ICB **Informed Consent** Builder

NEW

INFORMED CONSENT BUILDER

CLOUD-BASED INFORMED CONSENT FORM MANAGEMENT SOLUTION

Informed Consent Builder is a cloud-based software solution that changes the way ICF's are built. It was designed to ensure more accurate forms and eliminate the process inefficiencies and time-consuming tasks.

TEMPLATE CONTROL AND FLEXIBILITY

Informed Consent Builder provides IRB's with the ability to manage all Informed Consent Form templates in one place:

- Decide which templates will be presented to users for editing
- Lock sections with required content so that users cannot change
- Present users with different options of sample text that are all compliant

SPEEDS UP COLLABORATION

The process of developing an Informed Consent Form can be held up by breakdowns between collaborators on the form. With Informed Consent Builder you can:

- Establish one portal for investigators, research coordinators, and IRB administrators to collaborate on Informed Consent Forms

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

ICB **Informed Consent** Builder

- Ensure everyone is working on the same version of the protocol – no more email misses or version control issues
- See all the changes you need to review in one place
- Compare revisions in a before and after format
- Receive notifications when changes are made.

AUTOMATIC FORMATTING

Automatically formats input from all collaborators and all sources.

INCREASE TRANSPARENCY AND ACCOUNTABILITY

It can be time-consuming to keep track of comments and changes, including who made them and when. Informed Builder makes that easy with:

- Needs Review List: a worklist, organized by date and by section, showing what changes need to be reviewed and which ones have been completed/accepted
- Audit Trail: go one level deeper to see all changes made to any section of the Informed Consent Form
- Progress Dashboard: at-a-glance quickly assess informed consent development progress.

ENTERPRISE-STRENGTH APPLICATION

Informed Consent Builder is the only ICF-writing application designed to support large quantities of individuals involved in research and compliance at any organization.

BACKED BY AN INDUSTRY LEADER

Informed Consent 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

ICB **Informed Consent** Builder

KEY FEATURES

GUIDANCE	▪ Step by step guided experience ▪ Templates by trial type (drug, device, observational, etc.) ▪ Institutional guidance for each topic ▪ Easy to navigate contents menu ▪ Collaborate with investigators, research coordinators and IRB administration
WRITE	▪ Automatic Informed Consent Form set up ▪ Easy-to-navigate contents menu ▪ Form completeness indicators ▪ Form cloning ▪ Advanced editing tools ▪ Compare revisions/tracked changes ▪ Informed Consent Form preview ▪ Document Archive
COLLABORATE	▪ Compare revisions/tracked changes ▪ Needs review alerts and review list ▪ Email notification of changes ▪ Informed Consent Form sharing ▪ Invite collaborators (inside/outside institution) ▪ Research administration access, including default IRB users on all ICF's (optional)
REVIEW	▪ Professionally-styled PDF or Word Output ▪ Automatic Summary of Changes ▪ Sponsor/Research administration specific access
MANAGE	▪ Add approval date stamps to approved IC form ▪ Template set up flexibility ▪ User management and reporting ▪ Institution's logo on form

ProtocolBuilder®

PROTOCOL BUILDER

CLOUD-BASED CLINICAL PROTOCOL PROCESS EFFICIENCY SOLUTION

Protocol Builder is a cloud-based software solution that changes the way clinical protocols are built. It was designed to eliminate the process inefficiencies: version control issues, time-consuming formatting, collaboration breakdowns and more.

AUTOMATIC FORMATTING

Protocol Builder eliminates time-consuming tasks that face any protocol author by:

- Automatically formatting input from all collaborators
- Automatically number and format references, footnotes, list of tables and appendices
- Automatically track all changes and pre-load them into the Summary of Changes – all that is needed is the rationale for the changes.

SPEEDS UP COLLABORATION

The protocol process is often held up by breakdowns and missed between collaborators on the project. With Protocol Builder you can:

- Ensure everyone is working on the same version of the protocol
- See all the changes you need to review in one place

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

ProtocolBuilder®

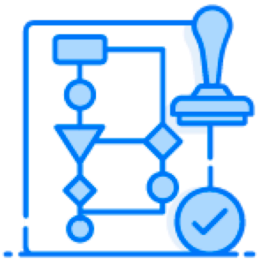
- Compare revisions in a before and after format
- Distribute same template or pre-written protocols to groups of collaborators or investigators
- Receive notifications when changes are made.

INCREASE TRANSPARENCY AND ACCOUNTABILITY

It can be time consuming to keep track of comments and changes, including who made them and when. Protocol Builder makes that easy with:

- Needs Review List: a worklist, organized by date and by section, showing what changes need to be reviewed and which ones have been completed/accepted
- Audit Trail: go when level deeper to see all changes made to any section of the protocol
- Protocol Dashboard: at-a-glance quickly assess protocol development progress.

CREATE A PROCESS THAT WORKS LIKE YOU WANT IT TO



Protocol Builder provides institutions with the tools to customize and manage the protocol development process:

- Customizable templates to fit your clinical needs.
- Cloud-based hub centralizes protocol development efforts
- Administrative reporting on users and protocols

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.

ProtocolBuilder®

KEY FEATURES

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

ProtocolBuilder®

PRE-LOADED STANDARD TEMPLATES

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)

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

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