



SOP: Electronic Signatures for Documentation of Consent				
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1 PURPOSE

- 1.1 This procedure outlines process for using electronic signatures to document consent.
- 1.2 The process begins after the consent information is provided to the potential subject or the subject's legally authorized representative (LAR).
- 1.3 The process ends when the consent process is documented in an electronic format to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDING PRINCIPLES

- 3.1 Investigators must obtain IRB approval of a plan to document consent in an electronic format.
- 3.2 The potential subject or the subject's LAR must have the option to use paper-based or electronic informed consent methods completely or partially throughout the information consent process.
- 3.3 An "electronic signature" means 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.
 - 3.3.1 For clinical investigations regulated by the FDA, the electronic signature must comply with 21 CFR Part 11.
- 3.4 A valid electronic signature for consent and HIPAA authorization could be the subject's typed name or it could even be as simple as a check mark or an X or any other symbol in a box on a form. Any method is valid provided that the mark or symbol is "logically associated" with the individual making that mark or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. To associate the individual to the mark, the subject/LAR could:
 - 3.4.1 Type their name
 - 3.4.2 Type a unique ID number provided via phone or email; or
 - 3.4.3 Type an answer to a "secret question," that the subject previously provided to the study team.
- 3.5 To satisfy the regulatory requirements for written consent and written HIPAA authorization, the following criteria must be incorporated into the electronic form:
 - 3.5.1 A valid electronic signature must be obtained;
 - 3.5.1.1 Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
 - 3.5.2 The electronic signature must be linked to the record to which it pertains to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.
 - 3.5.3 The meaning of the signature (such as review, approval, responsibility or authorship).
 - 3.5.4 The subject must receive a printed or emailed copy of the signed document; and
 - 3.5.5 The electronic document (consent or authorization) must reside in a system with timestamped audit trail indicating dates, times, location and the chain of custody.

4 RESPONSIBILITIES

- 4.1 Investigators and research staff members develop the e-signature process and obtain IRB approval.
- 4.2 The IRB reviews the entire consent process and determines whether the process is adequate for obtaining and documenting informed consent and authorization.

5 PROCEDURE

Investigator Responsibilities

- 5.1 Investigators should discuss with HSRO staff their plan for using an electronic consent (eConsent) process with electronic signatures before finalizing development of the eConsent form.
- 5.2 Investigators must adhere to the requirements of SOP: Informed Consent Process for Research (HRP-90) and SOP: Written Documentation of Informed Consent (HRP-91).



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- 5.3 The investigator must submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eConsent process.
- 5.4 The investigator must also submit paper consent documents for subjects who prefer signing a paper document with wet ink.
- 5.5 Any eConsent document should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful.
- 5.6 The eConsent should also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.
- 5.7 If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR.
- 5.8 The investigator should have methods in place to ensure that the eConsent process allows subjects the opportunity to consider whether or not to participate and to ask questions. This may be accomplished by in-person discussions with study personnel or through a combination of electronic messaging, telephone calls, video conferencing, or a live chat with a remotely located investigator or study personnel
- 5.9 The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy.

IRB Responsibilities

- 5.10 The IRB must ensure that the consent process is appropriate for the risk level of the proposed research. In some cases the IRB may decide that informed consent must be obtained face-to-face, which may preclude the use of an eConsent.

6 MATERIALS

- 6.1 TEMPLATE: Consent Template (HRP-502) (various versions)
- 6.2 HIPAA Authorization Form B

7 REFERENCES

- 7.1 45 CFR §46.116 and 117
- 7.2 21 CFR §50.25 and 27
- 7.3 21 CFR Part 11
- 7.4 FDA Guidance, Use of Electronic Informed Consent, 2016
- 7.5 Title XXXIX, Chapter 668, Florida Statutes
- 7.6 Federal Electronic Signatures in Global and National Commerce Act (ESIGN Act)
- 7.7 Uniform Electronic Transactions Act (UETA)