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eConsent

eBook

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Introduction

The COVID-19 pandemic made it clear that we need new ways of conducting clinical trials, which place less burden on participants. Even prior to COVID-19, obtaining informed consent in clinical trials required a complex, in-person process that often took hours. The administrative work and expense of maintaining paper records could be a serious drain on limited study resources.

As research centers closed down and travel restrictions were imposed, it became clear that the field would benefit greatly from a more efficient, remote process allowing researchers to focus on their most important work. eConsent is a digital, remote-enabled method of obtaining informed consent, which, when implemented correctly, improves participant experience.

In this eBook, we'll summarize the evolution and benefits of eConsent, as well as how it meets the regulatory requirements of informed consent. Additionally, we will walk through the key considerations when pursuing eConsent approval from an IRB. We'll also explore how Castor's all-in-one eConsent solution enables an effortless experience that saves researchers hours of time and improves participant retention.

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Background + history

Since it was first instituted in the 1960s, written consent to participate in research studies has undergone very little change other than tightening of regulations and increased participant education of their rights. At that time, it was decided that for research to be considered ethical, participation must be done in a voluntary and informed manner.

In order for consent to be ethically valid, a few critical elements are required. Participants must:

- **Know exactly what and how much they are agreeing to.**
- **Express their intent to participate.**
- **Decide freely and voluntarily to participate.**
- **Understand that they can withdraw consent at any time.**

Informed consent is critical for ethical research, but the process has been paper-based for all studies until recently, and often highly complex. Unfortunately, the complexity of the process and limitations of paper-based consent have meant that not all studies have provided adequate education to participants, leading to lower enrollment and reduced retention.

In brief, eConsent is the digital version of informed consent—and since it is one of the first interactions participants have with a study, it sets the tone and expectations for what participants will experience. It meets all the criteria of informed consent, simply removing the paper from the site and using a tablet or computer to capture consent instead.

eConsent represents an opportunity for broader and more diverse recruitment where consent can be obtained remotely in the comfort of a participant's home, local clinic, or anywhere else that's convenient.

Benefits of eConsent

Benefits of eConsent

In addition to meeting the regulatory requirements of informed consent in a more efficient manner, eConsent offers a number of benefits to researchers and participants.

1 Supports quality data collection

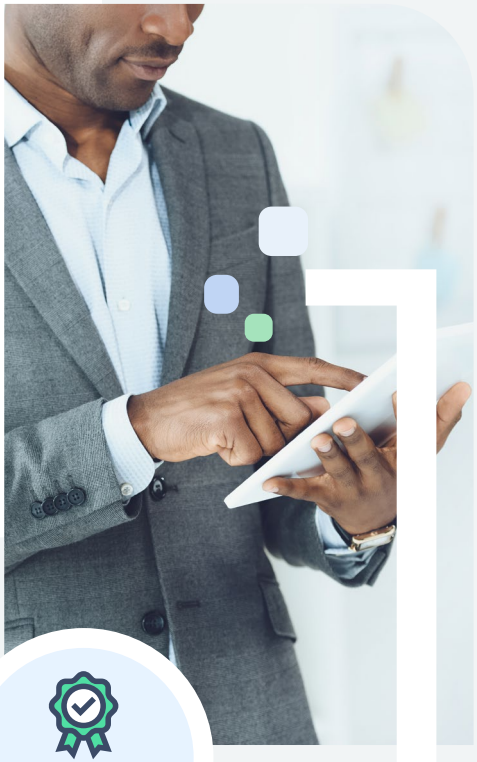
2 Improves productivity

3 Allows automated reporting of data

4 Increases valid consent

5 Improves participant access

6 Increases patient engagement & retention



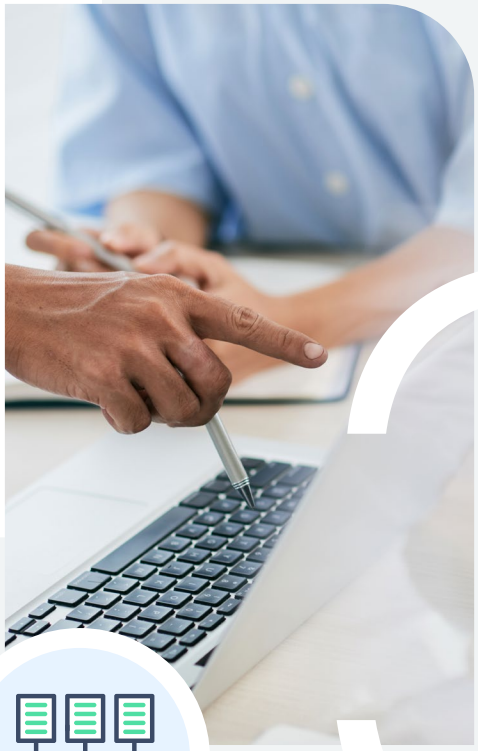
1. Supports quality data collection

eConsent supports data quality by standardizing the consent process, automating versioning, and reducing ICF entry errors. Depending on the platform, eConsent can also use embedded HIPAA-compliant authorization forms, thereby ensuring FDA compliance and necessary documentation at every step. In the EU, the GDPR's most recent guidance on eConsent requires "an effective audit trail of how and when consent was given, so you can provide evidence if challenged" and "an appropriate cryptographic hash function to support data integrity." Fortunately, some eConsent solutions offer access control, encryption, and traceability.

Quickly identifying and correcting errors is also on the list of eConsent benefits. It can trigger timely re-consent notifications linked to protocol amendments or safety updates, ensuring that a study is not stalled or stopped. It also reduces transcription errors since data fields (e.g., date of consent) can be copied automatically into the electronic data capture (EDC) system.

2. Improves productivity

Another benefit of eConsent is increased productivity in decentralized or hybrid trials—which is great for both a sponsor's budget and timeline. Site coordinators spend a significant amount of time hosting onsite source monitoring with clinical research associates (CRAs) from multiple trial sponsors. Managing paper informed consent forms (ICFs) is burdensome and error-prone for these inspections, not to mention the required storage, tracking, and maintenance of records. But with eConsent, CRAs can check data remotely without visiting the site, allowing them to concentrate on other site duties (e.g., safety monitoring). Or, a central team can review data in the core system and case report forms (CRFs) for all sites, further increasing team efficiency.



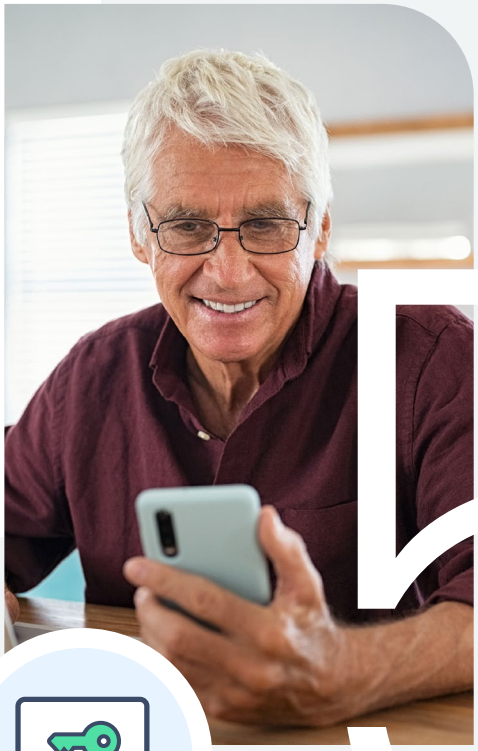
3. Allows automated reporting of data

Sponsors need to know where sites and participants are in the enrollment process to identify delays and potential risks. The automated data reporting built into some eConsent programs addresses this issue effectively. For example, it can run automated edit checks on completeness of ICFs and trigger alert messages to sponsors in case of eConsent errors. It can also leverage interdependency with core systems such as interactive voice response system (IVRS), CRFs, or the clinical trial management system (CTMS). All of these features can catch flaws in the intake, enrollment, and continued consent process before they threaten data in the study.

4. Increases valid consent

Every participant in a study represents an investment of time and money—and possibly the key to meeting required participation levels. Invalid consents, however, require hard-earned data to be tossed out. Flaws in the intake and enrollment process can create errors in the order in which consent is documented. At times, sites move along in the trial process without getting the ICF first—thus invalidating data in the study. eConsent, however, requires initials, signatures, and checkboxes coupled with automatic date and time stamps on documents, so trial materials are always audit-ready. eConsent also ensures that participants are always given the most recent IRB-approved version of consent forms, auto-triggering notifications when a re-consent is necessary.

Another way an eConsent program supports valid consent is by communicating clinical trial information in easy-to-understand formats. Through the use of interactive multimedia components such as videos, images, and audio, eConsent can make it much easier for participants to fully understand the information being presented to them. With better comprehension, participants are empowered to make decisions that they feel confident about.

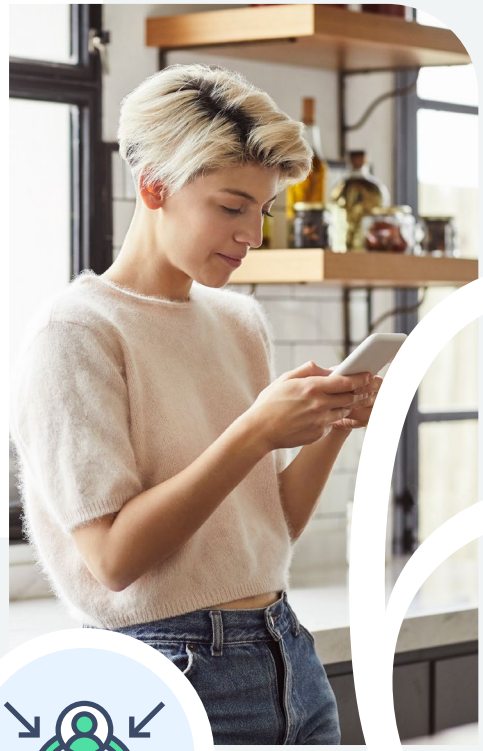


5. Improves participant access

A well-documented problem plaguing research trials is a lack of diversity and inclusivity. In the past, participants were often pulled from populations living near study sites, compounding the problem of underrepresentation. With increased awareness, more trials are actively seeking out diversity of race, gender, and geography amongst participants so that the studied population is representative of the distribution of the disease.

Individuals who have high-risk health conditions or who live in rural areas are much more likely to be able to participate when eConsent is used because it eliminates travel. eConsent can easily be adapted to meet the needs of a wide variety of participants by addressing language or literacy barriers, hearing or vision impairment, and other special needs. For example, the use of audio recordings, adjustable font sizes, and multiple language formats can easily serve the needs of a wider audience.

eConsent also makes it easier to accommodate participant needs. For example, sites can observe which form sections a participant is spending more time on. If participants have questions, these can be quickly resolved through video chats with the site team. This allows site staff to streamline services and allocate resources according to real needs instead of projected ones.



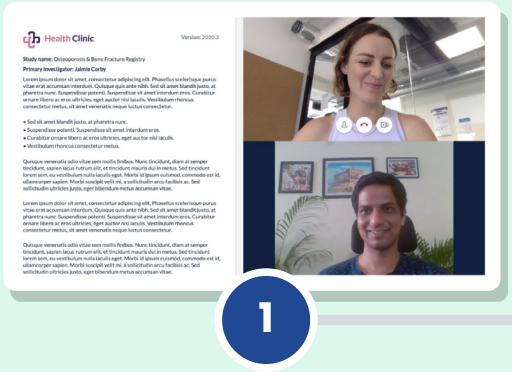
6. Increases patient engagement & retention

eConsent can ease many common anxieties that participants often experience during the consent process. By enabling a more interactive experience, eConsent allows participants to go through information at their own pace. When signing a document in person, participants may feel pressured and anxious as they review and sign the document. eConsent offers a refreshing alternative, where participants can take their time with each section of the document, even pausing to reflect or ask for input from family and friends. Any questions that come up can also quickly be answered by a researcher through the video chat feature. Because participants feel actively involved in the study process, they are more likely to feel invested and engaged with the study—leading to higher participant retention.

Case study: eSource & DCT with COVID-RED

17,824 participants enrolled in 15 weeks:
COVID-RED in 3 steps

World's first study to use machine learning in diagnosis of COVID-19, supported by TAKEDA and Julius Clinical

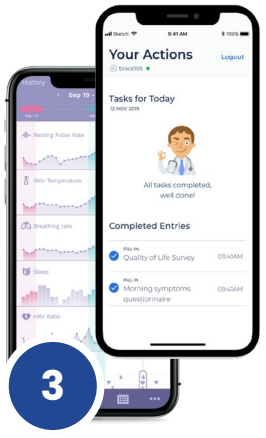


Enrollment via patient portal with integrated video eConsent

Each module in the platform is powerful alone, but the real magic happens when you use them together.

Here, eRecruitment and eConsent are integrated into a Castor DCT.

Ava device shipped and activated



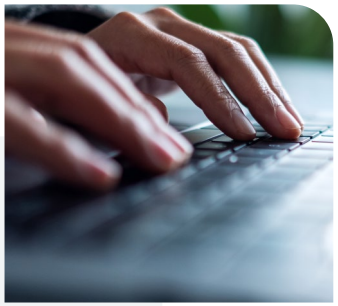
Receive real-time device data and ePRO

eConsent regulatory requirements

How does eConsent fulfill the regulatory requirements of informed consent?

There are strict guidelines and regulations governing how informed consent in clinical research is obtained, which all researchers are bound to follow. Prior to the start of any clinical research, an institutional review board (IRB) or independent ethics committee (IEC) confirms that adequate consent will be obtained in a way that does not jeopardize the rights, safety, or well-being of research participants. However consent is recorded—whether on paper or electronically—IRB approval hinges on how the criteria of valid informed consent are met, including:

- **Disclosure of information**
- **Competence**
- **Voluntariness**



Disclosure of information

Participants have a right to autonomy—the right to make decisions about their own health and medical conditions. To do so, participants must be provided with all the information that a reasonable person in their place would want about possible treatment.

Such information could include what the investigation involves, the possible benefits and risks, and the likelihood of complications. Even rare risks must be disclosed—especially if the harm could be severe. Researchers should encourage participants to ask questions and allow plenty of time for participants to read the informed consent document and provide a copy for them to review. Once all of the required information has been disclosed, participants must also be given an appropriate amount of time to ask questions and discuss their decision with family and friends.

To meet informed consent criteria, a researcher is also obligated to tell a participant about any conflicts of interest. For example, if the researcher is also the patient's physician, then he or she would need to reveal any ties to the pharmaceutical company sponsoring the trial, or if he or she has a financial interest in the trial's outcome.

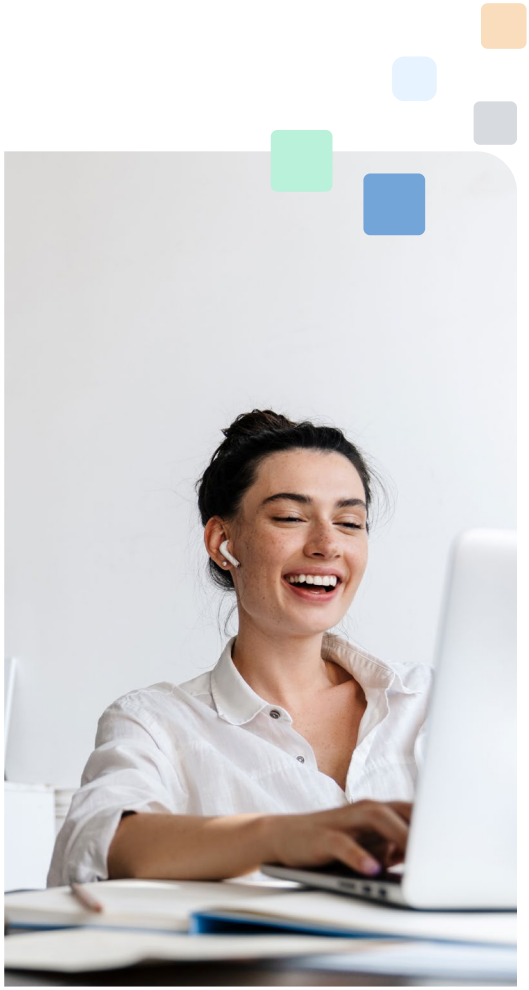
This is an area where remote eConsent shines, allowing all of the information mentioned above to be provided to the participant clearly and efficiently. From the comfort of their own homes, participants are able to access information and review it at their own pace and even involve family members. Multimedia components such as video, audio, and images can break down complex information. Best of all, participants can come back to the information again and again until they feel comfortable in their choice.

Competence

Once adequate information has been provided, researchers have an obligation to ensure that the information is understood by participants. In order to meet informed consent criteria, they must be able to understand the information presented and appreciate the potential consequences of participation. This principle refers to a participant's decision-making capacity. The participant must have the ability to make and be held accountable for their own decisions. It is important for site staff to ask potential participants questions to ensure they have grasped the information provided. In remote eConsent, videoconferencing with site staff can be used for this purpose.

Voluntariness

Consent for clinical research must be obtained without manipulation, undue influence, or coercion. Due to the vulnerability of participants, sensitivity is required to ensure there is no undue influence and the decision to participate is truly voluntary. For example, if the researcher also works as a physician, then his or her patients must understand that they are free to consent to or refuse participation in the study without repercussions to their patient/provider relationship. Voluntariness extends throughout the entire duration of the trial—participants can withdraw consent at any time.



Regulations pertaining to the use of eConsent vary amongst countries. At the time of writing, no EU regulation or guidance about eConsent in clinical trials exists.

In general, the Institutional Review Board (IRB) or ethics committee requirements for paper and electronic consent are the same, although countries and regions differ in exact policy, so an understanding of local IRB guidelines is essential. When making a submission for an eConsent-based study, it's important to address the following questions:

- **Who will conduct this discussion?**
- **How will participants be identified?**
- **How will participants be approached for consent?**
- **When will participants be asked to provide consent?**
- **What video conferencing platform will be used for remote consent discussion? (e.g., phone, Skype, Castor eConsent)**

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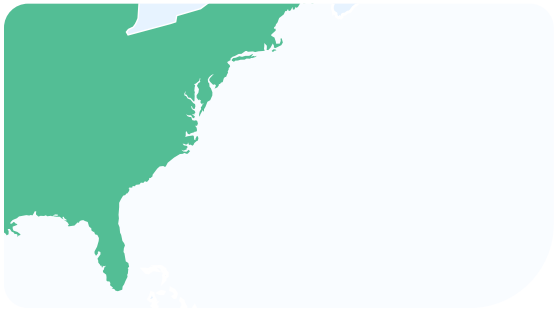
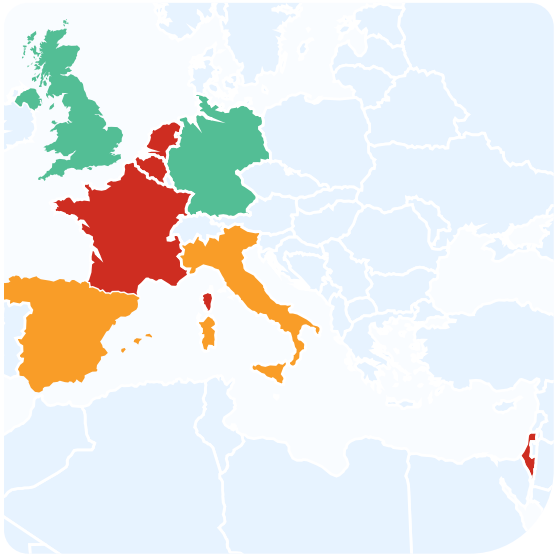
eConsent by country

Using eConsent also has many advantages over the traditional paper method—it's faster, more secure, and provides more flexibility when enrolling research participants. However, regulations regarding the use of eConsent vary widely across countries. In particular, the signature itself raises the most uncertainties. While informing the participant via digital tools is typically accepted worldwide, the use of an electronic signature in place of a physical or "wet" signature is not. Below is a summary of the current regulations in some of the top countries for clinical research.





	eConsent allowed	eSignature allowed
Australia	✓	✓
Belgium	✓	✗ **
Canada	− *	− *
France	✓	✗
Germany	✓	−
Israel	✓	✗

	eConsent allowed	eSignature allowed
Italy	✓	− *
Japan	✓	✓
The Netherlands	✓	✗
Spain	✓	− *
United Kingdom	✓	✓
Unites States	✓	✓

* e-signature studies running, but no legislation or guide available.

** Legislation officially requires signature to be in writing. There are exceptions.

eConsent approval by IRB

How to pursue eConsent approval by an Institutional Review Board (IRB) for your trial

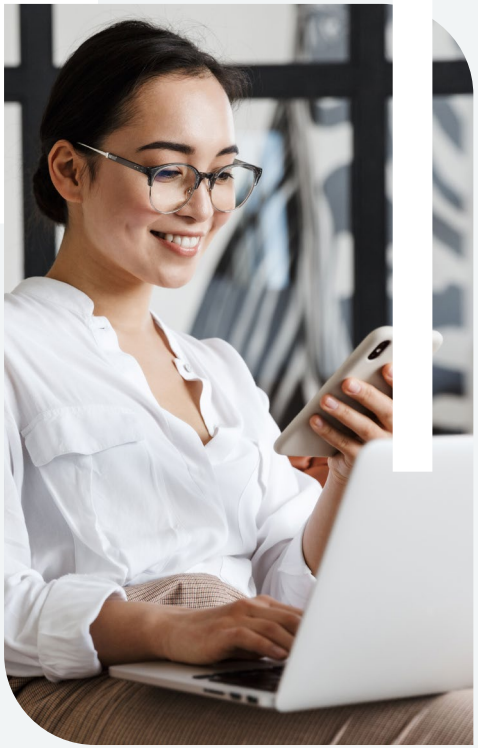
From an IRB point of view, reviewing an eConsent study is different from reviewing a paper-based consent study. When considering an eConsent study, the IRB considers both the informational content and the platform participants will use. Screenshots will not suffice, as reviewers need to engage with the content in the same context as a participant will—including any hyperlinked content or interactive sections.

During the review, the IRB will consider the overall length and presentation of information. They'll also want to see technical concepts broken down and medical jargon eliminated or explained whenever possible.

As we explored above, countries and regions differ in policy regarding eConsent, so researchers need to familiarize themselves with their applicable IRB guidelines. In general, however, the IRB and ethics committee have consistent requirements for paper and electronic consent, which include:

- **IRB-approved language and format**
- **All elements of informed consent as required by HHS or FDA**
- **Study staff involvement**
- **Signatures of participant and researcher**
- **A copy of consent provided to the participant**

A well-prepared eConsent submission will result in fewer requests for changes by the IRB—saving your trial both time and money. Must-have items in an IRB submission include information about the consent workflow, assessment of patient comprehension, the wording of documents, the eSignature process, and any special circumstances. Let's look at each of these more closely.



1. The consent process

The informed consent section of the IRB application form should include a description of whether the consent discussion will be face-to-face, remote, or a combination.

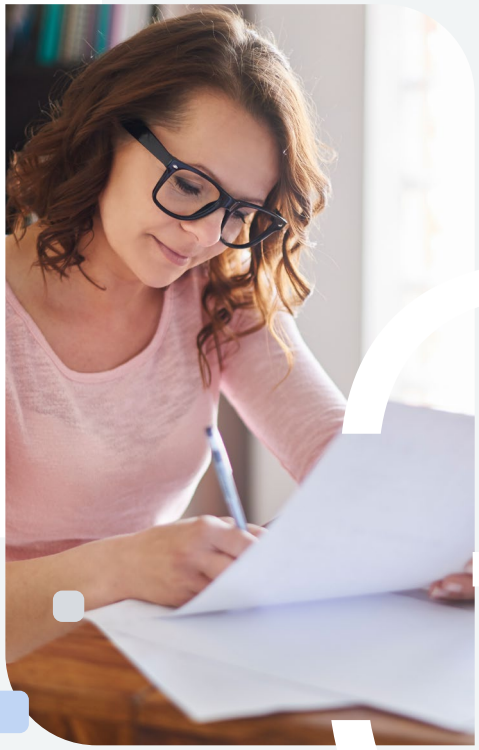
If the consent procedures will not happen face-to-face, then the IRB will consider whether the procedures will be as effective and meet the goals of the informed consent process. Therefore, when using eConsent, it's important to address the following questions:

- **Who will conduct this discussion?**
- **How will participants provide proof of identification?**
- **Who is introducing consent?**
- **How will participants be approached for consent?**
- **When will participants be asked to provide consent?**
- **What platform will be used for remote consent discussion? (e.g., phone, Castor eConsent videoconferencing, Skype, etc.)**

2. Patient comprehension assessment

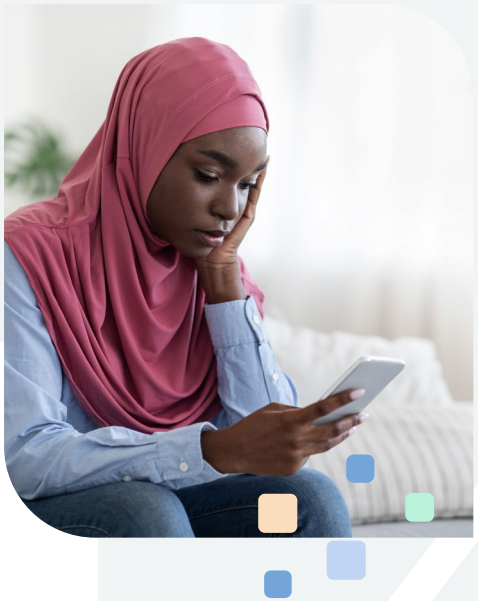
An IRB submission should also clearly explain how researchers will ensure patients meet the criteria of informed consent. Explanations should answer questions such as:

- **How will the study be explained to participants?**
- **How will their understanding be assessed?**
- **How will questions be answered?**



3. The wording of documents

Some studies plan to use a mix of paper consent and eConsent. In such a case, the wording in the eConsent document might be different than that of the paper consent form. (For example, it may reference the collection of email addresses or the use of video chats.) If this is the case, then the eConsent text should be provided to the IRB as a separate document. However, if the exact same wording will be used for both processes, then this should be clearly noted in the submission.



4. eSignature process

An electronic signature is an integral aspect of eConsent, but eSignature requirements vary by country—a factor impacting global eConsent adoption. While not every country accepts both eConsent and eSignature, the situation is evolving and it is anticipated that eSignature acceptance will soon become universal.

In the US, for example, a valid electronic signature for consent can be the subject's typed name or even simply a checkmark or an X—as long as the symbol is logically associated with the person making it. When reviewing the eSignature element of a study, an IRB will want answers to the following questions:

How will the electronic signature be created?

How can the signature be proven legitimate?

Also, in order to satisfy HIPAA regulatory requirements, an electronic signature is only valid if there is an option "for the signatory to receive a printed or emailed copy of the contract." An IRB application should therefore include a description of how participants will be provided with a copy of their signed consent document. For example:

Can participants download a PDF of the signed consent?

Will the site staff download the PDF, print it, and send a paper copy to each participant?

Will site staff send an emailed version to each participant?*

*In this scenario, the IRB application needs to 1) include the collection of email addresses as part of the data security plan and 2) show how participants will be informed of such in the privacy/ confidentiality section of the consent form.

5. Special circumstances

Finally, an IRB submission may need a section to address special circumstances related to eConsent. These would be customized to meet a trial's unique needs. For example, this section might contain answers to questions such as:

How will assent and parental permissions be obtained for minors? What if two parent signatures are needed?

How will the translation be addressed for non-English speaking participants? How will consent be witnessed in this scenario?

What if a participant doesn't have the right technology to use eConsent?

If the research is already approved but now needs to be modified to incorporate eConsent processes, then an amendment should be submitted for IRB review. It should include:

- **The rationale for making these changes.**
- **A statement of whether the eConsent is a temporary (e.g., to support social distancing) or permanent addition to the study.**

An IRB often asks for modifications to a proposed study and reviews it again once changes are made. An IRB review can be an extended and iterative process, requiring careful documentation along at each step.

5. Special circumstances (cont.)

IRBs are increasingly supportive of eConsent solutions—perhaps because they are all too familiar with paper-based consent issues such as outdated ICFs and lack of traceability. Even so, researchers may find themselves in need of guidance as they prepare for an eConsent IRB review.

A well-prepared IRB submission can greatly reduce modifications or the risk of rejection. If you are planning on using eConsent in a trial, clearly document in your submission how it will be used and cover potential questions that the IRB may have. This will give you the best chance of early success in obtaining approval and moving into patient recruitment.


eConsent with
Castor

Castor's eConsent solution

Accelerate patient recruitment and improve retention in decentralized, hybrid, and traditional trials with an all-in-one eConsent solution that is effortless for your patients.

- **Patient experience is priority #1**: Video calls, signatures, and screening questionnaires—all together—with no switching between applications.
- **Increase patient retention through deeper participant involvement:** Engage your patients with visuals, videos, and screen readers with a process that makes them feel comfortable, informed, and in control.
- **Happy sites with real-time insights:** Study coordinators can see and track their patients' screening and enrollment progress in real time—reaching out to assist if needed.

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Trusted by 300+ Companies

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3 ways to get started with Castor eConsent

eConsent essentials

Core eConsent

On-site or remotely consent patients with video calls and eSignature

- ✓ Built-in video calling and eSignature
- ✓ ICF and participant reporting with status overview
- ✓ Global regulatory compliance

Recruitment and enrollment

eConsent + recruitment and screening

Accelerate patient recruitment with integrated screening

- ✓ Customizable patient eRecruitment portal
- ✓ Integrated pre-screening questionnaire

One system, one trial

eConsent + recruitment and screening + data capture

Manage all clinical trial touchpoints with Castor

- ✓ One login, one experience for eConsent, ePRO & eCOA, EDC and device/wearables
- ✓ Designed to optimize the patient and site experience

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Experience the power of Castor today

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