

## **OHSU's eIRB System: 21 CFR Part 11 Compliance, Approval Signatures, and Approval Stamps**

### **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.

### **Requirements for Compliance**

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. OHSU's eIRB system meets regulatory requirements in each of these areas. Record archiving is facilitated by the comprehensive logging of every action taken within the eIRB 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.

The eIRB system addresses the requirements for electronic signatures and security controls by including:

- **Controls for identification:** every eIRB user must have a registered account with a unique name and password and a specified level of system authority.
- **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.
- **Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures:** OHSU has written SOP's which prohibit the sharing of passwords.
- **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.

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.

The OHSU Institutional Review Board (IRB) Chair 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 the procedure that IRBs must use regarding signatures of IRB approval letters, only that the IRB must outline the procedure followed. OHSU's IRB Policy Manual does not require signature of approval letters by the Chair.

In addition, there is no regulatory requirement for a stamp on approval letters or approved documents. The OHSU IRB does not stamp approval letters or approved documents and OHSU's IRB Policy Manual does not indicate that stamping of approval letters or approved documents is required. 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.