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 below). The Food and Drug Administration (**FDA**) requirements for electronic records/electronic signatures, informed consent, and IRBs are set forth in 21 CFR Part 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: October 2024.

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.

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

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 October 2024 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. Adobe Acrobat Sign CFR Part 11

Adobe Acrobat Sign is a secure cloud service that provides eSignature technology for the signing of documents and the creation of document signature workflows. Adobe Acrobat Sign can streamline the process of getting documents signed and routing documents through a review and approval cycle.

Note: Adobe Acrobat Sign Standard CANNOT be used to obtain CFR Part 11 eConsent!

REDCap at UR is ***not*** currently CFR Part 11 compliant. For REDCap to be CFR Part 11, it must be placed in an environment with security, personnel, policies, procedures, training, validation, and documentation meeting the requirements of Part 11 and the predicate rules for the underlying legislation. **This is not yet available within the Institution.**

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	REDCap	Adobe Acrobat Sign CFR Part 11
Fees	eConsent implementation is available at no cost to the researcher. All eConsents must be created by and modified by the Office of Research IT.	There is an initial Office of Research IT fee of $250 for each setup. All eConsents must be created by and modified by the Office of Research IT.
Permitted Uses and Limitations on Use	**HIPAA:** Compliant **21 CFR Part 11:** 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 Business Associate Agreement with Adobe, which permits Adobe Acrobat Sign to be used when PHI is involved. **21 CFR Part 11:** Adobe Acrobat Sign may be used when obtaining eConsent for FDA-regulated research so long as the documentation required by 21 CFR Part 11 is obtained.
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. As a general rule, the signed eConsent PDFs must be downloaded from the PDF Archive and stored in the study binder.	All Part 11 documents must remain in the Adobe Acrobat Sign system. In order to meet CFR Part 11 compliance, Adobe Acrobat Sign is not intended for long-term storage of documents. Consent forms and other materials signed via Adobe Acrobat Sign must be downloaded and saved in an appropriate platform that follow the University of Rochester's Storage and Retention Policy.