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

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

**New Packages** are needed for the creation of any submission.

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

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**.

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**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**.

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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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