Pennington Biomedical Research Center IRBManager System: Request for User Access

Instructions

Please complete this form in order to request a valid user ID and password for access to Pennington Biomedical Research Center IRB's IRBManager. IRBManager is PBRC's web portal for submitting and tracking requests for IRB review.

You will receive an email notification regarding your username and password within 24-48 hours. If you do not receive a notification, please contact the IRB office 225-763-2693.

Name:
Title:
Degree(s):
Email Address:
Site Address: (not needed, if primary address is PBRC)
Site phone number:
Please check one: ☐ Principal Investigator ☐ Sponsor ☐ Sub-Investigator ☐ IRB Member/Staff ☐ Study Coordinator ☐ Other: _____
If you are an external researcher/researcher staff that is part of multi-center research study, please also complete the following. Site Name: _____ Protocol Number (if applicable): _____
☐ Check this box after reading PBRC's IRBManager policy summary (see next page) ☐ Check this box if you would like to schedule a demonstration of the system. An IRBManager instruction manual can be found at: http://www.pbrc.edu/hrpp/resources/
Compliance Statement: I am aware of PBRC's policies regarding IRBManager systems, electronic records and electronic signatures. Any user ID and password that I use to enter data into the IRBManager system is considered to be the equivalent of an electronic signature. When completing such tasks as submission applications, I realize that this signature carries the same authority as my handwritten signature. I am also aware that under no circumstances should any other user enter data under my user ID and password, and that knowingly permitting this to occur is considered non-compliance with the PBRC HRPP Policy 18.0. Upon notification of any non-permitted actions, PBRC will immediately disable your access to IRBManager.

Signature:	Date:

Send completed form to irb@pbrc.edu

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 CFR11 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 an 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, the IRB Coordinator or Director 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 (see item 4) 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 ETSU Office for the Protection of Human Subjects 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