**INSTITUTIONAL REVIEW BOARD**

THE UNIVERSITY OF UTAH

# MEMO

**TO:**        To Whom It May Concern

**FROM:**    Ann Johnson, PhD, MPH
             Director
             Institutional Review Board
             University of Utah

**DATE:**     January 23, 2018

**SUBJECT:**  ERICA System Electronic Signature Policy

Since August 2005, the University of Utah has used the Electronic Research Integrity and Compliance Administration (ERICA) system within the Human Research Protection Program.  The ERICA system authenticates all users according to their role within the institution. In order to log in, users must authenticate via a Lightweight Directory Access Protocol (LDAP) server by providing a user ID and password.  The IRB Chair, Co-Chair, and Vice Chairs are the only user roles authorized to issue approval for research reviewed by the University of Utah IRB.

Electronic signature is defined 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 when the Chair/Co-Chair/Vice Chair logs in using the authenticated process and initiates the approval action with the intent to sign the record.  While the documents may not display a visible mark as a signature, we can validate that all approved documents have been properly submitted, reviewed, and approved using this process.

**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