

UNIVERSITY OF ROCHESTER

GUIDANCE ON ELECTRONIC INFORMED CONSENT FOR RESEARCH

I. BACKGROUND

This document provides guidance to researchers at University of Rochester on the use of electronic systems to document informed consent for research and establishes requirements for use of an electronic signature in lieu of handwritten signatures for research. It also describes several systems available for researchers to facilitate electronic informed consent (**eConsent**), and the procedures for using those systems.

Federal regulations for the protection of human subjects in research support the use of eConsent and eSignatures (as defined in Section III (A) below). The Food and Drug Administration (**FDA**) requirements for electronic records/electronic signatures, informed consent, and IRBs are set forth in 21 CFR Parts 11.

Utilizing eConsent to facilitate the consent process does not change the regulatory and/or institutional requirements related to obtaining informed consent (see the [Office for Human Subject Protection Policy 701 Informed Consent](#)). **The manner in which consent will be obtained and documented (paper consent or eConsent) must be described in the protocol and approved by the Reviewing Institutional Review Board (IRB) *prior* to implementation.**

II. EFFECTIVE DATE: December 31, 2023.

III. DEFINITIONS

1. **Electronic Consent (eConsent):** is a system to facilitate the consent process using a computer-based system to disclose the necessary elements of consent and to document consent, rather than a traditional paper consent form. It can also be used as a method to evaluate comprehension of the study, with questions built into the eConsent process. eConsent provides the ability to obtain consent in person or remotely via an electronic device (i.e., computer, mobile phone, or tablet).
 - **In Person eConsent:** the person obtaining consent (**POC**) and the potential research subject are physically in the same location, the consent process occurs in person, the consent document may be presented electronically and is signed electronically.
 - **Remote eConsent:** the person obtaining consent is not in the physical presence of the subject when consent is obtained, the consent document may be presented electronically or through the paper document.
2. **Electronic Signature (eSignature):** means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

IV. REQUIREMENTS

Utilizing eConsent and/or eSignature to facilitate the consent process does not change the regulatory and/or institutional requirements related to obtaining informed consent (see the [Office for Human Subject Protection Policy 701 Informed Consent](#)). The manner in which consent will be obtained and documented (paper consent or eConsent) must be described in your protocol and approved by the Reviewing Institutional Review Board (IRB) prior to implementation.

1. eConsent

- When consent information is presented in an electronic format, the eConsent system should be easy to navigate, allowing the user to proceed forward and backward in the document and to stop and continue later.
- Each program for obtaining eConsent must generate a copy of the signed consent document that can be accessed by the subject (e.g., PDF document printable from a website or mailed paper copy).
- Each program for obtaining eConsent should include the capability to archive all versions of the IRB-approved eConsent and all signed eConsent documents. Archiving should be accessible and retrievable.
- HIPAA authorization may be obtained through eConsent, either as a separate document or as part of the consent document. If a separate document, the same requirements as above apply.

2. eSignature

- The eSignature must be linked to the person signing the eConsent document. This can be done using any of the following:
 - Verification with an established passcode
 - Verification with known information
 - Verification with a passcode based on known information.
- The date and time of the subject's signature and the person obtaining consent's signature must be captured and stored.

V. FDA CONSIDERATIONS

Use of electronic systems, archiving and retention of consent documentation for FDA-regulated clinical research studies that use electronic records and eSignatures must meet the requirements of the FDA 21 CFR 11 regulations (the **Part 11 Requirements**). The Part 11 Requirements are outlined in the [FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures-Scope and Application \(September 2003\)](#).

See also the FDA March 2023 Draft Guidance: "[Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers](#)" and the FDA's March 2018 "[Important Information about Digital/Electronic Signatures](#)."

VI. eCONSENT SYSTEMS AVAILABLE AT UNIVERSITY OF ROCHESTER

1. REDCap

REDCap is a secure web application for building and managing online surveys and databases, particularly for research studies. REDCap offers a digital method to obtain and store consent forms through an eConsent Framework and PDF Auto-Archiver. More information on REDCap can be found on the [URMC REDCap Portal](#) and in the [Guideline for Using REDCap for Electronic Informed Consent \(eConsent\)](#).

2. DocuSign Part 11

DocuSign Part 11 is a secure cloud service that provides eSignature technology for the signing of documents and the creation of document signature workflows. DocuSign Part 11 can streamline the process of getting documents signed and routing documents through a review and approval cycle. See the University of Rochester DocuSign Part 11 information at: Office of [Research IT DocuSign – 21 CFR Part 11](#).

Note: DocuSign Standard cannot be used to obtain eConsent.

	REDCap	DocuSign Part 11
Fees	eConsent implementation is available at no cost to the researcher.	There are fees to use DocuSign for CFR Part 11. There is an initial Office of Research IT fee of \$250 for each setup, in addition to a cost for each “envelope” or for each time a consent is obtained.
Permitted Uses and Limitations on Use	HIPAA Compliant Not compliant with 21 CFR 11 and therefore cannot be used to obtain consent for Food & Drug Administration (FDA) regulated studies.	HIPAA: University of Rochester has a BAA with DocuSign, which permits DocuSign to be used when PHI is involved. DocuSign Part 11 may be used when obtaining eConsent for FDA-regulated research so long as the documentation required by 21 CFR Parts 11 is obtained. A Standard Operating Procedure with IRB and Office of Research IT will be implemented to facilitate the approval for DocuSign Part 11 approval and templates.
Record Retention	Signed consent and HIPAA Authorization Forms may be retained in REDCap when a project has been configured to do so. When properly configured, REDCap will automatically store such documents so long as the project is not deleted from the system. <ul style="list-style-type: none">As a general rule, the signed eConsent PDFs must be downloaded from the PDF archive and stored in the study binder.	DocuSign Part 11 is not a records retention system, and all consent forms must be retrieved from the DocuSign Part 11 site and stored by the investigator in another location, i.e., wherever the investigator stores all other study-related documents.