

# 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).

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Name:			
Title:			
Degree(s):			
Email addre	ess:		
Site addres	s:		
Business phone number:			
Mobile phone number (optional):			
Please check one:			
	Investigator	☐ Sponsor Representative	☐ IRB Member/Staff
☐ Sub-Inve	•	☐ CRO Representative	☐ IBC Member/Staff
_	· ·	<u> </u>	IBC Member/Stail
	ordinator	Other:	
Do you need your User Account to be associated with any studies in IRBManager?			
∐ No			
☐ <b>Yes</b> – Provide any available study identifying information below. Include BRANY # if known.			
Study ID (or BRANY #):			
Study title			
Principal	Investigator:	Sponsor	
			· <del></del>
NOTE: Subm			
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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.