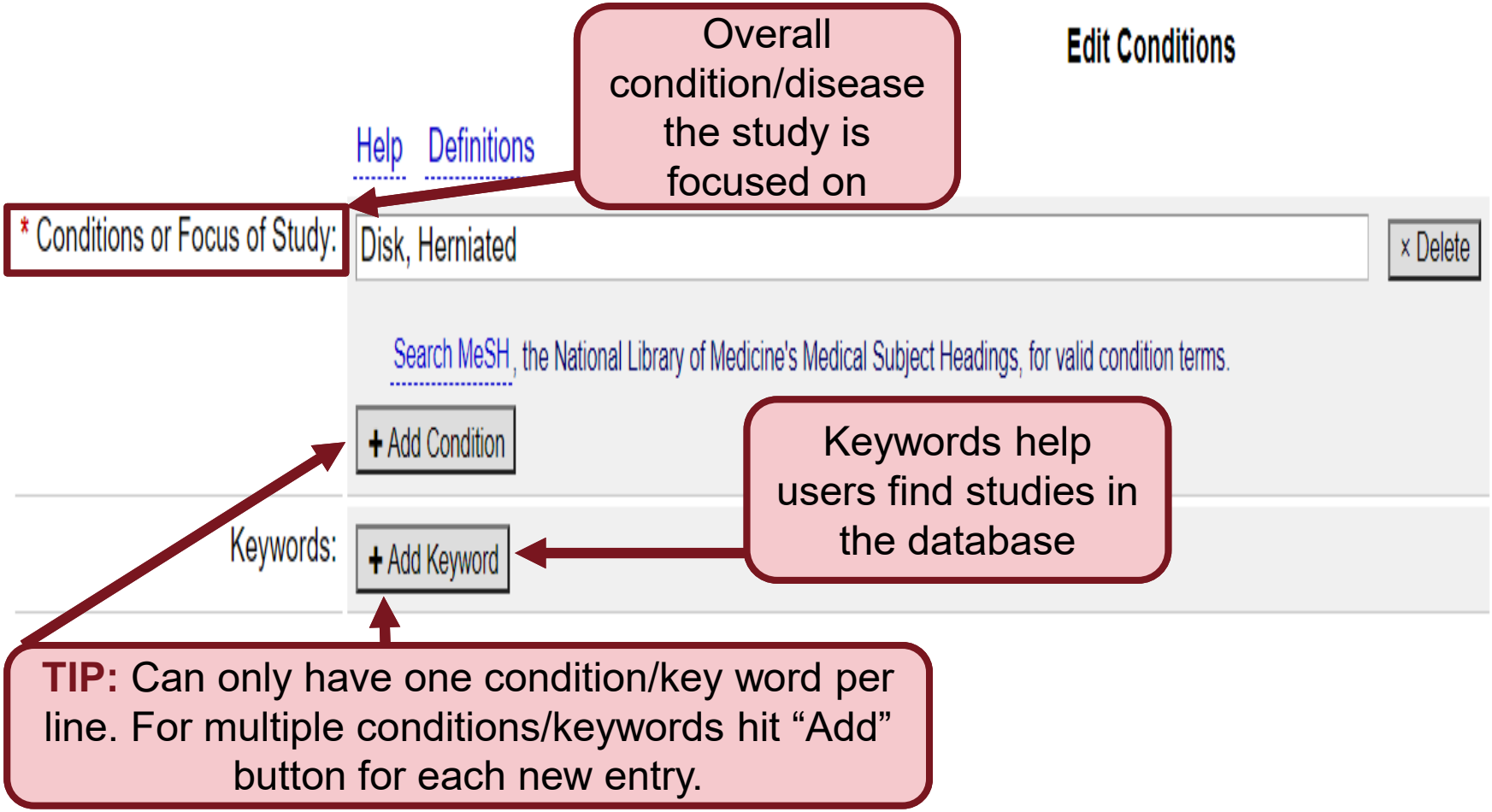


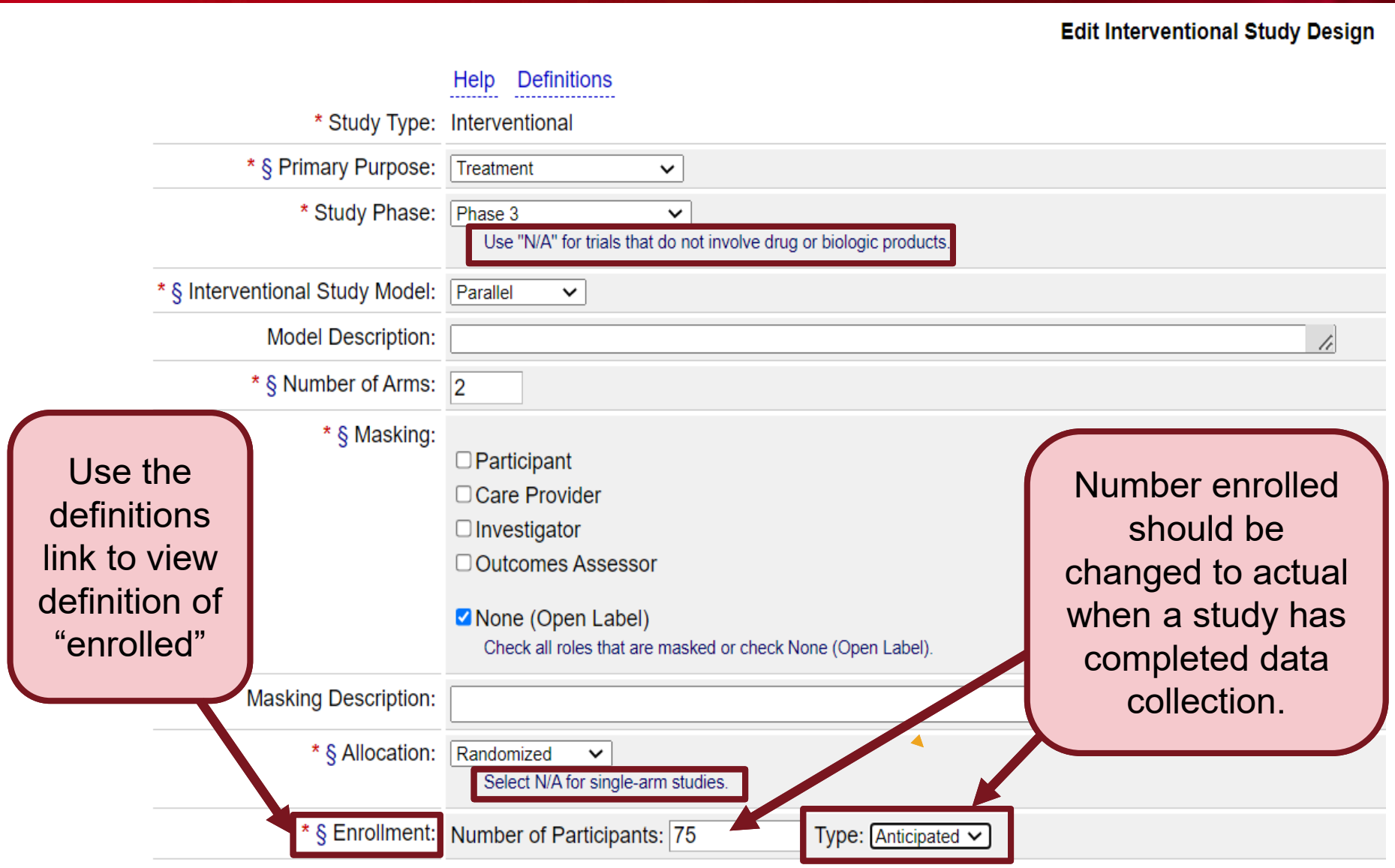


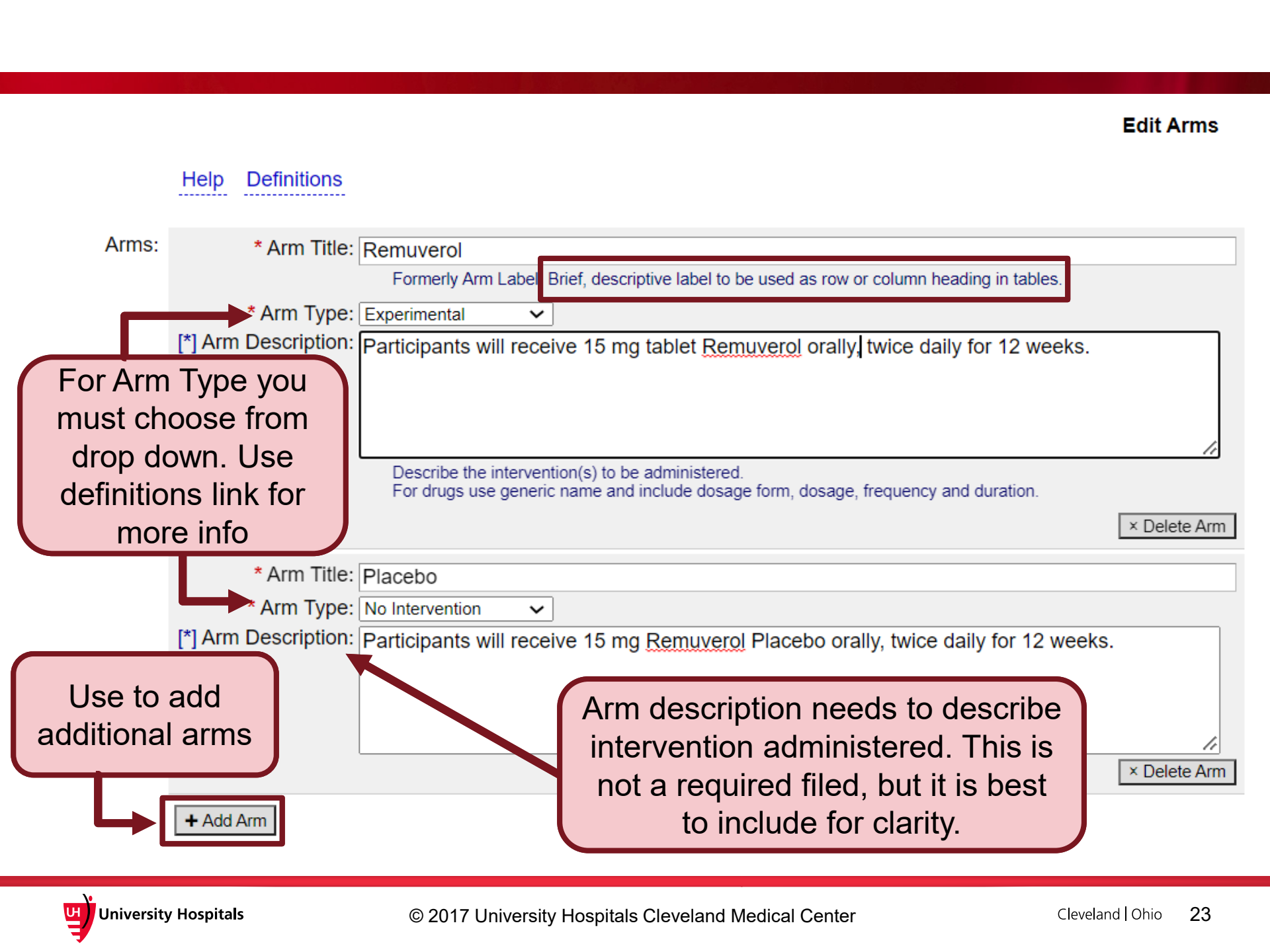
TIP: Do not use first or second person. Replace “I” and “we” with “the investigator”; replace “you” with “subjects”

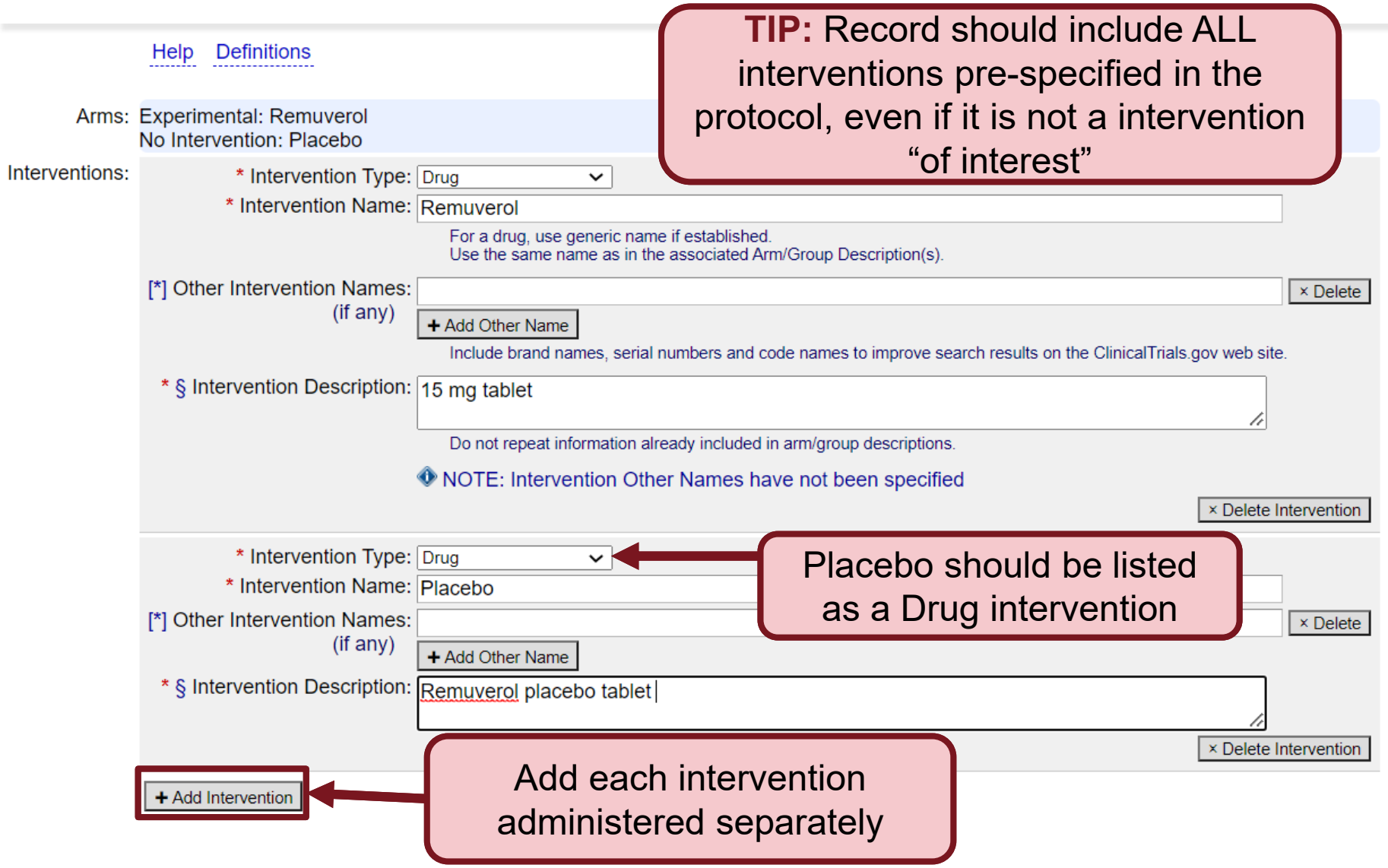


Conditions









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

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 tolderated 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

Time Frame should include specific time point data was collected

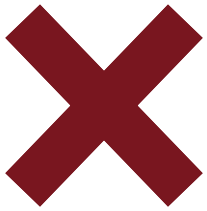
- Specific time point of data collection for that outcome measure (e.g. # of minutes, hours, weeks, months, years)
  - Ex: During hospitalization, approximately 5 days
  - Ex: End of study, up to 12 weeks
- Should only have one time point in the time frame, unless you are measuring a change. If you are 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

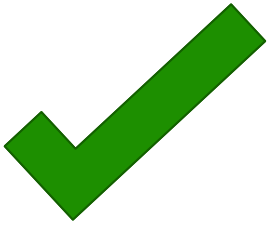
Outcome Measure: Description

- 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



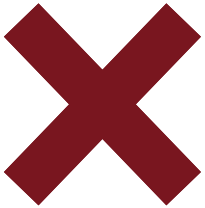
Title:	Change in pain as measured by the Visual Analogue Scale (VAS)
Description:	The Visual Analog Scale is a 10 item questionnaire ranking the severity of pain. Scores are measured on a 5 point likert scale, with 5 being extreme pain and 1 being no pain at all.
Time Frame:	Baseline, 12 weeks

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

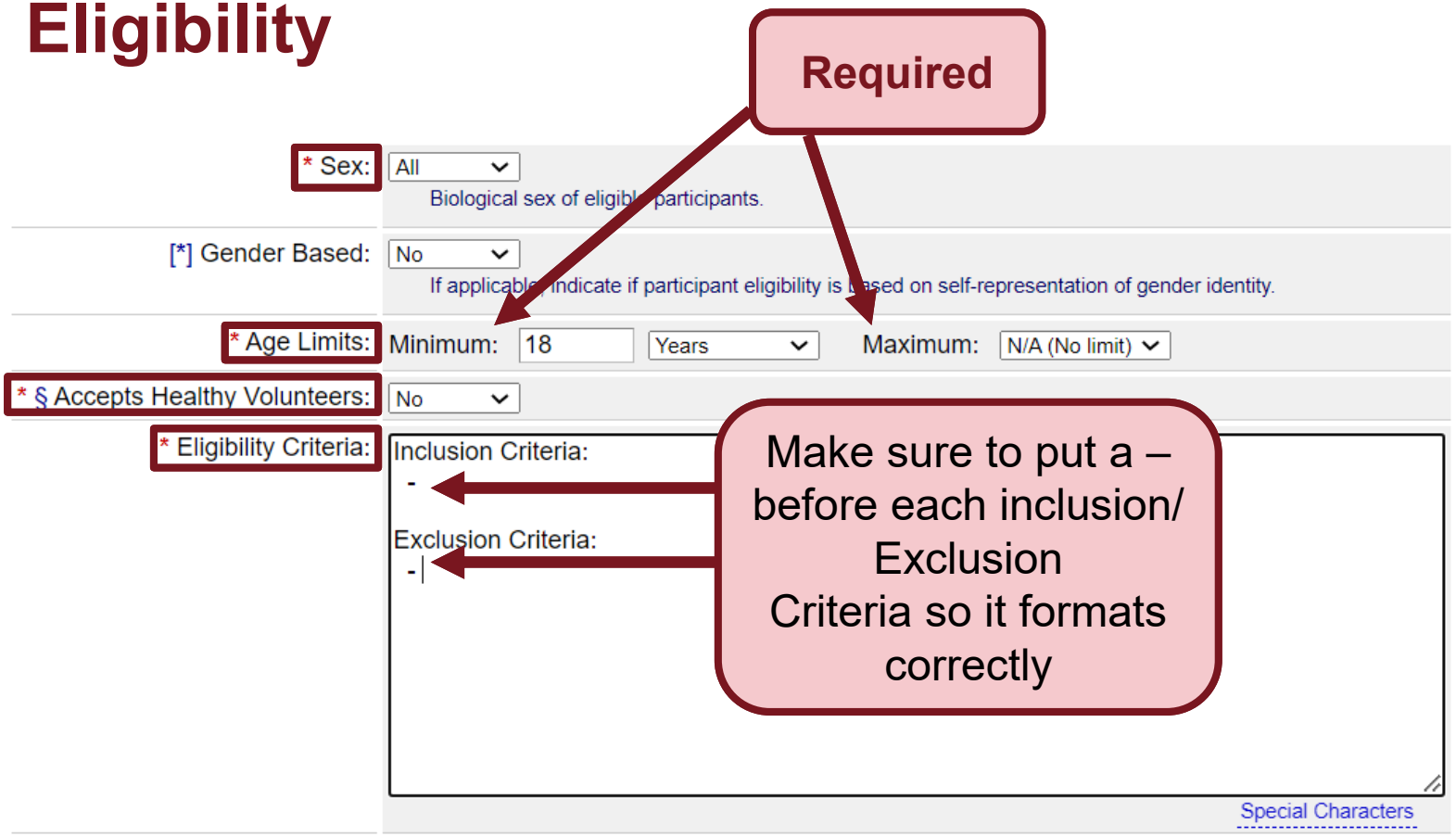
Title:	Number of participants with at least one adverse event as measured by patient report
Description:	Adverse events will include any AE related to study drug.
Time Frame:	End of study, up to 24 weeks

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

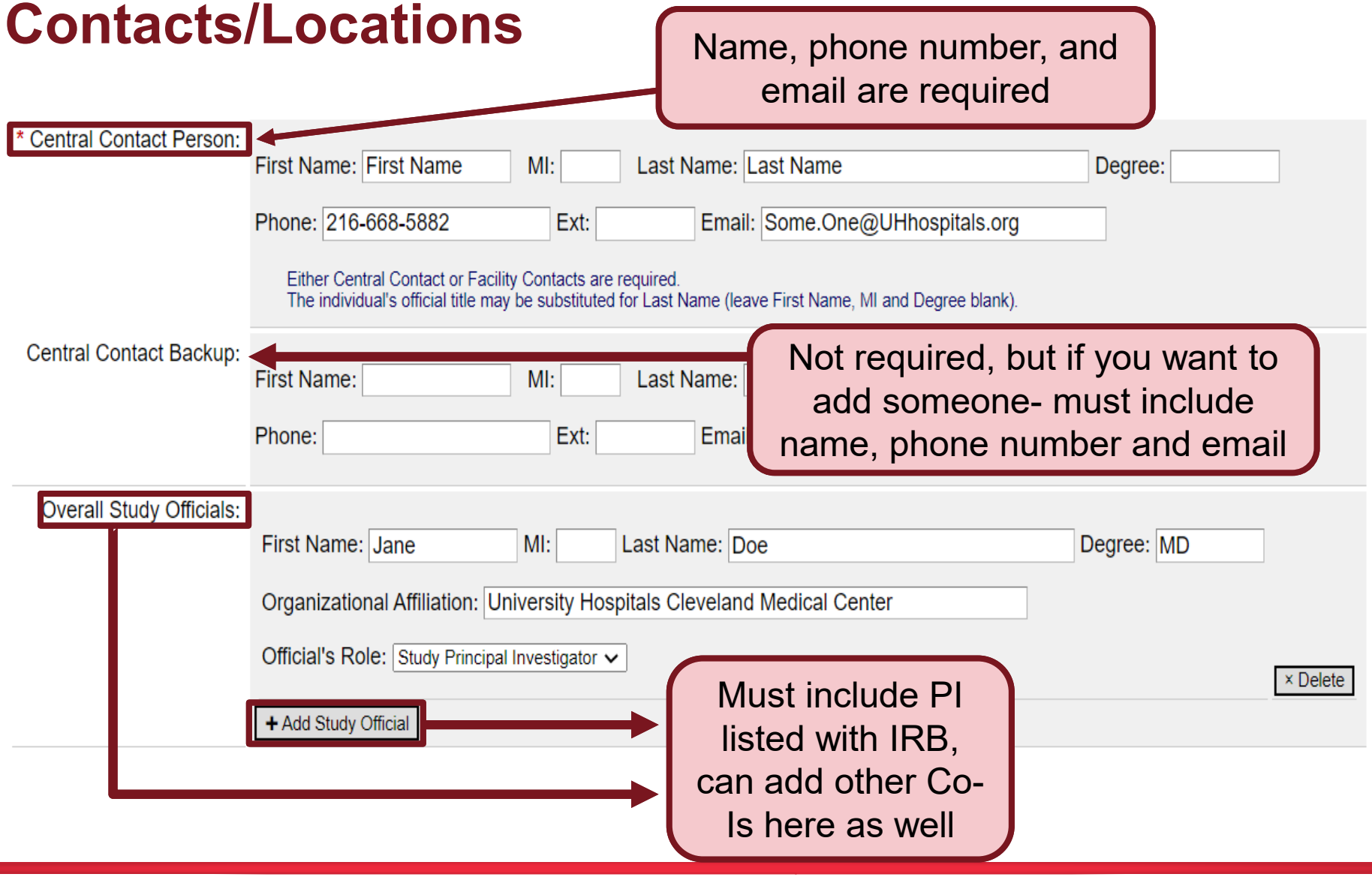
"End of study" is not descriptive enough, need to add actual length of time

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

Eligibility



Contacts/Locations



IPD Sharing Statement

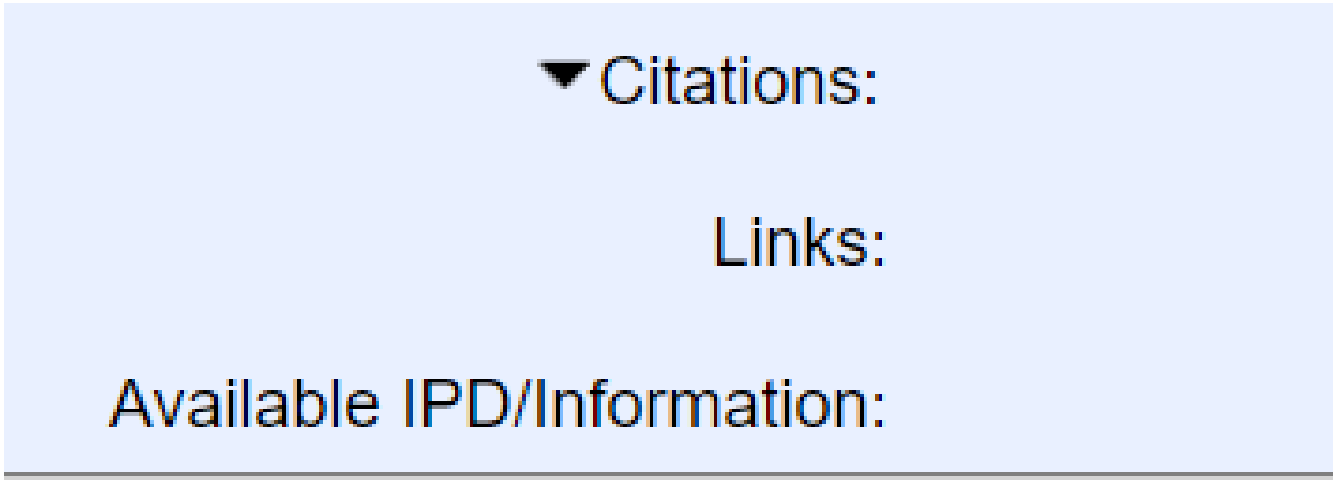
This is sharing individual participant level data, not aggregate data sets. If you plan to share this level of data you must present your plan and have it IRB approved.

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



Here you made include any citations or links.
NOTE: CT.gov does not like the use of foot notes in the record.