CHAPMAN UNIVERSITY | INSTITUTIONAL REVIEW BOARD

ClinicalTrials.gov Registration User's Guide

What is ClinicalTrials.gov?

ClinicalTrials.gov is a service of the U.S. National Institutes of Health that acts as a registry and results database of publicly and privately supported clinical studies of human participants. The Department of Health and Human Services (HHS), the Food and Drug Administration, the National Institutes of Health (NIH), and the International Committee of Medical Journal Editors (ICMJE) all require the public registration of clinical trials and, in some cases, the posting of trial results.

When is Registration and Reporting Required?

ClinicalTrials.gov registration is required for all federally sponsored clinical trials or studies that meet FDA's definition of an "applicable clinical trial" (ACT) regardless of funding. ACTs, as defined in section 402(j) of the PHS Act, include the following:

- Controlled clinical investigations (other than phase 1 investigations) of any U.S. Food and Drug Administration (FDA)-regulated drug or biological product for any disease or condition

- Certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric postmarket surveillances of a device product

Checklist for Evaluating Whether a Clinical Trial is an Applicable Clinical Trial

What does registering with ClinicalTrials.gov achieve?

Researchers, authors, and sponsors have an ethical obligation to publish and disseminate research results, whether positive, negative, or inconclusive. As outlined by the ICMJE and ClinicalTrials.gov, registering your trial and posting results serves to:

- Help patients and the public know what trials are planned or ongoing into which they might want to enroll.
- Prevent selective publication and selective reporting of research outcomes.
- Prevent unnecessary duplication of research effort.
- Help give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering.
- Help editors and others understand the context of study results.
- Promote more efficient allocation of research funds.

How do I obtain an account in order to register?

Principal Investigators must register their own studies in the PRS (Protocol Registration & Results System) at http://register.clinicaltrials.gov. To obtain a user account or to appoint a designee to maintain the ClinicalTrials.gov record on their behalf, Principal Investigators must contact Chapman PRS Administrator: mibriggs@chapman.edu

Please note that only Principal Investigators can appoint their own designee(s) and a designee must have a Chapman.edu email address to qualify for a user account.

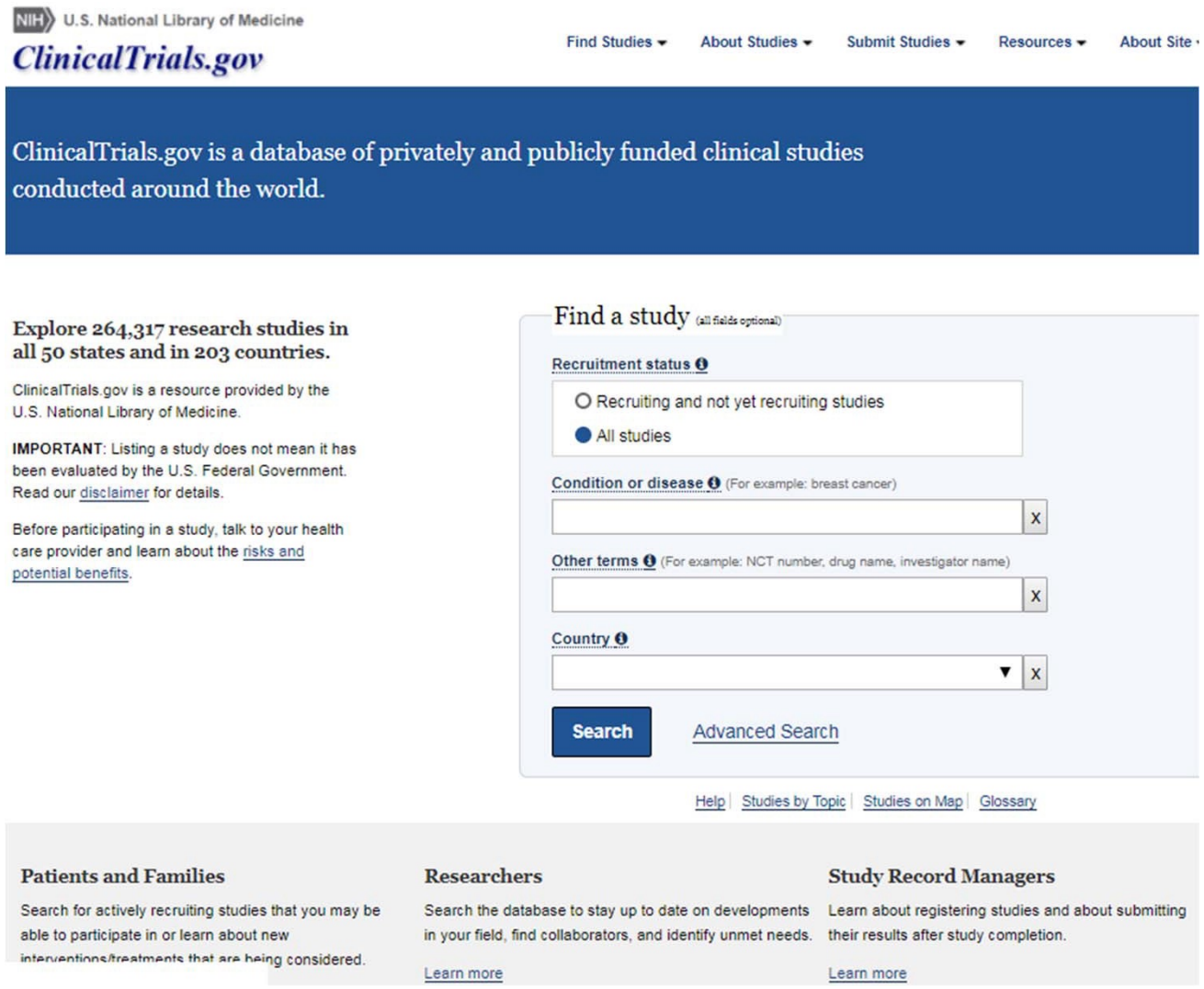
Tips and Recommendations

- ✓ Chrome and Firefox are more likely to let you “expand” text boxes to see more
- ✓ Use MS Word to create and edit these fields carefully
- ✓ Do not use first or second person. Replace “I” and “we” with “the investigator”; replace “you” with “participants”
- ✓ Typos and spelling errors are not acceptable
- ✓ Define all acronyms
- ✓ Use notes provided by PRS system to guide you (suggestions/reminders; not mandatory)
- ✓ The Draft Receipt function provides a copy of your record as it appears in PRS

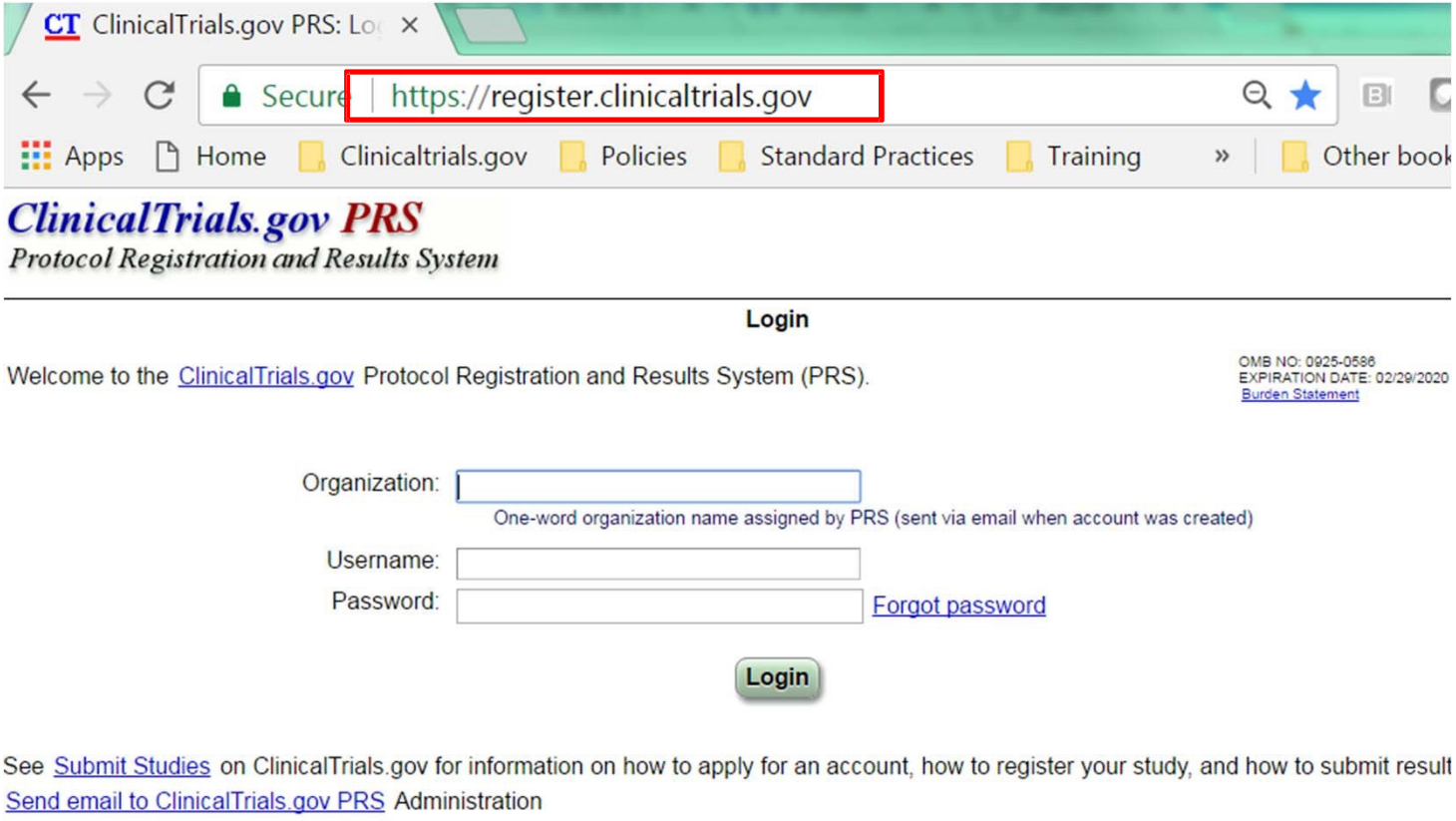
Validation Messages

- As you enter information, system validation (error, warning and note) messages may appear and disappear.
- Start by entering information for all required data elements.
- Note that some data elements are required, while others are conditionally required (based on information entered for other data elements).
- Finish by addressing all remaining validation messages.
- Complete all required fields before checking/stressing on validation.

Public Site


U.S. National Library of Medicine
ClinicalTrials.gov
Find Studies
About Studies
Submit Studies
Resources
About Site
ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.
Explore 264,317 research studies in all 50 states and in 203 countries.
ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.
IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.
Before participating in a study, talk to your health care provider and learn about the risks and potential benefits.
Find a study (all fields optional)
Recruitment status
Recruiting and not yet recruiting studies
All studies
Condition or disease (For example: breast cancer)
Other terms (For example: NCT number, drug name, investigator name)
Country
Search
Advanced Search
Help | Studies by Topic | Studies on Map | Glossary
Patients and Families
Search for actively recruiting studies that you may be able to participate in or learn about new interventions/treatments that are being considered.
Researchers
Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.
Learn more
Study Record Managers
Learn about registering studies and about submitting their results after study completion.
Learn more

Protocol Registration and Results System



Organization Name: ChapmanU. To obtain a new ClinicalTrials.gov user account, please contact mibriggs@chapman.edu

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

User: Test User Logout

Quick Links
New Record
Quick Start Guide
Problem Resolution Guide

Records Accounts Help

The system flags records with problems to be addressed

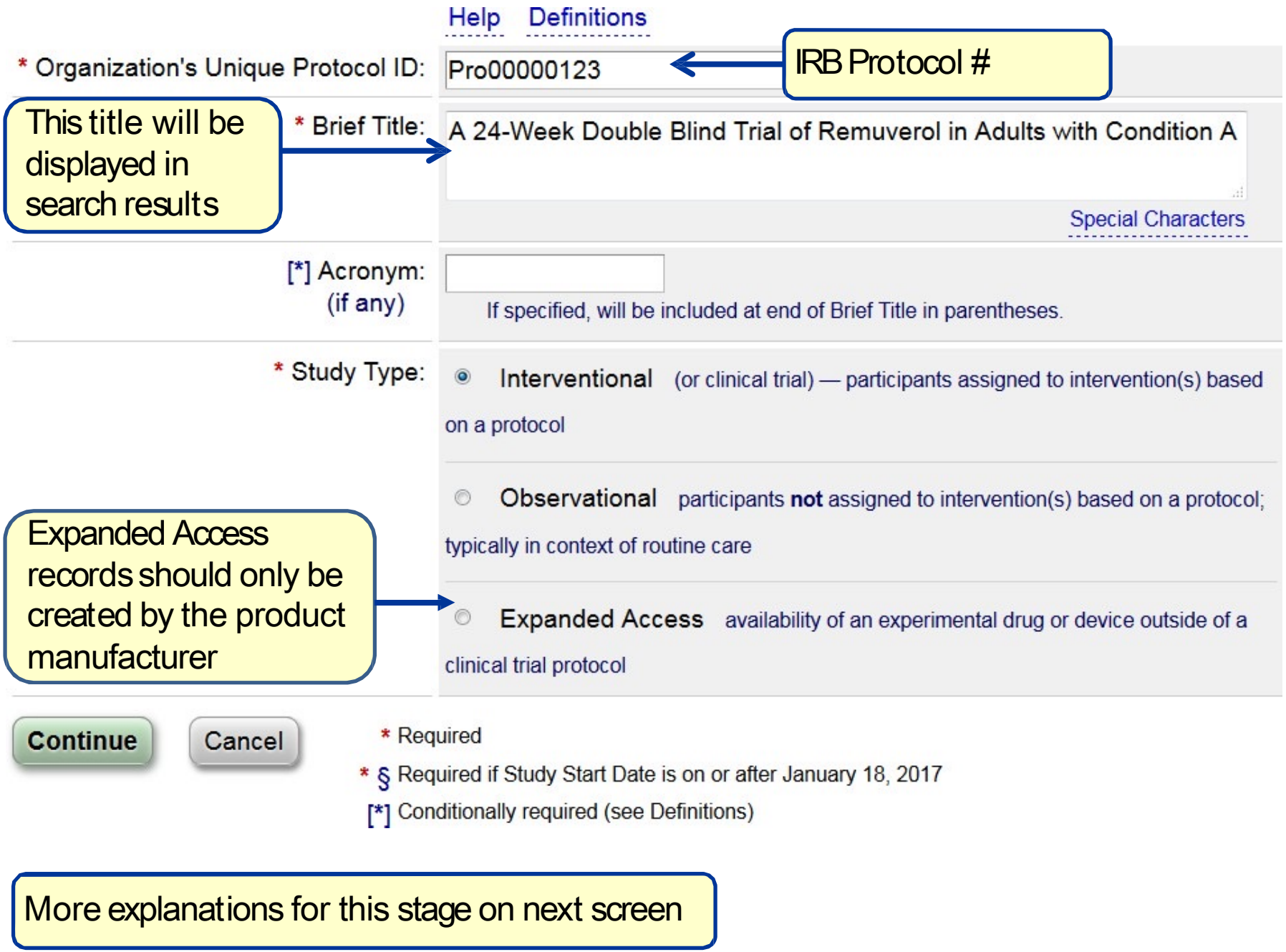
Record List

Showing: **7** records

Search:

Show/Hide Columns

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Responsible Party	Problems
Open	Pro00012345		A 24-Week Double-Blind Trial of Remuverol in Adults With Condition X	In Progress	07/31/2015 14:20	[Sponsor]	• Entry Not Completed • Never Released • Missing FDAAA Information
Open R	ProXXXXXXX1		Parallel Study Design Example	In Progress	07/24/2015 13:31	[Sponsor]	• Entry Not Completed • Never Released • Late Results - per FDAAA
Open	Protocol123		A 24-Week Double-Blind Trial of Remuverol in Adults With Condition A	In Progress	07/15/2015 16:30	[Sponsor]	• Entry Not Completed • Never Released • Missing FDAAA Information
Open R	Pro000DOCR1		A 24-Week Double-Blind Trial of Remuverol in Adults With Condition A	Entry Completed	12/16/2014 14:43	[Sponsor]	• Ready for Review and Approval • Never Released • Late Results - per FDAAA


Help
Definitions
* Organization's Unique Protocol ID:
Pro00000123
IRB Protocol #
This title will be displayed in search results
* Brief Title:
A 24-Week Double Blind Trial of Remuverol in Adults with Condition A
Special Characters
[*] Acronym: (if any)
If specified, will be included at end of Brief Title in parentheses.
* Study Type:
Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
Observational participants not assigned to intervention(s) based on a protocol; typically in context of routine care
Expanded Access records should only be created by the product manufacturer
Expanded Access availability of an experimental drug or device outside of a clinical trial protocol
Continue
Cancel
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
More explanations for this stage on next screen

The Help link contains examples and data entry tips

The Definitions link contains the meaning of terms and useful information about field lengths

Help | Definitions

* Organization's Unique Protocol ID: Pro00000123

* Brief Title: A 24-Week Double Blind Trial of Remuverol in Adults with Condition A

Special Characters

[*] Acronym: (if any)

If specified, will be included at end of Brief Title in parentheses.

* Study Type:

- (•) **Interventional** (or clinical trial) — participants assigned to intervention(s) based on a protocol
- ( ) **Observational** participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
- ( ) **Expanded Access** availability of an experimental drug or device outside of a clinical trial protocol

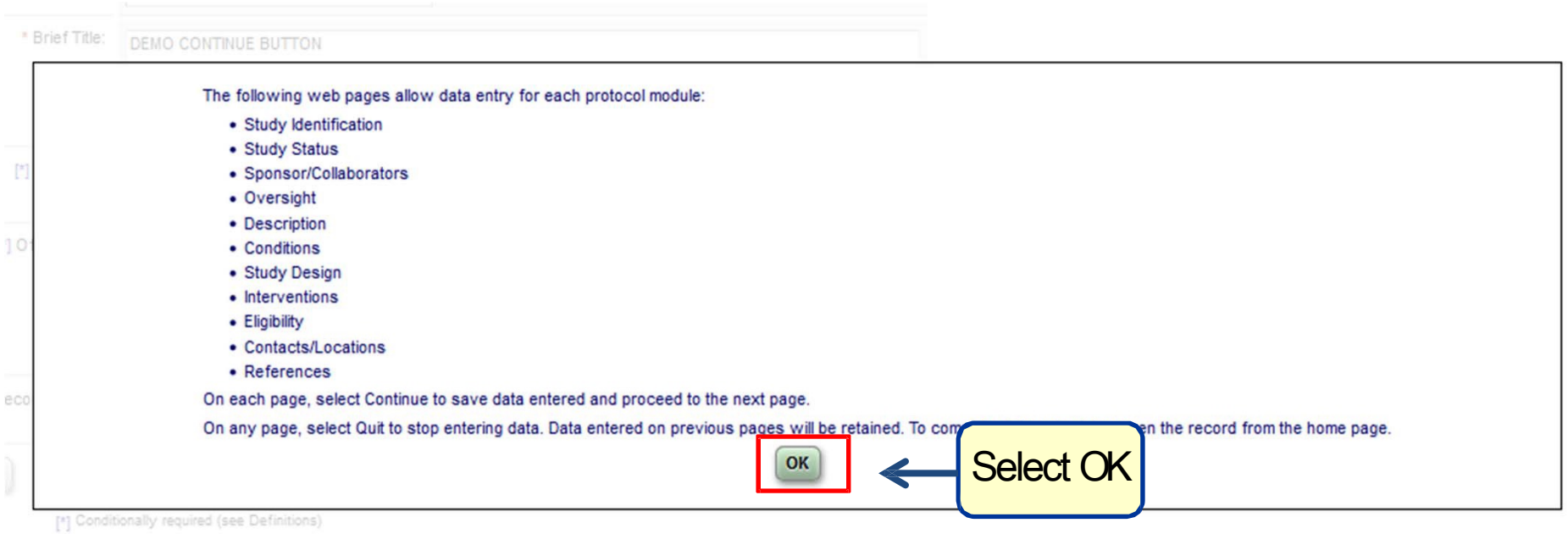
Continue | Cancel

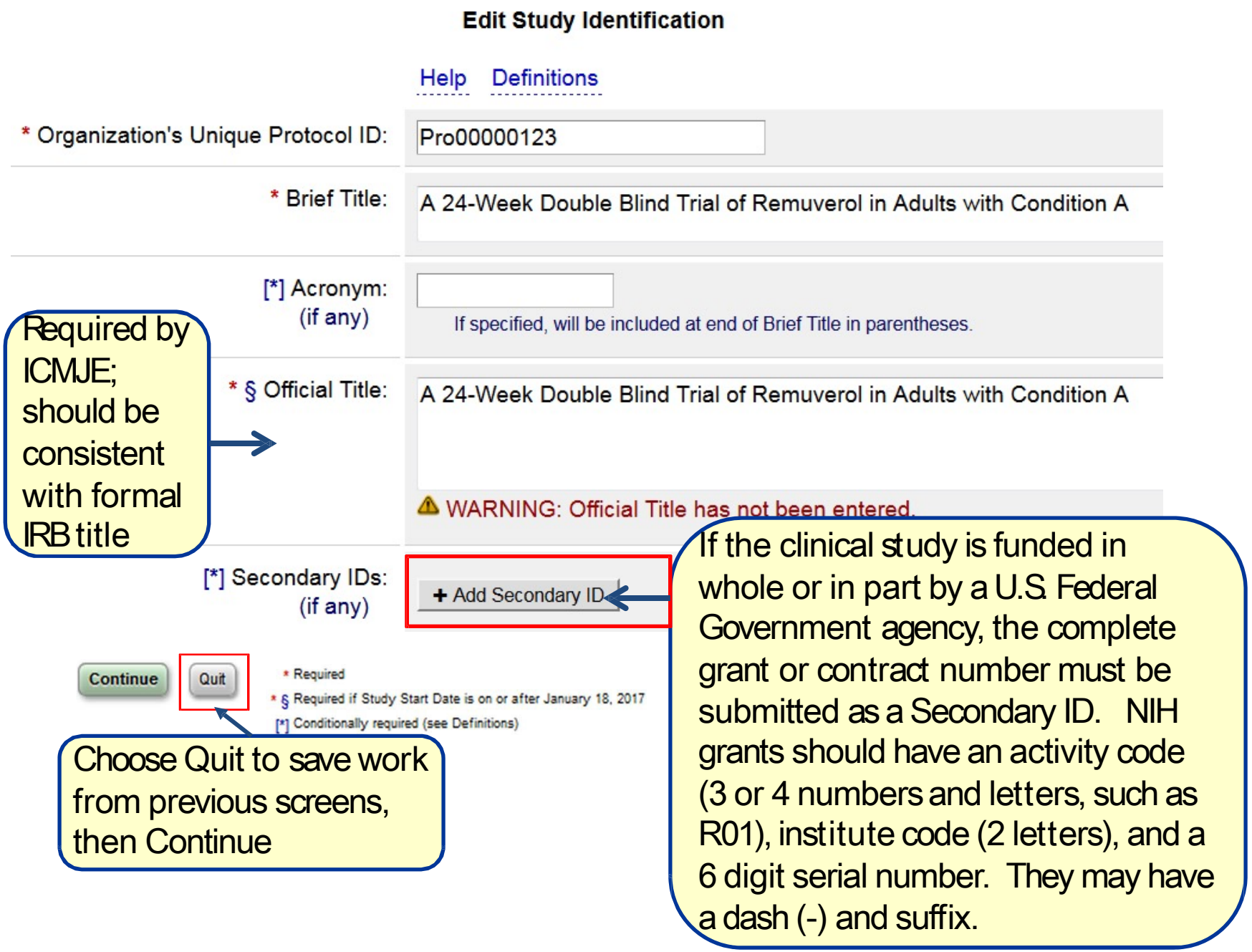
* Required

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

[*] Conditionally required (see Definitions)

After you click “Continue”, you will see this dialog box

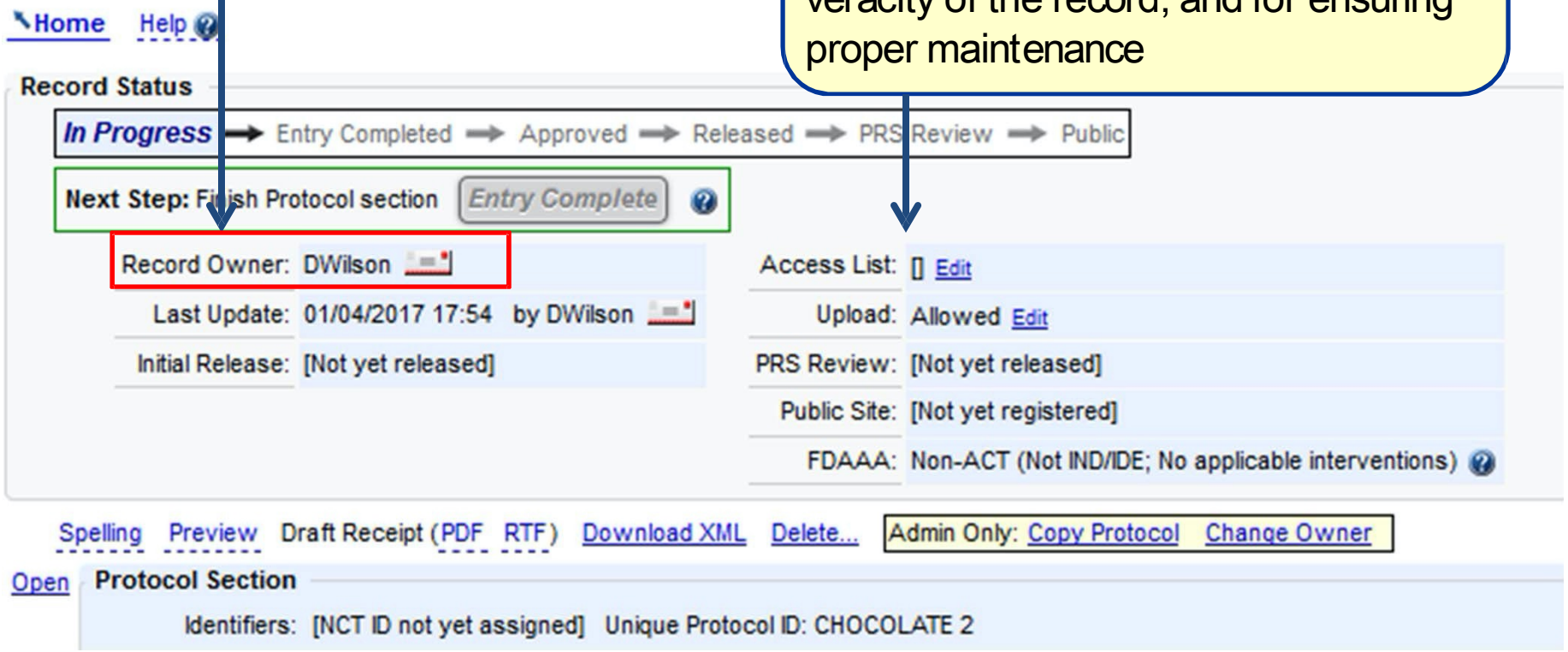



Edit Study Identification
Help
Definitions
* Organization's Unique Protocol ID:
Pro00000123
* Brief Title:
A 24-Week Double Blind Trial of Remuverol in Adults with Condition A
[*] Acronym: (if any)
If specified, will be included at end of Brief Title in parentheses.
* § Official Title:
A 24-Week Double Blind Trial of Remuverol in Adults with Condition A
WARNING: Official Title has not been entered.
[*] Secondary IDs: (if any)
+ Add Secondary ID
Continue
Quit
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
Required by ICMJE; should be consistent with formal IRB title
Choose Quit to save work from previous screens, then Continue
If the clinical study is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID. NIH grants should have an activity code (3 or 4 numbers and letters, such as R01), institute code (2 letters), and a 6 digit serial number. They may have a dash (-) and suffix.

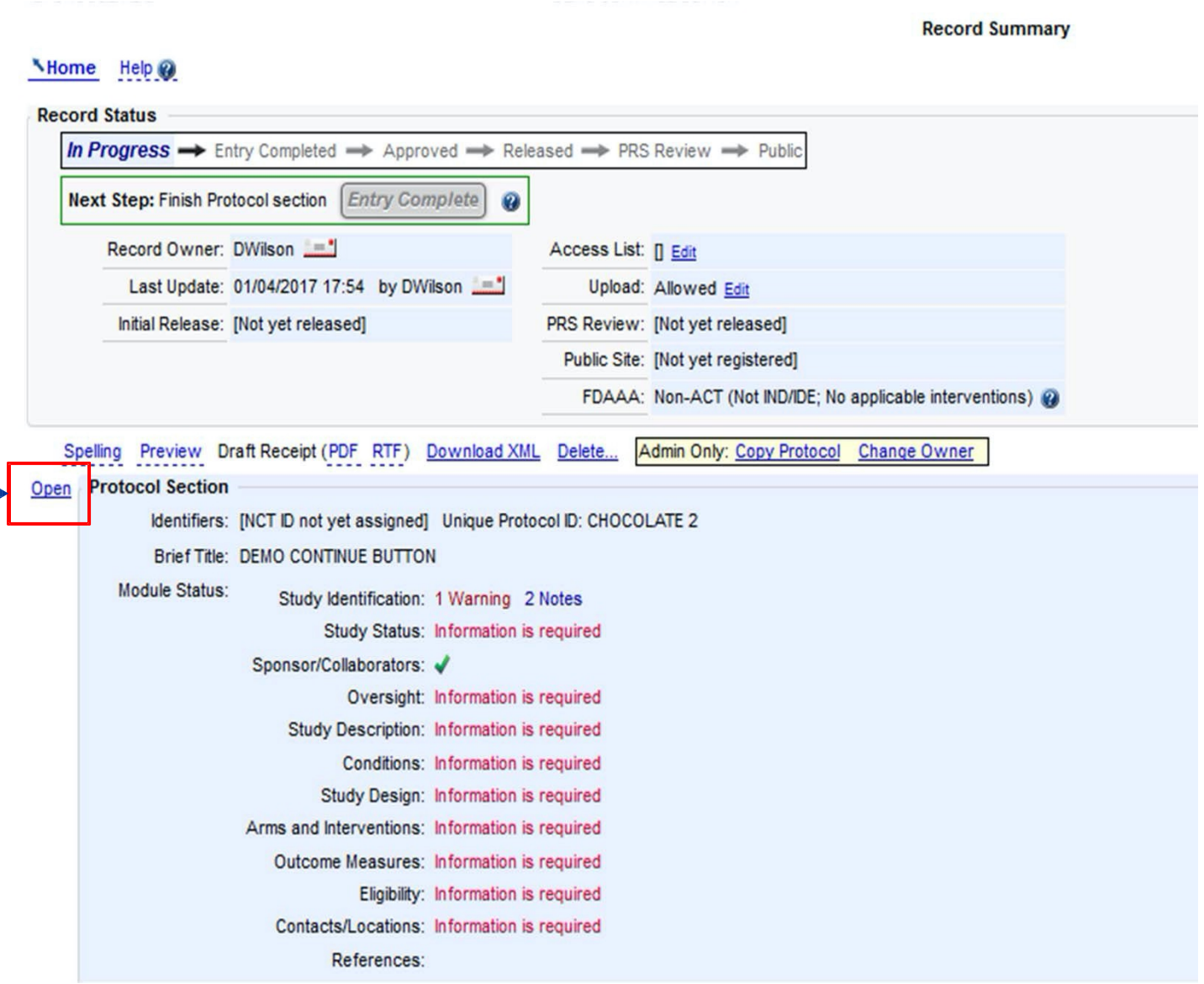
After you click “Quit”, you will see this dialog box

The Record Owner is the primary contact for the record. Only an administrator can change the Record Owner.

PI can now share access with study team members and support staff
PI is legally responsible for accuracy and veracity of the record, and for ensuring proper maintenance



Click Open to edit information section by section



Open **Protocol Section**

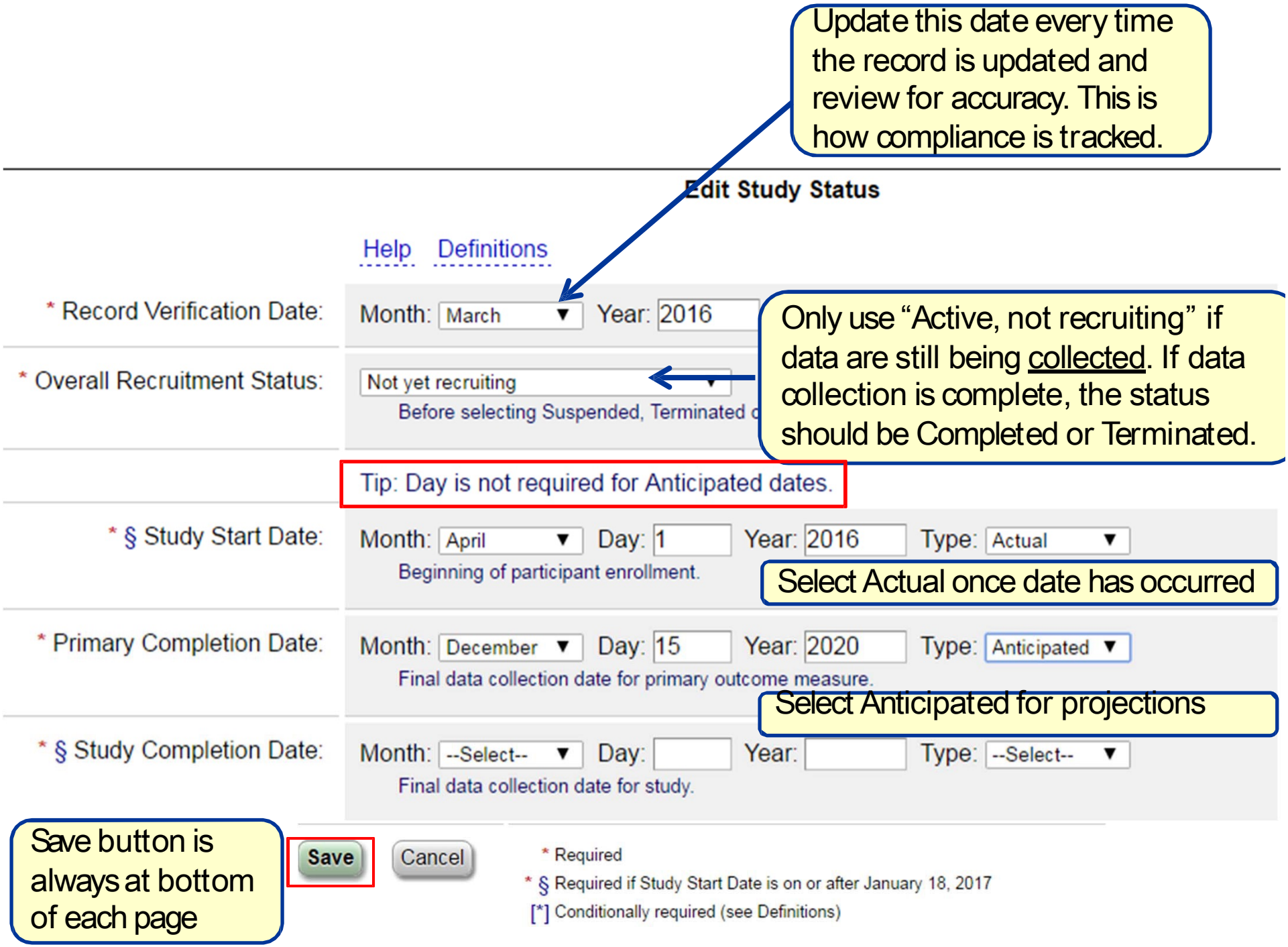
Identifiers: [NCT ID not yet assigned] Unique Protocol ID: HUM000# C&M Secondary IDs: GHI99999

Brief Title: Chocolate & Music Headache Relief Study

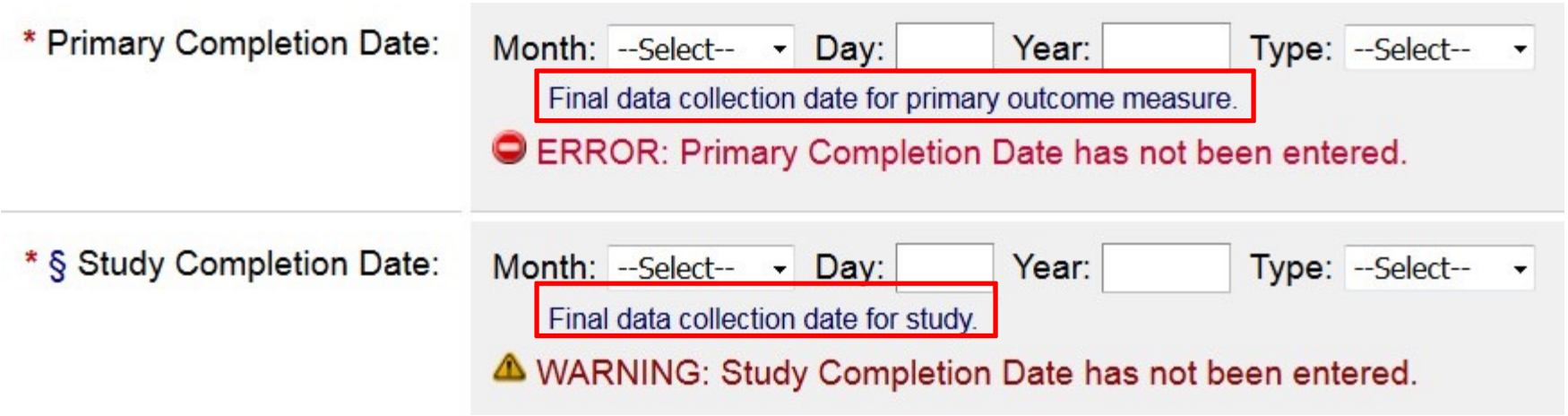
Module Status:

Study Identification:	✓
Study Status:	✓
Sponsor/Collaborators:	2 Warnings
Oversight:	✓ 1 Note
Study Description:	✓
Conditions:	✓
Study Design:	✓
Arms and Interventions:	1 Warning 7 Notes
Outcome Measures:	✓
Eligibility:	✓
Contacts/Locations:	1 Error
References:	

As you fill in more information, the Record Summary will show your progress


Update this date every time the record is updated and review for accuracy. This is how compliance is tracked.
Edit Study Status
Help
Definitions
* Record Verification Date:
Month: March
Year: 2016
* Overall Recruitment Status:
Not yet recruiting
Before selecting Suspended, Terminated
Only use "Active, not recruiting" if data are still being collected. If data collection is complete, the status should be Completed or Terminated.
Tip: Day is not required for Anticipated dates.
* § Study Start Date:
Month: April
Day: 1
Year: 2016
Type: Actual
Beginning of participant enrollment.
Select Actual once date has occurred
* Primary Completion Date:
Month: December
Day: 15
Year: 2020
Type: Anticipated
Final data collection date for primary outcome measure.
Select Anticipated for projections
* § Study Completion Date:
Month: --Select--
Day:
Year:
Type: --Select--
Final data collection date for study.
Save button is always at bottom of each page
Save
Cancel
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Primary and Study Completion Dates



Completion Dates are based on <u>data collection</u>

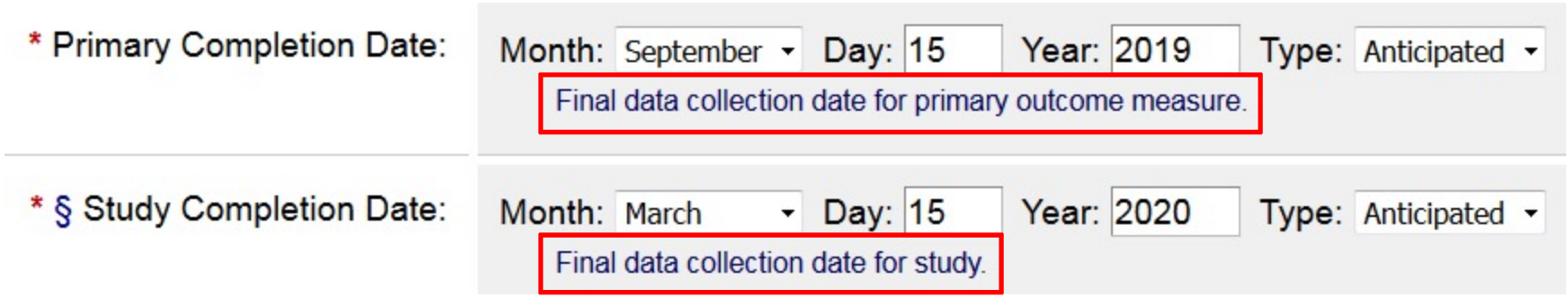
They are NOT based on:

- data analysis
- database lock
- publication
- IRB closure

If you use these as Completion Dates, you may have LATE RESULTS

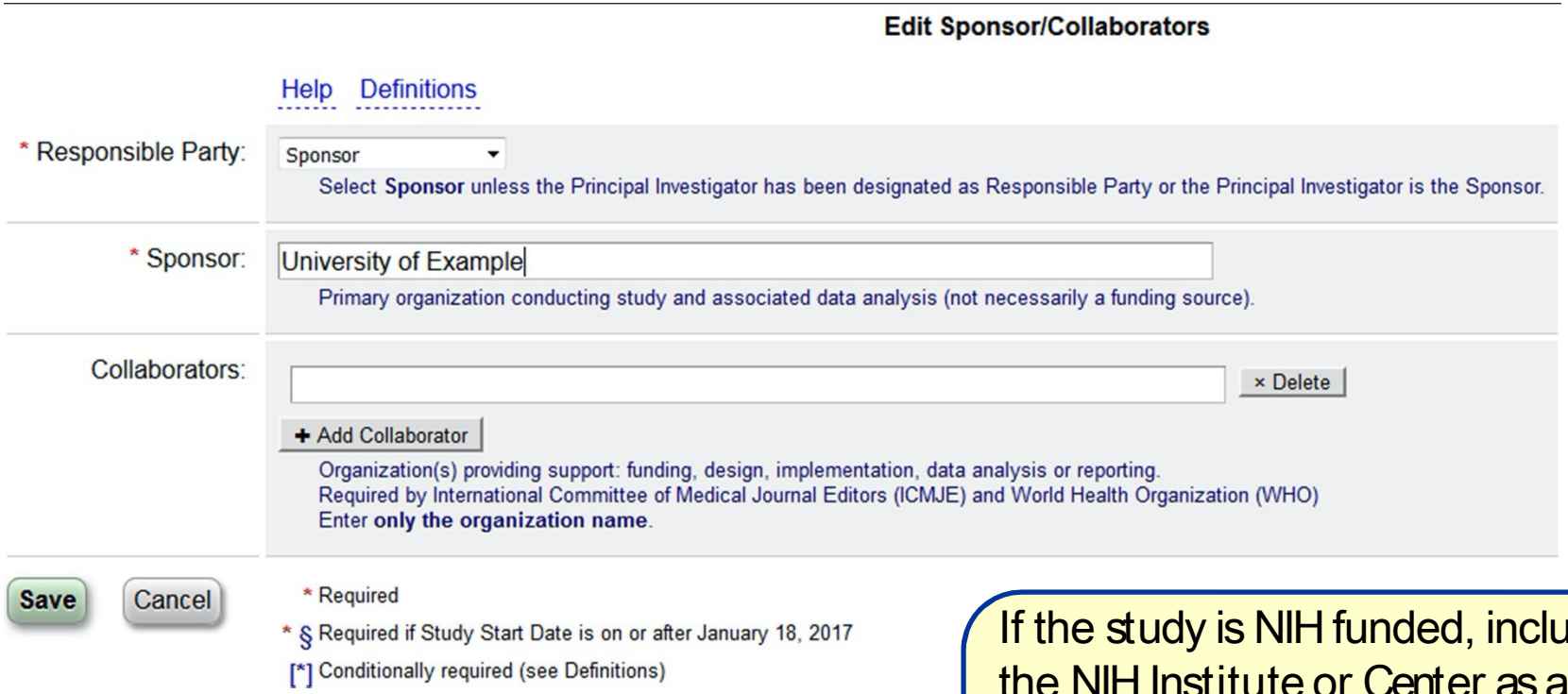
Primary and Study Completion Dates

Remember: 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.



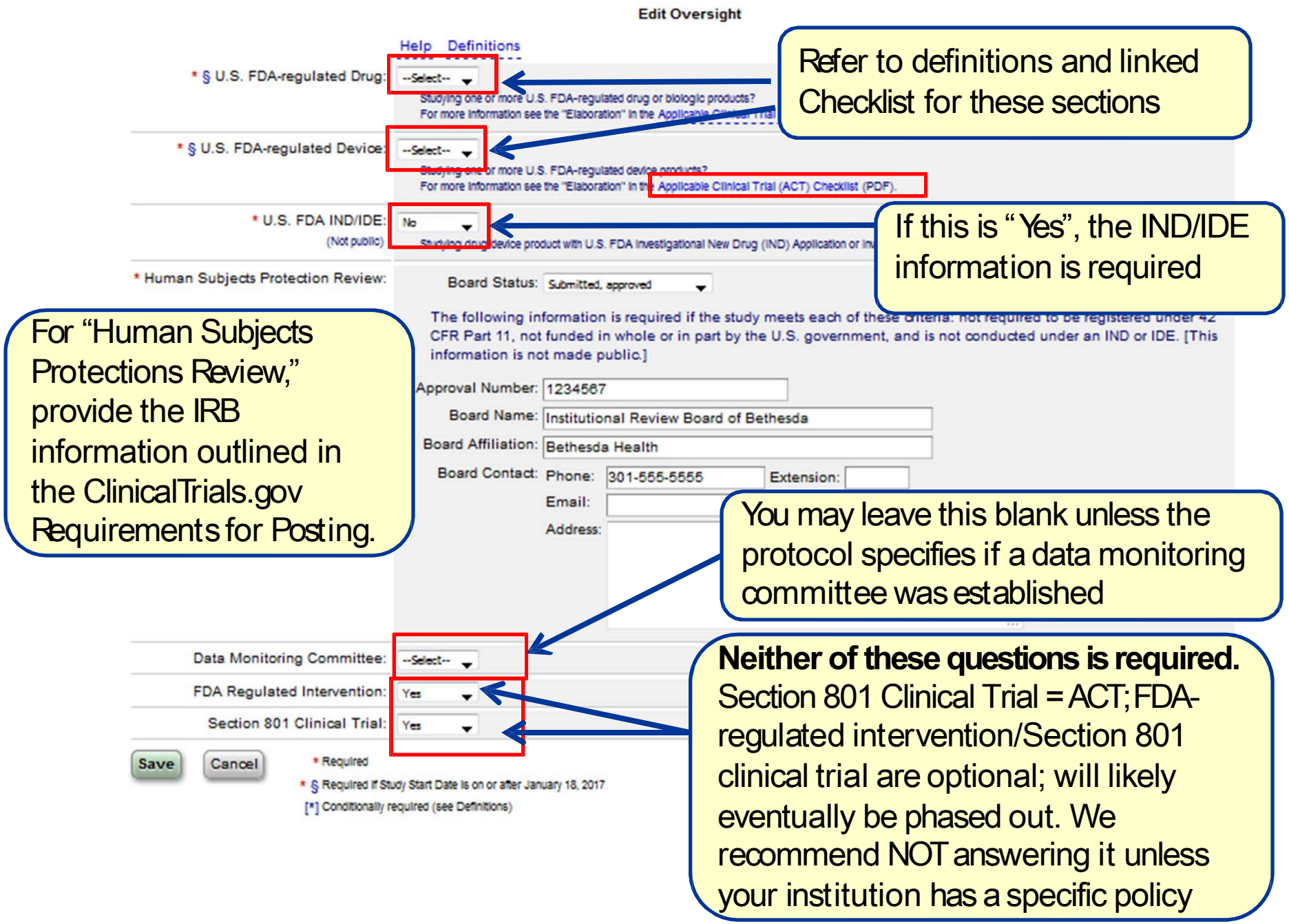
In this example, Primary Outcome results are due by **September 15, 2020**. All study results must be entered by **March 15, 2021**. Some secondary results may be due earlier depending on data collection time frames.

Choosing sponsor

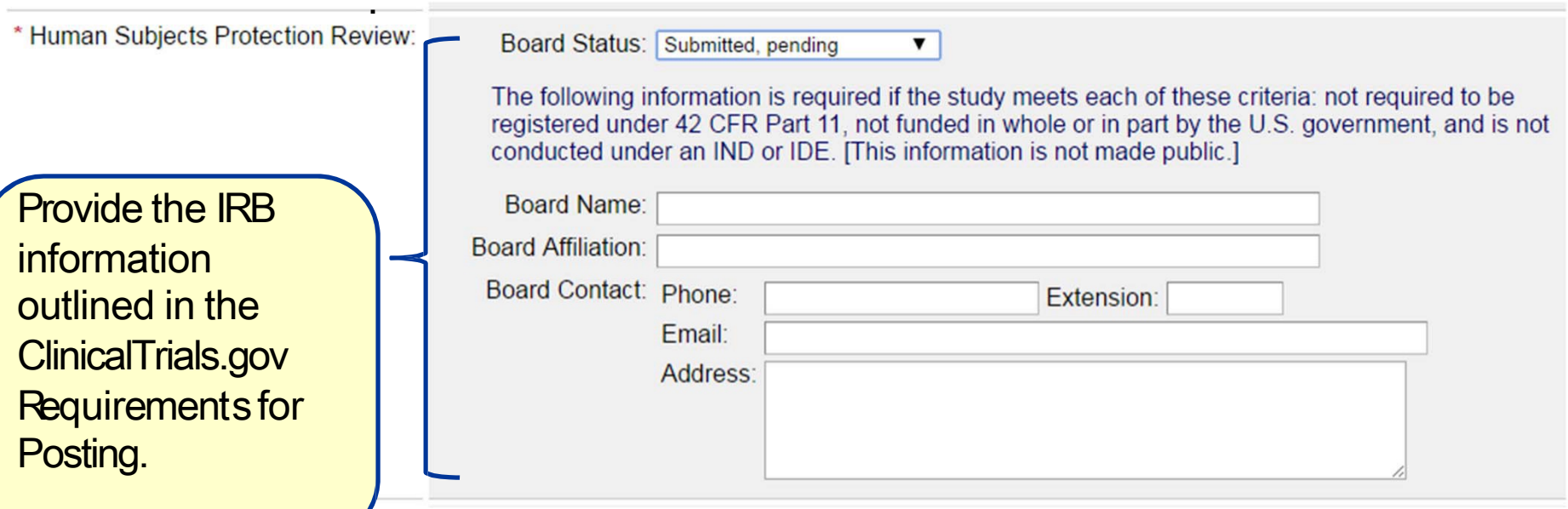


- Responsible Party must be listed as "Sponsor"
- Sponsor should be "Chapman University"

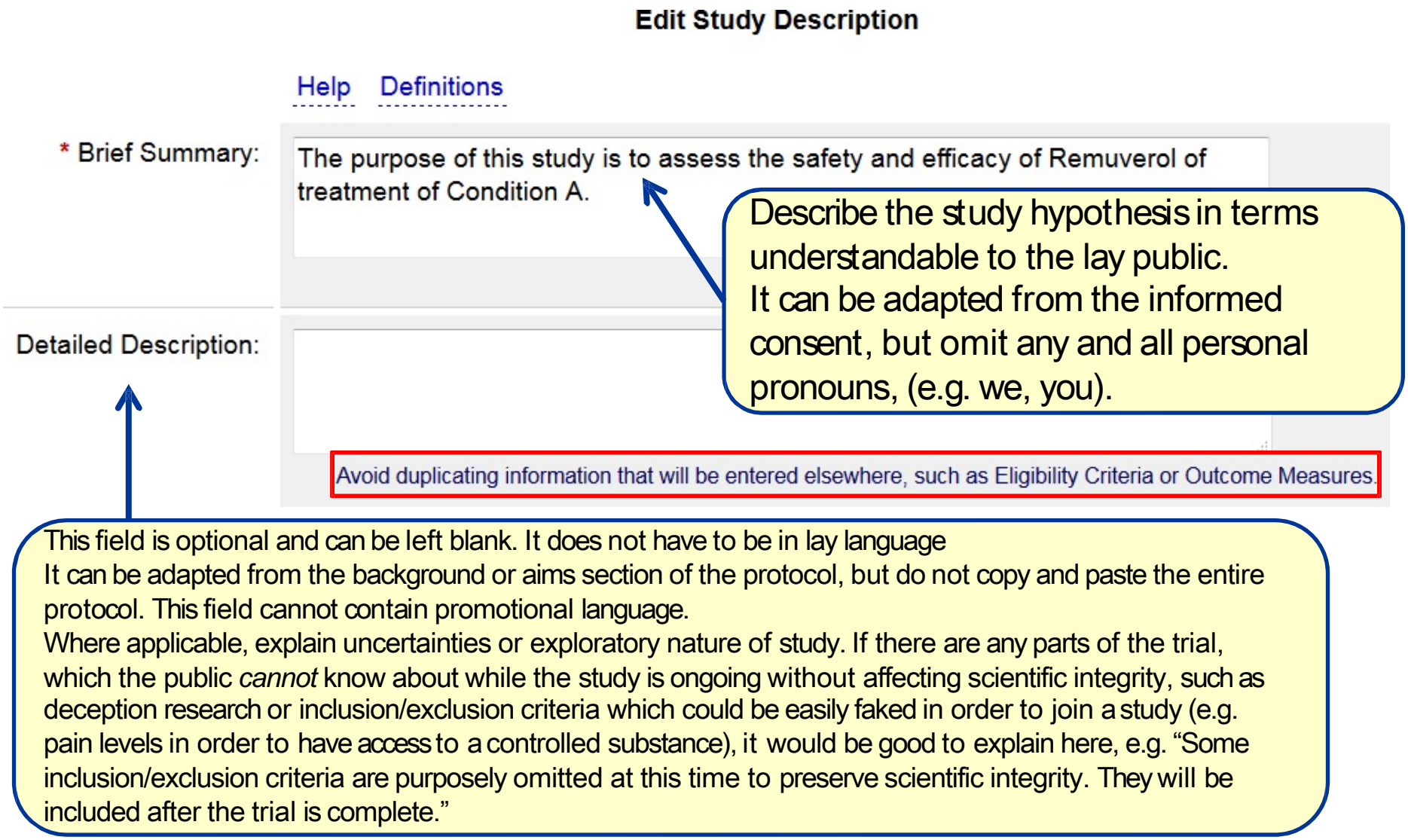
If the study is NIH funded, include the NIH Institute or Center as a Collaborator.
Collaborators include other funders, etc. Add as many as necessary.

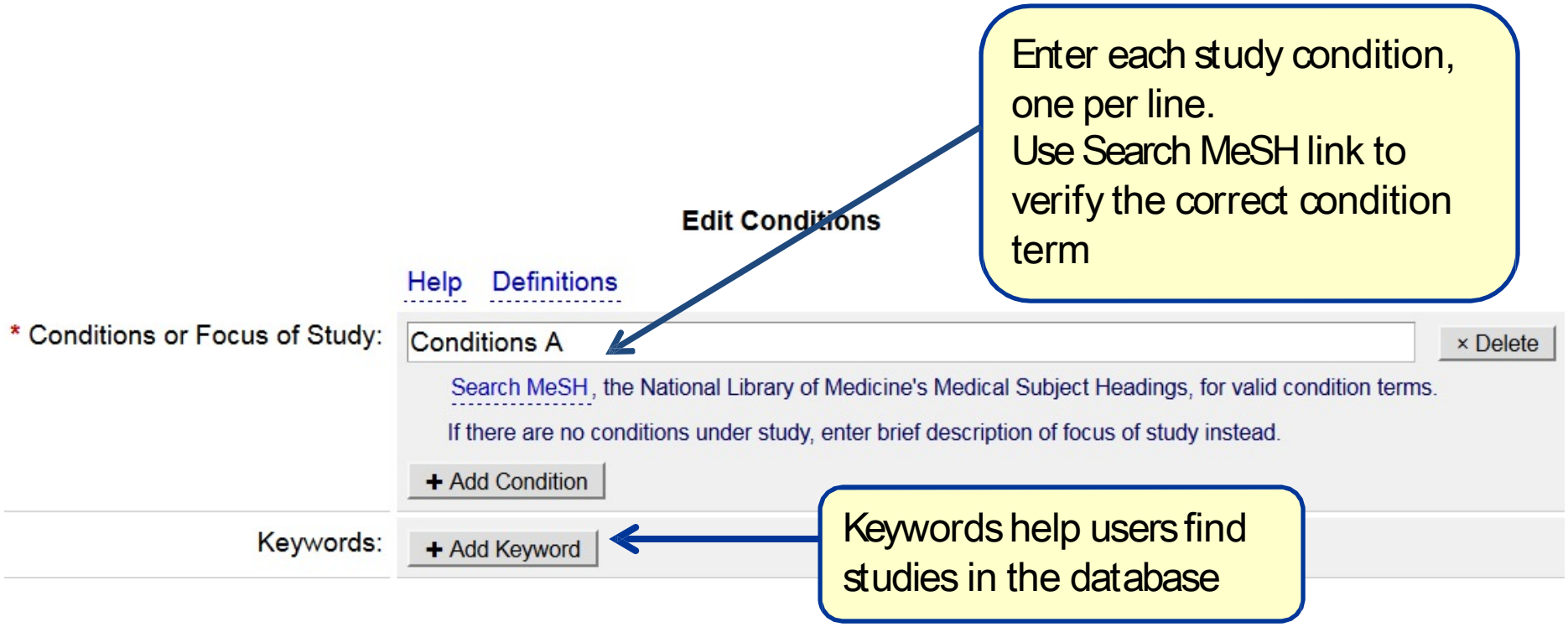

Edit Oversight
Help Definitions
* § U.S. FDA-regulated Drug:
--Select--
Studying one or more U.S. FDA-regulated drug or biologic products?
For more information see the "Elaboration" in the Applicable
* § U.S. FDA-regulated Device:
--Select--
For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).
* U.S. FDA IND/IDE:
(Not public)
No
* Human Subjects Protection Review:
Board Status: Submitted, approved
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: 1234567
Board Name: Institutional Review Board of Bethesda
Board Affiliation: Bethesda Health
Board Contact: Phone: 301-555-5555 Extension:
Email:
Address:
Data Monitoring Committee: --Select--
FDA Regulated Intervention: Yes
Section 801 Clinical Trial: Yes
Save
Cancel
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
Refer to definitions and linked Checklist for these sections
If this is "Yes", the IND/IDE information is required
For "Human Subjects Protections Review," provide the IRB information outlined in the ClinicalTrials.gov Requirements for Posting.
You may leave this blank unless the protocol specifies if a data monitoring committee was established
Neither of these questions is required. Section 801 Clinical Trial = ACT; FDA-regulated intervention/Section 801 clinical trial are optional; will likely eventually be phased out. We recommend NOT answering it unless your institution has a specific policy

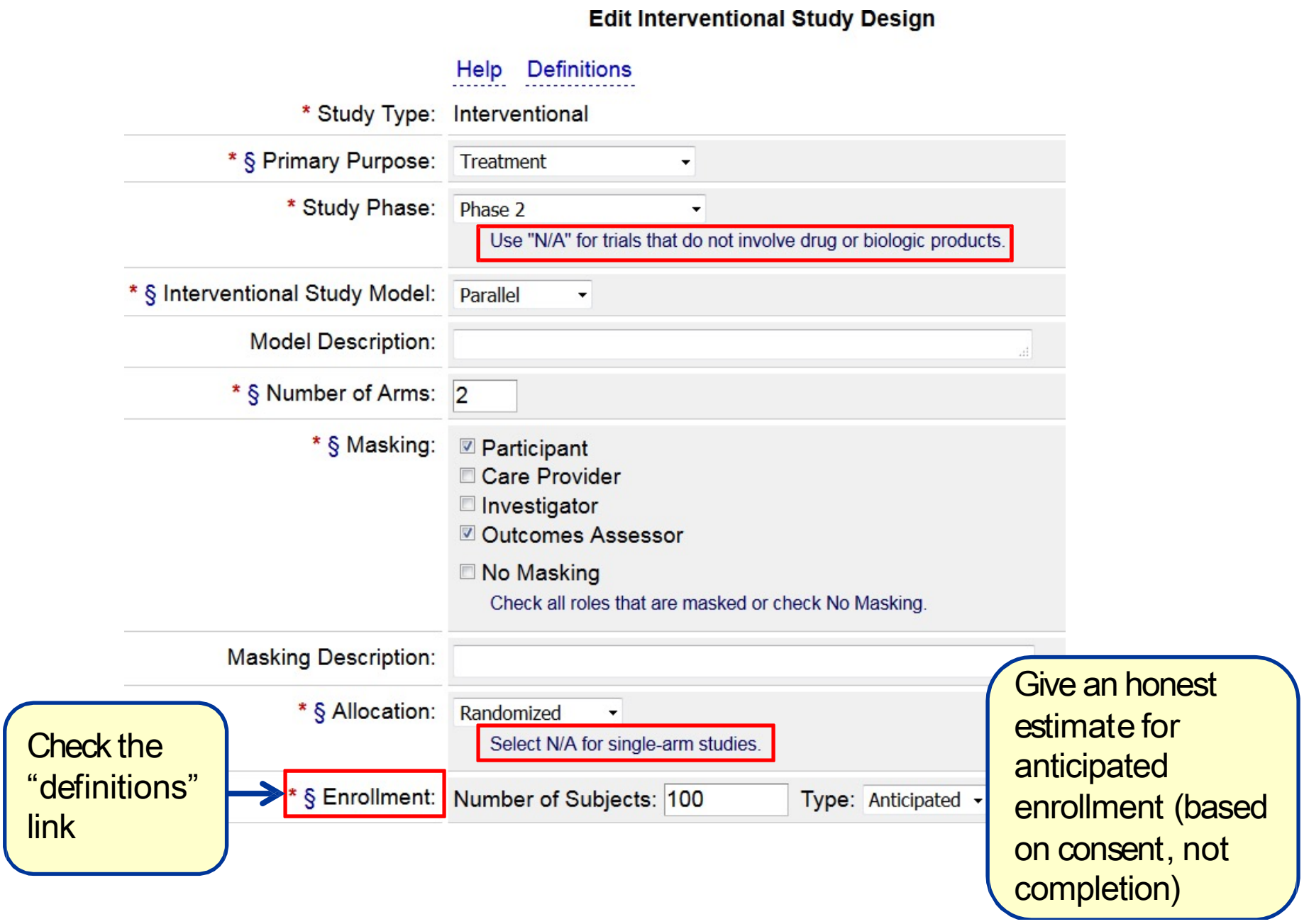
Register **before** any enrollment begins



Provide the IRB information outlined in the ClinicalTrials.gov Requirements for Posting.


Edit Study Description
Help
Definitions
* Brief Summary:
The purpose of this study is to assess the safety and efficacy of Remuverol of treatment of Condition A.
Describe the study hypothesis in terms understandable to the lay public.
It can be adapted from the informed consent, but omit any and all personal pronouns, (e.g. we, you).
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. It does not have to be in lay language
It can be adapted from the background or aims section of the protocol, but do not copy and paste the entire protocol. This field cannot contain promotional language.
Where applicable, explain uncertainties or exploratory nature of study. If there are any parts of the trial, which the public *cannot* know about while the study is ongoing without affecting scientific integrity, such as deception research or inclusion/exclusion criteria which could be easily faked in order to join a study (e.g. pain levels in order to have access to a controlled substance), it would be good to explain here, e.g. “Some inclusion/exclusion criteria are purposely omitted at this time to preserve scientific integrity. They will be included after the trial is complete.”


Edit Conditions
Help
Definitions
* Conditions or Focus of Study:
Conditions A
× Delete
Search MeSH, the National Library of Medicine's Medical Subject Headings, for valid condition terms.
If there are no conditions under study, enter brief description of focus of study instead.
+ Add Condition
Keywords:
+ Add Keyword
Enter each study condition, one per line.
Use Search MeSH link to verify the correct condition term
Keywords help users find studies in the database


Edit Interventional Study Design
Help
Definitions
* Study Type:
Interventional
* § Primary Purpose:
Treatment
* Study Phase:
Phase 2
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
No Masking
Check all roles that are masked or check No Masking.
Masking Description:
* § Allocation:
Randomized
Select N/A for single-arm studies.
* § Enrollment:
Number of Subjects:
100
Type:
Anticipated
Check the "definitions" link
Give an honest estimate for anticipated enrollment (based on consent, not completion)

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 receive Remuverol 15 mg tablet orally twice daily for 24 weeks.

Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.

× Delete Arm

* Arm Title: Placebo

* Arm Type: Placebo Comparator

[*] Arm Description: Participants receive Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.

× Delete Arm

+ Add Arm

Arms may not pre-exist based on how many arms you defined in the previous section. You must add each arm. Do not title your arm as Intervention or Arm 1. Arm title should be more descriptive.

Edit Interventions

Help Definitions

Arms: Experimental: Remuverol
Placebo Comparator: 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 Names: (if any)

× Delete

+ 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

× Delete Intervention

* Intervention Type: Drug
* Intervention Name: Placebo

List Placebo as a Drug intervention

[*] Other Names: (if any)

+ Add Other Name

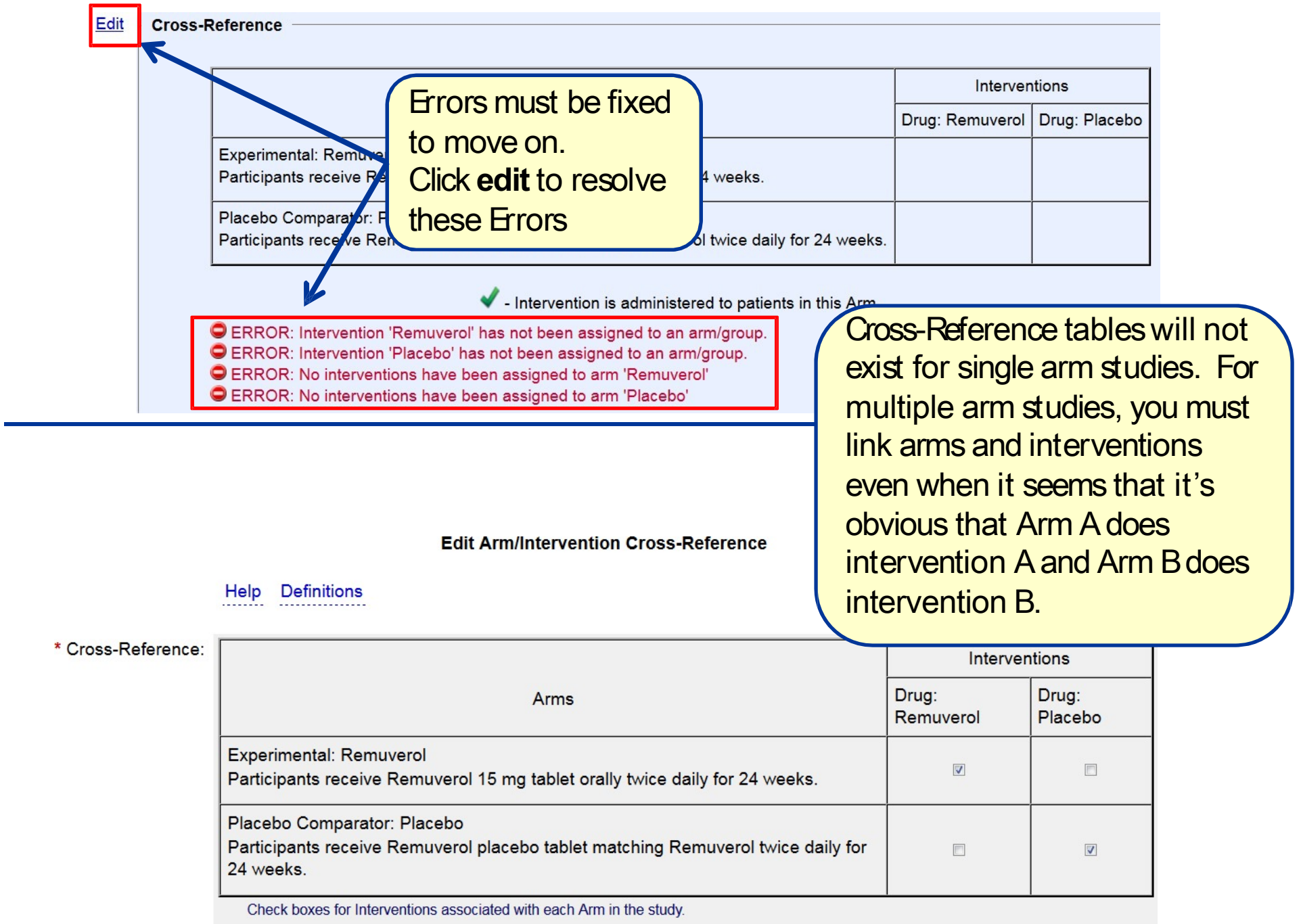
* § Intervention Description: Remuverol placebo tablet

NOTE: Intervention Other Names have not been specified

× Delete Intervention

+ Add Intervention

Frequent PRSComment: The preferred format is to include *all* interventions that were pre-specified to be administered as part of the protocol, even if a particular intervention is not "of interest“


Edit
Cross-Reference
Errors must be fixed to move on.
Click **edit** to resolve these Errors
Interventions
Drug: Remuverol
Drug: Placebo
Experimental: Remuv
Participants receive Re
4 weeks.
Placebo Comparator: P
Participants receive Rem
ol twice daily for 24 weeks.
- Intervention is administered to patients in this Arm
ERROR: Intervention 'Remuverol' has not been assigned to an arm/group.
ERROR: Intervention 'Placebo' has not been assigned to an arm/group.
ERROR: No interventions have been assigned to arm 'Remuverol'
ERROR: No interventions have been assigned to arm 'Placebo'
Cross-Reference tables will not exist for single arm studies. For multiple arm studies, you must link arms and interventions even when it seems that it's obvious that Arm A does intervention A and Arm B does intervention B.
Edit Arm/Intervention Cross-Reference
Help
Definitions
* Cross-Reference:
Arms
Interventions
Drug: Remuverol
Drug: Placebo
Experimental: Remuverol
Participants receive Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo Comparator: Placebo
Participants receive Remuverol placebo tablet matching Remuverol twice daily for 24 weeks.
Check boxes for Interventions associated with each Arm in the study.

Outcome Measures

- Protocol/statistical analysis plan must be submitted with results and will be public for studies with a primary completion date of 1/18/2017 or later
  - Ensure coherence among protocol and registration for primary, secondary and “other” outcomes
  - PRS reviewers may assume all outcomes are primary or secondary unless they are specified in the protocol as other or exploratory
- Include all PRIMARY and SECONDARY outcomes (tertiary/exploratory are optional)
- Label outcomes as “primary” or “secondary” per the protocol
  - Can list more than one primary if applicable

Outcome Measures

- More registrations get rejected for inadequate Outcome Measure precision or inaccurate or multiple time frames than anything else.
- Outcome Measures should be specific and indicate what is being measured and is (or planned to be) reported.
- Remember the mantra: *Outcome Measures must be measurable outcomes*.

Outcome Measure Tips: Title

- Include the metric (i.e. scale, score, number, percentage)
  - ✗ Ex: Safety
  - ✓ Ex: Safety, as measured by number of subjects with at least one AE
- Be clear and concise; omit verbs
  - ✗ Ex: To determine the maximum tolerated dose of Drug A in patients with breast cancer.
  - ✓ Ex: Maximum Tolerated Dose of Drug A in patients with breast cancer
- List outcomes separately
  - ✗ Ex: All-cause mortality, hospitalizations, ER visits
  - ✓ Ex: Number of hospitalizations, Number of ER visits, Number of ER visits.

  Should be listed as 3 separate outcomes
- Exception: if a composite score of multiple measures will be used
  - Example: Count of individuals who experience any of the following: all-cause mortality, hospitalizations, and emergency room visits

Outcome Measure Tips: Time Frame

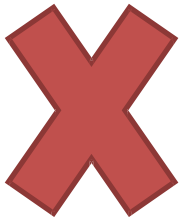
- Be specific (e.g. # of minutes, weeks, months)
  - Ex: Baseline, week 2
  - Ex: During hospitalization, approximately 5 days
  - Ex: Post-intervention, week 12
- If multiple time points are included:
  - If measuring change between the time points, add the word “change” to the title
  - If not measuring change, each time point needs to be listed as a separate outcome measure
- Remember that completion dates should reflect completion of data collection for your outcome measures. Refer back to study status section.

Average time, expected average time, or max assessment time would all be acceptable when the protocol cannot specify precise time frame

Outcome Measure Tips: Description

- If a scale will be used, include the range and meaning of the scores
  - Example: The Hamilton Depression Rating Scale is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression.
- If a scale is not linear (e.g. logarithmic), that would be good to note as well.

Outcome Measures: Example 1



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

Outcome Measure Title:	Change from baseline in pain, as measured by the Visual Analog Scale (VAS)
Outcome Measure Description:	Scores are measured on a 100 mm VAS. The VAS ranges from 0 to 100 with 0 indicating no pain and higher scores indicating greater pain.
Outcome Measure Time Frame:	Baseline, 12 weeks

There are 2 time points, so the word "change" is added to the title

The Title includes the scale that will be used to assess change in pain

The Description includes the range of the scale and what the scale means

Outcome Measures: Example 2

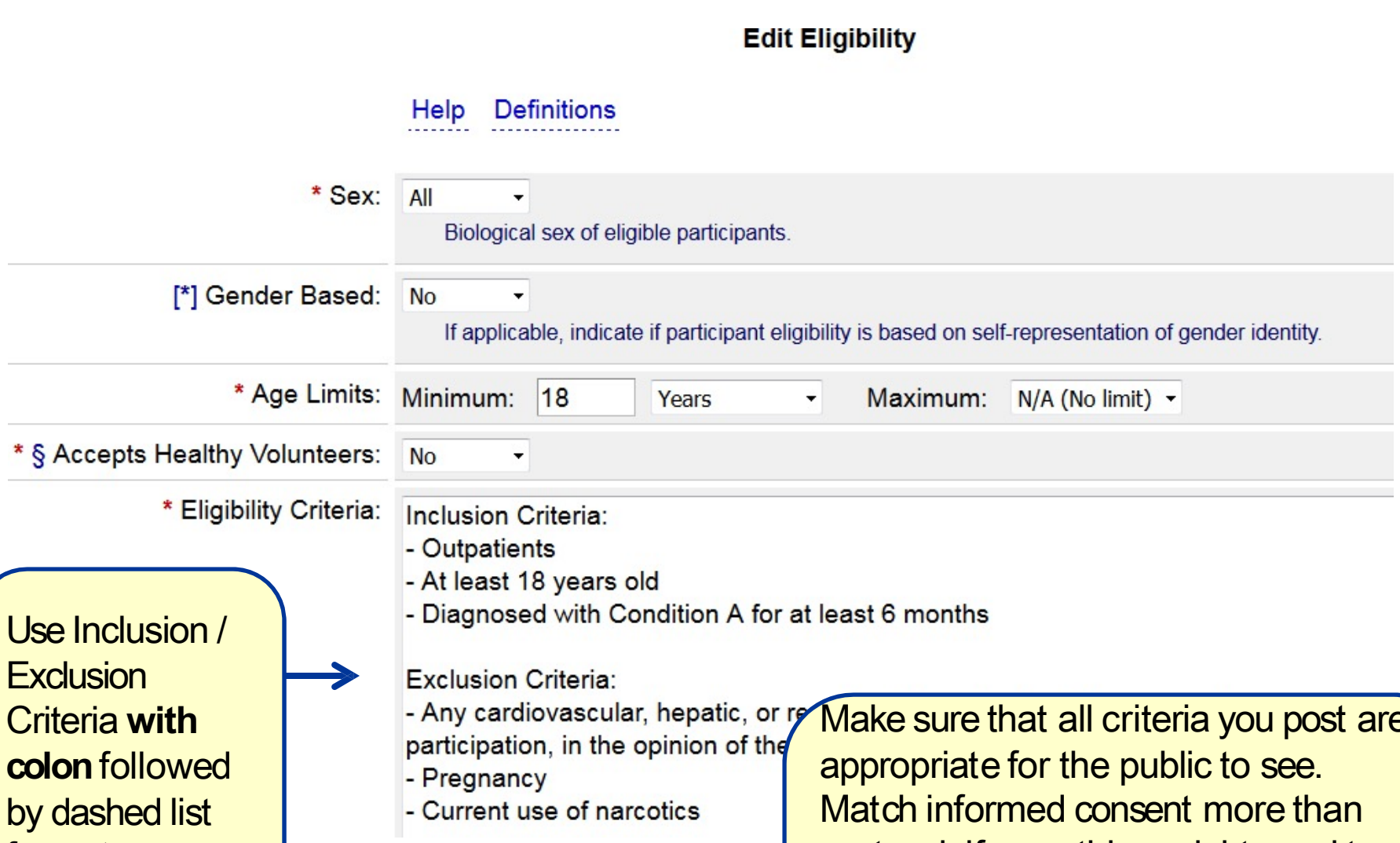
Title:	To assess the safety of Remuverol
Description:	
Time Frame:	End of study

Title:	Number of participants with at least one adverse event
Description:	Adverse events will only include those that are determined to be related to the study drug.
Time Frame:	End of study (24 weeks)

The title includes the metric

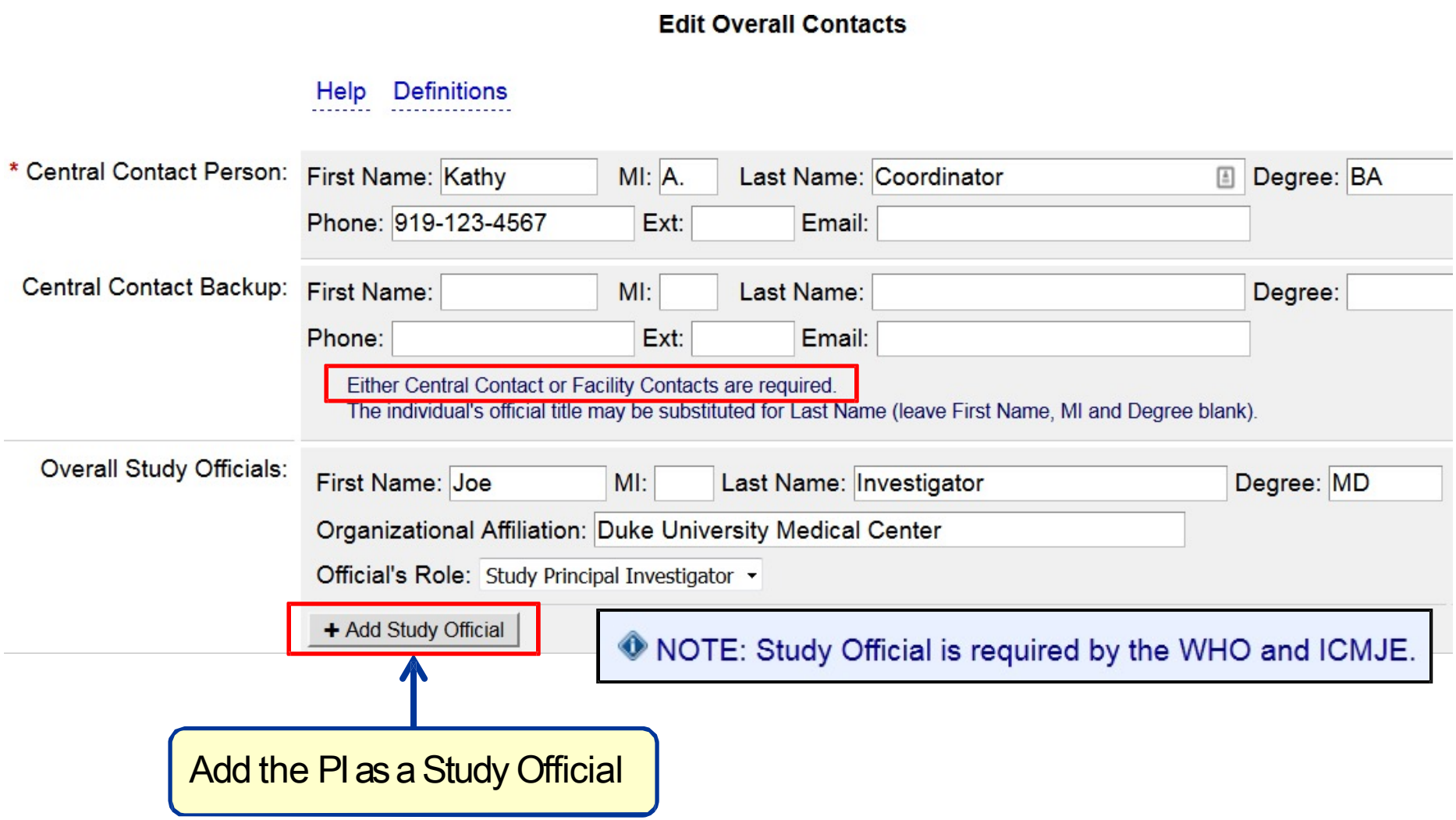
The Time Frame includes the specific length of time

The Description defines “adverse events”

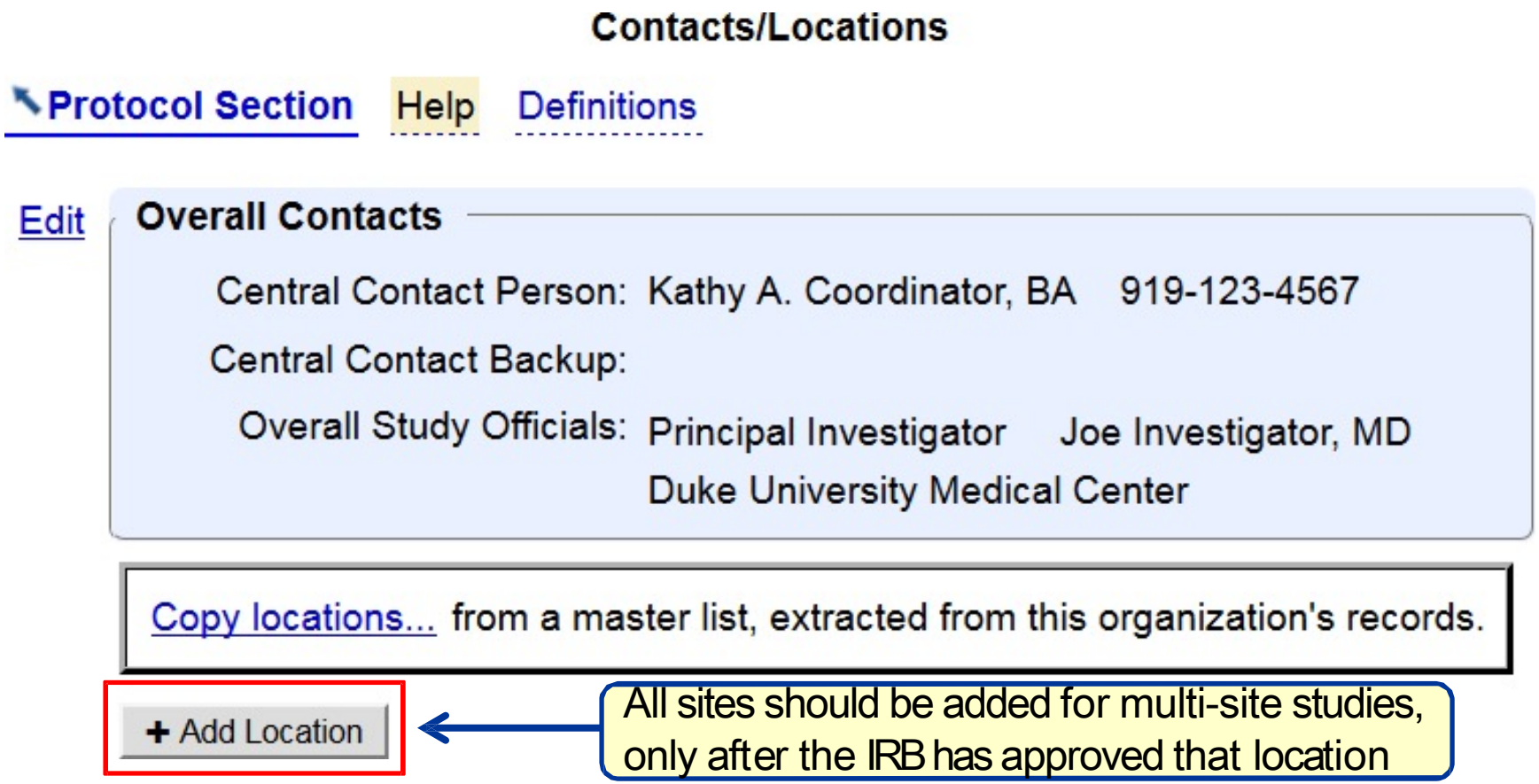


Use Inclusion / Exclusion Criteria **with colon** followed by dashed list format
No paragraphs

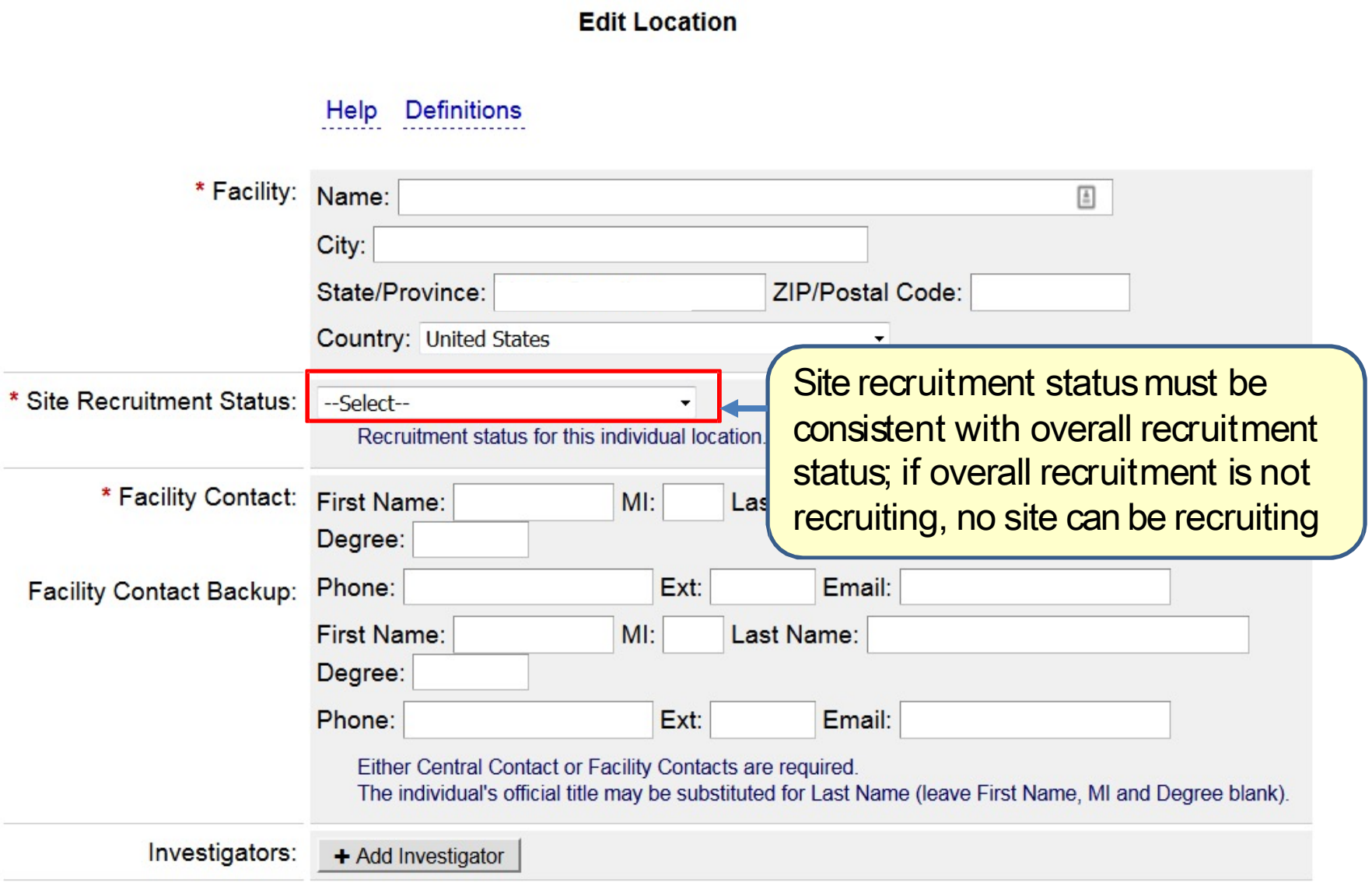
Make sure that all criteria you post are appropriate for the public to see.
Match informed consent more than protocol, if something might need to be masked from participants.
If necessary, use Detailed Description field to flag that the eligibility criteria are deliberately incomplete to preserve the scientific integrity of the study

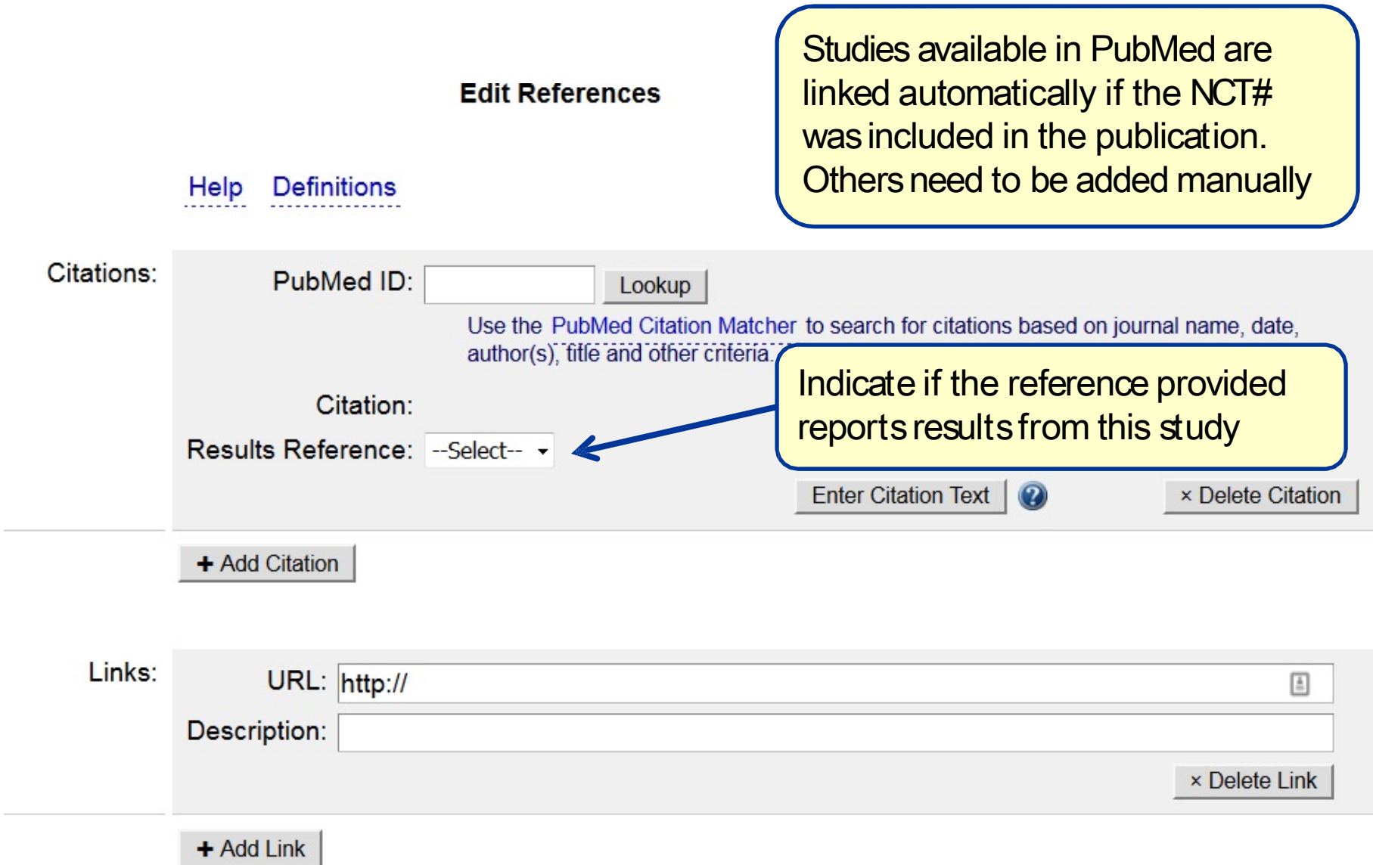

Edit Overall Contacts
Help
Definitions
* Central Contact Person:
First Name: Kathy
MI: A.
Last Name: Coordinator
Degree: BA
Phone: 919-123-4567
Ext:
Email:
Central Contact Backup:
First Name:
MI:
Last Name:
Degree:
Phone:
Ext:
Email:
Either Central Contact or Facility Contacts are required.
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).
Overall Study Officials:
First Name: Joe
MI:
Last Name: Investigator
Degree: MD
Organizational Affiliation: Duke University Medical Center
Official's Role: Study Principal Investigator
+ Add Study Official
NOTE: Study Official is required by the WHO and ICMJE.
Add the PI as a Study Official

Overall contact may be used to differentiate a study coordinator or administrator from the study official.

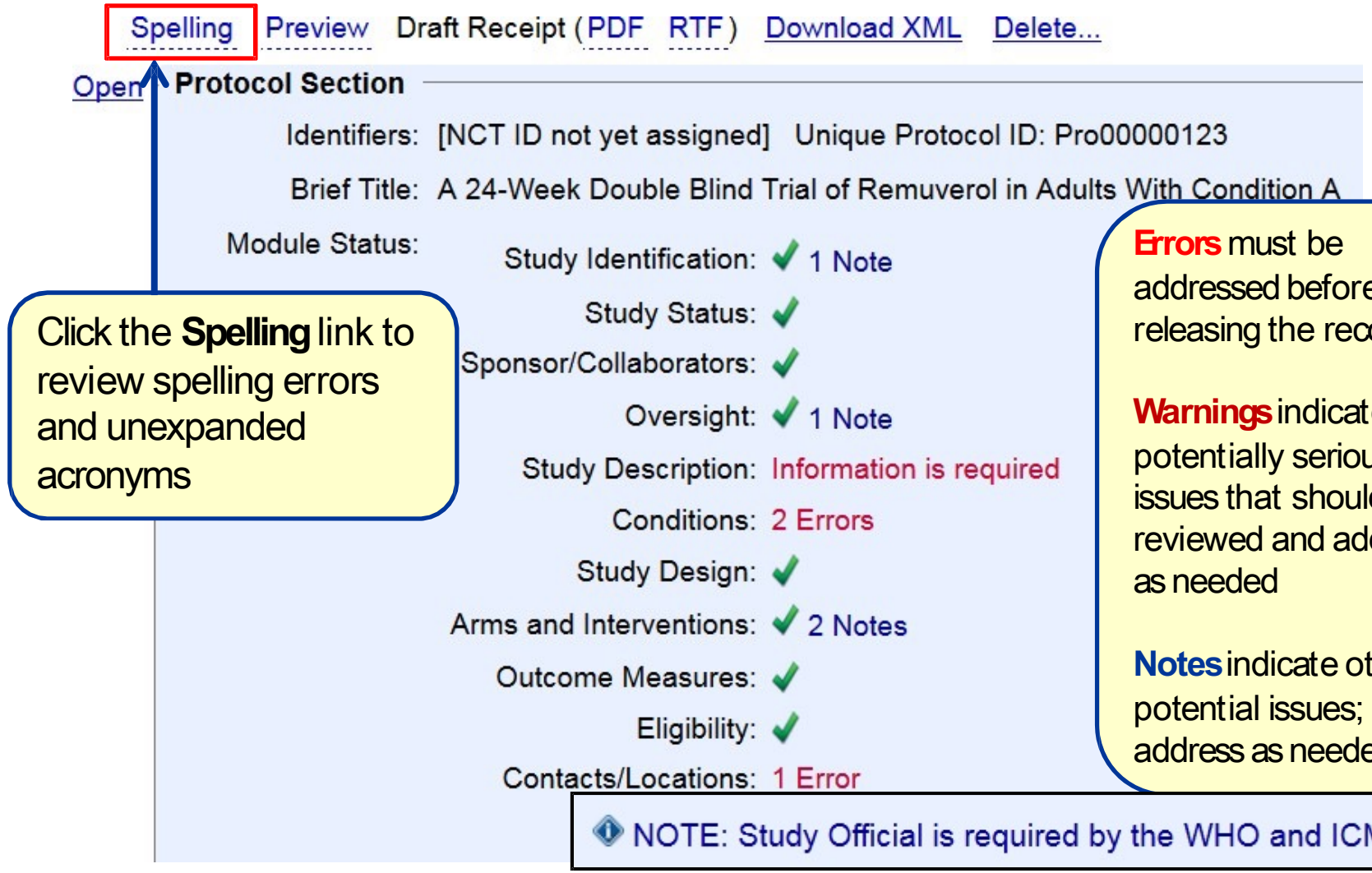


All sites should be added for multi-site studies, only after the IRB has approved that location


Edit Location
Help
Definitions
* Facility:
Name:
City:
State/Province:
ZIP/Postal Code:
Country:
United States
* Site Recruitment Status:
--Select--
Recruitment status for this individual location.
Site recruitment status must be consistent with overall recruitment status; if overall recruitment is not recruiting, no site can be recruiting
* Facility Contact:
First Name:
MI:
Degree:
Facility Contact Backup:
Phone:
Ext:
Email:
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).
Investigators:
+ Add Investigator


Edit References
Help
Definitions
Studies available in PubMed are linked automatically if the NCT# was included in the publication. Others need to be added manually
Citations:
PubMed ID:
Lookup
Use the PubMed Citation Matcher to search for citations based on journal name, date, author(s), title and other criteria.
Citation:
Results Reference:
--Select--
Indicate if the reference provided reports results from this study
Enter Citation Text
× Delete Citation
+ Add Citation
Links:
URL:
http://
Description:
× Delete Link
+ Add Link

The Record Summary



Click the **Spelling** link to review spelling errors and unexpanded acronyms

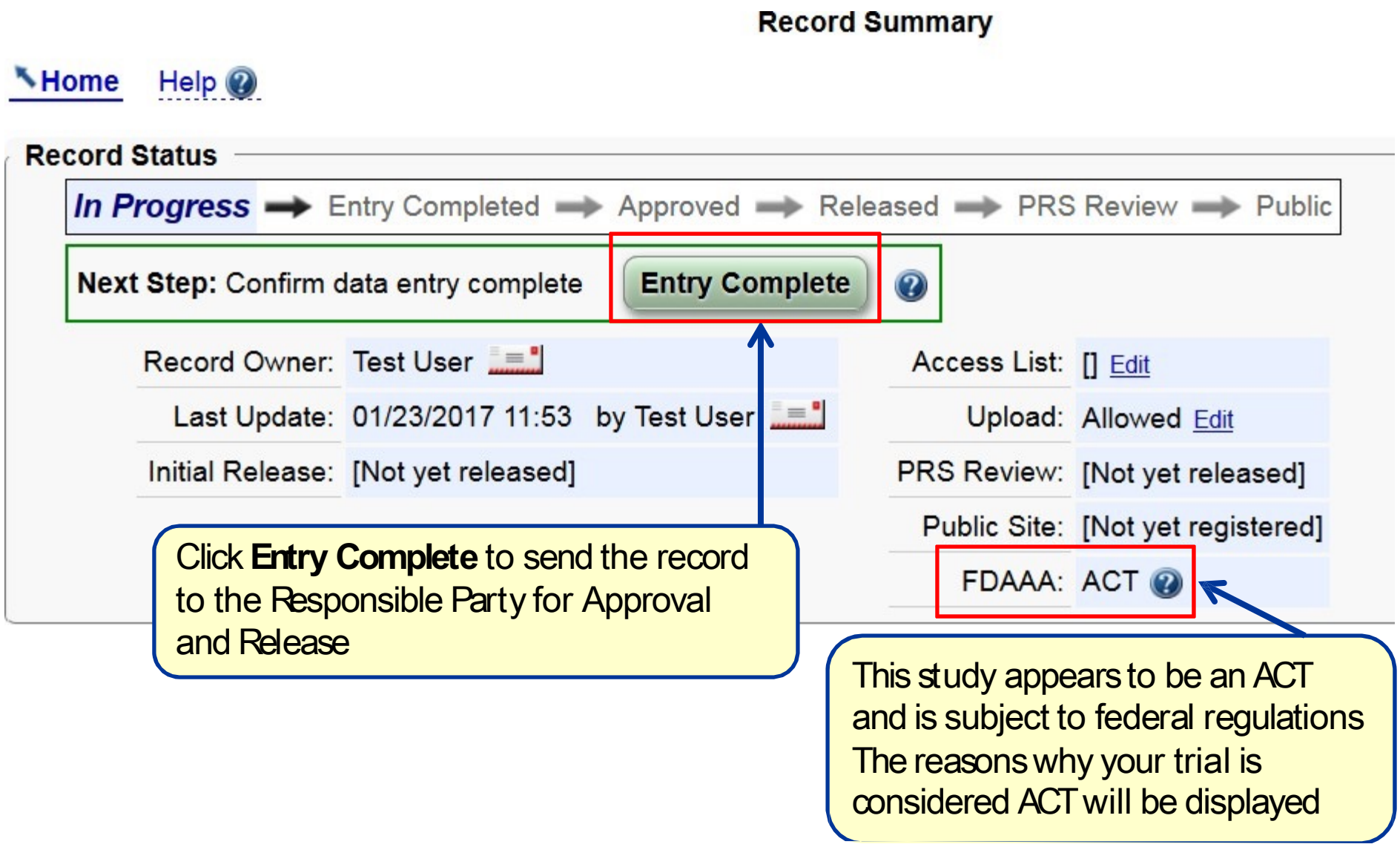
Errors must be addressed before releasing the record

Warnings indicate potentially serious issues that should be reviewed and addressed as needed

Notes indicate other potential issues; address as needed

When the Record Summary shows all green checks, the PI should carefully review the record. False statements are criminal under the regulations! For new registrations, the PI should read each section carefully

The Record Summary – to complete



The Record Summary – User Information

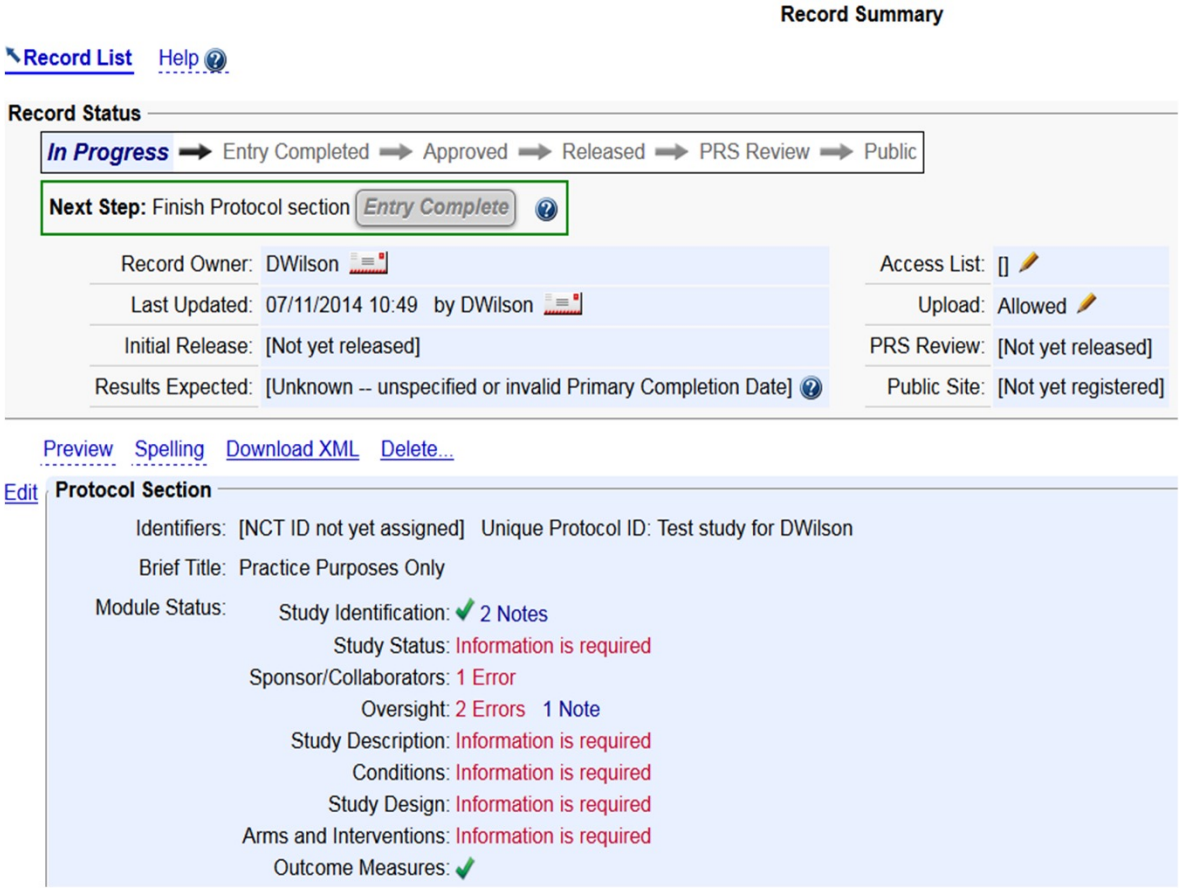
The Record Owner is the primary contact for the record. Only an administrator can change the Record Owner

Add the PI and anyone else who should have edit rights. The Record Owner can do this

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

Can a Study Record be Deleted?

- Only if the study record has never been published on ClinicalTrials.gov
- Otherwise, No.
- ClinicalTrials.gov serves as a long-term public registry. Once a study record is published, it remains in the system even after a trial has closed.
- If you find a duplicate, contact ClinicalTrials.gov at register@clinicaltrials.gov.



PRS Review

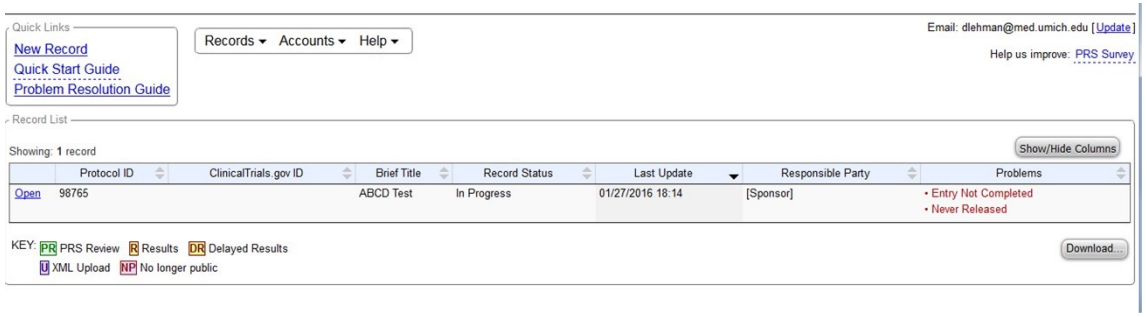
Once the record is released, ClinicalTrials.gov conducts a manual review

- If major issues are identified, the record owner and RP will receive notification from ClinicalTrials.gov with comments
- The study will be reset to In Progress
- Study Owner/RP must correct the issues and re-release it **within 15 calendar days (new in 42 CFR 11)**
- If no major issues are identified, the study is assigned an NCT number and published on the public side of the database (clinicaltrials.gov)
- This process takes about 2-5 business days
- Even if its published, advisory comments may be posted. Corrections are not mandatory

Ongoing Responsibilities of Record Owners

- Records can be transferred to other user accounts as staff change
- **Records must be updated every 12 months and within 30 days of Recruitment Status changes or amendments that affect information in clinicaltrials.gov record, especially recruitment status, location and contact information**
- Always update the Record Verification Date to indicate that you have updated or reviewed the record
- **Records must be updated within 30 days after the completion date (last data collection)**
- Failure to update information on ClinicalTrials.gov can result in penalties. There are more specific update requirements in 42 CFR 11.64

Checking your Problem Records

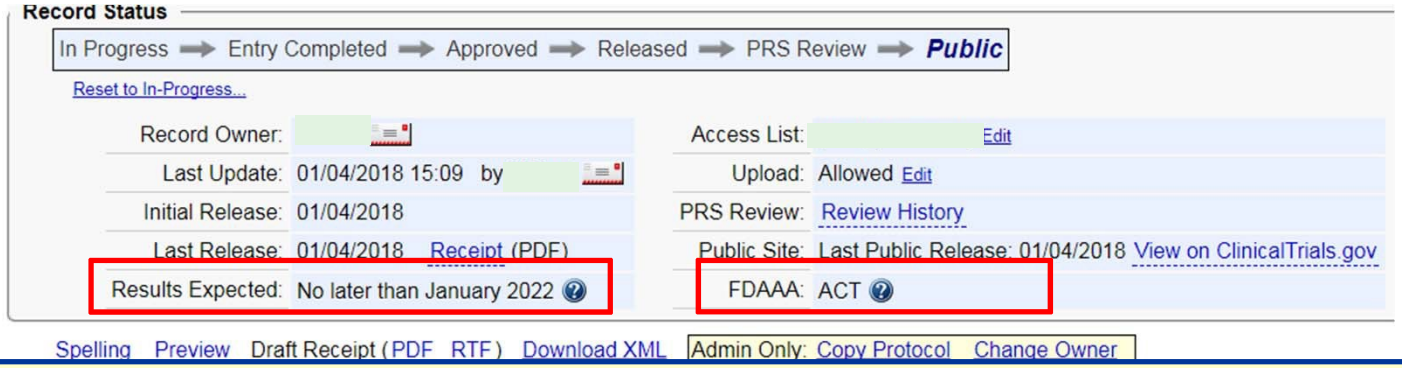


PRS System identifies current 'Problem Records'

- Records that have not been marked as completed
- Active studies that have not been updated (or the Record Verification Date has not been updated)
- Records missing one or more FDAAA-required data elements:
  - Responsible Party
  - Study Start Date
  - Primary Completion Date
  - Primary Outcome Measure
- Records that appear to be overdue for FDAAA results reporting

Do You Need to Submit Results?

- All Applicable Clinical Trials (ACTs) are required to submit results
- All NIH-funded trials begun on after 1/18/2017 and applied for on or after 1/18/2017 must report results, whether ACTs or not
- Other grantors may require results submission



Based on registration information entered, the system will assess whether the trial appears to be:

1) An ACT with results required by law
2) A Non-ACT: results ARE not required by law, though NIH policy (if so funded) or other funders' policies may still require results reporting

3)Older trials may be designated Probable ACT or Probable Non-ACT

Note: There is no reminder flag for NIH-funded trials.

Acknowledgements

This user guide was adapted from Weil Cornell which was developed as a collaborative effort on the part of ClinicalTrials.gov administrators at 11 academic medical centers around the nation to share efficient, best practices for most registrations based on their experience.

This slide set was developed collaboratively by contributors from

- Beth Israel Deaconess Medical Center,
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- Cambridge Health Alliance
- Duke University
- Fred Hutchinson Cancer Research Center
- Harvard University
- Mayo Clinic
- Partners
- Rutgers State University
- University of Michigan
- University of Pittsburgh
- University of South Florida