

University of Utah Institutional Review Board 21 CFR Part 11 Compliance

Background

Since August 1997, 21 CFR Part 11 has established the requirements for electronic records. It also determined standards to make electronic signatures trustworthy, reliable, and essentially equivalent to paper records and handwritten signatures. It was created primarily to prevent fraud while permitting the widest possible use of electronic technology to reduce costs of paper processes.

Requirements for Compliance

Because the IRB system maintains information electronically, 21 CFR Part 11 requires assurances in three areas: Record Archiving (Audit Trail), Electronic Signatures, and Security Controls. The University of Utah's IRB system meets the regulatory requirements in each of these areas.

Audit Trail: Record archiving is facilitated by the comprehensive logging of every action taken within the IRB system. These logs record each action, the identity of the individual performing the action, and the action's date and time.

Security Controls: The IRB system addresses the security requirements by including:

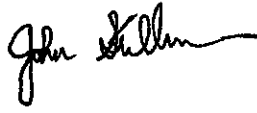
- **Controls for identification:** every IRB user must have a registered account with a unique name and password and a specified level of system authority.
- **System access is limited to authorized individuals:** only users with a registered account can perform IRB actions and system privileges vary depending on assigned authority.
- **Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures:** University of Utah has written SOP's that prohibit sharing passwords.
- **Controls for a closed system*:** IRB is a closed system. University of Utah maintains all of the information associated with research proposals and reviews and this information is governed by University of Utah policies and procedures for data security.

Electronic Signatures: University of Utah Institutional Review Board (IRB) Chairs do not manually sign approval memos generated in the IRB. Federal regulations do not specify how IRBs must sign approval letters, only that the IRB must outline its procedure. The University of Utah IRB procedures do not require signature of approval letters from the Chair. These documents are generated electronically and all approved documents are clearly identified and locked in the IRB system. Approval letters and documents include all relevant dates in headers or in the body of the text.

* *Closed system* means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system. CFR 21 Part 11.3.b.4

Memorandum

To: To Whom It May Concern

From: John Stillman
Director
University of Utah IRB 

Date: July 5, 2006

Subject: Electronic Research Integrity and Compliance Administration (ERICA) System
Electronic Signature Policy

The University of Utah Electronic Research Integrity and Compliance Administration (ERICA) system authenticates all users according to their role within the Institution and Human Research Protection Program (HRPP). In order to log-in, users must authenticate via a Lightweight Directory Access Protocol (LDAP) Server by providing a user ID# (UNID) and password. The IRB Chair, Co-Chair, and Vice Chair are the only user roles authorized to approve minimal, moderate, and high risk research.

The IRB defines an electronic signature as "a process/action that is logically associated with a record and executed by an authorized person with the intent to sign the record." IRB approval notices are digitally signed because the Chair/Co-Chair/Vice Chair who grants approval has been authenticated as part of the log-in process and understands that his/her submission process following review is done with the 'intent to sign the record'. While the documents may not display a visible mark, we can validate that any document has been properly submitted, reviewed and approved. If you have any questions, please contact our office and we will be glad to assist you.