



# 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





- ▶ 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.





## KEY FEATURES

<b>GUIDANCE</b>	<ul style="list-style-type: none"><li>▪ Step by step guided experience</li><li>▪ Templates by trial type (drug, device, observational, etc.)</li><li>▪ Institutional guidance for each topic</li><li>▪ Easy to navigate contents menu</li><li>▪ Collaborate with investigators, research coordinators and IRB administration</li></ul>
<b>WRITE</b>	<ul style="list-style-type: none"><li>▪ Automatic Informed Consent Form set up</li><li>▪ Easy-to-navigate contents menu</li><li>▪ Form completeness indicators</li><li>▪ Form cloning</li><li>▪ Advanced editing tools</li><li>▪ Compare revisions/tracked changes</li><li>▪ Informed Consent Form preview</li><li>▪ Document Archive</li></ul>
<b>COLLABORATE</b>	<ul style="list-style-type: none"><li>▪ Compare revisions/tracked changes</li><li>▪ Needs review alerts and review list</li><li>▪ Email notification of changes</li><li>▪ Informed Consent Form sharing</li><li>▪ Invite collaborators (inside/outside institution)</li><li>▪ Research administration access, including default IRB users on all ICF's (optional)</li></ul>
<b>REVIEW</b>	<ul style="list-style-type: none"><li>▪ Professionally-styled PDF or Word Output</li><li>▪ Automatic Summary of Changes</li><li>▪ Sponsor/Research administration specific access</li></ul>
<b>MANAGE</b>	<ul style="list-style-type: none"><li>▪ Add approval date stamps to approved IC form</li><li>▪ Template set up flexibility</li><li>▪ User management and reporting</li><li>▪ Institution's logo on form</li></ul>