



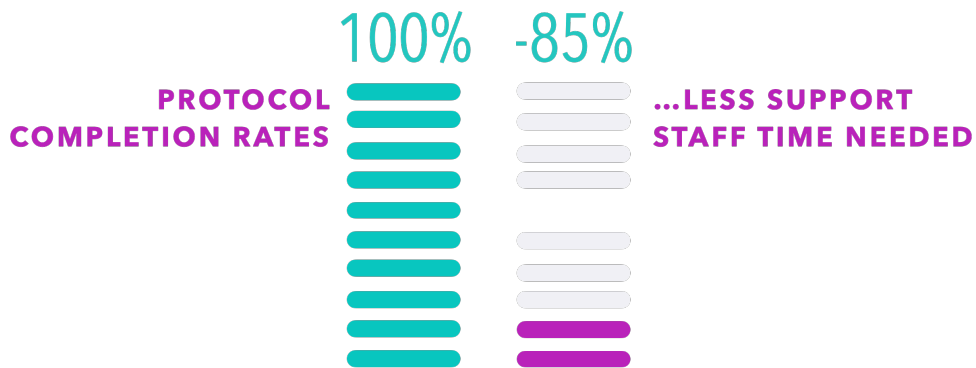
PROTOCOL BUILDER

BOOST YOUR GME RESEARCH TRAINING AND 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



Visit www.tetondata.com or call 800-901-5494 to request a demo.



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

<p>OBSERVATIONAL</p>	<p>YOUR TEMPLATE/S</p>
<ul style="list-style-type: none"> ▪ 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 	
<p>SOCIAL BEHAVIORAL</p>	
<ul style="list-style-type: none"> ▪ NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans ▪ Social Behavioral 	
<p>INTERVENTIONAL</p>	
<ul style="list-style-type: none"> ▪ 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) 	



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 TO STREAMLINE PROCESSES

	<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
WRITE	<ul style="list-style-type: none"> Protocol cloning Advanced editing tools
	<ul style="list-style-type: none"> 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
	<ul style="list-style-type: none"> 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
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
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 that need to be followed. Simple instructions and expert tips allow institutions to enforce both regulatory and organizational standards for protocols. The application's collaborations features make reviewing and making revisions easier. Templates and guidance can be customized and can be integrated with your IRB, CTMS, or single sign on platforms.

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 the BRANY, a leader in providing hospitals and academic medical centers IRB, research ethics consulting and training, and end-to-end clinical trial support services.

