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OFFICE OF RESEARCH

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eCompliance System

21 CFR Part 11 Compliance, Approval Signatures and Approval Stamps

Background

21 CFR Part 11 establishes the requirements for electronic records. It also sets standards for making electronic signatures trustworthy, reliable and functionally the equivalent of paper records and handwritten signatures.

Requirements and Compliance

21 CFR Part 11 requires assurances in the following areas for systems that maintain electronic information such as the eIRB system:

1. Record archiving (audit trail)
2. Security controls
3. Electronic signatures

The University of Missouri's eIRB system meets the regulatory requirements in each of these areas.

Audit Trail

Record archiving is supported by the comprehensive logging of every action taken within the eIRB system. Logs record each action, the identity of the individual performing the action and the action's date and time.

Security Controls

The eIRB system addresses the security requirements by including:

1. Identification controls: Every user must have a registered account with a unique name and password and a specified level of authority.
2. Authorized individuals: Only users with a registered account can perform actions within the system. Privileges vary depending on the level of authority assigned to the user.



3. Written policies: The University of Missouri's Acceptable Use Policy (Collected Rules & Regulations, 110.005) requires users to protect their user ID, password and systems from unauthorized use.

4. Controls for a closed system: The eIRB is a closed system (per the definition in 21 CFR Part 11.3.b.4.) The University of Missouri maintains all of the information associated with research proposals and reviews which are governed by University policies and procedures for data security.

Electronic Signatures

The electronic signature in the eIRB system differs from more elaborate digital signatures, however, technical and procedural controls ensure that it is fully compliant with 21 CFR Part 11.

The University of Missouri's Institutional Review Board does not manually sign approval memos generated in the eIRB because the electronic signature is deemed equivalent to the handwritten signature. Federal regulations do not specify how IRBs must sign approval letters, only that the IRB must outline its process. The University's IRB procedures do not require signature of approval letters by the Chair or designee. In addition, the University's IRB does not stamp approval letters or approved documents. These documents are generated electronically and all approved documents are clearly identified and locked in the eIRB system. Approval letters and documents include all relevant dates in headers or in the body of the text.



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