



## IRBManager and SMART System – Request for User Access

Complete to obtain a user login for BRANY’s IRBManager & SMART systems.

Check this box if this submission is for an existing user that has changed institutions.

Name:

Your position or title:

Highest earned degree(s):

Your Organization/Institution email address:

Check here if personal email has been provided because no organization/institution email address exists.

If applicable, CITI Program email address:

If different than the email provided above, provide the email address associated with your CITI Program user account.

Organization/Institution name:

Address: Street:

City, State, ZIP Code:

Business phone number:

Check to make primary

Mobile phone number (optional):

Check to make primary

Your role - check one:

- Principal Investigator
- Co- or Sub-Investigator
- Sponsor representative
- CRO representative
- Study coordinator
- IRB or IBC member/staff
- Other:

Specify BRANY Study ID (optional):

To associate your account with the IRBManager record for a study already submitted to BRANY IRB for your site, list the BRANY study ID number(s) here. Include the site code:

- Site code = numerical code at the end of the BRANY study # – designated by “XXX” in this example: 20-02-123-XXX).
- Leave blank for new study submissions, single IRB submissions, or if study ID is unknown.

**Submission of this form does not equate to approval from BRANY IRB 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 your user account to a study in IRBManager does not equate to IRB approval.*

**REQUIRED:** Check to confirm you read the IRBManager policy summary (next page).

Send completed form to [sabramov@brany.com](mailto:sabramov@brany.com). Account information will be sent via email within 24-48 hrs.

### 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: Wet ink signature is preferred. BRANY recognizes this may be challenging due to remote work requirements or other restrictions. BRANY will temporarily accept digital/electronic signatures.*



## 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.