18.0 Electronic Signatures and Electronic Records in IRBManager Software

18.1 Summary Policy

21 CFR Part 11 has been in effect since August 1997 and establishes certain requirements of the Food and Drug Administration (FDA). 21 CFR 11 covers two issues: electronic records and electronic signatures.

18.2 Electronic Records and Signatures

18.2.1 Identification controls and limiting of system access to authorized individuals

The access to the system used for electronic IRB submissions and reviews (IRBManager) will be limited to authorized users. Each IRBManager user must have a registered account with a unique name and password and a specified level of system access/authority. Only IRB staff is authorized to enable log-in of authorized users. Before access is granted, the user must sign an attestation agreeing that the individual user is accountable and responsible for actions initiated under their electronic signature, and that the user will not disclose their username and password to anyone else. Before enabling access, an IRB staff member will ensure that the attestation has been signed by the user. In addition, the IRB staff will assign the appropriate access level (IRB member, investigator, etc.) based on the user status and document that assignment on the attestation form.

18.2.2 Determination that persons who develop, maintain or use the electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks

In addition, the attestation requires a certification that a potential system user has completed training on IRBManager, either by attending an IRB provided training session or reviewing the on-line IRB training modules.

18.2.3 Establishment of written policies that hold individuals responsible and accountable for actions initiated under their electronic signatures

The HRPP Office notes that “Only the individual owner of an account is authorized to use that account. Providing passwords or in any way permitting or making it possible for anyone other than the authorized owner of the account to use computer resources is not authorized and may be a violation of Pennington Biomedical Policy 603.00.”

In addition, this policy addresses this requirement with regard to electronic signatures.

18.2.4. Electronic Signatures within IRBManager

The first sign-in to the system requires a three- part identifier, consisting of username, password and ClientID. Subsequent signings are executed by entering the password.

Each individual user is accountable and responsible for actions initiated under their electronic signature. Each user is accountable and responsible for maintaining confidentiality of their username and password and must not disclose their username and password to anyone else. Each user must contact the IRB Office and Computing Services to report any potential compromise of their password.

An audit trail of all actions, including signing, that occur within the system is maintained by IRBManager.

References: FDA 21CFR11, Guidance for Industry Part 11, Electronic Records; Electronic Signatures- Scope and Application. Issued August 2003, IRBManager and Validation, Revision: 2011-06, PBRC Policy 603.00