














Electronic Signatures for Informed Consents

The Office of the Chief Information Officer and the Office of Responsible Research Practices have partnered to create general recommendations and guidelines for gathering electronic signatures on informed consents. This document serves as an informative guide to help you align methods with available solutions.

Systems for Gathering Electronic Signatures on Informed Consents

Method	REDCap	REDCap PHI	Qualtrics	DocuSign	Epic	Signet
IRB protocol does not require a Signature	 *	 *		 *	 *	
IRB protocol requires you to document consent with a Signature	 *	 *	 **	 *	 *	 *
IRB protocol requires you to document consent with a Signature <u>and</u> FDA Informed Consent Regulations						

* Capable of capturing Witness eSignature

** Must be configured to require OSU SSO authentication or native password capabilities.



= Optimal Solution



= Capable Solution



Definitions

Electronic Signature

An electronic process, symbol, or sound attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. Electronic signatures must meet the following requirements as defined by the eSignature Guide to Implementation:

- Authenticity – The person signing is who they say they are.
- Nonrepudiation – The signer must take an affirmative action of some kind to sign it. The signer cannot make a legitimate or supportable claim they did not sign it.
- Integrity – It is possible to tell if a completed electronic signature has been falsified or tampered with.
- Recipient Copy (ORC §1306.07) – Electronic records being capable of retention by recipient at time of receipt.
- Recipient Opt Out (ORC §1306.04 and ORC §1306.16 – In some cases, it is possible to opt out of signing electronically for a particular transaction.

<p>REDCap</p> <ul style="list-style-type: none"> • Designed for researchers • Consent form builder • Witness capabilities • Collaboration support • Protocol amendment support • Longitudinal study support <p>Contact: Heather Lansky – CCTS- Informatics@osumc.edu</p>	<p>REDCap PHI</p> <ul style="list-style-type: none"> • All the features of REDCap • Readily available with Med-Center credentials • Can be a university option via Med-Center request. • Med-Center firewall protected <p>Contact: Heather Lansky – CCTS- Informatics@osumc.edu</p>	<p>DocuSign</p> <ul style="list-style-type: none"> • Strongest for eSignatures • Strong workflow and approval capabilities • University-wide service offering • Integrated with university-wide enterprise document management system for document storage <p>Contact: Wyatt Wortkoetter – OCIO – eSignature@osu.edu</p>
<p>Qualtrics</p> <ul style="list-style-type: none"> • Survey based tool • Easy and fast setup • Available to all OSU users • Strong reporting capabilities • Note: A specialized version exists with Tim Huerta integrated with EPIC MyChart Bedside <p>Contact: Liana Crisan-Vandeborne – crisan- vandeborne.1@osu.edu</p>	<p>Epic</p> <ul style="list-style-type: none"> • Patient Management Tool <p>Contact: Troy Haines – Troy.Haines@osumc.edu</p>	<p>Signet</p> <ul style="list-style-type: none"> • Uses university lastname.# login for investigators • Access controlled by Buck-IRB team member responsibilities • Built in templates for informed consent and HIPAA authorization • Easy-to-use visual form builder • Flexible signature options • Archival storage included <p>Contact: Office of Research – econsentforresearch@osu.edu</p>

