Electronic Consent

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What is Informed Consent?

Considerations for Electronic Consent

Using DocuSign for Electronic Consent

UNC IRB Procedures for Electronic Consent Approval

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What is Informed Consent?

What is Informed Consent?

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...is for subjects to understand their role as a "subject of research".

...is to explain the purpose of research to the potential subject, including what their role would be and how the trial will work.

The Purpose of Informed Consent...

What is Informed Consent?

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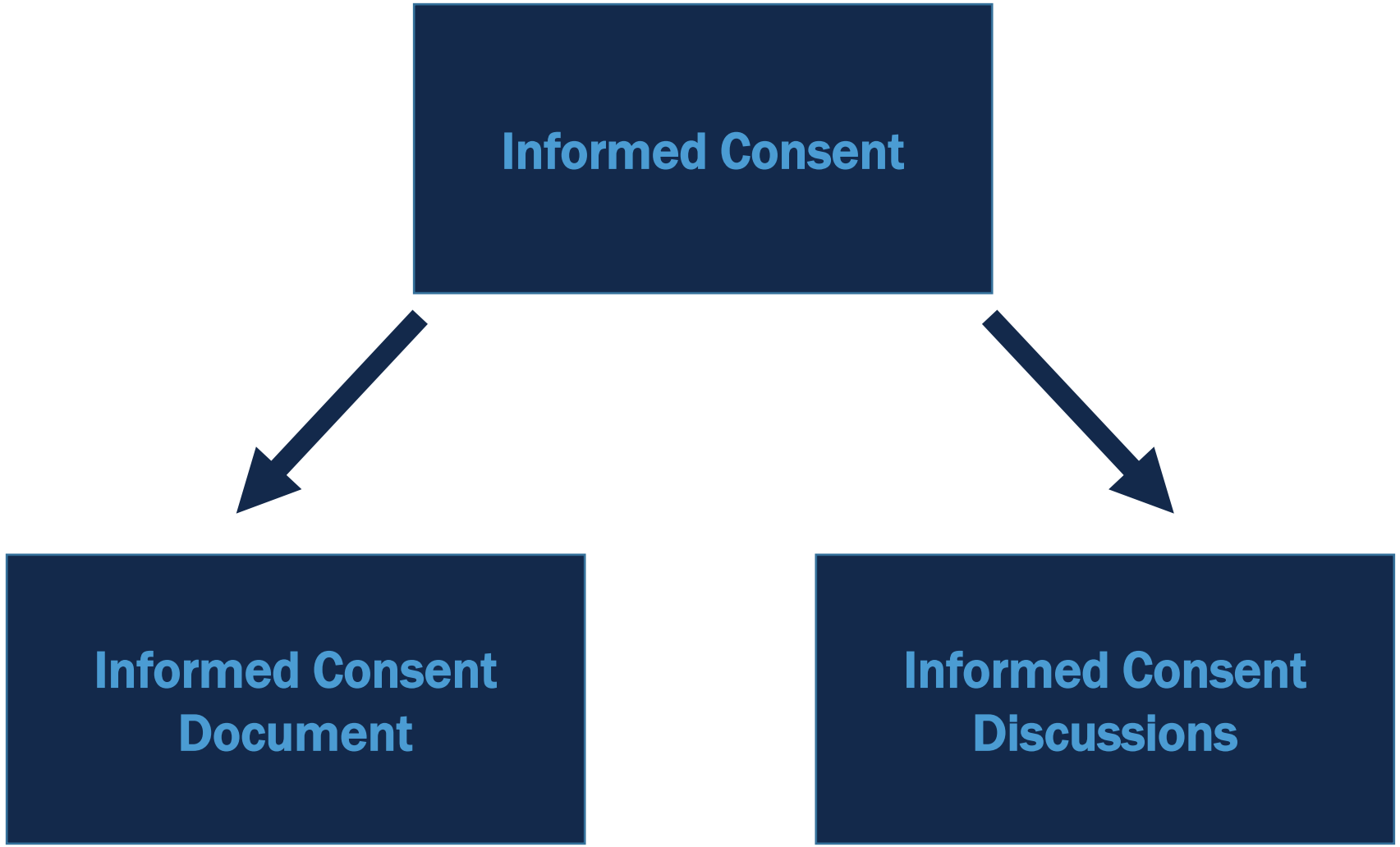

What is Informed Consent?

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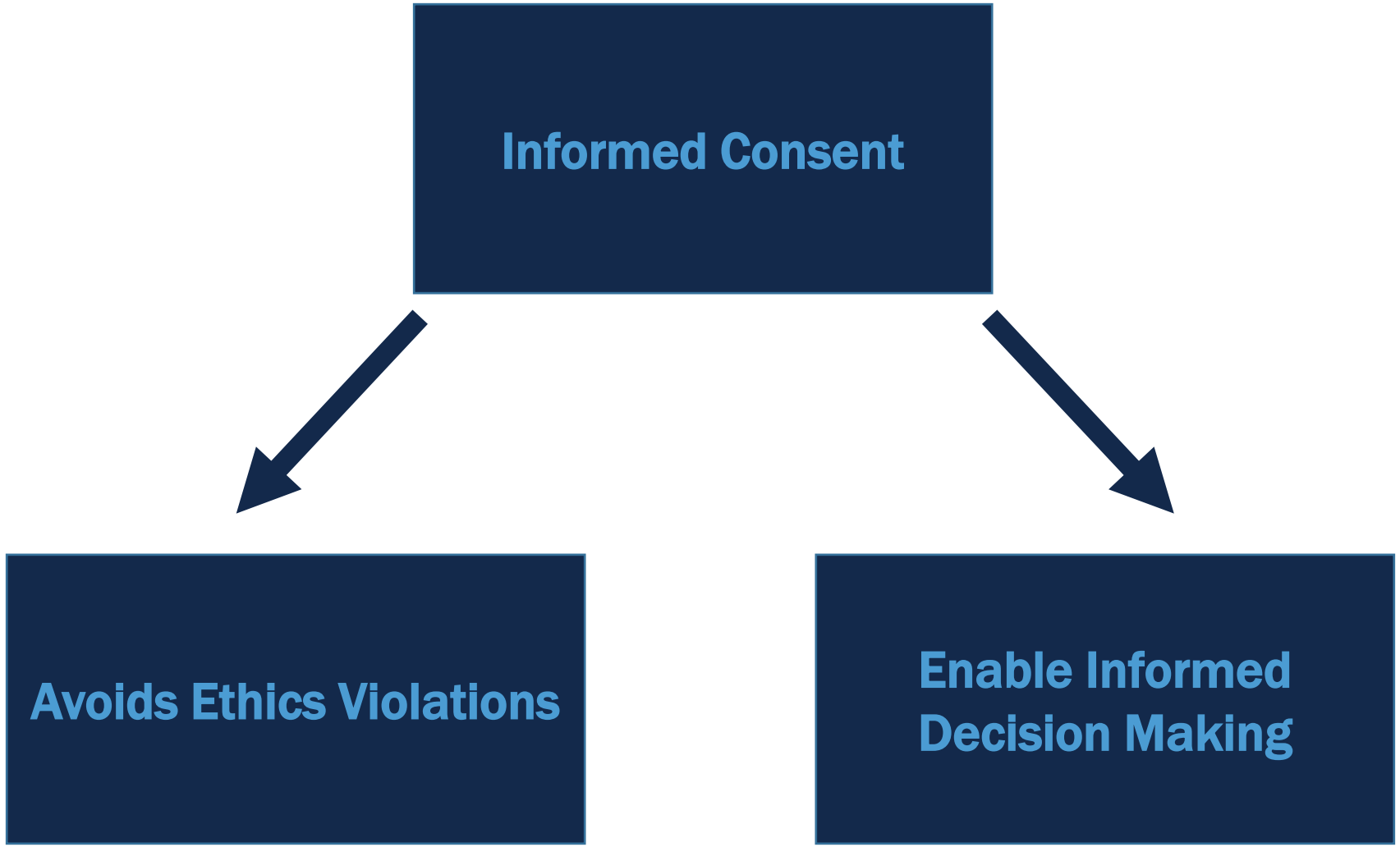

What is Informed Consent?

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Elements are Required Per 45 CFR 46.116(a):

- Consent Must Be Obtained Prior to Initiating Research Procedures
- The Participant Must Have Opportunity to Consider Whether or Not to Participate and Discuss the Consent Form
- The Process Must Minimize Coercion or Undue Influence
- The Information Must Be Presented in a Language that is Understandable
- Participants Must be Presented with the Information that a Reasonable Person Would Need to Make a Decision
- Must Begin With a Concise Summary That Facilitates Comprehension
- Must be Organized and Presented in a Way That Does Not Just Provide Facts, but Facilitates Understanding
- May Not Include Any Language Where the Subject Waives or Appears to Waive Legal Rights
- May Not Include Any Language That Releases Any Study Team from Liability or Negligence

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Considerations for Electronic Informed Consent

Considerations for Electronic Consent

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Use of Electronic Informed Consent: Questions and Answers (OHRP)

Use of Electronic Consent in Clinical Investigations (FDA)

**Both are guidance documents, containing non-binding recommendations.

Form & System

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What content in the consent changes when it is electronic?

None.

Informed consent forms, regardless of format (i.e., electronic or paper), must have all required elements per DHHS (45CFR46) and FDA (21CFR50) regulation.

Form & System

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The electronic informed consent must be easy for potential participants to navigate by…

Allowing participants to easily move back and forth through the system

Allowing participants to stop and resume later

The electronic informed consent system must not hinder the process of informed consent.

Form & System

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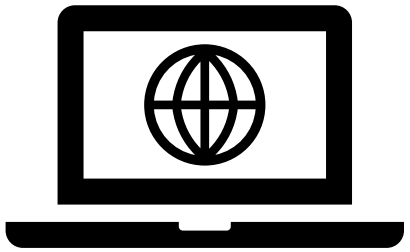
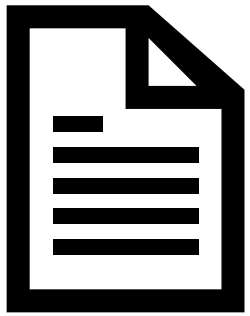
Ensure your electronic consent forms are as accessible as possible.

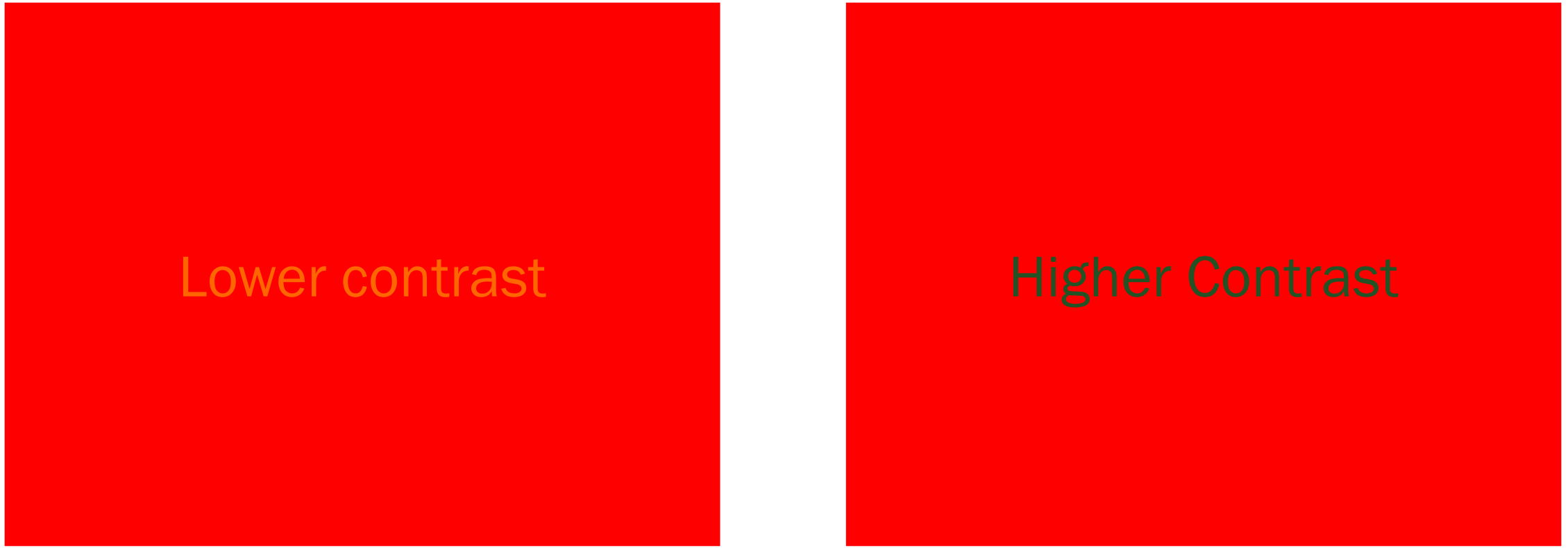


Ensure fonts are an appropriate contrast, font text is large enough for potential participants to read, etc. You may also help participants navigate the system if necessary.



Potential participants must have the option to use paper-based forms if needed or preferred.

Form & System



Form & System

Systems must have the ability to send a copy of the consent form to the participant.

Form & System

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Hyperlinks may be used in electronic systems if:

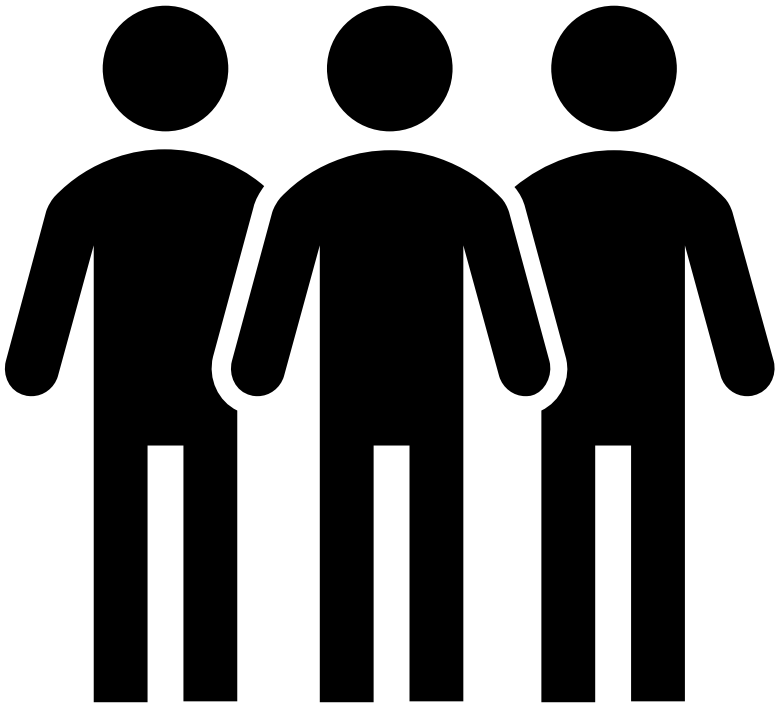
All content included is approved by the reviewing IRB

All content included will be provided to potential participants who use paper consent forms

They are maintained throughout the life of the study.

Personnel & Training

Before using the electronic system, research team members should…



- ☑ Check the IRB application to ensure they are listed as personnel
- ☑ Train on the study protocol
- ☑ Train on informed consent and the use of the electronic system
- ☑ Be delegated by the Principal Investigator to complete informed consent processes

Personnel & Training

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The electronic system may not be delegated the task of obtaining informed consent.

Remote Consenting

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Remote consenting is allowed; however, the participant must be reminded to be in private area and the following must be considered:

FDA Regulated

There must be procedures in place to ensure that the person signing the electronic form is the person who will be participating in the study.

Non-FDA Regulated

Investigators should use a risk-based approach to determine what measures should be in place to ensure participant identity.

Remote Consenting

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Reconsenting

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All regulations surrounding reconsenting and the presentation of new information to the participant still applies when using an electronic format.

Paper and electronic consents may be used interchangeably throughout the trial but ensure all consent forms and processes are documented and stored appropriately.

E-Signatures

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E-signatures are permitted for use in research consents if they are valid in the jurisdiction where the research is to be conducted.

E-signatures used in FDA regulated research must comply with Part 11.

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Using DocuSign for Electronic Consent

Using DocuSign

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DocuSign is a HIPAA-compliant digital signing software used at UNC-CH to send documents and collect electronic signatures.

DocuSign Standard eSignature	May be used to sign any research document except FDA-regulated documents.
DocuSign Part 11	May be used to sign FDA-regulated documents. Part 11 accounts must also be used for minors.

More information about DocuSign can be found on the CRSO's website.

Using DocuSign

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You must request access to both the standard and Part 11 DocuSign accounts.

These are separate accounts, so ensure you are using the correct account when sending documents.

If you work on FDA and non-FDA regulated trials…

Using DocuSign

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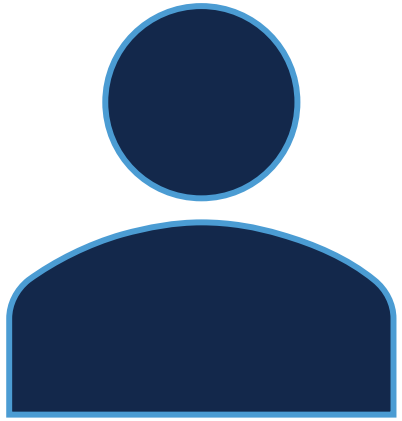

Senders

The person who creates, manages, and sends materials through DocuSign.

Signers

The person who signs the documents that are sent by the sender.

In FDA-regulated studies, the signer must also have a DocuSign account.

Using DocuSign

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Documents are created in the DocuSign Platform

↓

Senders Assemble Envelopes of Documents
(all documents in one envelope will appear as one continuous document)

↓

Sender Sends Envelope to Appropriate Party

↓

Signer Signs the Document; Copies are Sent to the Signer and are also Available on the DocuSign Website

Using DocuSign

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What's an Envelope?

An envelope is where documents are packaged in DocuSign.

Envelopes may contain:

Statuses
Documents
Recipient Names
Tabs/Fields
Timestamps
Sender Information
Document-related Metadata

Using Docusign

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Training is required to use DocuSign.
To request access and begin the training process, visit:

https://www.med.unc.edu/crso/resources/tools-and-services/docusign/

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UNC IRB Procedures for Electronic Consent Approval

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Electronic Signature (under North Carolina law)

An electronic signature can be any electronic sound, symbol, or process attached to, or logically associated with, a record and executed or adopted by a person with the intent to sign the record. An electronic signature is attributable to a person if it was the act of the person.

This broad definition is why “click through” agreements, typically associated with the use of software applications, are considered legally binding.

UNC IRB Procedures

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To use an electronic system for electronic consent…

Detail out the consent procedures and all electronic systems in section D.1 of the UNC IRB application.

Attach all consent forms and other applicable materials to the “attachments” section of the UNC IRB application.

Do not change language in the consent form or switch electronic systems without prior IRB approval.

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