1. PURPOSE

1.1. 21 CFR Part 11 has been in effect since August 1997 and establishes the requirements for electronic records and electronic signatures to be trustworthy, reliable, and essentially equivalent to paper records and handwritten signatures.

1.2. The HIPAA privacy rule at 45 CFR 164.530(j)(1) allows that all required documentation or signatures may be maintained in electronic form.

1.3. Additionally, federal regulations do not specify the procedure that IRBs must use regarding signatures of IRB approval letters, only that the IRB must designate and follow procedures for communicating decisions of the IRB. There is no regulatory requirement for a stamp on approval letters or approved documents.

2. POLICY

2.1. OSU CHS uses the IRBManager system to receive IRB submissions and track all IRB review actions. Because the IRBManager system maintains information electronically, 21 CFR Part 11 requires assurances in three basic areas: Record Archiving (Audit Trail), Electronic Signatures, and Security Controls. OSUCHS's IRBManager system meets regulatory requirements in each of these areas. Record archiving is facilitated by the comprehensive logging of every action taken within the IRBManager system. Within these logs is a record of each action, the identity of the individual performing the action, and the date and time the action occurred.

2.2. The IRBManager system addresses the requirements for electronic signatures and security controls by including:

2.2.1. Controls for identification: Every IRBManager user must have a registered account with a unique user name and password and a specified level of system authority

2.2.2. System access is limited to authorized individuals: Action in the IRBManager system is only allowed by users with a registered account and system privileges vary depending on assigned authority. All users are trained to ensure they have the education, training and experience to perform their assigned tasks.

2.2.3. Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures: OSU CHS prohibits the sharing of passwords for the IRBManager system. All IRBManager users are required to sign a statement indicating they are aware any user ID and password used to enter data into the IRBManager system is considered to be the equivalent of an electronic signature, that this signature carries the same authority as a handwritten signature, that under no circumstances should any other user enter data under another user's ID and password, and that knowingly permitting this to occur is considered noncompliance with this policy. Upon notification of any non-permitted actions, OSU CHS will immediately disable the user's access to the IRBManager system.

2.2.4. Controls for a closed system: IRBManager is an open system. In compliance with 21 CFR 11.30, OSU CHS maintains SOPs that describe procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. IRBManager is an open system that has appropriate system controls in place to address the requirements for a closed system enumerated in 21 CFR 11.

2.3. The electronic signature in the IRBManager system is distinct from more elaborate digital signatures which replicate handwritten signatures. However, the technical and procedural controls in place make the IRBManager electronic signature fully compliant with 21CFR Part 11.

3. REFERENCES

3.1. IRBManager and 21 CFR 11 Compliance

3.2. 21 CFR Part 11: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

3.3. §46.103(b)(4) and the terms of the FWA require only procedures for reporting its findings and actions to the investigator and the institution. No stamp or signature is required.

3.4. 45 CFR 164.530(j)(1) Standard: documentation. A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.