

Packages versus Projects

Packages are groups of documentation submitted to reply, request, or inform the oversight committee(s) about Projects.

New Packages are needed for the creation of any submission.

i.e.- amendments, continuing review, annual monitoring, revisions/modifications, adverse events, etc.

When creating **New Packages**, you should **NOT** be prompted to enter a title! If you are prompted to enter a title you are creating a **New Project!**

To Create a **New Package**:

1. Click the Title of the Project which needs a **New Package**.
2. Go to **Designer**.
3. Click "Add New Document" button (scroll down if not visible).
4. Choose to "Create New Package".
5. Click the blue "New Document Package".

You are now on the **Designer** page of the **New Package**.

Package is Locked

[000000-1] The Title of your Project

Your current document package has already been submitted and is presently locked by your Board.

You may contact your Board and request that they unlock the package. This will allow you to make modifications directly to this package instead of creating a new package.

You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package for this study. Creating a new document package will allow you make changes while also automatically retaining the current versions of all documents as part of your electronic audit trail.

Projects are completely independent protocols, procedures, or other information describing the activities of a study.

Projects are only created ONCE! If you are prompted to enter a title you are creating a **New Project!**

New Projects are needed when a proposed new study requires initial approval by the oversight committee(s).

i.e.- new human subjects study, new animal activities, new type(s) of biological registrations.

To Create a **New Project**:

6. Click the "Create New Project" button in the left-hand navigation bar.
7. Enter the requested information: Title, Sponsor, PI Name, etc. Only the Title and PI Name are required.
8. Click the "Continue" button.

You are now on the **Designer** page of the **New Project**.

Create a New Project

Research Institution:

Title: *

Principal Investigator: First Name: * Degree(s):

Last Name: *

Keywords:

Sponsor:

You may specify an internal account number, billing identifier or reference number for this project.

Internal Reference Number:

* required fields



Please reference the guides on the webpage below and your respective committee's webpage for assistance. If additional needs exist, please contact the appropriate personnel below:

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