



**BRANY's IRBManager System & BRANY's SMART System:
Request for User Access**

Instructions Complete this form to obtain a user ID & password for BRANY's IRBManager & SMART systems.

- **IRBManager:** Submit and track requests for IRB review.
- **SMART:** Submit and track study enrollment information (BRANY Classic clients only).

Check box if you are submitting this form because you changed institutions.

Name:
Title:
Degree(s):
Email address:
Site address:
Business phone number:
Mobile phone number (optional):

Please check one:

- Principal Investigator Sponsor Representative IRB Member/Staff
 Sub-Investigator CRO Representative IBC Member/Staff
 Study Coordinator Other: _____

Do you need your User Account to be associated with any studies in IRBManager?

- No**
 Yes – Provide any available study identifying information below. Include BRANY # if known.
 Study ID (or BRANY #): _____
 Study title: _____
 Principal Investigator: _____ Sponsor: _____

NOTE: Submission of this form does not mean you have requested BRANY IRB approval to participate in a study as key personnel. If you need IRB approval, log into the study details page and submit xForm #02. An IRB determination letter will be provided once you have been approved. **Association of a user account to a study in IRBManager does not equate to IRB approval.**

- ← Check this box after reading BRANY's IRBManager policy summary (next page).**
 OPTIONAL: I would like to schedule IRBManager & xForm Basics.
 OPTIONAL: I would like to schedule SMART Portal training (BRANY Classic clients only).

Send completed forms to Svetlana Abramova (sabramov@brany.com or fax: 516-706-5066).
Your account information will be sent via email within 24-48 hours.

Compliance Statement

I am aware of BRANY's policies regarding the IRBManager and SMART 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. 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 noncompliance with this policy. Upon identification of any non-permitted actions, BRANY will immediately disable my access to the IRBManager and SMART systems.

Signature _____ **Date** _____

NOTE: Supply wet ink signature only. Electronic signature is not accepted on this form.



BRANY's *IRBManager* System & 21 CFR Part 11 Compliance

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 *IRBManager* system maintains information electronically, 21 CFR Part 11 requires assurances in three basic areas: Record Archiving (Audit Trail), Electronic Signatures, and Security Controls. BRANY's *IRBManager* system meets regulatory requirements in each of these areas. Record archiving is facilitated by the comprehensive logging of every action taken within the *IRBManager* 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 *IRBManager* system addresses the requirements for electronic signatures and security controls by including:

- **Controls for identification**

Every *IRBManager* user must have a registered account with a unique user name and password and a specified level of system authority.

- **System access is limited to authorized individuals**

Action in the *IRBManager* system is only allowed by users with a registered account and system privileges vary depending on assigned authority, and completion of the Request for User Access form. All users are trained to ensure they have the education, training and experience to perform their assigned tasks.

- **Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures**

BRANY prohibits the sharing of passwords for the *IRBManager* system. All *IRBManager* users are required to sign a statement indicating they are aware any user ID and password used to enter data into the *IRBManager* system is considered to be the equivalent of an electronic signature, that this signature carries the same authority as a handwritten signature, that under no circumstances should any other user enter data under another user's ID and password, and that knowingly permitting this to occur is considered noncompliance with this policy. Upon notification of any non-permitted actions, BRANY will immediately disable the user's access to the *IRBManager* system.

- **Controls for a closed system**

IRBManager is an open system. In compliance with 21 CFR 11.30, BRANY maintains SOPs that describe procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. *IRBManager* is an open system that has appropriate system controls in place to address the requirements for a closed system enumerated in 21 CFR 11.

The electronic signature in the *IRBManager* system is distinct from more elaborate digital signatures which replicate handwritten signatures. However, the technical and procedural controls in place make the *IRBManager* electronic signature fully compliant with 21CFR Part 11.