

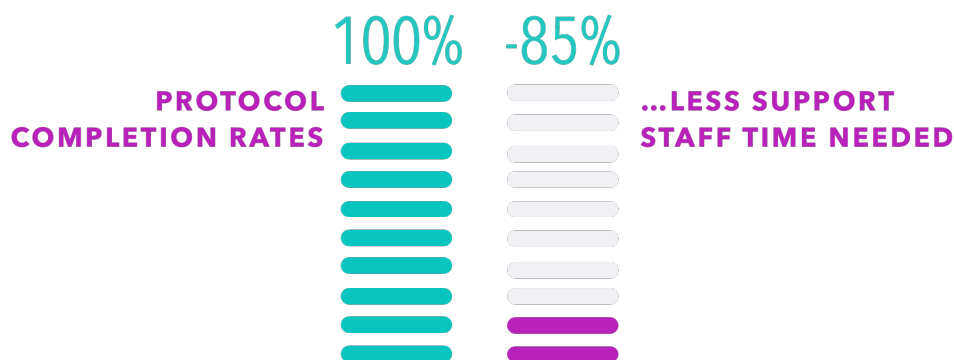
PROTOCOL BUILDER

BOOST YOUR GME RESEARCH TRAINING
MAKE SCHOLARLY ACTIVITY COMPLETION EASIER



SAVE TIME AND EFFORT ON SCHOLARLY ACTIVITY

Protocol Builder is an online platform designed to save everyone in your GME research training program time. Significant time. The tools and resources will make scholarly activity and mentorship easier helping to ensure 100% protocol completion rates for residents. And it decreases your support staff's time by up to 85%.



BOOST RESEARCH TRAINING WITH COURSES FROM CITI PROGRAM



Complimentary access to relevant CITI Program Courses:

- ▶ Observational Prospective Protocols: An Introduction
- ▶ Research Study Design

FACILITATE FACULTY MENTORING AND STUDENT COLLABORATION



Protocol Builder makes faculty/student collaboration easier:

- ▶ Spend more time mentoring and guiding than teaching and correcting protocol
- ▶ Distribute same template or pre-written protocols to groups of students
- ▶ Comment and edit student protocols online
- ▶ Receive notifications when changes are made
- ▶ View student progress

PRE-LOADED STANDARD TEMPLATES + CUSTOM TEMPLATES

OBSERVATIONAL

- Chart Review
- QA/QI
- Repository with the use of Broad Consent
- Repository without the use of Broad Consent
- Observational study of a FDA regulated product
- Observational study of individual or group characteristics or behavior, or human factor evaluation

SOCIAL BEHAVIORAL

- NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans
- Social Behavioral

INTERVENTIONAL

- NIH and FDA Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials
- Interventional FDA Approved Drug/Biologic
- Interventional Investigational New Drug/Biologic
- Interventional Non-Significant Risk Device
- Interventional Significant Risk Device
- Interventional Combination
- Behavioral Intervention (incl. benign behavioral intervention)

YOUR TEMPLATES



AN INSTITUTIONAL-STRENGTH APPLICATION

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

► **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

► **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
- Protocol Template Assistant helps determine protocol type and whether an IND/IDE is needed

► **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

► **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

► **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 TO STREAMLINE PROCESSES

TRAIN	<ul style="list-style-type: none"> ▪ 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
WRITE	<ul style="list-style-type: none"> ▪ 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
COLLABORATE	<ul style="list-style-type: none"> ▪ 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
REVIEW	<ul style="list-style-type: none"> ▪ Professionally-styled PDF or Word Output ▪ Automatic Summary of Changes ▪ NIH Template Output ▪ Research administration specific access
MANAGE	<ul style="list-style-type: none"> ▪ User management ▪ Account Users reporting ▪ Institutional Branding ▪ Standard Confidentiality Statement ▪ Home Page messaging

BENEFITS FOR OTHER GROUPS

HRPP and IRB - Save time, enforce regulatory and institutional standards

Protocol Builder can help you enforce protocol standardization and increase protocol quality with pre-set templates. Simple instructions and expert tips allow institutions to enforce both regulatory and organizational standards for protocols. The application's collaboration features make reviewing and making revisions easier. Templates and guidance can be customized and can be integrated with your IRB or single sign on platforms.

Research Investigators - Save time and effort writing protocols

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 academic medical centers IRB, coverage analysis, ethics and research compliance training and consulting.

