Status **Active** PolicyStat ID **15961091**

Origination	07/2023	Owner	Kellcee Johnson: 4580 Manager - Research and Sponsored Studies
Last Approved	07/2024		
Effective	07/2024		
Next Review	07/2025	Department	HRPP/Research

Research: eSignature- AD.0207

PURPOSE

The purpose of this policy is to provide guidelines for the use of electronic signatures for research documentation. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

1. Federal regulations require documentation of all study-related activities. Investigators are responsible for maintaining study documents in accordance with applicable federal regulations, HIPAA, and International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. At all times, study documents must be readily accessible for review and/or inspection by the regulatory agency (i.e., FDA, DHHS, CDC), approving Institutional Review Board (IRB), and/or organizational personnel as appropriate.
2. This policy describes the information necessary to use electronic signatures for research documentation, and establishes the process by which roles and responsibilities are delegated to applicable personnel. This policy outlines the Lakeland Regional Health (LRH) Research and Sponsored Studies' approach for adopting electronic signature technology and best practices to ensure electronic signatures are in accordance with applicable federal regulations.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce**.

POLICY

1. This policy applies to all electronic records for the clinical research studies and trials where electronic signatures may be utilized by LRH. When using electronic signatures for FDA regulated research, electronic signatures must meet certain criteria to ensure compliance (21 CFR Part 11).
2. There are two (2) software solutions for electronic signatures that may be used at LRH for

research purposes: DocuSign and Florence. Both software products are 21 CFR Part 11 compliant. When obtaining official signatures for research, electronic signatures can only be used via DocuSign and/or Florence.

3. This policy applies to personnel engaged in the collection, creation, retrieval, modification, maintenance, transmittal and/or storage of research documents from the planning and study startup stage through study completion/archival, where electronic signatures may be needed. This policy retroactively applies to legacy studies.
    - Legacy studies are defined as studies where the Clinical Trial Agreement (CTA) was signed previously to the original date of publication of this policy. Legacy research documents which previously contain electronic signatures will be identified and examined by the Manager or Director of Research and Sponsored Studies, or designee, to ensure appropriate compliance with electronic signature requirements for research.
4. This policy excludes any related research documents where electronic signature is expressly not permitted in LRH practices or CTA. Electronic signatures may not be used when an applicable CTA, regulation, or organization policy or process specifically requires a handwritten (or "wet") signature.

PROCEDURE

1. All LRH personnel that may electronically sign research documents via DocuSign or Florence must demonstrate appropriate education and training on either system to authorize access to electronically sign research documents.
    - The AVP of Research and Sponsored Studies, or designee, is responsible for ensuring training on DocuSign and/or Florence prior to granting access to the system for electronic signatures for research documents.
2. Upon confirmation of the above, the AVP of Research and Sponsored Studies, or designee, will coordinate with Information Service Department's designee to provide individual User access to Florence and/or DocuSign. The AVP of Research and Sponsored Studies, or designee, is responsible for the creation of new User accounts within the Florence and/or DocuSign systems.
    - Upon a change in employment status for a User that discontinues the need for specific access to DocuSign and/or Florence, the Information Service Department's designee is responsible for removing all permissions for the user. The AVP of Research and Sponsored Studies, or designee, is responsible for removing user access within the Florence and/or DocuSign systems to ensure controlled access to confidential research documentations outside of user scope.
3. The Manager or Director in the Department of Research and Sponsored Studies, or designee, is responsible for reviewing quarterly, all roles and permissions to ensure that all documented users are authorized to use DocuSign and/or Florence.
4. All users utilizing electronic signatures shall ensure the following:
    a. Credentials are unique, secure, and remain confidential (i.e., not reused by, not reassigned to, and not shared with other individuals).

b. The user profile in DocuSign and/or Florence is complete to assure the signature manifestation includes all components required per applicable governing regulatory bodies.

c. Signatures are performed only by the authenticated user.

5. Electronic signatures may be used for all research related documents except original wet-ink signed contracts, and research documents which clearly state that electronic signatures may not be used, which is on an individual CTA basis.
6. Signatures only apply to the version of the document signed. Any updates to a version of the document do not carry over signatures from the previous version. Any updates which require review, acknowledgment, and/or approval must be signed by the appropriate users.
7. Signing Documents:
    a. The individual signing the document reviews the document and the requested reason for their signature in DocuSign and/or Florence.
        - Notifications for electronic signatures are generated via the email associated with the profile in DocuSign/Florence, and also can be accessed directly by logging into each system.

    b. If s/he agrees, the username (authorized organization email address) and password (or signing PIN) are entered, and the system confirms that they match the user's verified secure credentials.

    c. Recording, filing, and retention for electronically signed documents are the responsibility of the Manager and/or Director of Research and Sponsored Studies.

    d. There may be instances where a study contains wet-ink handwriting and signatures. If so, on an individual study basis, an access control log and signature log are to be kept by the Manager and/or Director of Research and Sponsored Studies, or designee. The purpose of access control and signature logs are to have a record of the handwriting sample of every individual involved in study-related activity, but also as a supplemental measure to assure that electronic signatures are compliant with 21 CFR Part 11.

DEFINITIONS

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

1. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry (here)
2. FDA Compliance Policy Guidance Programs (here)
3. US FDA 21 CFR Part 11 Electronic Records; Electronic Signatures (here)
    a. General Principles of Software Validation; Final Guidance for Industry and FDA Staff (here)
    b. Part 11, Electronic Records; Electronic Signatures – Scope and Application (here)

c. Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions & Answers (here)

4. 21 CFR §312.62(c) – Investigational New Drugs – Drugs for Human Use (here)
5. 21 CFR Part 812 – Investigational Device Exemption (here)
6. US FDA Industry Guidelines and Information Sheets (here)

Approval Signatures

Step Description	Approver	Date
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