

## Protocol Builder Instructions

### To access Protocol Builder:

<https://app.protocolbuilderpro.com/>

### To create an account:


If you are a Western Reserve Hospital Employee, Medical Staff, Resident or a Rotating Medical Student and would like to create a Protocol Builder account, please email Lauren Cowan ([lcowan@westernreservehospital.org](mailto:lcowan@westernreservehospital.org)). Include your name, department, medical school (if a current student) and the email you would like to use to set up the account. Your request will be processed in 1-3 business days.

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### Creating a New Protocol:

Tip: To get started entering a new protocol, make sure you have the email addresses of the individuals working with you on the research project. Email will be required to invite them to join the protocol if they are not already a registered user.

#### 1. Select Protocol Type:

 Protocol Type \*

Select Protocol Type

Select Protocol Type


**Master**

- Behavioral Intervention (incl. benign behavioral intervention)
- Chart Review
- Interventional FDA Approved Drug/Biologic
- Interventional Investigational New Drug/Biologic
- Interventional Non-Significant Risk Device
- Interventional Significant Risk Device
- NIH IND/IDE Protocol Template
- Observational study of a FDA regulated product
- Observational study of individual or group characteristics or behavior, or human factor evaluation
- QA/QI
- Repository with the use of Broad Consent
- Repository without use of Broad Consent
- Social Behavioral


#### 2. Enter Protocol Set Up

- In the Principle Investigator Field, type the name or email of the investigator. If the individual has a protocol builder login, their name will populate with a number after it as shown below.


## Protocol Set Up

 File Name \*

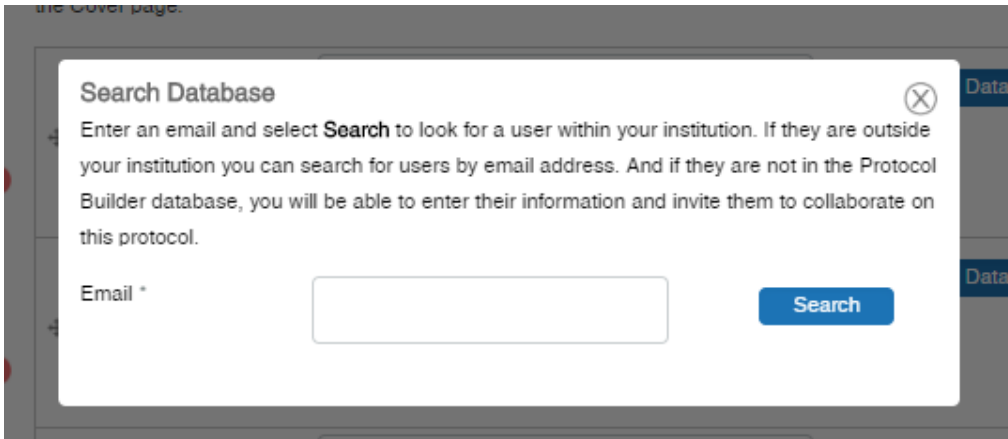
  

 Principal Investigator \*

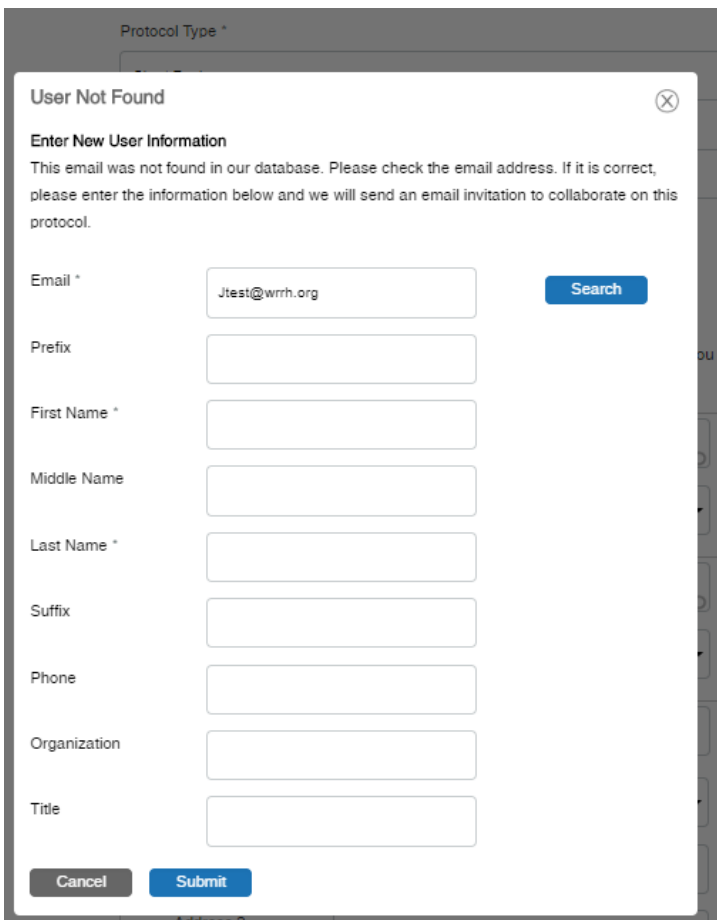
  

 Protocol Type \*

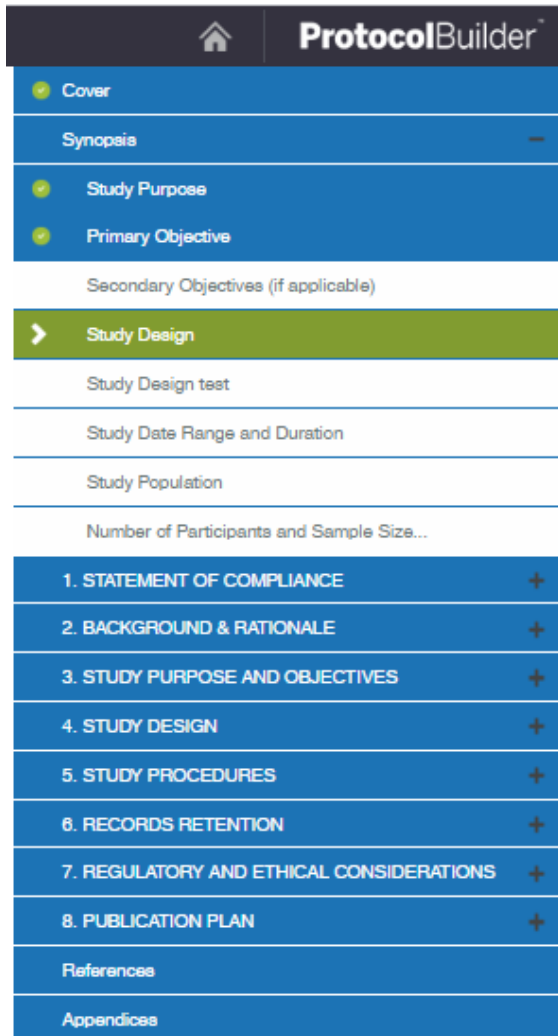
3. Click "Save". The Cover section will load for you to fill in.
4. As you enter Personnel (individuals involved in doing the research), you may need to search the database:
  - a. Use the "Search Database" button to find users by entering their email address.



- b. If the user is "not found" when completing the above process, enter the information so an email invitation can be sent to collaborate on the protocol.



5. When the initial Cover section is complete, click “Next” at the bottom of the page.
6. The menu on the left of the screen shows each of the sections of the protocol.
  - a. A green dot will appear to the left of the section when you have entered information in a section.
  - b. Larger sections have a + or – symbol toward the right of the row indicating there are sub-sections.
  - c. The Synopsis section is meant to be just that, a synopsis of what you will be doing in your study. Further detail will be placed in the numbered sections below the synopsis.
  - d. Sub-sections have several areas of consideration when building your protocol that will need to be addressed when looking to achieve IRB approval or IRB exemption for your study.



7. Using the Study Design section as an example, make note of the options on each page.
  - a. The red “i” provides details about what information belongs in each section.
  - b. If more detail will be required later in the protocol, the text will link to the area, as is seen in “4.1 Study Design” below.
  - c. Sample Text is available to help get you started in the upper right corner above each box.
  - d. The basic word processing options (bold, italic, etc) are available.
  - e. Below the word processing icons are blue words you can click to add symbols, abbreviations, a glossary, references, footnotes or tables.
  - f. There is an appendix attachment option that can be used in each section as appropriate

Test Protocol Example > Synopsis > Study Design

## i Study Design

Preview

This should be a summarized version of 4.1 Study Design. Please ensure these sections accurately reflect one another.

Sample Text

B / *I* U

+ Symbols + Abbreviation + Glossary + Reference + Footnote + Table

|

Appendix attachment

i

Title

Attachment

### Accessing a Protocol

1. The protocol can be accessed though icon that looks like a file drawer. All protocols that are shared with you will be listed here. This is also where you start a new protocol.

ProtocolBuilder

 ADMIN

Welcome Lauren Cowan | Logout

✓ Protocol *Test Protocol Example* has been deleted.

### Protocol List

Number	Title	Version	Principal Investigator	Last Saved <span style="font-size: small;">▼</span>	🗑️
	Test Protocol Example	Draft	Lauren Cowan	01/17/2020	🗑️



2. By clicking on the title of the protocol in your list of protocols, you can access the Dashboard. The dashboard tells you how far along you are on your protocol. By clicking the “Preview” button under each section, you will be able to view the detail. From there, you can make edits on any section. Remember to use the red “i” information icons and Sample text options if you are unsure of what to put in a section of your protocol.

