PURPOSE

This document provides guidance on the allowable use of electronic systems and processes to obtain and document informed consent for UW research. It also describes the two UW-vetted e-signature tools (i.e., DocuSign and REDCap) and the conditions of their use.

Contents

1 CONTEXT

The word "**consent**" is used in this document to mean any of the following:

- Obtaining consent from a subject or a subject's legally authorized representative;
- Obtaining parental permission from the parent(s) of a child subject;
- Obtaining assent from a child subject.

Electronic informed consent ("e-consent") refers to the use of electronic systems and processes that employ some type of electronic media (including text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, card readers, etc.) to convey consent information and/or to document informed consent. These may be used in place of, or in combination with, paper-based consent methods.

- Many people use the terms "**electronic signature**" and "**digital signature**" interchangeably. However, a digital signature is a very specific, highly protected type of electronic signature. Most electronic signatures used today are not digital signatures. There are currently no UW-supported tools that have been vetted for capture of digital signatures.

Relationship with remote or virtual interactions with participants. Electronic consent processes are invaluable when it is not possible to have an in-person interaction with a participant. However, electronic processes may also be useful and appropriate for in-person consent interactions. For example, a consent form may be emailed in advance to a potential participant, followed by an in-person meeting in which the study is discussed, after which an electronic signature is obtained.

The **consent process** has three components:

- Providing information to prospective subjects;
- Facilitating comprehension, and providing the opportunity to consider the information;
- Documenting consent.

2 ELECTRONIC DELIVERY OF CONSENT INFORMATION

A paper consent form is not the only way to deliver consent information. There are many electronic alternatives. Examples include: Consent information or document that is delivered electronically (e.g., email, text message); passive or interactive websites; social media platforms; audio; video; podcasts; or any combination of these.

Regulatory requirements. Electronic delivery of consent information must meet the same human subjects regulatory requirements as paper-based delivery of the information:

- **General required characteristics**, such as delivering the information in a language understandable to the participant and providing the information that a reasonable person would want in order to decide whether or not to participate;
- **Specific elements (content)**, such as a description of the reasonably foreseeable risks;
- **Records retention requirements** (e.g., Washington State; federal funding agencies; Food and Drug Administration (FDA);
- **Easily retrievable for auditors and monitors;**
- **Accessible by participants for the duration of the research**. For example, if a website is used to deliver consent information and/or website links are embedded in the consent information, the website consent information must be maintained and accessible until the study has been completed.
- **If the consent signature will be obtained electronically**: The consent information must be made available to the participants (or parents, if the participants are children) in a format they can retain.

FDA-regulated research. Use of electronic systems, archiving, and retention of consent materials must meet the FDA "Part 11" requirements. The Part 11 regulations are separate from the FDA's human subject regulations and have nothing to do with IRB review and approval. Part 11 compliance is the responsibility of the researcher.

- The Part 11 requirements are outlined in the FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (September 2003).
- The UW-ITHS-supported version of REDCap meets the FDA's Part 11 electronic system requirements. However, to fully comply with Part 11, researchers must also implement all other procedural requirements for Part 11 (e.g., limiting system access to only authorized users).

3 FACILITATING COMPREHENSION AND THE OPPORTUNITY TO CONSIDER PARTICIPATION

This refers to the processes used to ensure that subjects understand the information and have adequate time to make an informed decision.

When a subject is consented in the presence of a study team member, this will typically include a question-and-answer opportunity. When consent is not an "in-person" process, the researcher and the IRB must consider whether there is a way to provide this opportunity (if appropriate) and/or whether alternative ways of facilitating comprehension may be appropriate. For example, this may be accomplished through telephone calls, electronic messaging (examples: email, text messages), video conferencing, live chat, or other methods. Regardless of the subject's location, there may also be optional information (for example,

hyperlinks or help text) embedded in the electronically delivered material to aid in comprehension of key study elements. Similarly, subjects may be asked questions embedded during the electronic process to gauge their comprehension.

Regulatory requirements. There are no regulatory requirements about this component of consent, regardless of whether it is done in person or remotely, or on paper versus electronically.

4 DOCUMENTATION OF CONSENT (e-signature)

Note: It may be appropriate for minimal risk studies to obtain a waiver of the requirement to obtain documentation of consent. In the IRB application, researchers should describe why it does not make sense to obtain consent signatures in their study.

The traditional way to obtain documentation of consent is to have participants sign a paper consent form. However, there are many electronic alternatives, including: electronic signatures through e-sign providers such as DocuSign or REDCap, digital signatures, computer-readable ID cards, biometrics, or username and password combinations.

These two electronic signature tools have been vetted by the UW and legal counsel as meeting the federal and Washington State definitions of a "legally valid" electronic signature. Exception: See the FDA-regulated research section below.

- UW ITHS REDCap (consult with the UW Human Subjects Division (HSD) about REDCap administered through other institutions)
- UW eSignatures (DocuSign)

Regulatory requirements. Electronic documentation of consent must meet the same requirements as paper documentation.

a. Legally effective electronic signature. The signature method must be consistent with general laws about electronic signatures in the jurisdiction in which the research will be conducted. As stated above, only UW eSignatures (DocuSign) and UW ITHS REDCap have been vetted as meeting these requirements. HSD cannot advise researchers about other e-signature methods.

- Federal law: Electronic Signatures in Global and National Commerce (E-Sign) Act; Uniform Electronic Transactions Act (UETA)
- Washington State law: Laws of 2020, Ch. 57 (Washington's adoption of UETA); replacing the previous law RCW 19.360, effective June 11, 2020).

b. Requirements of human subjects regulations. The requirements for consent documentation obtained by e-signature are the same as for paper-based consent documentation:

- **Date of consent**. Capture and record the date when the participant provides consent. This is a UW and an FDA requirement.
- **Confidentiality and integrity**. Appropriately protect the confidentiality and integrity of the consent documentation. This is generally addressed as part of the study's data security protections.
- **Copy of consent information**. Offer a copy of the consent information to the participants. The consent information must be made available to the participants (or parents, if the participants are children) in a format they can retain and access (e.g., PDF document; printable website; mailed paper copy).

- **Records retention requirements** (e.g., Washington State; federal funding agencies; Food and Drug Administration (FDA).
- **Easily retrievable for auditors and monitors.** This could be in electronic or paper format.

c. **FDA-regulated research**. The key issues to consider are (a) the FDA's definition of "electronic signature", (b) the general Part 11 regulations about electronic systems; and (c) whether verification of the participant's identity is required.

- **UW e-Signature (DocuSign) is not allowed** because DocuSign at the UW is not compliant with the FDA Part 11 regulations.
- **UW ITHS REDCap is allowed** because it is compliant with Part 11. FDA considers documentation of consent using REDCap to be a handwritten signature captured as an electronic record rather than a true electronic signature.
- **Other e-signature tools** must be considered against the three key issues named above.

d. **Verification of identity**. This refers to the process for confirming that the individual who provided the electronic signature is the participant (or the participant's legally authorized representative, parent, or guardian).

- **Examples.** Visually witnessing the signature; some form of official identification shared with the research team as a scanned copy or digital photo; security questions (similar to questions sometimes used by banks).
- **General principle.** A signature that is personally witnessed by a member of the study team, either in-person or visually using a video conferencing service (e.g., Zoom, Facetime, Skype) is generally considered sufficient verification and documentation of a participant's identity. In all other circumstances, federal Common Rule guidance encourages researchers and the UW IRB to apply a risk-based approach to determine if more formal verification is required. For example, how likely is it that someone other than the participant would provide the consent and signature, and how risky would that be to the actual participant and to the integrity of the study?
    - Examples where more formal verification might be appropriate include: (a) a study that involves giving alcohol to participants (verify age); (b) a longitudinal study where it is necessary to ensure that the same person is providing information over time; and (c) a study involving access to sensitive data such as a person's mental health or sexually-transmitted infections (STIs) records.
- **FDA-regulated research**. The FDA requires verification of identity when electronic signatures are used to document consent. However, the UW-vetted system (UW ITHS REDCap) that is allowed for FDA-regulated research is considered by the FDA to be a handwritten signature captured as an electronic record rather than a true e-signature. Therefore, verification of identity (except as described above under *General principle*) is not regulatorily required in these circumstances. However, researchers are encouraged to document how identity is confirmed, to draw upon in case of a FDA audit.

e. **Required consent information**. Washington State and federal e-signature laws require specific information to be provided to participants when signatures are obtained electronically or through capture of a handwritten signature as an electronic record. It is HSD's general expectation that this information is communicated as part of the consent form(s).

The required information:

- A statement that a copy of the consent information (e.g., consent form) will be provided electronically, including a description of the hardware and software requirements necessary to access/read the document;
- Information regarding how a participant can request and receive a paper copy of the consent form at no cost;
- Information regarding how a participant can withdraw consent (for example, by contacting the researcher, including a description of how).

In rare instances, HSD may permit the required information to be communicated to study participants via an alternate method. For example, there may be no UW site-specific form when a UW investigator participates in a multicenter trial using an external IRB. Any such method must still provide the information:

- In writing;
- Prior to obtaining documentation of informed consent (i.e., e-signature);
- In a manner that allows the participant to print, access it at a later date, or otherwise retain a copy in some fashion.

f. HSD and/or IRB approval. It is HSD policy that that IRB approval must be obtained in advance for the use of any e-signature or electronic signature capture system (e.g., DocuSign, UW ITHS REDCap).

g. Special considerations.

- **HIPAA authorization**. Both DocuSign and the UW ITHS REDCap system (and equivalent, IRB-approved non-UW REDCap installations) may be used to obtain HIPAA authorization for access to PHI at UW Medicine, Seattle Children's, and Seattle Cancer Care Alliance. E-signatures captured in any other systems are not acceptable. For authorization to obtain/access PHI at any other HIPAA-covered institution, consult that institution's privacy and/or health records information office.
- **Review by an external IRB.** UW research that is being reviewed by an external IRB instead of the UW IRB must obtain HSD concurrence before implementing the use of e-signatures for consent and/or HIPAA authorization. This is accomplished by answering the e-signature questions in the **REQUEST External IRB Review** form and, if applicable, uploading the **SUPPLEMENT Other REDCap Installation** or **TEMPLATE Other eSignature Attestation Letter** to the *Local Site Documents* SmartForm.
- **International research**. Other countries may have their own laws regarding the legal validity of an e-signature and what methods of capture are acceptable. It is the researcher's responsibility to be aware of and comply with these laws. Check out online resources such as DocuSign eSignature Legality Guide and consult with collaborating partners and experts in the target country(ies). This resource is published by DocuSign and is informational only. HSD cannot guarantee that it remains current and accurate.
- **Using an e-signature method not vetted by the UW** is permitted on a case-by-case basis. The researcher must provide (as part of their HSD application) a signed **Other E-signature Attestation Letter** confirming the system meets all the applicable e-signature laws in the jurisdiction where the signature will be obtained and follows current best practices for technical security. This letter must be signed by the Chief Information Officer, Chief

Information Security Officer, or other individual at the company/institution with sufficient authority and subject matter expertise to make the above attestation. HSD and the UW will not vet other e-signature methods.

5 USING eSIGNATURES SERVICE (DocuSign)

eSignatures Service (DocuSign) is an electronic signatures service provider, centrally managed and supported by UW-IT.

The conditions for using DocuSign are:

- All of the applicable requirements in described above in section 4 must be met.
- DocuSign cannot be used with any FDA-regulated study because the UW-supported system does not meet the FDA's Part 11 electronic system requirements.
- Specific approval to use DocuSign for consent signature and/or HIPAA authorization signature must be obtained in advance from the UW IRB. For studies reviewed by an external IRB, approval must be obtained from the external IRB **and** from HSD.
- After obtaining IRB approval to use DocuSign, the study team must apply through UW-IT to use DocuSign. The application process requires uploading a copy of the IRB approval letter (or Exempt letter) that specifically states that approval to use DocuSign has been granted.
- The study team must promptly retrieve signed consent forms from the DocuSign site and store them, because DocuSign is not a records retention system.

Applying through UW-IT to use DocuSign. All documents put into DocuSign must have approval by the legal team overseeing the use of DocuSign at the UW. In addition, there is a mandatory onboarding process to ensure that eSignatures are a good fit for the study's needs and to confirm that the intended usage meets University policy and guidelines for eSignature usage. **As a result, the process of setting up for e-signatures cannot be done with significant speed. Plan ahead!** See this website for details and additional information: https://itconnect.uw.edu/work/administrative-systems/esignatures/

See the DocuSign company website for a 1-minute video demonstration. Scroll down the homepage to the *Video: How it works*.

6 USING REDCap ELECTRONIC SIGNATURE: A tool provided and supported by the UW Institute of Translational Health Sciences (ITHS)

REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support online or offline data capture for research studies and operations. The **UW ITHS-supported version** of **REDCap** can be configured to capture legally valid electronic signatures.

The conditions for using REDCap are:

- All of the applicable requirements described above in section 4 must be met.
- Specific approval to use the REDCap electronic signature process for consent signature and/or HIPAA authorization signature must be obtained from the UW IRB. For studies reviewed by an external IRB, approval must be obtained from the external IRB **and** from HSD.

- REDCap may also be used for FDA-regulated studies. The UW-ITHS-supported version of REDCap meets the FDA's Part 11 electronic system requirements. To fully comply with Part 11, researchers must also implement all other procedural requirements for Part 11 (e.g., limiting system access to only authorized users). A complete list of requirements is outlined in the FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (September 2003).
- The REDCap consent survey must be set up for the individual project using one of the ITHS REDCap e-consent templates. See the ITHS REDCap website for an online tutorial on how to do this.
- The signed consent form must be retained in REDCap. REDCap will automatically store the consents so long as no records or the project itself are deleted. The researcher is responsible for ensuring the signed consent forms are retained for the appropriate record retention period.

- **Studies that are required to use a non-UW REDCap system** (i.e., that is run by another institution) must provide HSD with a completed **SUPPLEMENT Other REDCap Installation**. The use of the REDCap system cannot begin until it has been approved by the UW IRB or (if review is from an external IRB) by HSD.

7 RELATED MATERIALS

7.1 REQUEST External IRB Review
7.2 SUPPLEMENT Other REDCap Installation
7.3 TEMPLATE Other eSignature Attestation Letter
7.4 WORKSHEET Consent Requirements and Waivers
7.5 UW IT website: https://itconnect.uw.edu/work/administrative-systems/esignatures/

8 REGULATORY REFERENCES

8.1 21 CFR Part 11
8.2 "Use of Electronic Informed Consent: Questions and Answers", guidance from the Food and Drug Administration and from the Department of Health and Human Services Office for Human Research Protections. December 2016.
8.3 "Part 11, Electronic Records: Electronic Signatures – Scope and Application", guidance from the Food and Drug Administration, August 2003
8.4 FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (updated July 2, 2020)
8.5 Chapter 19.360 Revised Code of Washington (RCW) Electronic Signatures and Records
8.5 Washington State Chapter 57, Laws of 2020 (Washington's adoption of UETA)
8.6 15 U.W. Code Chapter 96 - The Electronic Signatures in Global and National Commerce Act (E-Sign Act)
8.7 National Conference of Commissioners of Uniform State Laws, Uniform Electronic Transactions Act (UETA), 1999

Version Number	Posted Date	Implementation Date	Summary of Changes
2.1	03/25/2021	03/25/2021	Clarify consent material requirements; add requirement for HSD approval for use of e-

			signature for UW research reviewed by an external IRB; add DocuSign as valid tool for capturing HIPAA authorization e-signatures; add new requirements for use of 'Other' e-signature systems
2.0	10/15/2020	10/15/2020	Significant reorganization of information; add REDCap documentation of consent
1.0	8/24/2018	8/24/2018	Document newly implemented