Protocol Builder®
Application Tour
Protocol Builder helps make it faster and easier to develop research protocols that comply with IRB and regulatory standards.
SIGN IN

Sign in securely with your email address and password. Click on “Forgot Password” to receive a password reset email.
Click to start a new protocol, or open a recently saved protocol from the quick pick list. Or duplicate an existing protocol to repurpose the content and references easily. You will also find links to instructional videos and Important News from Protocol Builder our your IRB.

Features and Tips

- NCI CTEP Cancer Protocol Review
  08/06/2019
- QA/QI Protocol test
  08/06/2019
- resident7162019
  07/16/2019

Important News

Protocol Template Changes
We have updated sections, guidance and sample text on the repository, observational and behavioral protocol templates including information on how the Revised Common Rule may impact study design. For organization choosing to implement the use of Broad Consent, we’ve added a new template for Repository Studies using Broad Consent. For the list of new templates, please visit the Resource Center.

Important things to know:
- Changes will take effect on 6/1
- It will not affect protocols in progress and completed protocols
- Old templates will no longer be available in the Protocol Set Up dropdown
- Old protocols can still be cloned. However, please check with your IRB regarding the right template to use if you are using a repository, observational or behavioral protocol template
PROTOCOl SET UP

Set up your protocol quickly by entering basic information. Wait for system to find the PI's name to show up when you enter the first letters of their name.
PROTOCOL SET UP

Choose the protocol type to set up the table of contents and guidance that will guide you through the process of writing the protocol.
COVER PAGE

Enter the key information about the protocol that will show up on the cover page (the file name will not show on the final protocol output).

Cover

This section includes study identification details and individuals responsible for the research. It will be used to create the cover page.

File Name *

New Protocol

Protocol Type *

Interventional Investigational New Drug/Biologic

Study Title

Protocol Number (if available)

Investigational Product

IND Number

Clinical Phase

- None -
COVER PAGE

Start typing in a name and Protocol Builder will search for it in your organization’s list of users. Simply select the name when it appears. Make sure you choose the access role you want to them have for your protocol: “Writers” can edit, “Reviewers” can only read and comment. At the bottom of the personnel list you will find the Research Admin box for IRB, HRPP or other personnel you want to share the protocol with, but do not want to show on the cover page.
SEARCH FOR PERSONNEL

If the name is not found, click “Search Database”. Type in an email address to search the entire Protocol Builder database. If the user is in the system fields will show populated. If the user is not in the system, you can enter the information manually and an email invitation to join the protocol will be sent out.
Once the set up is completed, you can start writing the protocol sections. We suggest starting with the Synopsis sections as part of your first draft. The tool will automatically populate those sections that are the same in body of the protocol, so you don’t have to type them in twice.
WRITING THE PROTOCOL - CONTENTS MENU

You can jump straight to the section you want to work on using the left hand navigation that contains all protocol sections. As you go working on the sections you will see a check mark appear: a grey checkmark means it is still a draft, a free checkmark means it is complete.
CONTENTS MENU

If you’d like to jump to a specific section of a protocol, open the Contents Menu and click the name of that section.
Click on the “i” icons anywhere to display the guidance for completing the section.
To save time Protocol Builder provides, where possible, sample text that can be inserted and edited.
As you’re writing, you can click the editing toolbar buttons to format text.
WRITING THE PROTOCOL - REFERENCES

As you’re writing, you insert references you’ve improved into your References Library. Protocol Builder will take care of formatting them, numbering them and adding them to the References page at the end of the protocol.
WRITING THE PROTOCOL - LINKED SECTIONS

If you are working on a Synopsis section that is repeated later these sections will be linked so you don’t have to re-enter information or make the changes in two places.
NEEDS REVIEW LIST

The Needs Review List shows all sections that need to be reviewed before being completed - all in one place. Whenever a new section needs review, the Needs Review alert is added to the bottom of the left navigation/table of contents bar.
PROTOCOL DASHBOARD

The Dashboard gives you a quick snapshot of your protocol and how much has been completed. Click the Preview button under any section to navigate and see it in Preview mode.
The Resource Center provides additional tools and information to help investigators complete and improve the quality of their protocols. You will find a helpful content such as a summary of the Revised Common Rule, Residency and New Investigator Resources, and NIH IND/IDE Template Resources to name a few.
THE GEAR ICON - SHARING & OUTPUT

Use the “gear” icon in the bottom right to go to Preview mode, invite others to review or share a pdf via email.
OUTPUT OPTIONS

Protocol Builder provides the option to output the final protocol document in either PDF or Word format.
FINAL CHECKLIST & IRB TRACKING

Once you’ve finished writing your protocol (and made sure all sections are complete), you can go through the checklist to make sure you’ve completed all the necessary step before submitting your protocol. Protocol Builder also provides a way to keep track of the versions submitted for IRB Review and the corresponding tracking number.
THANK YOU FOR TAKING THE TOUR!

Protocol Builder helps make it faster and easier to develop research protocols that comply with IRB and regulatory standards.