

# White Paper

## e-Consent with Knowledge Checks in Clinical Trials



Anzubridge®  
Clinical

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# e-Consent with Knowledge Checks in a Clinical Trial

## Introduction

Electronic informed consents (EICs) are a tool used in clinical trials that allow participants to electronically read and sign consent forms. Rather than using paper forms, EICs allow participants to access information about the trial and sign a consent form using a computer or tablet. This can be done remotely, and in some cases, study staff can even witness the consent online. Studies have found that EICs can improve participant understanding of the trial, as well as increase their satisfaction with the process.

In addition to increasing participant comprehension, knowledge checks can also help improve the safety of clinical trials. By using an EIC that includes knowledge checks, researchers can identify and prevent potential risks associated with participants not understanding the consent form.

Overall, EICs with knowledge checks provide a more efficient and comprehensive method for participants to consent to a clinical trial. They can improve participant understanding, satisfaction, and safety, making them a valuable tool in the clinical trial process.



## Definition of an Electronic Informed Consent with Knowledge Checks in a Clinical Trial

An electronic informed consent (EIC) is a form of consent that seeks to better inform and protect research participants in clinical trials. It is a digital version of a paper-based consent form and is designed to ensure that the participant is sufficiently informed about the risks, benefits, and procedures of the clinical trial prior to providing consent. The EIC also includes knowledge checks, which are questions posed to the participant to ensure they have read and understood the information they have been presented with.

### What is 21 CFR Part 11?

21 CFR Part 11 is a set of regulations issued by the United States Food and Drug Administration (FDA) that establishes the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable, and equivalent to paper records. The regulation is intended to ensure that electronic records and signatures are secure and auditable, and that the data is reliable and accurate. It sets out the requirements for the creation, maintenance, and use of electronic records, as well as the requirements for the implementation of electronic signatures. Additionally, Part 11 requires that organizations that use electronic records and signatures to comply with certain criteria, such as implementing appropriate system validation, providing access control for users, and ensuring that all records are securely stored and maintained.

### FDA Guidance on e-Consent with Knowledge Checks

The FDA (Food and Drug Administration) has stated that electronic informed consent (eConsent) with knowledge checks is an acceptable method of obtaining informed consent for clinical trials. In their guidance document, “Use of Electronic Informed Consent Questions and Answers,” the FDA states that “optional questions and other methods may be used as tools to gauge subject comprehension of key study elements and highlight areas where the subject might need further explanation and discussion before signing the informed consent to enter the study.”

The FDA also provides some recommendations for how to implement eConsent with knowledge checks. These recommendations include:

- Using a variety of approaches to ensure that subjects understand the information presented.
- Ensuring that appropriate documentation of consent is obtained.
- Ensuring the quality and integrity of eConsent data.
- Convey additional information, including significant new findings, to the subject during the course of the research.

## Guidelines for eConsent with Knowledge Checks by the Association for the Assessment of Learning in Higher Education (AASHE)

**Purpose:** The purpose of eConsent with knowledge checks is to ensure that research participants understand the risks and benefits of participating in a research study before they give their consent.

**Approach:** eConsent with knowledge checks should use a variety of approaches to ensure that participants understand the information presented. This may include using plain language, providing visual aids, and asking participants to answer questions about the information.

**Documentation:** Appropriate documentation of consent should be obtained. This may include a signed consent form or a record of the participant's answers to the knowledge checks.

**Data:** The quality and integrity of eConsent data should be ensured. This may include using a secure system to store the data and using procedures to prevent unauthorized access to the data.

**Communication:** Additional information, including significant new findings, should be conveyed to participants during the course of the research.

The AASHE guidelines provide a helpful overview of the principles for implementing eConsent with knowledge checks. However, it is important to note that the AASHE guidelines are not legally binding. Researchers should consult with their Institutional Review Board (IRB) to ensure that their eConsent process complies with all applicable regulations.

### Additional tips for Implementing eConsent with Knowledge Checks:

- Make sure that the information presented in the eConsent is clear and easy to understand.
- Use plain language and avoid jargon.
- Provide visual aids, such as diagrams or illustrations, to help participants understand the information.
- Ask participants to answer questions about the information to assess their understanding.
- Provide participants with an opportunity to ask questions if they do not understand something.
- Make sure that the eConsent process is secure and that participants' data is protected.
- Communicate with participants throughout the research study to keep them informed of any new information or changes to the study

## Use of Knowledge Checks in Clinical Trials



Knowledge checks are increasingly being used in clinical trials to assess the understanding of trial information by participants. This is particularly important in trials that involve complex medical concepts and is seen as a key strategy for improving participant safety. Knowledge checks involve asking study participants questions about the information they have been given about the trial, such as the risks and benefits, or the protocols they must follow. This helps to ensure that participants are aware of the trial information and can make an informed decision about whether to participate.

In addition to improving participant safety, knowledge checks can help sponsors to measure the effectiveness of the informed consent process. This allows sponsors to identify any gaps in understanding or areas of confusion that need to be addressed. Knowledge checks can also be used to measure the effectiveness of training materials and educational strategies.

## Benefits of Electronic Informed Consents

### Increased Efficiency

Electronic informed consents (e-Consents) are increasingly being used in clinical trials for their ability to improve the efficiency and accuracy of the consent process. e-Consents provide a secure and reliable way of collecting and storing data and can also be used to track changes to the consent form, allowing for more accurate and up-to-date records. Additionally, they can allow for better communication between researchers and participants, allowing for more thorough understanding of the study, its risks and benefits, and the participant's rights.

The use of eConsents in clinical trials has been shown to reduce the time to enroll subjects, improve the accuracy of the consent process, and reduce the burden on clinical research staff. eConsents can also help to reduce the risk of mistakes or misunderstandings caused by manual entry of data, as well as reduce the need for paper forms, saving both time and resources.

Overall, the use of eConsents in clinical trials can provide numerous benefits, from improved efficiency and accuracy to easier communication between participants and researchers. As such, it is increasingly being used as a standard practice in clinical trials.

## Benefits of Electronic Informed Consents (continued)

### Strengthen Regulatory Compliance

Electronic informed consents with knowledge checks can help strengthen regulatory compliance by providing a secure and reliable platform for collecting and tracking consent forms. Knowledge checks can ensure that the participant understands the terms and conditions of the informed consent and is aware of any potential risks and benefits associated with the study. Footnotes should be included to provide additional information about the study, such as the purpose, duration, and any potential risks or benefits associated with participation. Additionally, electronic informed consents can be used to track participant data over time to ensure that all consents are up to date and in compliance with regulations.

## Challenges of Implementing Electronic Informed Consents with Knowledge Checks

### Cost of Implementation

The primary challenge of implementing electronic informed consents with knowledge checks is cost. Electronic informed consent systems require significant upfront investments in software and hardware, as well as ongoing maintenance costs. Additionally, these systems may require specialized training for staff. Furthermore, depending on the type of knowledge checks used, third party software products may be required. Platforms that offer this capability as an integrated feature, may be the ideal solution for many organizations considering this option.

### Technical Challenges in Implementation

- **Technical complexity:** Implementing electronic informed consents with knowledge checks requires a certain level of technical competence and may be difficult for organizations with limited resources or technical expertise.
- **Security and data protection:** To ensure that the data collected from electronic informed consents is secure, system security measures must be in place. This can be a challenge for organizations that lack the resources or knowledge to implement such measures. Once again, this issue favors a solution integrated with the EDC system.
- **User experience:** Electronic informed consents must be user friendly and easy to understand to ensure that users are informed about the consent process. This may be difficult to achieve if the knowledge checks are overly complex or difficult to understand.
- **Legal implications:** Electronic informed consents must meet the same legal standards as traditional paper-based consents, which can be a challenge. Organizations must ensure that they are compliant with all applicable laws and regulations.

## The Anzubridge® CDMS Solution



The Anzubridge® Clinical Data Management System (CDMS) has a fully integrated Electronic Informed Consent and Knowledge Checks Feature. This 21 CFR Part 11 compliant system has a full-featured e-Consent and Knowledge Checks builder. The system allows the Sponsor, CRO or the Anzubridge® technical team to perform the following functions:

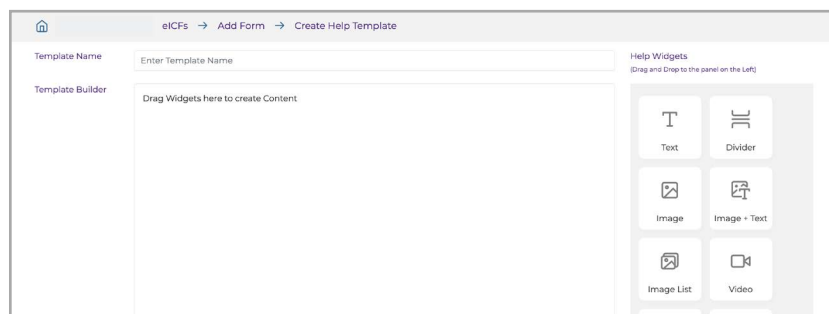
1. Upload, configure and activate multiple types of Informed Consent documents required in a study
  - Configure the signatory workflow and identify the location of the role-based signatures on each document.
  - Create different versions of the document.
    - » Based on the site
    - » Based on version updates of any document
2. Configure the Knowledge Checks for any Informed Consent document in the study. Knowledge checks can be attached in any part of the document and include:
  - Introductory video
  - Videos in the document
  - Text
  - Images
  - Images with text
  - Question and Answers
  - Post document review questions

Using this integrated system, the onboarding process for subjects in a study can be automated. Triggers can be designed in the EDC workflow to automatically change the status of the subject based on the signing of the electronic informed consent.

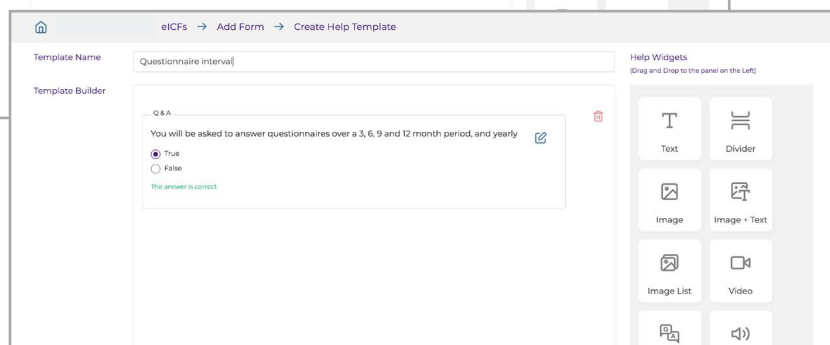
The site can view and manage the signing status of subjects in the study. The system will identify subjects (or their legal guardians) who have not logged into the e-Consent website or signed the e-Consent. Notifications will be set up on a configurable schedule, or the site can manually resent an invitation to complete the signature process.



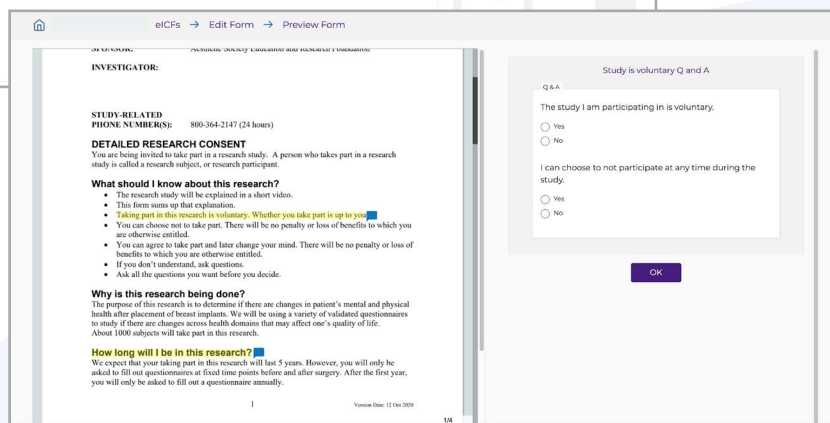
## Creating a Knowledge Check in an Informed Consent Document



This is the Knowledge Check Builder screen for the Anzubridge® Electronic Informed Consent Module. Access to this builder is role-based. The user can create different templates and drag and drop different widgets into the screen to create the desired learning experience for the subject.



In this example, the user has created a question with a list of potential answers. The user has also identified the correct answer. The questionnaire template will then be linked to a specific sentence in the informed consent document with blue flag icon.



This is the Document Viewer Screen. On the left, is the informed Consent. The areas of the document associated with knowledge checks are highlighted in yellow with a blue flag icon. By clicking on the icon, the associated knowledge check will open on the right portion of the screen.

## Value Propositions of the Anzubridge® Electronic Informed Consent and Knowledge Checks Feature

- e-Consents created with this platform can be used to provide participants with the study protocol in a more understandable way. The knowledge checks can help ensure that participants understand the details and risks of the study.
- The Knowledge Check Builder has a user-friendly interface, which most users will be able to master in a short period of time.
- These e-consents can help speed up the process of obtaining informed consent from participants by eliminating the need for paper forms and in-person meetings. This can save time and money while providing an easier, more convenient way for participants to understand and agree to the study.
- These e-Consents can also be used to track the consent process. This can help ensure that all participants understand the risks and benefits of the study before they agree to participate.
- These e-consents can also be used to improve data accuracy. Knowledge checks can help ensure that participants answer questions accurately and completely, reducing the risk of errors in the data.

# About the Anzubridge® Clinical Data Management System (CDMS)

Innovative Features | Creative Deployments | Patented Technology

The Anzubridge® CDMS is the culmination of years of multiple product design and development by a team of innovators and engineers.

This system is HIPAA and 21 CFR compliant and has many features:

1. Electronic Data Capture
2. Electronic Informed Consent With Knowledge Checks
3. ePRO (Electronic Patient Reported Outcomes)
4. Media Capture
5. Media Review
6. Laboratory Information Management System (LIMS) Connectivity
7. Learning Management System (LMS)
8. Integration and Data Exchange With Validated External Data Sources
  - Device Registration Platforms (The Aesthetic One Breast Implant Platform)
  - Point of Care Device Analysis Modules (in development)

Multiple patents awarded to the company, are incorporated into the Media, LIMS, LMS, and Point of Care Device Analysis Modules.

The seasoned team of engineers have years of multi-stack development of complex platforms.

Our goal is to provide unique and innovative solutions that streamline onboarding, data access, training and education to all stakeholders.

## Contact Information

[sales@anzubridge.com](mailto:sales@anzubridge.com)