

**IRB Policy and Procedure**

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|  | **Wayne State University** **Institutional Review Board**  |
| **Subject**  | 04-20 Electronic Signatures on IRB Records Compliance with 21 CFR Part 11 for FDA regulated research |
| **Form Date**  | 12/2024  |
| **Approvals**  |  IRB Approval 3/2025 |

**This policy applies only to FDA regulated research**

**Background:** To ensure compliance with 21 CFR Part 11 for the use of electronic signatures in clinical investigations, all document signatures required by investigators and IRB personnel that cannot be captured within the eProtocol electronic submission system must be documented using Adobe Sign whenever 21 CFR Part 11 compliance is required. For studies that are not in the eProtocol electronic submission system, paper submissions, which previously required the original ink signature, are no longer accepted. Investigators with studies that are not in the eProtocol electronic submission systemare currently required to provide an electronic signature on these IRB submission documents. IRB Personnel completing reviewer checklists must provide an electronic signature on all applicable reviewer forms.

**Purpose:** This policy ensures compliance with 21 CFR Part 11 for the use of electronic signatures on IRB the Human Research Protection Programs (Sponsored Program Administration, Office of Environmental Health and Safety, etc) records using Adobe Sign. It defines the standards and controls necessary to maintain the integrity, security, and reliability of electronic records and signatures.

**Scope:** This policy applies to all personnel who create, maintain, and sign IRB records for studies that are not in the eProtocol using Adobe Sign, including investigators who provide an electronic signature on IRB submission forms and IRB personnel who provide an electronic signature on reviewer checklists.

**Policy Statement:** Wayne State is committed to maintaining compliance with 21 CFR Part 11 by implementing the following measures when using Adobe Sign:

**1. System Validation**

* Adobe Sign has been validated at Wayne State for its intended use. Documentation verifying system validation will be maintained and reviewed periodically to ensure ongoing compliance.

**2. User Access Controls**

* Access to Adobe Sign is restricted to authorized Wayne State personnel only.
* Users have unique Wayne State network credentials that require multi factor authentication (e.g., access ID & password See WSU Access ID policy <https://tech.wayne.edu/policies/accessid-mail-directory>).
* Access permissions will be reviewed periodically (no less frequently than every 2 years) to ensure only current, authorized Wayne State users have access.

**3. Electronic Signature Requirements**

* Electronic signatures will consist of a unique user ID and password combination.
* Electronic signatures must include the printed name of the signer, the date and time of signature, and the reason for signing (e.g., approval, verification).
* When an electronic signature cannot be placed in a specified signature block, a “wet” (handwritten) signature will be executed in its place.

**4. Audit Trails**

* Adobe Sign is configured to generate computer-generated, time-stamped audit trails that record the date, time, and action taken for each IRB record.
* These audit trails will be securely maintained and will be accessible only to authorized personnel.

**5. Record Retention and Retrieval**

* **Adobe is not meant for long-term document storage.** IRB documents signed by Investigators or study team members through Adobe Sign must be downloaded and saved in the Investigator’s research file for appropriate record-keeping. IRB documents signed by IRB personnel through Adobe Sign must be downloaded and saved in the IRB file for appropriate record-keeping.
* Electronic IRB records and associated audit trails will be retained in accordance with IRB policy 4-15 IRB Document Retention for Research Protocols, IRB Policy 4-8 Closure of a Research Protocol and WSU Signature policies that govern contracts signed by the Sponsored Program Administration Office (https://policies.wayne.edu/administrative/04-06-Contract-Signatories-6th-release) and WSU Document Retention policies and applicable regulations.
* Records will be protected to prevent unauthorized access or alteration and will be retrievable in human-readable format upon request.

**6. Training and Accountability**

* All personnel using Adobe Sign for electronic signatures will receive training materials on the requirements of 21 CFR Part 11, this policy, and their responsibilities. Users will attest to having received and reviewed the training materials.
* Users will be held accountable for all actions initiated under their electronic signatures and must immediately report any security breaches.

**7. Certification to the FDA**

* Wayne State has submitted a one-time certification (aka letter of non-repudiation) to the FDA that electronic signatures are intended to be the legally binding equivalent of handwritten signatures. This certification will be updated as required by regulatory changes.

**8. Periodic Review and Updates**

* This policy will be routinely reviewed and updated per the WSU IRB policy 5-3 Policy and Procedure Development and Approval and as needed to reflect changes in technology, regulations, or internal processes.

**Responsibilities**

* The Wayne State University Computing & Information Technology (C&IT) in conjunction with designated Human Research Protection Program (HRPP) staff identified by the HRPP Director will conduct system validation. Wayne State C&IT will maintain system access controls.
* When applicable; researchers and IRB personnel must adhere to this policy and report any issues related to electronic signatures or records promptly.