

# ClinicalTrials.gov

"How to Do Record Updates"

Regulatory Support Office- HRPP

# How to Do Record Updates ?

Log in to PRS account

Open the record

Open "Protocol section"

Microsoft Teams CT ClinicalTrials.gov PR... CT Home - ClinicalTrial... >> | Other bookmarks

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

**Login**

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS). OMB NO: 0925-0586  
EXPIRATION DATE:  
02/28/2023  
[Burden Statement](#)

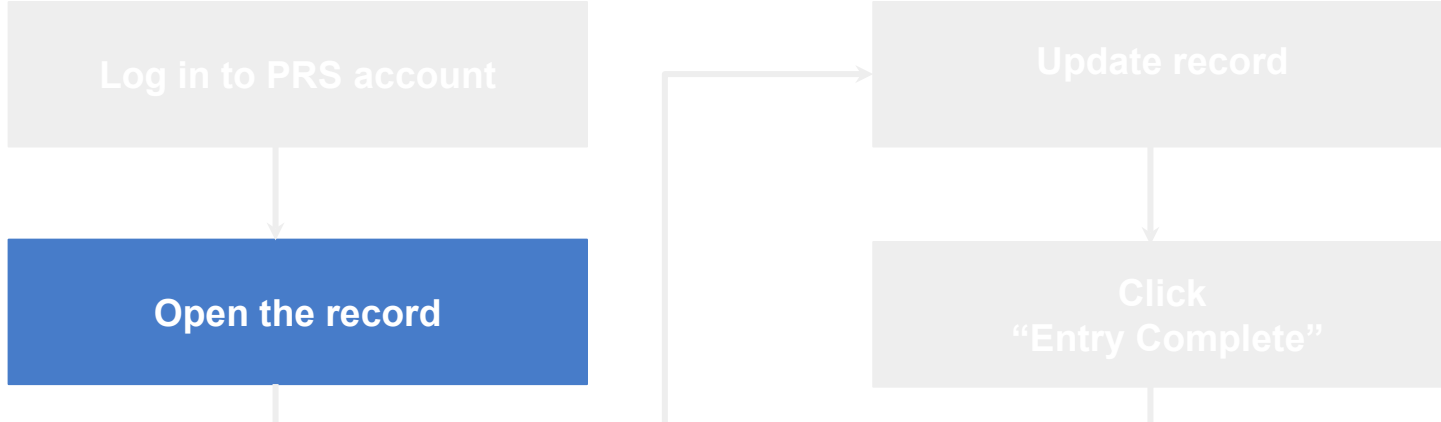
Organization:   
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password:  [Forgot password](#)

1. Log in to register.clinicaltrials.gov
2. Enter your UTSW username and password
3. List organization as **UTexasSouthwestern**

# How to Do Record Updates ?



**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Org: UTexasSouthwestern [Logout](#)

Email: [edu](#) [\[Update\]](#)

Help us improve: [PRS Survey](#)

Quick Links

- [New Record](#)
- [Admin Quick Reference](#)
- [Lookup Users](#)
- [Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Record List

Group: [ALL] All Records (796) Problem Records (19) Custom Filter

Showing: 1-796 of 796 records All records per page Search:  Show/Hide Columns

| Protocol ID | Secondary IDs | ClinicalTrials.gov ID | Brief Title | Overall Status | Verification Date | Primary Completion Date | Record Status | Results Status | Delayed Results Status | Responsible Party | Problems |
|-------------|---------------|-----------------------|-------------|----------------|-------------------|-------------------------|---------------|----------------|------------------------|-------------------|----------|
|             |               |                       |             | Recruiting     | 07/2021           | 12/2023                 | Public        |                |                        |                   |          |

[Open](#)

# How to Do Record Updates ?

Log in to PRS account

Open the record

Open "Protocol section"

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

[Home](#) > Record Summary

ID: \_\_\_\_\_

**Record Summary**

[Home](#) [Help](#)

**Record Status**

[In Progress](#) → [Entry Completed](#) → [Approved](#) → [Released](#) → [PRS Review](#) → [Public](#)

**Next Step:** Confirm data entry complete [Entry Complete](#) ?

|   |   |
|---|---|
| Record Owner: <a href="#">[User]</a>                    | Access List: <a href="#">Edit</a>   |
| Last Update: 09/17/2021 13:21 by <a href="#">[User]</a> | Upload: Allowed <a href="#">Edit</a>  |
| Initial Release: 02/05/2021                             | PRS Review: <a href="#">Review History</a>  |
| Last Release: 06/15/2021 <a href="#">Receipt (PDF)</a>  | Public Site: Last Public Release: 06/15/2021 <a href="#">View on ClinicalTrials.gov</a> |
|   | FDAAA: Non-ACT (No FDA-regulated drug/device) ?   |

[Spelling](#) [Preview](#) [Draft Receipt \(PDF, RTF\)](#) [Download XML](#) [Admin Only: Copy Protocol](#) [Change Owner](#)

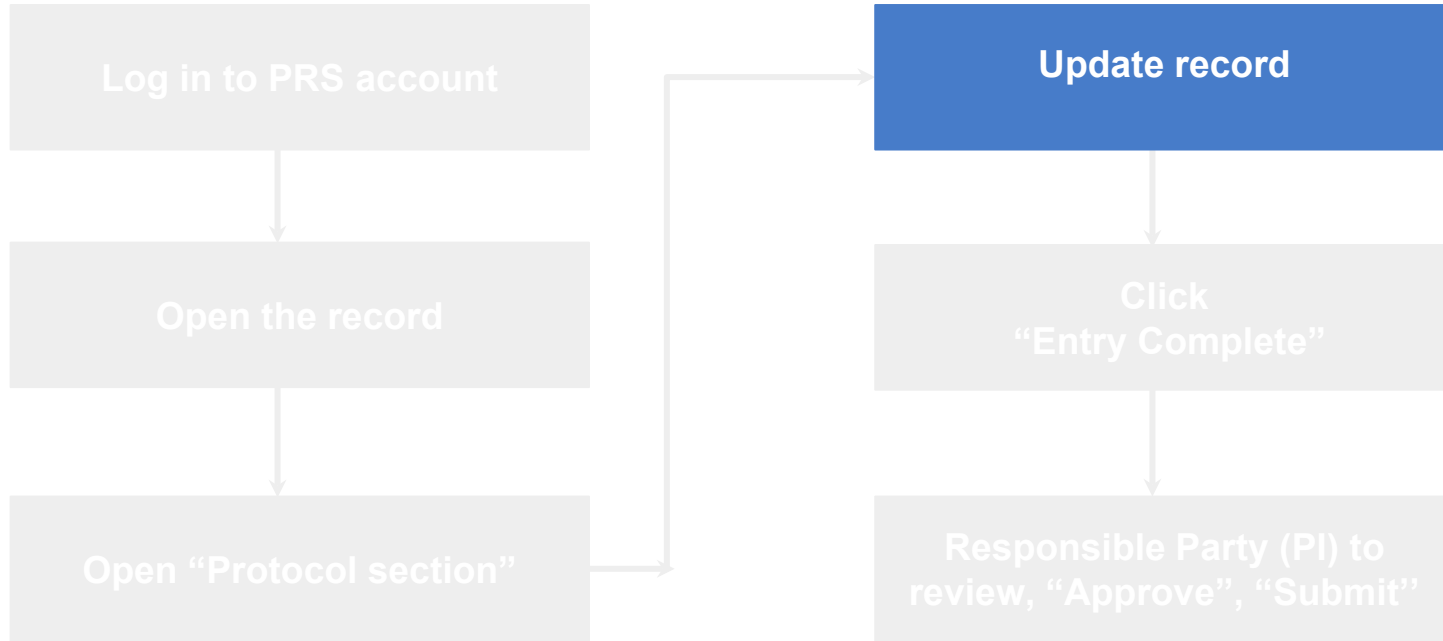
[Open](#) **Protocol Section**

Identifiers: \_\_\_\_\_ Unique Protocol ID: \_\_\_\_\_

Brief Title: \_\_\_\_\_

Module Status: \_\_\_\_\_ Study Identification: ✓

# How to Do Record Updates ?



# How to Do Record Updates ?

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section

ID: \_\_\_\_\_ Protocol Section

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#) [Definitions](#)

[Edit](#) **Study Identification**

Unique Protocol ID:  
Brief Title:  
Official Title:  
Secondary IDs:

[Edit](#) **Study Status**

Record Verification: August 2021  
**Overall Status: Active, not recruiting**   
Study Start: July 2006 [Actual]  
Primary Completion: August 2022 [Anticipated]  
Study Completion: August 2023 [Anticipated]

[Edit](#) **Sponsor/Collaborators**

Sponsor: University of Texas Southwestern Medical Center  
Responsible Party: Principal Investigator  
Investigator:  
Official Title:  
Affiliation: University of Texas Southwestern Medical Center  
Collaborators:

Open "Protocol section"

Update record

Click  
"Entry Complete"

Responsible Party (PI) to  
review, "Approve", "Submit"

# How to Do Record Updates ?

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section

ID: \_\_\_\_\_

Protocol Section

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#) [Definitions](#)

[Edit](#) **Study Identification**

Unique Protocol ID: \_\_\_\_\_  
Brief Title: \_\_\_\_\_  
Official Title: \_\_\_\_\_  
Secondary IDs: \_\_\_\_\_

[Edit](#) **Study Status**

Record Verification: August 2021


**Overall Status: Active, not recruiting**

Study Start: July 2006 [Actual]

Primary Completion: August 2022 [Anticipated]  
Study Completion: August 2023 [Anticipated]

[Edit](#) **Sponsor/Collaborators**

Sponsor: University of Texas Southwestern Medical Center  
Responsible Party: Principal Investigator  
Investigator: \_\_\_\_\_  
Official Title: \_\_\_\_\_  
Affiliation: University of Texas Southwestern Medical Center  
Collaborators: \_\_\_\_\_



Open "Protocol section"

Update record

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Study Status

ID: \_\_\_\_\_

**Edit Study Status**

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

\* Record Verification Date: Month:  Year:

\* Overall Recruitment Status:

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

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).

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


Final data collection date for primary outcome measure.

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

Final data collection date for study.

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

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



# How to Do Record Updates ?

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section

ID: \_\_\_\_\_ Protocol Section

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#) [Definitions](#)

[Edit](#) **Study Identification**

Unique Protocol ID: \_\_\_\_\_  
Brief Title: \_\_\_\_\_  
Official Title: \_\_\_\_\_  
Secondary IDs: \_\_\_\_\_

[Edit](#) **Study Status**

Record Verification: August 2021  
Overall Status: Active, not recruiting  
Study Start: July 2006 [Actual]  
Primary Completion: August 2022 [Anticipated]  
Study Completion: August 2023 [Anticipated]

[Edit](#) **Sponsor/ Collaborators**

Sponsor: University of Texas Southwestern Medical Center

[+](#) **Responsible Party - Principal Investigator**

Investigator: \_\_\_\_\_  
Official Title: \_\_\_\_\_  
Affiliation: University of Texas Southwestern Medical Center

Collaborators: \_\_\_\_\_

Open "Protocol section"

Update record

Click  
"Entry Complete"

Responsible Party (PI) to  
review, "Approve", "Submit"



# How to Do Record Updates ?

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section

ID: \_\_\_\_\_ Protocol Section

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#) [Definitions](#)

[Edit](#) **Study Identification**

Unique Protocol ID: \_\_\_\_\_  
Brief Title: \_\_\_\_\_  
Official Title: \_\_\_\_\_  
Secondary IDs: \_\_\_\_\_

[Edit](#) **Study Status**

Record Verification: August 2021  
Overall Status: Active, not recruiting  
Study Start: July 2006 [Actual]  
Primary Completion: August 2022 [Anticipated]  
Study Completion: August 2023 [Anticipated]


[Edit](#) **Sponsor/Collaborators**

Sponsor: University of Texas Southwestern Medical Center

**Responsible Party** [Principal Investigator](#)

Investigator: Robert Timmerman [rtime]  
Official Title: Professor of Medicine  
Affiliation: University of Texas Southwestern Medical Center

Collaborators: \_\_\_\_\_



Open "Protocol section"

Update Record

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Sponsor/Collaborators

ID: \_\_\_\_\_ **Edit Sponsor/Collaborators**

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

\* Responsible Party:

Select **sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

**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.  
[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**.

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



# How to Do Record Updates ?

ClinicalTrials.gov **PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section

ID: \_\_\_\_\_ Protocol Section

**ERROR(S) in Protocol Section** See ERROR or information required messages below

Record Summary Preview Edit All Help Definitions

**Edit** Study Identification

Unique Protocol ID:  
Brief Title:  
Official Title:  
Secondary IDs:

**Edit** Study Status

Record Verification: March 2021  
Overall Status: Not yet recruiting  
Study Start: October 2021 [Anticipated]  
Primary Completion: October 2023 [Anticipated]  
Study Completion: December 2025 [Anticipated]

**Edit** Sponsor/Collaborators

Sponsor: University of Texas Southwestern Medical Center  
Responsible Party: Principal Investigator  
Investigator 1  
Official Title 1  
Affiliation: University of Texas Southwestern Medical Center  
Collaborators: National Institute on Drug Abuse (NIDA)

**Edit** Oversight

U.S. FDA-regulated Drug: Yes  
U.S. FDA-regulated Device: No  
U.S. FDA IND/IDE: Yes  
IND/IDE Information:  
FDA Center:  
IND/IDE Number:  
IND Serial Number:  
Has Expanded Access: Unknown

**+** Human Subjects Review: Board Status: Not yet submitted

Board Name: Institutional Review Board  
Board Affiliation: University of Texas Southwestern Medical Center  
Phone: 214-648-3060 | Email: IRB@UTSouthwestern.edu  
Address:  
5323 Harry Hines Boulevard  
Dallas, Texas 75390-8843

Update record

Click  
"Entry Complete"

Responsible Party (PI) to  
review, "Approve", "Submit"

# How to Do Record Updates ?

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section

Protocol Section

Record Summary Preview Edit All Help Definitions

**Edit** Study Identification

Unique Protocol ID:  
Brief Title:  
Official Title:  
Secondary IDs:

**Edit** Study Status

Record Verification: March 2021  
Overall Status: Not yet recruiting  
Study Start: October 2021 [Anticipated]  
Primary Completion: October 2023 [Anticipated]  
Study Completion: December 2025 [Anticipated]

**Edit** Sponsor/Collaborators

Sponsor: University of Texas Southwestern Medical Center  
Responsible Party: Principal Investigator  
Investigator: [Redacted]  
Official Title: [Redacted]  
Affiliation: [Redacted]  
Collaborators: National Institute on Drug Abuse (NIDA)

**Edit** Oversight

U.S. FDA-regulated Drug: Yes  
U.S. FDA-regulated Device: No  
U.S. FDA IND/IDE: Yes

IND/IDE Information:

FDA Center:  
IND/IDE Number:  
IND Serial Number:  
Has Expanded Access: Unknown

**+** Human Subjects Review: Board Status: Not yet submitted

Board Affiliation: University of Texas Southwestern Medical Center  
Phone: 214-648-3660 Email: IRB@UTSouthwestern.edu  
Address:  
5323 Harry Hines Boulevard  
Dallas, Texas 75390-6843

Update record

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Oversight

Edit Oversight

Help Definitions

\* § U.S. FDA-regulated Drug: Yes  No

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  Yes

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: Yes  No  (Not public)

Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

FDA Center: CDER

Formerly IND/IDE Grantor

IND/IDE Number: PENDING

IND Serial Number:

4 digit number entered on the U.S. FDA IND application, Form 1571, if any.

[\*] Availability of Expanded Access: No  Yes

Will any non-protocol access to the investigational drug, biologic or device be provided? [[About Expanded Access records](#)]

\* 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 101.39.

Approval Number:

Board Name:

Board Affiliation:

Board Contact: Phone:  Extension:

Email:

Address:

Data Monitoring Committee: --Select--

FDA Regulated Intervention: --Select--

**Save** Cancel

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

# How to Do Record Updates ?

**Edit**

**Eligibility**

Minimum Age: 18 Years  
Maximum Age: 65 Years  
Sex: All  
Gender Based: No  
Accepts Healthy Volunteers: No

Criteria:

**Inclusion Criteria:**

Individuals must meet all of the inclusion criteria in order to be eligible to participate in the study:

1. P
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Exclusion Criteria:

- 1.

Update record

Click  
"Entry Complete"

Open "Protocol section"

Responsible Party (PI) to  
review, "Approve", "Submit"

# How to Do Record Updates ?

Edit

## Eligibility

Minimum Age: 18 Years

Maximum Age: 65 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria:

### Inclusion Criteria:

Individuals must meet all of the inclusion criteria in order to be eligible to participate.

1. Be 18 to 65 years of age;
2. Be interested in reducing or stopping cocaine use;
3. Meet DSM-5 criteria for moderate or severe CUD (4 or more criteria);
4. Provide at least 2 urine samples positive for cocaine (out of a possible 3 samples);
5. Self-report cocaine use on 18 or more days in the 30-day period prior to consent;
6. If female, agree to use acceptable birth control methods and have periodic urinalysis;
7. Provide a urine sample negative for opioids and self-report no opioid use in the 30-day period prior to consent;
8. Be willing to comply with all study procedures and medication instructions.

Exclusion Criteria:

1. Have a psychiatric condition that, in the judgement of the site medical clinician, would prevent the participant from completing the study.

Examples include:

Update record

Open "Protocol section"

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Eligibility

ID: \_\_\_\_\_

**Edit Eligibility**

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

\* Sex: --Select--  
Biological sex of eligible participants.

[\*] Gender Based: --Select--  
If applicable, indicate if participant eligibility is based on self-representation of gender identity.

\* Age Limits: Minimum: --Select-- Maximum: --Select--

\* § Accepts Healthy Volunteers: --Select--

\* Eligibility Criteria:

|                     |   |
|---------------------|---|
| Inclusion Criteria: | - |
| Exclusion Criteria: | - |

[Special Characters](#)

**Save** **Cancel**

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

# How to Do Record Updates ?

Log in to PRS account

Update record

The screenshot displays the ClinicalTrials.gov PRS interface. At the top, the logo reads "ClinicalTrials.gov PRS Protocol Registration and Results System". Below the logo, a breadcrumb trail shows "Home > Record Summary > Protocol Section". An "ID:" field is present but empty. A navigation menu includes "Record Summary" (highlighted with an orange box and a hand cursor), "Preview", "Edit All", "Help", and "Definitions". The "Protocol Section" header is visible on the right. Two main sections are shown: "Study Identification" and "Study Status".

**Study Identification**

- Unique Protocol ID: [Redacted]
- Brief Title: [Redacted]
- Official Title: [Redacted]
- Secondary IDs: [Redacted]

**Study Status**

- Record Verification: June 2021
- Overall Status: Recruiting
- Study Start: June 14, 2021 [Actual]
- Primary Completion: June 14, 2023 [Anticipated]
- Study Completion: June 14, 2023 [Anticipated]

Complete"

Party (PI) to  
e", "Submit"

# How to Do Record Updates ?

**ClinicalTrials.gov PRS**  
Protocol Registration and Results System

[Home](#) > Record Summary

ID: \_\_\_\_\_

**Record Summary**

[Home](#) [Help](#)

**Record Status**

[In Progress](#) → [Entry Completed](#) → [Approved](#) → [Released](#) → [PRS Review](#) → [Public](#)

**Next Step:** Confirm data entry complete **Entry Complete** ?

Record Owner: \_\_\_\_\_  
Last Update: 09/17/2021 13:21  
Initial Release: 02/05/2021  
Last Release: 06/15/2021 [Receipt](#) (PDF)

Access List: [Edit](#)  
Upload: Allowed [Edit](#)  
PRS Review: [Review History](#)  
Public Site: Last Public Release: 06/15/2021 [View on ClinicalTrials.gov](#)  
FDAAA: Non-ACT (No FDA-regulated drug/device) ?

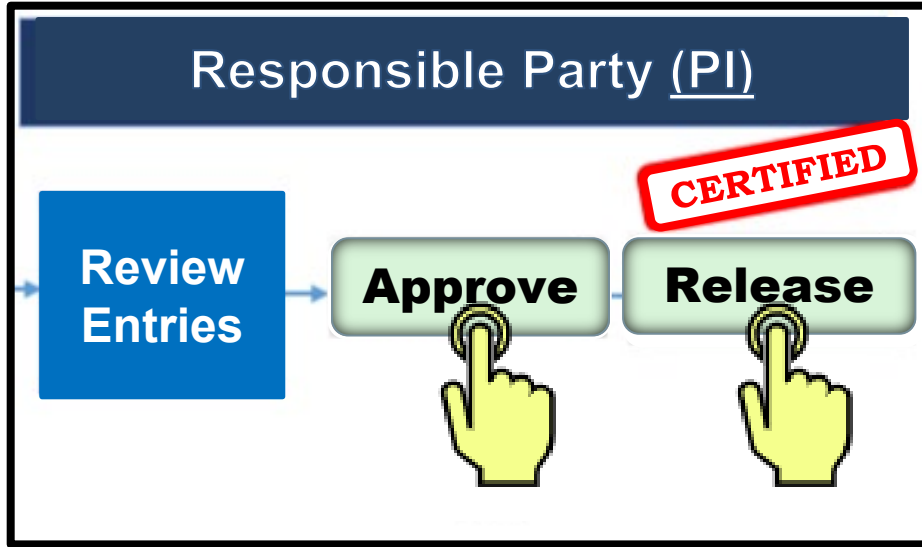
Update record

Click  
“Entry Complete”

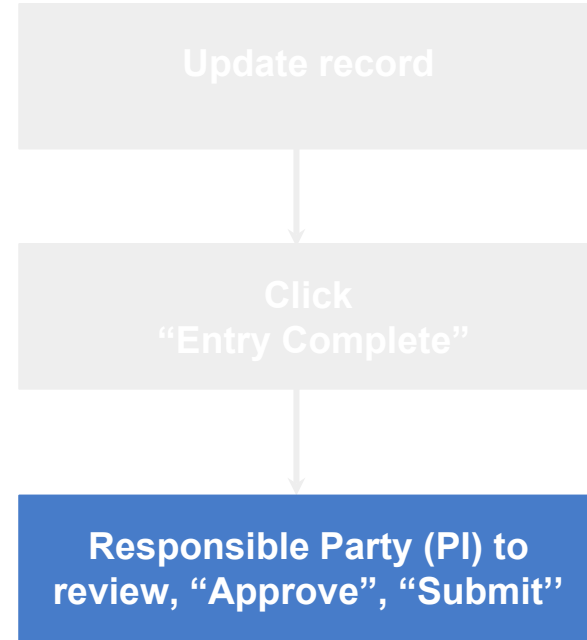
Open “Protocol section”

Responsible Party (PI) to  
review, “Approve”, “Submit”

# How to Do Record Updates ?



Open "Protocol section" →





# How to Do Record Updates ?

