



INFORMED CONSENT BUILDER

MANAGING CONSENT FORMS AND
TEMPLATES MADE EASIER



Informed Consent Builder is a cloud-based software solution changing the way consent forms are built and managed. Designed to ensure more accurate forms and eliminate process inefficiencies and time-consuming tasks.

MANAGE CONSENT FORMS MORE EFFECTIVELY

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

- ▶ Informed Consent Forms, Assent Forms and Parental Consent forms – customized for your institution's template
- ▶ Standard consent form templates available
- ▶ Determine templates will be presented to investigators for editing
- ▶ Locked sections with required content so that users cannot change



DEPLOY CONSENT FORM TEMPLATES AND CHANGES FASTER

New templates and form changes can be deployed immediately for use on the platform once they are approved internally.





LOCKED SECTIONS AND COMPLETENESS CHECKS IMPROVE COMPLETENESS AND ACCURACY

Accuracy of language and being comprehensive is paramount in consent forms: it must follow regulatory guidelines and meet institutional requirements. With Informed Consent Builder:

- ▶ It's easy to ensure that the same language is deployed across all templates
- ▶ Sections can be locked so that investigators cannot edit them by mistake (a big issue with Word documents)
- ▶ The forms dashboard and completeness checks will ensure that investigators complete all required sections of the form/s.

REDUCED ADMINISTRATIVE BURDEN FOR INVESTIGATORS AND IRB

Getting it right the first time significantly reduces the amount of time spent by the investigator and IRB staff reviewers correcting and commenting on the form. Informed Consent Builder ensures that:

- ▶ More certainty that the right consent form template has been chosen by investigators
- ▶ Form completeness will increase, so that the IRB can focus on the material sections of the consent form
- ▶ Everyone is working on the same version – no more email misses or version control issues
- ▶ The number of review rounds can be minimized



AUTOMATIC FORMATTING

Automatically formats input from all collaborators and all sources.

CENTRALIZED, ENTERPRISE-STRENGTH APPLICATION

Informed Consent Builder is the only consent form-writing application designed to support large quantities of individuals involved in research and compliance at any organization. It is a single portal for investigators, research coordinators, and IRB administrators to collaborate on Consent Forms.



BACKED BY AN INDUSTRY LEADER



Informed Consent Builder is powered by the BRANY, a leader in providing hospitals, academic medical centers, CROs, and Pharma/Biotech companies with IRB review, IBC administration, research ethics consulting and training, and end-to-end clinical trial support services.



KEY FEATURES

GUIDE	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ Automatic Informed Consent Form set up▪ Easy-to-navigate content menu▪ Form completeness indicators▪ Form cloning▪ Advanced editing tools▪ Compare revisions/tracked changes▪ Informed Consent Form preview▪ Document Archive
COLLABORATE	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ Professionally-styled PDF or Word Output▪ Automatic Summary of Changes▪ Sponsor/Research administration specific access



Informed Consent Builder

MANAGE

- Add approval date stamps to approved IC form
- Template set up flexibility
- User management and reporting
- Institution's logo on form