

## Electronic Consent (eConsent): Guidance for Human Subjects Research

### Regulatory summary

The use of eConsent for research is supported by both the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA), as well as the Office for Civil Rights for obtaining HIPAA Authorization. The signature must be *legally effective* under state and federal law. The content and process for obtaining informed consent and HIPAA Authorizations must fulfill all the usual requirements.

For research subject to FDA oversight, the electronic system used must be compliant with 21 CFR Part 11<sup>1</sup>, Electronic Records; Electronic Signatures. For purposes of obtaining eConsent, the only electronic systems currently available that are materially compliant with 21 CFR Part 11 are those already part of the electronic medical record (EMR) systems of our affiliate health care systems. However, using the EMR to obtain eConsent may not be a feasible option for other reasons.

When obtaining HIPAA Authorization, the electronic system used must be HIPAA compliant<sup>1</sup>. There are several electronic systems that are certified as HIPAA-compliant and may be useful for eConsent and for facilitating an informed consent process. For HIPAA compliance, researchers must use an instance of these applications licensed by the University or one of our affiliate health care systems.

HIPAA – Certified Systems
REDCap
Qualtrics
Docusign (School of Medicine)
MS Office
Zoom
Patient IQ
Skype
Vidyo

Under Colorado Law, C.R.S. § 24-71.3-101 *et. seq.*, electronic signatures are specifically permitted if 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”).

Colorado state law defines an “electronic signature” 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 definition is also used in the federal E-SIGN Act. For purposes of human subjects research, COMIRB requires that subjects type or sign (*e.g.*, with a stylus or their finger) their name and date on the eConsent form.

<sup>1</sup> Third-party applications may advertise compliance with HIPAA or 21 CFR Part 11. However, unless compliance is documented in the university licensing agreement, do not treat the applications as compliant.

If you have questions or a request for a different application for use for research, please [contact the OIT for an assessment](#).

### General documentation requirements for informed consent

An eConsent 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 be provided to the subject.
- 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.
- Consent must always be obtained by an appropriately qualified and trained individual. The specific requirements depend on the research being conducted.
- For research involving patients and clinical services within one of our affiliate health care systems, a copy of the signed eConsent form must be uploaded to the electronic medical record (*i.e.*, Epic).
- For all research, PIs:
  - Are expected to keep signed consent forms confidential; and
  - Must follow record retention requirements of the sponsor, University and involved regulatory agencies.

### Case examples

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

#### Case 1: Research in which informed consent is obtained in person

In this context, eConsent is used instead of a paper consent form but everything else about the consent process is the same. For example, the eConsent is presented to the subject on a tablet computer. The researcher and potential subject have a face-to-face informed consent discussion and the subject's questions are answered. The subject documents their informed consent electronically on the eConsent in the presence of a researcher obtaining consent. The Researcher obtaining consent also electronically signs the eConsent. A witness is not needed.

#### Requirements for the COMIRB Application, Section L:

- Describe the consent process above;
- Describe how subjects can take the eConsent home to consider or discuss with friends and family;
- Describe how subjects will be given a copy of the signed eConsent form (*e.g.*, the eConsent could give subjects the option to print, download or email themselves a copy of the signed eConsent); and
- The protocol needs to address whether subjects who refuse eConsent will be included. If so, Section L should describe how subjects who refuse eConsent will be provided paper versions of the consent form to sign.

#### Requirements for the eConsent:

- In the text preceding the signature section, add a statement that the subject agrees to provide consent electronically<sup>2</sup>;
- Add text instructing the subjects how to document their consent, *e.g.*, “To indicate that you agree to sign electronically and that you consent to participate in the study, type your name and today’s date in the space below<sup>2</sup>;” and
- Add text instructing the person obtaining consent how to document their signature, *e.g.*, “To indicate that you agree to sign electronically, that you obtained consent and the subject’s questions were answered, type your name and date in the space below.<sup>2</sup>”

#### Case 2: Research in which informed consent will be obtained remotely by telephone or video

In this context, eConsent is used in conjunction with a consent process conducted over the phone or by video. A link to the eConsent is emailed or otherwise available to the subject in advance of the informed consent discussion. If the research is FDA-regulated, an impartial witness must also participate in the informed consent discussion. The discussion begins with identification of who is participating. During the informed consent discussion the subject’s questions are answered and at the end the subject verbally confirms they agree to be in the study. The subject documents their informed consent electronically on the eConsent. The witness (if needed) and the researcher electronically sign the eConsent.

#### Requirements for the COMIRB Application, Section L:

- Describe the consent process above;
- If using video<sup>3</sup>, identify the service from the list above;
- Explain how the eConsent is delivered to the subject in advance of the informed consent discussion;
- Explain that the eConsent form is designed to allow the subject to navigate forward and backward through the form, and to access the form at a later time if they want to think about their participation;
- For FDA-regulated research, explain who may serve as the impartial witness (*i.e.*, a person not involved with the research, not a family member or friend of the subject);
- Describe how subject will be delivered a copy of the signed eConsent form (*e.g.*, the eConsent could give subjects the option to print, download or email themselves a copy of the signed eConsent); and
- The protocol needs to address whether subjects who refuse eConsent will be included. If so, Section L should describe how subjects who refuse eConsent will be provided paper versions of the consent form to sign, and how those will be returned to the study team.

<sup>2</sup> Some electronic systems automatically add statements regarding permission to provide consent electronically and time and date stamping if they are configured to do so.

#### Requirements for the eConsent:

- Same as Case 1 above; and
- For FDA-regulated research, add text instructing the impartial witness how to document their signature, *e.g.*, “To indicate that you agree to sign electronically, and that you witnessed the informed consent discussion, that the subject’s questions were answered, and that the subject agreed to participate, type your name and date in the space below.”

#### Contact COMIRB

Implementing an eConsent solution is more complicated than it might appear. We encourage you to contact [COMIRB](#) to discuss your specific eConsent plans, and we will facilitate soliciting input from involved Privacy Officers and Legal Counsel.

#### FAQs

Q: The website for an eConsent application I want to use states it is fully compliant with 21 CFR Part 11. Is that all I need for 21 CFR Part 11 compliance?

A: No, an eConsent application is not compliant with 21 CFR Part 11 on its own. The application must be licensed by the University or one of our affiliate health care systems and then certified as 21 CFR Part 11 compliant.

Q: Can a family member of the subject serve as the witness?

A: Yes. A family member is not considered partial to the study team.

Q: How do I get the subject, the person obtaining consent, and the witness all to sign the same eConsent?

A: There are several ways to accomplish this and researchers have flexibility. If you are using a system like REDCap, the eConsent can be configured so that electronic signatures are obtained separately but all get recorded in a single file. In the case of obtaining documentation from the witness, an email from the witness could suffice. For example, if the witness is a University employee, they could send an email to the study team from their University email account and include the following: “I witnessed the informed consent discussion with [subject identifier] on [date]. The subject’s questions were answered, and the subject agreed to participate.” A copy of the email would need to be included in the study file, appended to the signed eConsent documentation.

<sup>3</sup> If you are using the telehealth system licensed by one of our affiliate health care systems for research, be sure this use for research is in compliance with health system policies.

Q: Can eConsent be used for a proxy or Legally Authorized Representative (LAR)?

A: Yes. COMIRB must first approve the use of a proxy or LAR for consent and the process for obtaining eConsent. As a reminder, under Colorado State law, a proxy may only be used for consent for research for studies which might provide direct benefit to the subject. State law, University and health system policies must also be followed for properly identifying a proxy or a LAR.

Q: Can eConsent be used for documenting assent?

A: Yes, although documentation of assent can be accomplished through other means. For example, for clinical research the study team may be required by the hospital to document assent in the medical record. Describe your plan in the COMIRB application, as COMIRB must approve the assent process.