

# consent solutions

www.consentsolutions.com

*When clinical trial informed consent is clouded by patient anxiety, incomplete communication and institutional time pressure, unnecessary risks are created for both subjects and investigators. But a consent process that is well designed and implemented can lead to increased subject compliance, decreased time to full enrollment and a reduced threat of legal liability.*

*Secure Consent™ allows researchers to create online clinical-trial consent documents and present them to subjects in user-friendly multimedia formats that are accessible any time, from anywhere. The result—a solid first step toward building an open, trusting relationship between investigators and trial subjects.*



## THE PROBLEM

The informed consent process too often involves little more than obtaining a signature on a legal form. When the consent process is rushed and information is delivered in the unfamiliar and intimidating setting of a clinic, subjects are often afraid to ask questions and don't have time to fully weigh benefits and risks. Lack of standardization and miscommunication during the consent process can easily jeopardize the entire investigator-subject relationship.

## OUR SOLUTION

We turn the informed consent process into an interactive, educational activity that increases efficiency, encourages an atmosphere of cooperation and reduces the risk of legal action. With Secure Consent, informed consent isn't only a way to help subjects understand the consequences of participating in a study, it's also a first opportunity to create an environment of trust and cooperation between subjects and investigators.

## Create

Working collaboratively from multiple sites, institutions, investigators and IRB members can create, modify and comment on proposed consent content based on your standard organizational templates.

## Inform

Subjects log in securely from anywhere to view a multimedia presentation of all of the consent information for the trial. Subjects can choose from multiple languages, and can elect to have information presented in audio or on-screen text. Unfamiliar terms are explained in animated audio-visual presentations. Self-assessment questions assure that the patient understands key elements of the study. Values-clarification options can ensure understanding of meaning of trial.

## Track

Each action a patient or potential subject takes while working through the consent process is recorded. Researchers can review subject activity to ensure full participation and subjects' online actions are saved in the event of a subsequent consent-related dispute.

## The Result

Secure Consent lets institutions deliver consistent, high-quality consent information with better efficiency, resulting in a lower per-patient cost and higher retention rates. Subjects participate with realistic expectations, reduced anxiety and in an atmosphere of trust.

## DESIGN CONSENT DOCUMENTS COLLABORATIVELY

We include pre-built, customizable templates that comply with FDA and HHS regulations. If the IRB has already created forms for your study, we can incorporate the information they contain.

Once the stakeholders reach agreement on the sequence and content of the consent materials, our library of multimedia materials is used to supplement the consent language. Where appropriate, the content is also converted to audio formats and to other languages for non-English speakers.

When the content is complete, a link is sent to the IRB for final approval. The entire presentation is then placed on a web-accessible server.

## EDUCATE PATIENTS AND PROSPECTIVE SUBJECTS

Patients are given a user name and password that they use to log into a secure server. The consent presentation can be viewed from anywhere, including home. For those without Internet access, PCs can be installed at trial sites.

Secure Consent presentations are divided into sections following the NIH simplified consent guidelines. For each section, subjects can

choose to receive the information in text or with audio, and can work through the material at their own pace. When a subject reaches the end of the section, he or she cannot go on to the next section without clicking a button acknowledging that they have reviewed the material in that section. Patient questions are logged for later discussion with trial staff. Any of the web pages can also be printed.

Unusual or technical terms used during the consent presentation are linked to multimedia presentations that provide full explanations. All terms can also be looked up in a custom glossary.

Subjects have the option to go to a "Learn More" section at any time during the consent process. Learn More allows users to test their knowledge of the consent information, log questions for investigators, look up unfamiliar words, or work through a pro/con exercise that clarifies the patient's understanding of the benefits and risks of the trial.

At the completion of the presentation, the program automatically generates a printable consent form for signature and placement in the trial records. At that point, research-team members can initiate a consent-related discussion with the subject. At any time after consent is obtained, subjects can return to the secure website to review the consent information.

### IRB

- Track initial use by prospective subjects
- Track amended use by enrolled subjects
- Manage liability—with subject use tracking
- Assure uniform presentation of trial information
- Assure understanding of key points and terms

### CROs

- Accelerate qualified subject enrollment
- Increase compliance—decrease trial dropouts
- Monitor enrollment in multiple sites
- Easily manage site specific changes to consent
- Provide added value for trial sponsors

### CLINICAL INVESTIGATORS

- Decrease staff time spent in education
- Assure uniform presentation of trial information
- Monitor enrollment in multiple sites
- Present information in multiple languages
- Present narrated consent for low reading levels.



Consent Solutions was founded by HealthMark Multimedia LLC and Enforme Interactive, Inc. to enhance the quality of clinical trial informed consent. The organization's flagship product was designed to provide high-quality informed consent information by combining customizable clinical trial consent data with an interactive, online learning platform that lets subjects choose the method of information presentation that works best for them.

Since 1998, HealthMark Multimedia has been a leading developer of interactive, user-friendly software and Web sites for patients to make treatment and self-care decisions and for encouraging shared decision making. HealthMark Multimedia also develops customized multimedia projects for companies and other organizations needing specialized health communications. Many of Healthmark's projects are funded by the National Cancer Institute, Centers for Disease Control, the American Psychological Association, and other public organizations.

Enforme Interactive, an award-winning developer of interactive media, is best known for making dynamic scientific and medical content accessible through websites and CD ROM applications. The principals of Enforme Interactive have more than two decades experience in technical project management, interactive design and programming, and writing for a variety of media, including video, interactive videodisc, computer-based training, CD-I, CD-ROM, and Web applications. The company's clients include numerous national and international medical and scientific associations, major scientific publishing companies, government agencies and bio-technology companies.

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