



BRANY

IRBManager & xForm Basics

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Overview

- Useful information
- xForm submission process
- Navigating IRBManager
 - Dashboard – Home page (Studies)
 - Submission status (xForms & Events)
- Sample xForm Submission
 - E.g., 01-Modification/Request for Review

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Useful Information - BRANYIRB.COM

www.branyirb.com you can:

- Download Forms for submission guidance, COI forms, etc.
- Download Current IRB Member List (also available via Generate Docs)
- View IRB Associate Contact Information by IRB function (www.branyirb.com/contact-irb/)

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Useful Information in IRBManager

Always available in the left margin of IRBManager.

Useful Links

- Blank IRB Auth. Agrmt.
- BRANY IRB SOPs
- BRANY IRB Website
- CR Multisite Supplement
- IRBManager Support
- User Access Form
- Webinar IRBManager Basics
- Weblet Approval Docs
- Weblet Find Study
- Weblet Start xForm
- Weblet/Webinar PDFs
- xForms QUICK Guide
- xForms User Guide

- IRB Policies, guidance, branyirb.com, etc.
- User Access Form (UAF)
- Online webinars
- IRBManager User Guides:
 - IRBManager xForm User Guide – full guide
 - xForms QUICK Guide – single page for desktop

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BRANY User Access Form (UAF)

One time form which grants IRBManager login rights only!

IRBManager password xForm = paper/wet signature

Required for ALL staff who are part of study submission process:

- PI: authorize xForm submission (IRBManager password = signature)
- Main Research Coordinator: view/submit submissions
- Others: view/submit (e.g., regulatory, administrative staff)

IRBManager Contact Role

- Contact role is assigned **per study** to enable each contact to receive appropriate study email alerts

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IRBManager Account Credentials

| User Name | Password Reset | Valid Password |
|--|---|--|
| <ul style="list-style-type: none"> • Typically your institutional email address | <ul style="list-style-type: none"> • Required every 3 months • IRBManager will automatically force password change. | <ul style="list-style-type: none"> • at least 6 characters • one upper case letter • one lower case letter • one number OR one special character: #,\$&{} space <p>Examples:</p> <ul style="list-style-type: none"> • {Love} or Brany1 |

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How to Access IRBManager

Login URL: <https://brany.my.irbmanager.com>

- Bookmark/Save to Favorites
- Enable Pop-ups for <https://brany.my.irbmanager.com>

Platforms:


- Apple/Macintosh or PCs
- Web Browsers: Firefox, Safari, Chrome, Internet Explorer

Smart Devices

- Android, iPhone, iPad
- xForms = accessible via Smart Devices (helpful when PI is out of office xForms need PI password)
- View attachments: need app for viewing PDFs or Word files

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IRBManager Login




Forgot Password?

- Click link on login screen to reset.
- Follow instructions displayed.
- Temporary link will be sent to email entered to assist password reset.

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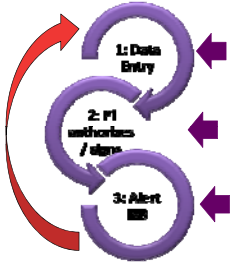
xForm Submission Process

- Useful information
- xForm submission process**
- Navigating IRBManager
 - Dashboard (Home)
 - Submission status (xForms)
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 - 01-Modification/Request fo



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xForm Submission Stages




- xForm started and can still be modified
- Data Entry Stage with Signatures Required OR PI Notify and Signature
- Accepted >> forwarded for processing
- Rejected >>
 - Back to Stage 1 for modification
 - Re-submit, PI required to **re-authorize**

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Navigating IRBManager

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Dashboard – Home Screen



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Study Details

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Event Details Page

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IRBManager Contact Roles

- Study-Site Contact**
 - View study and attachments, initiate/review all xForms.
 - Copied on all IRB staff correspondence.
 - Receives continuing review automated email alert.
- CC Recipient**
 - View study and attachments, initiate xForms.
 - Cannot view xForms others create.
 - Copied on all IRB staff correspondence.
 - Does not receive continuing review automated email alert.
- Organization Contact**
 - View study and attachments.
 - Copied on all IRB staff correspondence.
 - Does not receive continuing review automated email alert.

| Name | Role |
|--------------------------|----------------------|
| Coordinator, Research RN | Study-Site Contact |
| Mouse, Mickey | Organization Contact |
| Recipient, CC | CC Recipient |

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Find Study using Dashboard

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xForm From Dashboard

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xForms You Start (Original Owner)

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xForm Ownership

| Form | Identifier | Owner | Stage/Status | Started |
|--------------------------|--|---|---|-------------|
| Register New Study | NOT LISTED-My health system/Facility NOT listed above PI: Dr. John Smith Mech: 09C3475-ABC-01 | Coordinator, Research IRB Coordinator | Alert IRB of Submitted Form | moments ago |
| 16-Reportable Event | 11/22/2017 - Serious Adverse Event (SAE) | 12-08-2017-01 Kara, Richard MD Amendment 15-08-2134-01 | PI Notify and Signature Reviewer Checklist Data Entry | moments ago |
| 17-Reviewer Checklist | Investigator's Brochure for Tucatinib (OBT-360) v1.0 (dated: 31-OCT-2017) Investigator's Brochure for Tucatinib (OBT-360) Version 5.0 - Erratum (dated: 31-OCT-2017) (00) - If for on and Malamud | | | moments ago |

xForms can be "owned" by:

- User
- Study
- Event


Owner tells you where the xForm currently "lives" in IRBManager.

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Start New Research Study


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    graph LR
      BRANYClassic[BRANY Classic] --> ContactBRANY[Contact BRANY Relationship Manager]
      IRBOnly[IRB Only] --> RegisterNewStudy[xForm: Register New Study]
      ContactBRANY --> StudyEntered[Study entered in IRBManager]
      RegisterNewStudy --> StudyEntered
      StudyEntered --> ResearchApplication[xForm: Research Application]
    
```

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Using Our Knowledge...


- Now let's log into IRBManager to find a study and start an xForm using what we have learned...


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Key Points

- **Home page**
 - ✓ Dashboard xForm section
- **xForms you started?**
 - ✓ Bottom left: *My Documents and Forms* - click # **xForms**
- **xForms you need to authorize (PIs especially)**
 - ✓ Click Home: *There are # xForms awaiting your attention*
- BRANY IRB website: <http://www.branymb.com>
- BRANY IRB contacts: <http://www.branymb.com/contact-irb>
- IRBManager login: <https://brany.my.irbmanager.com>

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Thank you...

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