Electronic Consent (e-Consent): Guidance for Human Subjects Research

This guidance covers issues for researchers to address when considering using e-Consent for research. This guidance does not apply to consent for clinical care.

For purposes of this guidance, electronic consent (e-Consent) refers to the use of an electronic system to obtain and document a research subject's informed consent for research, instead of relying on a paper process.

Note that any informed consent process may employ various forms of media to enhance the process of informed consent. This may include video, animation, images and graphics, podcasts, and links to websites. These approaches may all be used at the discretion of the researcher, with IRB approval, to enhance the process of informed consent, but they are not the focus of this guidance.

Regulatory summary

The use of e-Consent for research is supported by the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA), with the understanding that an e-Consent process must fulfill all the usual requirements for informed consent. e-Consent is also allowed for obtaining HIPAA Authorization. To obtain a *legally effective* electronic signature, compliance with state and federal law is required.

Under Colorado Law, C.R.S. § 24-71.3-101 *et. seq.*, electronic signatures are specifically permitted in Colorado, so long as both the researcher and the prospective research subject consent to the use of an electronic signature. Colorado law is not intended to limit, modify, or supersede the requirements of the federal "Electronic Signatures in Global and National Commerce Act", 15 U.S.C. sec. 7001 ("E-SIGN").

Under Colorado law, an "electronic signature" is defined as an 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. This is the same definition used in the federal E-SIGN Act. Based on this definition, a valid electronic signature for consent and HIPAA authorization could be the subject's typed name, or it could be a checkmark or any other symbol in a box on a form. Any method is valid, provided that the mark or symbol is "logically associated" with the individual making that mark.

General documentation requirements for informed consent

An e-Consent process must satisfy all the usual requirements for informed consent for research. These include the following:

- Both OHRP and FDA require that, "A copy [of the *signed* consent form] shall be given to the person signing the form.
- For FDA regulated research:
    - The investigator is responsible for obtaining *legally effective* informed consent.

  - If an electronic system is used to document informed consent, that system must be in compliance with 21 CFR Part 11, Electronic Records; Electronic Signatures. At present, neither RedCap nor Qualtrics is certified as 21 CFR Part 11 compliant under the University's license.
- For research conducted in compliance with Good Clinical Practices (GCP), the consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.
- For HIPAA regulated research:
  - The research subject must be provided with a copy of their *signed* authorization.
  - If an electronic system is used to document informed consent, that system must be HIPAA compliant. Both RedCap and Qualtrics are HIPAA compliant when using them under the University's license.
- Consent must always be obtained by an appropriately qualified and trained individual. The specific requirements depend on the type of research being conducted.
- For research involving patient care or clinical services within one of our affiliate hospital systems, a copy of the *signed* e-Consent form and HIPAA authorization must be uploaded into the electronic medical record (*i.e.*, Epic).
- For all research, PIs:
  - Are expected to keep signed consent forms confidential.
  - Must retain records beyond the completion of the study in accordance with applicable record retention requirements.

Authentication

To document legally effective e-Consent, it may be necessary to implement a process to verify the identity of the subject, that is, an authentication process.

Research which is FDA regulated or subject to HIPAA will require an authentication process. However, for much clinical research, an authentication process is already in place by virtue of hospital standard operating procedures, such as requirements for patients to show an ID and identify insurance upon check-in. In these cases, additional authentication procedures are unnecessary. However, if you are working outside of a hospital setting, or obtaining e-Consent remotely, and your research requires legally effective e-Consent, COMIRB may need to review an authentication process.

Scenarios

Researchers proposing to use e-Consent must ensure their plans meet the requirements above. The following cases illustrate how e-Consent might be implemented.

Research for which documentation of consent (*i.e.*, a signature) is not required

For some research the IRB may approve a consent process which does not require subjects to sign a consent form. In IRB terms, this is called waiver of *documentation* of consent.

Federal requirement - 45 CFR 46.117(c)

> An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
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> 1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
> 2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
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> In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

These studies typically pose minimal risk to subjects. The informed consent process may be verbal, may involve a written description of the study in the form of an information sheet or postcard consent, or may take place remotely with no face-to-face interaction between researcher and subject.

e-Consent requirements to address in your COMIRB application:

- Describe the process to provide a copy of the e-Consent (*e.g.*, information sheet or post card consent) to subjects who want one. For example, the e-Consent could include a button or link for the subject to request that a copy of the e-Consent be emailed to them.
- If an authentication process would not otherwise be required by COMIRB for use of a paper consent form, one is not required for e-Consent.
- The e-Consent system should be generally confidential and secure. It would not need to satisfy 21 CFR Part 11 unless the research is regulated by the FDA. It would not need to be HIPAA compliant unless PHI is collected.

Research in which informed consent will be obtained in person

In this context, e-Consent is used simply in replacement of a paper consent form. For example, the consent form could be presented to the subject on a tablet computer. The researcher and subject would have a face-to-face discussion and the subject's questions would be answered just as they would with a paper consent form. The subject would indicate his or her informed consent on the computer tablet in the presence of a researcher obtaining consent.

In-Person e-Consent requirements:

- Describe the process to provide a copy of the e-Consent form to subjects to take home to consider or discuss with friends and family.
- If an authentication process would not otherwise be required for a paper consent form, one is not required for e-Consent. Or, if an authentication process is already in place (*e.g.*, enrolling patients in a hospital system), this is adequate for e-Consent.
- Describe the process for confirming with the subject that they agree to providing consent electronically. This could be an additional sentence or phrase within the e-Consent form.
- Describe how the e-Consent process documents the name of the person who obtained consent.

- Describe how subjects will be given a copy of the signed e-Consent form. For example, this could take place by printing off the signed e-Consent, or by asking the subject if they would like to receive a copy of the signed e-Consent by email. In the latter case, describe how the email will be delivered. If the e-Consent form discloses PHI, the email may need to be encrypted. Also, the involved hospital system may not allow the use of the Electronic Medical Record system to email the e-Consent form.
- If this research is overseen by the FDA, the e-Consent system must be compliant with 21 CFR Part 11.
- If the research involves PHI (*i.e.*, requires HIPAA authorization), the e-Consent system must be HIPAA compliant.
- If the research involves patient care or services at a hospital or medical clinic, a copy of the signed e-Consent will have to be uploaded into the electronic medical record.
- For subjects who do not wish or are unable to use an e-Consent process, a paper consent option must be made available. Alternatively, the researcher could exclude subjects who do not want to use an e-Consent process, but this would need to be listed among the exclusion criteria in the IRB application, and the IRB would need to agree that this did not affect equitable selection of subjects.

Research in which informed consent will be obtained remotely

For researchers proposing to obtain informed consent remotely (*i.e.*, without a face-to-face discussion), additional information is needed. COMIRB will need to know if there is a verbal explanation of the study with the subject (*e.g.*, phone call or video chat) before informed consent is obtained and who will obtain consent. For some research, if the informed consent discussion takes place over the phone, an uninvolved witness may also be required. If there is no verbal discussion, is there another option for direct communication with the study team (*e.g.*, electronic messaging or electronic chatting)? Would the remote process be adequate to answer all the study participant's questions?

If informed consent is obtained remotely, and there is no verbal or electronic dialogue between researcher and subject, COMIRB will need to know how subjects have their questions answered.

Depending on the risks posed by the research, COMIRB may inquire into the following:

- Authentication: How does the researcher know the subjects are who they say they are?
- Evaluating subjects' understanding: If there is no opportunity for the researcher to assess whether the subject understands the study (*e.g.*, through verbal consent), the e-Consent process may need to include methods to assess subjects' understanding. For example, a short quiz could be included at the end of the e-Consent form.

All of the bullet points regarding in-person e-Consent also apply to this scenario.

Additional Considerations

Functionality

Additional information about the e-Consent functionality will need to be provided to COMIRB. For example, will subjects be able to navigate forward and backward through the consent form, and to stop and return at a later time? Is there functionality that prevents subjects from skipping to the end of the e-Consent form?

Supplemental Information

If the e-Consent process includes links to supplemental information such as informational brochures or videos, or Frequently Asked Questions, the content of that supplemental information should also be provided to COMIRB.

Electronic Signatures

The description of the e-Consent process in the application should explain how the signature will be documented. Options could include asking the subject to type out their name, typing their initials, clicking on an "I agree" button or checkbox, and others.

Storage of e-Consent forms

The signed e-Consents may be stored in the system in which they were obtained. Researchers using the RedCap and Qualtrics systems/environments under the University license need not provide additional information about long term storage. Researchers proposing to use systems which are not licensed by the University should provide information about the electronic system and explain their plans for document retention, including data backup if applicable.

Data Security

The electronic system that supports e-Consenting must be secure with restricted access and should include methods to ensure confidentiality of the Subject's identity, study participation, and personal information.

Additional PI Responsibilities

- The PI needs to ensure that the e-Consent system is used and operates as expected during the conduct of the study.
- The PI is responsible for making sure the approved version of the e-Consent is promptly loaded into the electronic system following IRB approval.

Administrative Issues

The e-Consent form should have a place for the IRB approval and expiration dates as appropriate. COMIRB cannot stamp the e-Consent form. Researchers may update the IRB approval and expiration dates after COMIRB approval without need to submit a subsequent amendment.

Contact COMIRB

Implementing an e-Consent solution is more complicated than it might appear, especially if a legally effective signature is required for the research. If you are considering this, we encourage you to contact COMIRB. We are happy to meet with you to discuss your e-Consent plans, and we will facilitate getting input from involved Privacy Officers and Legal Counsel.