

1. Enter your username and password and click **Login**.

2. Click on **My IRB Protocols**.

3. Click on **Create New Protocol**.

On the General Protocol Information screen, enter **Protocol Details**:

4. Click on the drop down menu for **Type** and choose **Standard**.
5. Enter the **Title** of the protocol.
6. Enter a **Description** of the research protocol. This is considered the study purpose or aim. **Note**, if the research is conducted internationally or with international data/samples, the name

of the country(ies) should be in the Description as well.

7. The **Application Date** defaults to today's date.
8. If applicable, enter optional information in the **Reference Num 1** field such as:
  - a. Yale investigator who holds an IND or IDE #
  - b. Name of company or sponsor that is providing a study drug
9. If applicable, enter optional information in the **Reference Num 2** field such as:

- Protocol-specific reference numbers
- IRB numbers
- Sponsor protocol numbers

10. Enter the **FDA Application No** if applicable.

11. Click **Save**.

12. The screen displays a protocol number and indicates the status (Pending/InProgress):

13. Proceed to the **Organization** screen on the left navigation bar.