ATRIUM HEALTH
OFFICE OF CLINICAL AND TRANSLATIONAL RESEARCH
STANDARD OPERATING PROCEDURE

Procedure No.:	M-105	Title:	Using Electronic Signatures to Document Informed Consent
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Last Revised:		Page:	1 of 5
Description:	Electronic Informed Consent	Version:	001

SUBJECT: Procedure outlines the process for using electronic signatures to document informed consent. This SOP should be used in conjunction with OCTR SOP M-100 Informed Consent Development and Implementation.

POLICY: Atrium Health recognizes electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures. For clinical investigations regulated by the FDA, the electronic signature must comply with 21 CFR Part 11.

A signature on an agreement between two or more parties is just as valid in electronic form as if it were written on paper. A party has the right to refuse to provide an electronic signature; however, electronic signatures are legal in every U.S. state and territory where federal law applies.

APPLICABLE REGULATIONS, GUIDELINES, POLICIES AND SOPs:

21 CFR part 11	Electronic records; electronic signatures
21 CFR 11.100	Electronic signatures
21 CFR 50.25	Elements of informed consent
21 CFR 50.27	Documentation of informed consent
45 CFR 46.116	General requirements for informed consent
	FDA Internal Compliance Program Guidance Manual, 1994; 7348.811: Clinical Investigators
45 CFR 46.117	Documentation of Informed Consent
FDA Guidance	Use of Electronic Informed Consent, 2016
Federal Electronic Signatures in Global and National Commerce Act (ESIGN Act)	
NC Gen Statue Chapter 66 Article 40 Uniform Electronic Transactions Act (UETA)	
2010 Georgia Code Title 10 – Commerce and Trade Chapter 12 – Electronic Transactions	
	§ 10-12-7 - Legal effect of electronic records or signatures
South Carolina Code of Laws - Title 26 - Notaries Public and Acknowledgements, Chapter 6	
	Uniform Electronic Transactions Act
OHRP Guidance	Use of Electronic Informed Consent
May 9, 1997	International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline
OCTR SOP M-100	Informed Consent Development and Implementation
Atrium Health IRB	Policy and Procedure Manual
Advarra IRB	Handbook for Investigators, Sponsors, and Sponsors' Representatives
Atrium Health ADM 240.00	Research Policy Statement
Atrium Health ADM 240.02	Integrity of Research
Atrium Health ADM 240.03	Research Consent Forms
Atrium Health ADM 240.18	HIPAA Research Policy

Health Insurance Portability and Accountability ACT (HIPAA) Policies:
Atrium Health PR PHI 140.05 Release/Review of Medical Information
Atrium Health PR PHI 140.02 De-Identification - Removal of Patient Identifiers
Atrium Health PR PHI 140.05 Minimum Necessary Requirement
Atrium Health PR PHI 140.08 Accounting for Disclosures
Atrium Health PR 120.06 Consent for Treatment

DEFINITIONS:

The following definitions apply to this SOP.

Electronic Consent (eConsent) is a method for conducting and recording consent for remote participants, or for participants in clinic on tablets or other touchscreen devices. Participants will be able to sign the consent form electronically with a stylus, mouse, or finger and submit it to the study team. Research electronic consent processes must be in compliance with **21 CFR part 11 Electronic records; electronic signatures**

Electronic Signature (eSignature) An e-signature is a digital version of a traditional pen and ink signature. In the United States, an e-signature provides the same legal commitment as a handwritten signature if it meets these four criteria:

- Intent to sign - the signatory intends to verify his or her identity.
- Consent to do business electronically - the signatory has agreed to do business electronically.
- Association of signature with the record - the system used to capture the e-signature can verify the process by which the signature was created.
- Record retention - the e-signature is stored for the required amount of time so it can be referenced by all interested parties.

Research electronic signature processes must be in compliance with **21 CFR part 11 Electronic records; electronic signatures**

Informed Consent is a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Institutional Review Board (IRB) is an independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Legally Authorized Representative is an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

Virtual Consent may be accomplished through remote interactions between participants and/or LARs with investigators or study personnel through a combination of electronic messaging, telephone calls, video conferencing (i.e. Amwell, Doxy.me, Microsoft Teams), or a live chat with a remotely located investigator or study personnel.

PROCEDURE:

A. General Requirements for Documenting Electronic Informed Consent for Research

Electronic Informed Consent for any research study must adhere to the following requirements.

1. Investigators must obtain IRB approval of a plan to document consent in an electronic format.
2. The potential subject or the subject's LAR must have the option to use paper-based or electronic informed consent methods throughout the information consent process.
3. For clinical investigations regulated by the FDA, the electronic signature must comply with 21 CFR Part 11.
4. An electronic signature for consent and HIPAA authorization is valid provided that the mark or symbol is "logically associated" with the individual making that mark, or is 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:
    a. Digitally write or draw their signature;
    b. Type their name;
    c. Insert a check mark, an X, or any other symbol in an appropriately identified signatory field on a form;
    d. Type a unique ID number provided via phone or email; or
    e. Type an answer to a "secret question," that the subject previously provided to the study team.
5. To satisfy the regulatory requirements for written consent and written HIPAA authorization, the following criteria must be incorporated into the electronic form:
    a. A valid electronic signature must be obtained, in accordance with item A(4) of this SOP.
    b. Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
    c. 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.
    d. The following information should be clearly indicated on the record:
        i. The printed name of the signer;
        ii. The date and time when the signature was executed; and
        iii. The meaning of the signature (such as review, approval, responsibility or authorship) associated with the signature.
6. The subject must receive a printed or emailed copy of the signed document; and
7. The electronic document (consent and/or authorization) must reside in a system with timestamped audit trail indicating dates, times, location and the chain of custody.

B. Additional Requirements for Clinical Investigations Regulated by the FDA

eConsent is available for Atrium Health researchers via REDCap. REDCap has the technical features necessary to serve as the database component of a 21 CFR Part 11 compliant study. However, a project in REDCap must have policies, procedures, training, validation and documentation meeting the requirements of Part 11 and the predicate rules for the underlying legislation. An FDA auditor will review all project documentation to determine **AT THE PROJECT LEVEL** if a study is compliant.

C. Investigator Responsibilities

Atrium Health investigators must adhere to the following requirements.

1. Investigators should discuss with their plan for using an electronic consent (eConsent) process with electronic signatures with their clinical research site staff, before finalizing development of the eConsent form.
2. Investigators must obtain permission from the sponsor (if applicable) for using an electronic consent process with electronic signatures.
3. Investigators and research staff members must develop and thoroughly test the electronic consent and signature process.
    a. REDCap is the preferred system for obtaining eConsent at Atrium Health.
    b. Investigators must adhere to the Atrium requirements of SOP M-100 Informed Consent Development and Implementation and P-101 Interactions with the Institutional Review Board.
    c. The REDCap team can assist with process development if needed and will audit the REDCap form for compliance with 21 CFR Part 11.
4. Investigators must secure IRB approval prior to implementation of eConsent.
    a. 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/LAR will receive and view during the eConsent process.
        i. For studies that are already IRB approved and want to add the eConsent option, the investigator must complete a Miscellaneous Form and submit to the IRB with appropriate documentation as stated in 4.a. above.
    b. The investigator must also submit paper consent documents for subjects/LARs who prefer signing a paper document with wet ink or for situations when electronic access is unavailable.
    c. The IRB reviews the entire consent process and determines whether the process is adequate for obtaining and documenting informed consent and authorization.
    d. The IRB must ensure that the consent process is appropriate for the risk level of the proposed research.
    e. In some cases the IRB may decide that informed consent must be obtained face-to-face (i.e. – in-person, virtual, or via telephone), which may preclude the use of an eConsent.
    f. Investigators must comply with IRB requests for modifications to the electronic consent process.
    g. The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy.
5. Any user(s) who are caught violating the use of REDCap and the intended use of an approved REDCap project can have the project restricted from use, and their REDCap account access immediately suspended or terminated. Unauthorized use of REDCap for eConsent will be reported to the IRB of record, OCTR, and the Atrium Research Compliance officer.

D. Documentation of Electronic Signature Consent

1. The 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.

2. The eConsent should also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.
3. 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.
4. 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. The investigator should ensure that the subject/LAR receives a copy of the signed consent in their preferred format, whether it be paper or electronic.

APPROVALS

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