ProtocolBuilder®

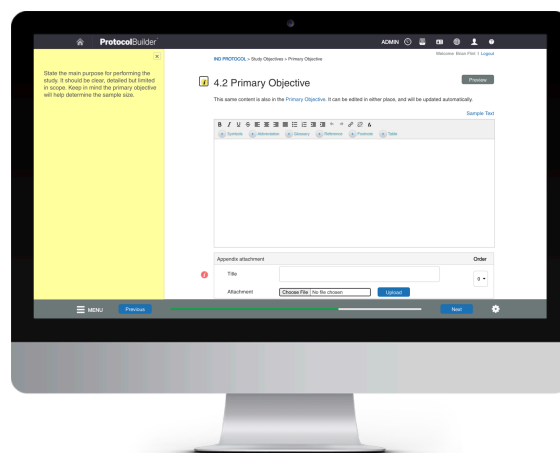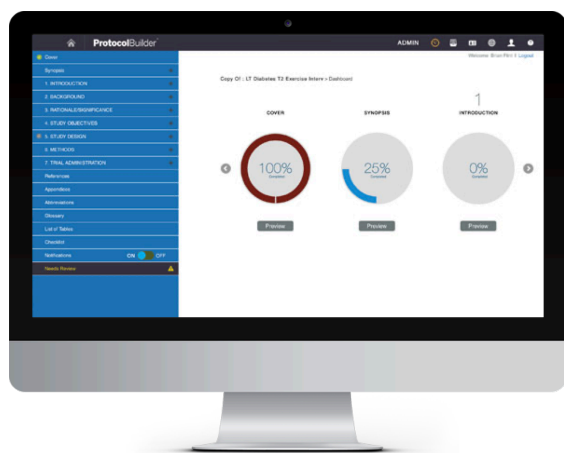# INTRODUCING PROTOCOL BUILDER

ACCELERATE THE SPEED OF YOUR PROTOCOL PROCESS

PROGRESS INSIGHTS, PROCESS CONTROL

When time is of the essence, it is important to know where you are and where you need to push in the protocol development process. Protocol Builder's dashboard provides instant at-a-glance updates on each investigator's protocol. Progress meters for each section tell you much they have progressed, but also where they may be stuck.

Protocol Builder ensures investigators avoid a big process time killer – submitting incomplete protocols to the IRB. The Protocol Dashboard together with section status indicators have proven to drive investigators to **submit 100% complete protocols**.

Visit www.protocolbuilderpro.com or call 516-477-5228 to request a demo.

ProtocolBuilder®

ROBUST FEATURES TO STREAMLINE THE PROCESS

Protocol Builder is an online platform designed to save time for everyone in the protocol development process. Significant time. The tools and resources make it easier for investigators to write better protocols for an easier passage through the IRB process.

GUIDANCE	- 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	- Automatic protocol set up 17 protocol templates (incl. SBER and NIH IND/IDE) - Easy-to-navigate contents menu - Protocol completeness indicators - Protocol cloning - Advanced editing tools - Compare revisions/tracked changes - Protocol preview - References Library - Resource Center - Protocol Archive
COLLABORATE	- Compare revisions/tracked changes - Needs review alerts and review list - Email notification of changes - Protocol sharing - Invite collaborators (inside/outside institution) - Research administration access
REVIEW	- Professionally-styled PDF or Word Output - Automatic Summary of Changes - Sponsor/Research administration specific access
MANAGE	- Template set up flexibility - User management and reporting - Corporate Branding - Standard Confidentiality Statement

TEMPLATE CONTROL AND CUSTOMIZATION

Exercise better control over your templates and what you want to change. Start with one of our 17 standard templates or build your own based on the unique requirements of your studies. And then, get investigators to follow them to the T.

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 TEMPLATE/S

EASE OF COLLABORATION

Protocol Builder makes collaboration with investigators easier:

▶ Distribute same template or pre-written protocols to groups of investigators

▶ Comment and edit investigator protocols online

▶ Receive notifications when changes are made

▶ View investigator progress

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![ProtocolBuilder®]

ENTERPRISE-STRENGTH APPLICATION

Protocol Builder is the only protocol-writing application designed to support large quantities of individuals involved in research and compliance at any organization:

▶ Acts as a central protocol repository

▶ Customizable to fit with clinical development focus

▶ Enables communication and collaboration

▶ Secure hosting and easy implementation

BENEFITS FOR IRBS

HRPP and IRB – Save time, enforce regulatory standards

Protocol Builder can help IRBs 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 collaborations features make reviewing and making revisions easier. Templates and guidance can be customized and can be integrated with your IRB submission or single sign on platforms.

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.

BRANY

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