When you first create a study, you also create the initial submission outlining the purpose of that

study by clicking on

on the Study Details page.

In addition to this initial submission, there are five other types of submissions that you may submit during the course of your research.

+ New Submission

Please note: Each submission type has its own template that the Analyst or Admin needs to configure via the Manage Submission Templates page before the submission type can be created.

Available Submission Types

- <u>Initial</u>: This is the first submission that you create when you enter a new study in the system. The initial submission describes the research you intend to do and the methodology you intend to use. The initial submission must be approved before any research can begin.
- **Modification:** If you wish to change any of the details of the study after it has been approved, you must submit a modification which must be approved before you can proceed with the changes.
- **Renewal:** When a study is nearing its expiration date, you must submit a renewal request in order to continue with the research. The renewal will need to be approved before you can continue with the study.
- **Incident:** You must submit an incident report to inform the Compliance Office of any adverse incidents, as required by your institution. Incident reports may be submitted at any time after a study has been approved, including after it has been closed. More than one incident report may be created for a given study, as needed.
- Withdrawal: A withdrawal submission notifies the Compliance Office that you no longer wish to submit your initial submission and want to withdraw the study. Withdrawn studies are marked as finalized and can no longer be modified. You may create a withdrawal submission at any point once an initial submission has been created, until it has been approved. If the initial submission has been approved, you must create a closure submission in order to close the study if you no longer wish to conduct the research.
- **Closure:** A closure submission indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified.
- Legacy: Used for studies imported from previous systems. The legacy submission replaces the initial submission for imported studies. Once the legacy submission is finalized, you can create additional submissions such as modifications, renewals, etc. An Analyst must create and publish a legacy template before users can create legacy submissions or work with studies that have been imported from other systems.

Submission Types Available to Analysts and Admins

- Admin Closure: Allows a study to be administratively closed when needed, for example when the PI leaves the institution or chooses to let a study expire.
- Admin Withdrawal: Allows a study to be administratively withdrawn when needed, for example when the PI leaves the institution.