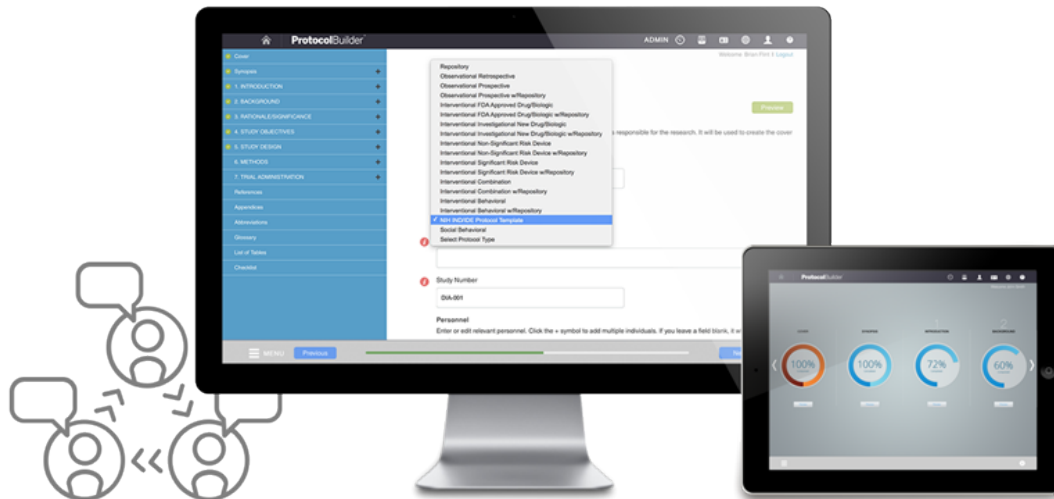


# Protocol Builder®

A more efficient way to write and review clinical and social behavioral research protocols



## Designed with compliance and efficiency in mind

Protocol Builder offers specific benefits to meet the needs and priorities of groups focused on clinical and social behavioral research and education.

### Write protocols using established compliance guidelines and standards

- ▶ Structured and guided experience that supports new and experienced researchers
- ▶ Teaches best practices during the writing process
- ▶ Saves writing time and effort by automating tasks

### Supports the collaborative protocol writing process

- ▶ Enables communication between all participants
- ▶ Fosters teamwork and mentorship
- ▶ Gathers feedback and streamlines workflow

### Makes the review process more efficient

- ▶ Enforces institutional protocol requirements
- ▶ Promotes adherence to regulations
- ▶ Confirms protocol completeness at a glance

## Benefits for research groups

### HRPP and IRB – Enforce regulatory and institutional standards

Protocol Builder can help you enforce protocol standardization and increase protocol quality with pre-set templates that need to be followed. Simple instructions and expert tips allow institutions to enforce both regulatory and organizational standards for protocols. It also enables collaboration between investigators and research administration staff to make the review and revision process easier. And Protocol Builder can be customized by tailoring templates and guidance, or integrating with your IRB, CTMS, or single sign on platforms.

### Residency Programs – Support research education

Protocol Builder not only helps residents develop consistent protocols more easily, it also helps them learn as they go. It offers a guided experience developed by protocol writing experts and can bolster your program's efforts to meet or exceed ACGME research requirements. In addition, it enables communication and collaboration between instructor and students to support the teaching experience and foster mentorship.

### Research Investigators – Save time and effort writing protocols

Whether you are an experienced or new research investigator, doctor, medical resident, or medical student, Protocol Builder can help you develop better protocols in less time with less effort—even if you are new to protocol writing. It's easy to get started and simple to use. It also enables collaboration and helps avoid multiple rounds of revisions, so you can get your research up and running faster.

### Testimonials

“Protocol Builder is helping us improve the consistency of our protocols, so we can work on protocol quality. The protocol dashboard has been a great tool to quickly check for completeness, especially with more complex protocols.”

Clinical Research Implementation Specialist  
Hackensack Meridian Health

“Our investigators really appreciate the step by step guidance, the collaboration tools and the protocol completeness dashboard features. Our goal is to use Protocol Builder as our protocol writing hub to enhance quality, reduce review time, and improve adherence to federal and IRB regulations.”

Clinical Research Navigator  
CTSI at Children's National

## Backed by an industry leader



Protocol Builder is powered by BRANY, a leader in providing hospitals and medical schools IRB and clinical research support services. Founded in 1998 by the leading New York area academic medical centers, BRANY's commitment to clinical research excellence and efficiency in clinical trial study start up is exceptional. BRANY is a nationally recognized company used by the leading academic institutions.

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# An institutional-strength application

Protocol Builder is the only protocol writing application designed to support large quantities of individuals involved in research, compliance and research education at an institution.

▶ **Boosts the quality and consistency of protocols**

Features including expert tips and resources improve adherence to IRB and regulatory standards  
Templates and relevant instructions promote standardization for easier development and review  
Tools are available to help determine protocol type and whether an IND/IDE is needed

▶ **Strengthens institutional research programs**

Helps increase study pipelines by improving the quality of protocols  
Frees up resources to focus on other tasks like getting approved research off the ground  
Assists residency programs in meeting ACGME research requirements

▶ **Customizable to fit with institutional processes**

Customize protocol template with institutions required topics  
Update guidance to fit with institution's process and standards  
Customize protocol output branding and confidentiality statement

▶ **Enables communication and collaboration**

Users can invite colleagues and supervisors to comment on or revise protocol topics  
Revisions can be tracked, compared, and accepted/rejected  
Protocol writers can message reviewers directly about specific changes

▶ **Saves significant time and effort for protocol writers**

Automatically sets up the table of contents to help ensure the right topics are included  
Automates time consuming tasks, such as creating the References and Glossary sections  
Eliminates the need to copy/paste content or rely on templates that may be missing sections  
Helps check for accuracy and completeness to avoid multiple rounds of revisions

▶ **Promotes learning and the ability to publish research**

Best practices, expert tips, and a robust resource center help users learn as they go  
Automated citation/reference functionality makes it easier to insert references correctly  
Reference search tools, including EndNote and RefWorks, can be pulled into the application

▶ **Secure hosting and easy implementation**

Protocol Builder is secure with SSL encryption as well as password and firewall protection  
It can be implemented in as little as 30 days  
Training webinars available several times a month

# Robust features streamline the process

Protocol Builder offers easy to use features developed by protocol writing and usability experts.

## Key Features List

<b>Write</b>	Automatic set up
	17 protocol templates (incl. SBER and NIH IND/IDE)
	Easy to navigate contents menu
	Expert guidance
	Protocol completeness indicators
	Protocol cloning
	Advanced editing tools
	Compare revisions/tracked changes
	Protocol preview
	References library
	Resource Center
	Protocol Archive
<b>Collaborate</b>	Compare revisions/tracked changes
	Needs review alerts and review list
	Email notification of changes
	Protocol sharing
	Contact list
	Invite collaborators (inside/outside institution)
	Research administration access
<b>Review</b>	Professionally styled PDF or Word Output
	Automatic Summary of Changes
	NIH Template Output
	Research administration specific access
<b>Train</b>	Step by step guided experience
	Templates by study type (drug, device, observational, etc.)
	Expert guidance for each topic
	Easy to navigate contents menu
	Collaborate with instructor
<b>Manage</b>	User management
	Account Users reporting
	Institutional Branding
	Standard Confidentiality Statement
	Home Page messaging