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Compliance Statement

eIRB Approval Signatures
and Stamps (21 CFR 11 Compliance)

Background

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. The driving force in its creation was to prevent fraud while permitting the widest possible use of electronic technology to reduce costs incurred from paper processes. Because the eIRB system maintains information electronically, 21 CFR Part 11 requires assurances in three basic areas: Record Archiving (Audit Trail), Electronic Signatures, and Security Controls.

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

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.

Scope

This compliance statement addresses electronic signatures and stamps on IRB documents and management of documents in the eIRB system.

Compliance with Regulatory Requirements

1. Compliance with record archiving requirements is met by the comprehensive logging of every action taken within the eIRB system. Within these logs is a record of:
   a. Each action,
   b. The identity of the individual performing the action, and
   c. The date and time the action occurred.

2. OHSU's eIRB system meets regulatory requirements for Electronic Signatures and Security Controls by including:
   a. **Controls for identification:** every eIRB user must have a registered account with a unique name and password and a specified level of system authority.

b. **System access is limited to authorized individuals:** action in the eIRB is only allowed by users with a registered account and system privileges vary depending on assigned authority.
c. **Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures:** OHSU has written policies and procedures that prohibit the sharing of passwords.
d. **Controls for a closed system:** eIRB is a closed system meaning all of the information associated with research proposals and reviews is maintained entirely by OHSU and is governed by OHSU policies and procedures for data security.

3. The OHSU Institutional Review Board (IRB) Chair does not manually sign approval memos generated in the eIRB or HIPAA documents that require signatures because the electronic signature is deemed equivalent to the handwritten signature.
   a. OHSU HRPP policies and procedures do not require signature of approval letters by the Chair.
   b. The electronic signature in the eIRB system is distinct from more elaborate digital signatures which replicate handwritten signatures. However, the technical and procedural controls in place make the eIRB electronic signature fully compliant with 21CFR Part 11.
   c. HIPAA documents requiring signature are electronically signed via execution of the "approve" or "determination" functions in the eIRB.

4. The OHSU IRB does not stamp approval letters and OHSU HRPP policies and procedures do not require stamping of approval letters or approved documents. Consent forms and advertisements are the only documents that receive an electronic stamp.

5. Approval letters and approved 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.

Related Issues

1. Sponsor is requesting a Signature or Stamp
   a. The research team should provide a copy of this compliance statement to the sponsor, informing them that our electronic process meets all FDA signatory requirements.
   b. If the sponsor still insists, refer the sponsor to the IRB Chair, Manager or Assistant Research Integrity Officer for resolution.

2. Missing Electronic Stamp
   a. The research team should contact ORIO via the main telephone line 503-494-7887, option 1, or by e-mail at irb@ohsu.edu and inform the Board Operations Support person of the error.
   b. The BOS will correct the error and upload the finalized documents.

3. Approval Dates
   a. For full board studies, the protocol approval date listed on the IRB memo reflects the date of the IRB meeting. The effective approval date of the other study documents reflects the date the IRB Chair determined that the board required changes (if applicable) were

incorporated into the study documents. The protocol expiration date will never be more than 1 year after the IRB meeting.

b. For expedited studies, the approval date is the date that the Designated Reviewer determined that the study protocol and associated documents could be approved.

2. Listing Approved Documents in Approval Memo

a. The IRB includes a list of approved study documents in the memo for industry sponsored studies only, unless otherwise requested by the study team.

b. The names of documents are sometimes changed when they are uploaded in the eIRB so they are shorter or can be more easily categorized. If you require a specific naming convention, please alert your IRB Analyst.

3. Availability of Approved Study Documents

a. After final approval, the IRB staff electronically stamp and upload the final approved documents into the Study Documents bin in the eIRB. It can take a few days for the documents to be available to the study team while this process takes place.

b. The date of document availability in the eIRB system is the date associated with the activity of "Post-Processing Complete."

Authority and Guidance

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

§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.

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.