



BRANY



How do I start a Continuing Review Application for my IRBManager Study?

A BRANY Help Weblet

Click to navigate through slide show. Right click displays menu options.

CONFIDENTIAL

How do I start an xForm for my IRBManager Study?

- As long as your study has a BRANY# assigned to it, you can find it in BRANY's IRBManager!
- Login to IRBManager: Dashboard/Home page displays
- Find and view the study you need to start an xForm for.
- Don't remember how to find your study? Quick review

Find Study Function

- Click in Find Study box (top right).
- Enter search criteria.

My Study Links

- Dashboard's Studies (# Active) (top)
- Click # active for active studies
- Click # total for all studies including closed)

Active Study List

- Dashboard's My Studies (# Active) list (scroll to list)

Study Details

When you need to view study information or submit new documents to BRANY IRB, you need to **find** and **open the study details page**.

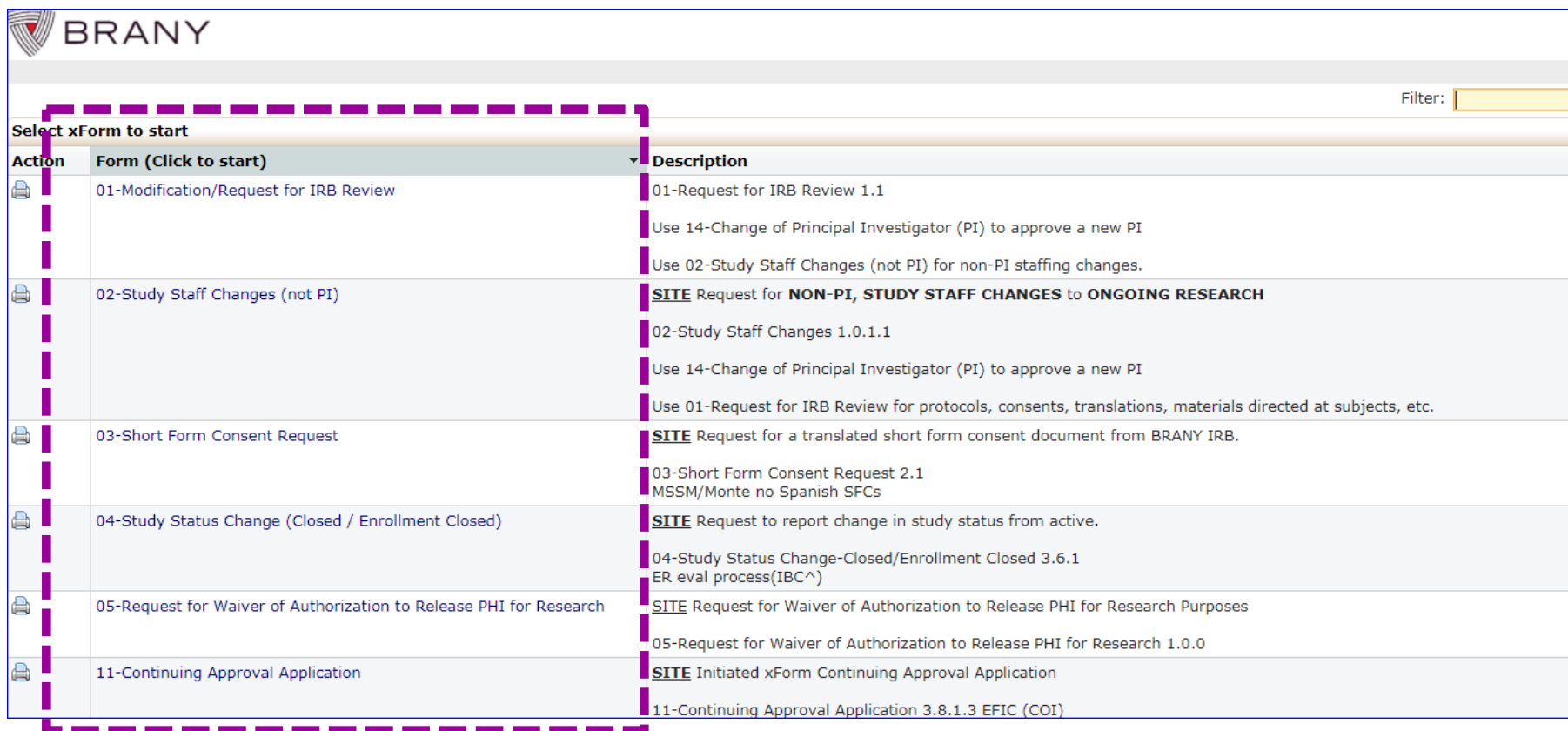
The screenshot displays the BRANY IRB interface. The top navigation bar includes 'Home', 'Find Study (Ctrl+Q)', 'Help', 'Research's Settings', and 'Sign off'. The main content area is titled 'Study 08-99-99-DEMO2 (IRB)' and is divided into several sections:

- Study Information:**
 - Study: 08-99-99
 - Committee: A-IRB00000080
 - Category: 02-General Medicine and Science
 - Department: 02-General Medicine and Science
 - Last Review: Full Board
 - Agent Types: Drugs
 - Study Title: Efficacy and Tolerability of Drug X Compared With Drug Y in >= 70 Patients with CORONARY ARTERY DISEASE and Stage I or II Hypertension
 - Conditions: IND - Investigational New Drug
 - Comments:
- Sponsor(s) Information:**
 - Sponsor(s): Pfizer/BMS (Primary)
 - Sponsor Id: 9999-99 Test
 - Grants: IRB Only
 - Next Review:
 - CRO: Test Sponsor
 - Year: 2008
- Study Contacts (1)**
- Study Attachments (1)**
- Study-Site Information:**
 - Site(s): DEMO2 - Research Site 2
 - Status: z_Approved (DEMO)
 - Approval: October 4, 2017 for 12 months
 - Initial Approval: October 7, 2012
 - Relationship Manager: Donna Baque - Coleen DeSouza
 - Tags: ***TEST Study-Site***
 - Comments: this is my test
 - Principal Investigator: Physician, Treating MD, PhD (Replacement)
 - Additional: N
 - Expiration: October 4, 2018
 - Other Expirations:
 - Translation: ***UNKNOWN***
- Contacts (2)**
- Events (5)**
- Notes (3)**
- Emails (9)**
- Generated Documents (16)**

The left sidebar contains navigation options: Actions (Generate Doc, Send EMail, Start xForm, xForms (11), Done), Recent Items (08-99-99-DEMO2, 15-02-999-DEMO1, 10-99-999-DEMO2, 09-06-999-DEMO1, 08-99-99-DEMO1, 08-99-99-355, 16-02-225-02), Messages (BRANY IRB: IRB00000080, SBER IRB: IRB00010793), Useful Links (Blank IRB Auth. Agrmt., BRANY IRB SOPs, BRANY IRB Website, FWA & IRB Registration, IRBManager Support, Sponsor CR Supplement, User Access Form, xForms QUICK Guide, xForms User Guide), and My Documents & Forms (0 User Attachments, 96 xForms).

Start xForm from Study Details







- Click on the Start xForm Action.
- List of available xForms will display.
- Click directly on the form name link to open the xForm you need to complete.



BRANY

Filter:

Select xForm to start

Action	Form (Click to start)	Description
	01-Modification/Request for IRB Review	01-Request for IRB Review 1.1 Use 14-Change of Principal Investigator (PI) to approve a new PI Use 02-Study Staff Changes (not PI) for non-PI staffing changes.
	02-Study Staff Changes (not PI)	SITE Request for NON-PI, STUDY STAFF CHANGES to ONGOING RESEARCH 02-Study Staff Changes 1.0.1.1 Use 14-Change of Principal Investigator (PI) to approve a new PI Use 01-Request for IRB Review for protocols, consents, translations, materials directed at subjects, etc.
	03-Short Form Consent Request	SITE Request for a translated short form consent document from BRANY IRB. 03-Short Form Consent Request 2.1 MSSM/Monte no Spanish SFCs
	04-Study Status Change (Closed / Enrollment Closed)	SITE Request to report change in study status from active. 04-Study Status Change-Closed/Enrollment Closed 3.6.1 ER eval process(IBC^)
	05-Request for Waiver of Authorization to Release PHI for Research	SITE Request for Waiver of Authorization to Release PHI for Research Purposes 05-Request for Waiver of Authorization to Release PHI for Research 1.0.0
	11-Continuing Approval Application	SITE Initiated xForm Continuing Approval Application 11-Continuing Approval Application 3.8.1.3 EFIC (COI)

Filter xForm List

- Filter the xForm list by typing a keyword in the Filter box at the top right (e.g., application, modification, staff, 11)
- Click on the **11-Continuing Approval Application** and the xForm will open. Answer the questions.
- If you click on “Save for Later” you can save the xForm to pick up again later.

Form (Click to start)	Description
11-Continuing Approval Application	SITE Initiated xForm Continuing Approval Application 11-Continuing Approval Application 3.8.1.3 EFIC (COI)
Research Application	DO NOT START this xForm until your study is assigned a BRANY# . <u>IRB Only</u> studies MUST submit a Register New Study xForm <u>BRANY Classic</u> studies: contact relationship manager Research Application 5.1.2

Filter:

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Continuing Approval Type

- Read the question (light blue box) and help text (white area) to aid in entering correct responses.
- Answer all questions that have “(Required)” at the end of the question text.
- Selecting the proper responses guides you to the appropriate section of the xForm
- Add attachments prompted (e.g., Adverse Event Log, Minor Deviation Log, Monitoring Visit Report)

CONTINUING APPROVAL TYPE - Select at least one (1) or both choices (IBC and IRB):

- Does your research involve interaction with human subjects, data about human subjects, or biospecimens from human subjects?
 - If YES, select IRB
- Does the research involve Human Gene Transfer (i.e. use of a study drug that includes transfer of genetic material like DNA or RNA into a human subject) AND IBC review was done by BRANY IBC?
 - If YES, select IBC

CONTINUING APPROVAL TYPE. PLEASE SELECT ALL THAT APPLY:

Note: Human Gene Transfer Research Projects require IBC continuing approval (Required)

- IBC - BRANY Institutional Biosafety Committee
- IRB - BRANY Institutional Review Board

DOES THE RESEARCH INVOLVE HUMAN GENE TRANSFER? (Required)

- Yes
- No

Study Status Selections: Ongoing (Part 1)

SELECT STUDY STATUS: Active (open to subject accrual) or Closed to enrollment

- **Ongoing** means study activities are not complete. The study is open to accrual, or closed to enrollment but subjects are in follow up, or remains open for data collection only.

A. IS THE RESEARCH ONGOING AT YOUR SITE?

Tips for specific scenarios:

- *If your study is experiencing a temporary recruitment/enrollment hold, select YES.*
- *If your study has been permanently closed to recruitment/enrollment at your site, select NO.*

Yes

Study Status Selections: Ongoing (Part 2)

- Select the study status at the time you submit the renewal application
 - **Open to subject accrual** means the study is active and the study is actively enrolling new subjects, or continues to collect data or specimens
 - **Closed to subject accrual** means the subject accrual target has been met, but there are subjects in follow up so the study activity is not complete.
 - Answer the questions about the different scenarios here if they apply to your study (e.g., does subject contact still occur, have all research related interventions been complete, etc.)

A. IS THE RESEARCH ONGOING AT YOUR SITE? Add

Tips for specific scenarios:

- *If your study is experiencing a temporary recruitment/enrollment hold, select YES.*
- *If your study has been permanently closed to recruitment/enrollment at your site, select NO.*

(Required)

Yes

B. DOES RESEARCH INVOLVE DIRECT INTERACTION WITH HUMAN SUBJECTS? (Required)

Yes
 No

STUDY INVOLVES EXCEPTION FROM INFORMED CONSENT ("EFIC") i **FOR PLANNED EMERGENCY RESEARCH?** (Required)

No

1. SUBJECT ACCRUAL: (Required)

Open to subject accrual
 Closed to subject accrual

RESEARCH ACTIVITIES:

HAVE ALL SUBJECTS COMPLETED ALL RESEARCH-RELATED INTERVENTIONS i ? (Required)

Yes

DOES THE RESEARCH REMAIN ACTIVE ONLY FOR (LONG-TERM) FOLLOW-UP OF SUBJECTS? (Required)

“EFIC” (21 CFR 50.24)

EFIC: Exception From Informed Consent

- Applies to **Planned Emergency Research only**
- This is applicable when research involves human subjects who present with a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory) and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent
- **ONLY select this option if you completed the EFIC review process at initial review**, which includes steps like:
 - Obtaining feedback from the community about the acceptability of the planned emergency research, and
 - Providing a method for community members to opt-out

A. IS THE RESEARCH ONGOING AT YOUR SITE? *(Required)* Add Note View Audit

Yes

B. DOES RESEARCH INVOLVE DIRECT INTERACTION WITH HUMAN SUBJECTS? *(Required)*

Yes ▾

STUDY INVOLVES EXCEPTION FROM INFORMED CONSENT (“EFIC”) ⁱ FOR PLANNED EMERGENCY RESEARCH? *(Required)*

No ▾

1. SUBJECT ACCRUAL: *(Required)*


Open to subject accrual

Account for All Subjects

- **Total ALL subjects who signed the consent form**
 - This number is **cumulative from the start of the study**, not from the last Continuing Review
- If you select “EXITED THE STUDY BEFORE COMPLETING...” be prepared to explain on the next page, by selecting reasons like:
 - Screen failure, withdrawn, lost to follow-up
 - If there is another reason, select “DON’T FIT INTO CATEGORIES ABOVE” and explain
- **DO NOT LEAVE BLANKS:** Enter a “0” whenever there is no subject for the specific category

D. HOW MANY SUBJECTS SIGNED CONSENT? [Add Note](#) [View Audit](#)

PLEASE ACCOUNT FOR ALL SUBJECTS WHO SIGNED CONSENT IN ONE (1) OF THE CATEGORIES LISTED BELOW:

a. HOW MANY ARE STILL UNDERGOING RESEARCH-RELATED INTERVENTIONS? 


b. HOW MANY ARE DONE WITH RESEARCH-RELATED INTERVENTIONS BUT IN FOLLOW-UP?

c. HOW MANY ARE DONE WITH RESEARCH-RELATED INTERVENTIONS AND ALL FOLLOW-UP IS COMPLETE?

d. HOW MANY EXITED THE STUDY BEFORE COMPLETING ALL THE PROTOCOL-REQUIRED PROCEDURES AND FOLLOW-UP? (I.e., How many subjects terminated early)

e. HOW MANY SUBJECTS WHO SIGNED CONSENT DON'T FIT INTO CATEGORIES a-d ABOVE? You will be required to explain the status of these subjects.

EXPLAIN THE STATUS OF THESE SUBJECTS:



Provide Gender & Ethnicity of Subjects

- For studies involving data or Bio-specimens, reflect the total number used for the study
- If the gender of subjects is known, provide the # female vs. #male
- If the study includes subjects of only one gender, you don't need to report the number.
- If the ethnicity/race of subjects is known, provide the # in the categories displayed
- DO NOT LEAVE BLANKS: Enter a "0" in any category that does not apply

IS THIS RESEARCH STUDY LIMITED TO SUBJECTS/RECORDS/BIOSPECIMENS FROM A SINGLE GENDER? *(Required)*

No - Distribution of male vs. female participants is known. ▼

YOU ENTERED THE FOLLOWING FOR #TOTAL ENROLLED
2

**PROVIDE A BREAKDOWN OF #TOTAL ENROLLED BY GENDER:
SUM OF THE NUMBER MALE + THE NUMBER FEMALE MUST EQUAL THE NUMBER ABOVE**

SPECIFY # MALE
1

SPECIFY # FEMALE
1

IS THE ETHNIC COMPOSITION OF SUBJECT ENROLLMENT KNOWN, I.E. DO YOU KNOW THE ETHNIC BREAKDOWN OF ALL THE SUBJECTS WHO SIGNED CONSENT? *(Required)*

Yes-Ethnicity breakdown is KNOWN for total enrolled. ▼

YOU ENTERED THE FOLLOWING FOR #TOTAL ENROLLED
2

Benefits, Experiences, Complaints, Adverse Events

- BRANY IRB wants to understand “the big picture” for the study as subjects progress.
- Summarize the experiences of subjects in the study so far:
 - Are subjects getting better or worse?
 - Were there any subject complaints (about their rights or welfare – not adverse events)?

SUBJECTS EXPERIENCE BENEFITS - HAVE ANY SUBJECTS AT YOUR SITE BENEFITED FROM PARTICIPATION IN THIS STUDY? *(Required)*

- Yes
 No

SUBJECTS EXPERIENCE COMPLAINTS - HAVE THERE BEEN ANY COMPLAINTS FROM SUBJECTS AT YOUR SITE?
(Required)

- Yes
 No

DESCRIBE SUBJECT COMPLAINTS

The subject think there are too many numbers of visit to be done.



Adverse Events & Minor Deviations Since the Last Review


- For Adverse Events
 - If there have been any adverse events, what occurred?
 - List the most common events or attach an existing Adverse Event Log (if you have one)
 - Provide a cumulative listing since the last Continuing Review
 - If none, state “none”
- Minor deviations do not affect the subject’s safety, rights, or welfare, or the integrity of the data.
 - Only submit the Minor Deviation Log at continuing review or study closure

PLEASE PROVIDE A SUMMARY OF UNEXPECTED AND ASSOCIATED ADVERSE EVENTS THAT OCCURRED **SINCE LAST REVIEW**. [Add Note](#) [View](#)

INCLUDE THE DESCRIPTION OF THE ADVERSE EVENT, THE RELATIONSHIP TO THE STUDY AGENT, AND WHETHER THE EVENT WAS EXPECTED OR UNEXPECTED.
(Required)

If **NO** Adverse Events occurred, please indicate: **"No Adverse Events have occurred since last review"**.

ADVERSE EVENTS DESCRIPTION

No Adverse Events have occurred since last review" 

Describe and/or attach separate documents.

HAVE ANY MINOR DEVIATIONS OCCURRED SINCE THE LAST REVIEW OF THIS STUDY? [Add Note](#) [View](#)

YOU ARE REQUIRED TO REPORT MINOR DEVIATIONS AT CONTINUING REVIEW BY COMPLETING AND SUBMITTING THE **MINOR DEVIATION LOG**. *(Required)*

No

Serious Adverse Events (SAE)

- Tell us about Serious Adverse Events that occurred in subjects at your site.
 - Submit previously unreported SAEs separately via the xForm **#16-Reportable Events**
 - You cannot report these within the Continuing Approval Application

HAVE THERE BEEN ANY SERIOUS ADVERSE EVENTS (SAEs) ⁱ AT YOUR SITE SINCE THE LAST CONTINUING REVIEW? (Required) [Add Note](#)

Yes

1. WERE THE SAEs REPORTED TO THE SPONSOR? (Required) [Add Note](#)

Yes
 No

2. HAVE YOU REPORTED THE SAE TO THE BRANY IRB? [Add Note](#)
PLEASE NOTE: YOU ARE REQUIRED TO SUBMIT AN ELECTRONIC 16-REPORTABLE EVENT xFORM TO BRANY IRB FOR EACH DEVIATION/SAE AS THEY OCCUR. (Required)

Yes
 No

3. WERE ANY EVENTS RELATED TO DRUG/DEVICE? (Required) [Add Note](#)

Yes
 No

Data Safety Monitoring Boards (DSMB) Or Safety Monitoring Committee

- The DMC, DSMB or Steering Committee, is a committee that oversees patient safety for a study.
- At initial review, your application indicated whether the study has a DSMB established.
 - Make sure your answer for continuing review matches and is accurate.
- If you not sure what these reports are, please contact the study sponsor. They will information regarding the DSMB report
- When the report is available, attach the document
- If you select **NO**, **explain:** (i.e. report not available, there is no safety committee established)

ng Approval Application -- UPIRTSO Subject Experience at Your Site & DSMB

HAS THE SPONSOR ESTABLISHED A DATA SAFETY MONITORING BOARD (DSMB) OR SAFETY MONITORING COMMITTEE?

Add

If you are unsure, please confer with the Sponsor representative prior to submitting this form.

Please check your protocol for this information **BEFORE** answering this question.

If report is **NOT** available, you will be required to explain why the report is not available in the following question.

If report is available, you will be required to attach and answer additional questions on another page. *(Required)*

- YES - A copy of the most recent DSMB/safety monitoring committee report is available (you will be required to attach a copy).
- YES - I contacted the Sponsor, and the report is currently NOT available
- NO
- N/A - Not Applicable

EXPLAIN WHY THE DATA SAFETY MONITORING BOARD (DSMB)/SAFETY MONITORING COMMITTEE REPORT IS NOT AVAILABLE.

Please provide as many details as possible in your explanation.

(Required)

Providing Signed Informed Consents/Assents

If your study involves obtaining consent/assent with a consent/assent form, and

1. Subjects have been enrolled subjects since the last review:
 - Attach a copy of the 2 most recently signed consent/assent forms
 - ***PLEASE DO NOT REDACT THE NAMES/SIGNATURES*** (BRANY IRB is authorized to view study subject information).
2. If no subjects have been enrolled, attach the latest stamped version of the consent form approved by the IRB.

PLEASE NOTE THAT RESEARCH FILES, INCLUDING DATED, SIGNED AND APPROPRIATELY WITNESSED CONSENT DOCUMENTS SHOULD BE READILY ACCESSIBLE FOR POSSIBLE MONITORING BY THE SPONSOR, FDA, BRANY QUALITY ASSURANCE TEAM, AND/OR BRANY IRB/IBC SERVICES TEAM. [Add Note](#) [View Audit](#)

PLEASE ATTACH A COPY OF THE TWO (2) MOST RECENTLY SIGNED CONSENT DOCUMENT(S). *(Required)*

This is to show you are in compliance with the consent requirements of the study.

*If NO subjects have been enrolled, please **attach** a copy of the **most recently approved** consent form(s).*

*If a **Consent Waiver** was approved for this study, **attach** proof of **Consent Waiver approval** (i.e. study's approval letter).*


HAVE ALL CONSENT MODIFICATIONS BEEN SUBMITTED TO THE BRANY IRB? *(Required)*

[Add Note](#) [View Audit](#)


- YES - All modifications have been submitted and approved
- NO - Modifications have been submitted and under review
- NO - Submitting modifications with this form

Supplement for Multi-center Research Projects

- BRANY IRB requires a representative of the Study Sponsor, the Lead Investigator, or the Master File site PI for a multi-site study to provide a brief summary of study-wide progress and findings, including study-wide subject accrual data, adverse event data, unanticipated problem reports, safety updates, recent literature, and any other interim findings or available study-wide progress information.
- This information is intended to assist the IRB in evaluating how the site-specific data and progress reported by local PIs with continuing review applications compare to the study-wide data and progress.


IS THIS A MULTI-CENTER OR MULTI-SITE STUDY?  (Required) [Add Note](#) [View](#)

YES
 NO

ARE YOU THE LEAD INVESTIGATOR?  (Required)

YES
 NO

ATTACH SPONSOR SUPPLEMENT/MULTI-CENTER TRIAL REPORT. [Click here](#) for a copy of the "Supplement for Multi-Center Research Projects" the sponsor to complete. (Required)

 [Sponsor_Supplement FINAL 20170823\(001_v.GEN-DOC\).docx](#) CR-Sponsor Supplement

BRANY IRB Contact Information

If your study does not have a BRANY# associated with it, contact BRANY IRB to start the study submission process:

- BRANY Classics contact your Relationship Manager.
- All others click START NEW STUDY action on Dashboard.

Questions? [Click here](#) to display BRANY IRB contact information list.

The BRANY IRB is happy to assist!



Thank you!