**BRANY IRB**

**Guidance and Guidelines for National Jewish Health Researchers**

***For Submitting New Studies to***

 ***BRANY IRB (Biomedical) and BRANY SBER IRB (Social Behavioral, & Educational)***

# BRANY Services

BRANY IRB (IRB00000080) or BRANY SBER IRB (IRB00010793) will review, approve/disapprove and monitor research protocols in accordance with all applicable laws and regulations regarding human subject protection, including requirements of applicable regulatory agencies.

**Primary Points of Contact for Submissions to BRANY’s IRB**

Raffaella Hart Kerri Friel

Office: (516) 470-6909 Office: (516) 622-2040

e-mail: rhart@brany.com email: kfriel1@brany.com

A full list of BRANY IRB Contacts are available [here](https://www.brany.com/irb-contacts/).

Questions concerning NJH’s human research protection program (HRPP) may be directed to:

Judy Matuk

Office: (631)-619-5990

E-mail: matukj@thehrpconsultinggroup.com

**Submitting to BRANY IRB and BRANY SBER IRB**

All submissions must be submitted using the BRANY ***IRBManager***electronic submission system.

In order to access the *IRBManager* online system, Principal Investigators (PIs) must complete the “**BRANY User Access Form**” (available here: <https://www.brany.com/forms-and-downloads>), sign in ink (Please note that temporarily during the COVID-19 pandemic, digital signatures or sending the form from a password-protected email address will be acceptable), and submit either via email: sabramov@brany.com or fax: 516-706-5066. After the request is processed, you will receive your account information (user ID and password) via email within 24-48 hours. **This form only needs to be submitted one time in order to obtain your user account.** ONLY study personnel that will need access to BRANY’s *IRBManager* will need to complete this process. It is not necessary for ALL personnel to complete this process.

IRB submissions will be pre-screened upon receipt to ensure completeness. Missing items will be solicited to enable a complete and timely review, prior to IRB review.

The Principal Investigator (PI) must be an active NJH faculty member.

## IRB Meetings and Submission Timelines

* **BRANY’s IRBs continuously review submissions that qualify for expedited review.**
* Expected turnaround time for a submission qualifying for expedited review is 5 – 7 days from receipt of a complete submission.
* When the IRB requires additional information to complete its review, the turnaround time is also dependent upon the researcher’s response time to supply any additional information that has been requested.
* **For SBER research requiring review by the convened BRANY SBER IRB committee,** a meeting will be scheduled approximately 10 business days from receipt of a completed submission.
* **For biomedical research requiring review by the convened BRANY IRB committee;** the IRB meets Monday and Thursday of every week. Meeting schedule available here: <https://www.brany.com/forms-and-downloads>
* **After the IRB has reviewed the project**, an e-mail with the IRB’s determination will be forwarded to the Principal Investigator, study contact (if applicable), and NJH Human Research Protection Program Office within 24 – 48 hours.
* **Final approval letters** for studies that are approved and/or conditionally approved by the IRB are generally released within five days after the IRB meeting takes place. The determination letter will indicate the date IRB approval expires or for non-expiring studies the date the annual report is due.
* **If a project is deferred** by the IRB, meaning the IRB defers action until additional information can be provided, the re-review can generally be completed within 10 - 15 days after receiving the researcher’s response addressing the IRB’s concerns.

## Submissions to BRANY IRB – Biomedical Research

* BRANY’s main website: <https://brany.com>
* BRANY’s website with information on *IRBManager:* <https://www.brany.com/irb-manager/>
* BRANY’s direct portal for *IRBManager:* <https://brany.my.irbmanager.com/Login.aspx>

When accessing *IRBManager, p*lease make sure your login screen looks like this:



### Initial Review

On your *IRBManager* home page, click on **START NEW STUDY**. Select the appropriate form.

**Register New Study**

This form is used to introduce a new study into *IRBManager* (NOT SBER-social, behavioral, or educational research). It is typically used for chart review research or biomedical research (observational or interventional). Once this form is complete, your study will receive a BRANY # so you can login to *IRBManager* and complete a **Research Application** xForm.

*Use this form when any of the following apply:*

* *You plan to submit biomedical research to BRANY IRB.*
* *Yours is the only site conducting the study, and it is not social behavioral research.*
* *The study is industry sponsored.*
* *The BRANY team has instructed you to complete the Register New Study xForm.*

Other required documents:

* Curriculum Vitae of the Principal Investigator (and the primary Co-Investigator, if applicable)
* Current clinical license for Principal Investigator, if applicable
* Completed BRANY User Access Form for anyone associated with the study that needs an *IRBManager* account and doesn’t already have one
* Research Protocol
* Any subject-facing materials (e.g., subject diaries, instructions, questionnaires, surveys)
* Any data collection tools to be used by the researchers (e.g., spreadsheets, case report forms, questionnaires, surveys)
* Recruitment materials (e.g., flyers, posters, advertisements)
* The IRB may require the researcher to supply additional information in order to complete the submission and enable a substantive review.

## Submissions to BRANY SBER IRB – Social, Behavioral, and Educational Research

* BRANY’s main website: <https://brany.com>
* BRANY’s website with information on *IRBManager:* <https://www.brany.com/irb-manager/>
* BRANY’s direct portal for *IRBManager:* <https://brany.my.irbmanager.com/Login.aspx>

When accessing *IRBManager, p*lease make sure your login screen looks like this:

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### Initial Review

On your *IRBManager* home page, click on Start New SBER Study

**Start New SBER Study Application**

This form is for introducing a new SBER (social, behavioral, or educational research) study into *IRBManager*. It is not for studies involving a biomedical intervention or FDA regulated product.

*Use this form when any of the following apply:*

* *The study involves social, behavioral, or educational interactions or interventions.*
* *The study does* ***not*** *involve a biomedical intervention or FDA regulated product.*
* *A member of the BRANY team has instructed you to complete the SBER Study Application.*

Other required documents:

* Curriculum Vitae of the Principal Investigator (and the primary Co-Investigator, if applicable)
* Current clinical license for Principal Investigator, if applicable
* Completed BRANY User Access Form for anyone associated with the study that needs an *IRBManager* account and doesn’t already have one
* Research Protocol
* Any subject-facing materials (e.g., subject diaries, instructions, questionnaires, surveys)
* Any data collection tools to be used by the researchers (e.g., spreadsheets, case report forms, questionnaires, surveys)
* Recruitment materials (e.g., flyers, posters, advertisements)
* The IRB may require the researcher to supply additional information in order to complete the submission and enable a substantive review.

## Multi-site Collaborative Research involving NJH is the Lead Site, and BRANY will be the IRB of Record

NJH researchers involved in multi-site investigator-initiated research are encouraged (and in the case of NIH and other federally-funded multicenter grants, required) to discuss with collaborators the possibility of having one IRB review on behalf of all sites. When it is proposed to have BRANY IRB be the sIRB for a multisite study, please contact BRANY (contact information above) for assistance:

**401-Single IRB: Master/Sponsor Application (Lead Site)**

This form is for the Lead Researcher or Sponsor to introduce into *IRBManager* a new multi-site study using BRANY as the single IRB (sIRB).

The 401 xForm is for creating a “Master File” submission to BRANY IRB. Be prepared to provide the information that will be common to all Participating Sites, such as:

1. Research protocol
2. Consent and assent forms that will be used by all participating sites (if applicable)
3. Materials directed at subjects (e.g., subject materials, survey instruments, interview guides, data collection tools, recruitment materials, etc.)
4. Name and contact information for the PI at each Participating Site

**If your site is both the Lead Site and a Participating Site, then you will need to complete both the 401 and 501 xForms.**

*Use this form when any of the following apply:*

* *You’re the Lead PI/Site/Sponsor for a multi-site study, BRANY IRB is the single IRB for the study, and you need to introduce a new study to BRANY IRB.*
* *A member of the BRANY team has instructed you to complete xForm #401*

*Do not use the 401 xForm if you are seeking IRB approval as a Participating Site.*

**501-Single IRB: Site Application – (Participating Site)**

This form is for researchers from Participating Sites involved in a multi-site study using BRANY as the single IRB (sIRB).

*Use this form when any of the following apply:*

* *You’re a Participating Site for a multi-site study, BRANY IRB is the single IRB for the study, and you need to obtain approval for your site from BRANY IRB.*
* *A member of the BRANY team has instructed you to complete xForm #501.*

**NJH Research Conducted at an External Site**

IRB submissions for NJH research conducted at an external site, (including accessing data from that external site) may require alternative submission procedures and/or additional forms depending on the purpose of the research and the level of involvement of the other institution/agency (e.g., is the external site ‘engaged’ in the activity).

When data are transferred from another institution to NJH, all NJH researchers are required to abide by Institutional policies related to data collection and data sharing.

For questions regarding the appropriate procedures and necessary forms for research projects being conducted at another institution, please contact BRANY directly for clarification.

**Requests for Waivers of HIPAA Authorization**

To request a Waiver of HIPAA Authorization for use/disclosure of protected health information (that does not constitute a limited data set):

* The **Request for Waiver of Authorization to Release PHI for Research Purposes** is embedded within the submission forms for BRANY IRB. Answer the appropriate questions within the **Register New Study**, **SBER Study Application**, **Research Application**, or **501-Site Application xForms**.

**Informed Consent**

NJH’s current consent document template is acceptable for submission to BRANY IRB.

**NJH consent forms will include the following contact information:**

“If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at [www.branyirb.com/concerns-about-research](http://www.branyirb.com/concerns-about-research). The IRB is a group of people who independently review research on humans to help protect their rights and safety.”

**Waiver of Documentation of Consent**

Federal regulations require that research subjects sign a consent document (45 CFR 46.117, unless waived by the IRB (under limited circumstances (45 CFR 46.117)).

**A waiver of signed (documentation of) consent does not exempt a researcher from obtaining informed consent.** Researchers may apply for a waiver of documented consent using the following form:

* The **Request for Waiver of Documentation of Consent** is embedded within the submission forms for BRANY IRB. Answer the appropriate questions within the **Register New Study**, **SBER Study Application**, **Research Application**, or **501-Site Application xForms**.

**Waiving or Altering Elements of Consent for Minimal Risk Research**

Researchers may apply for a waiver or alteration of consent using the following form:

* The **Request for Waiver or Altering Elements of Consent for Minimal Risk Research** is embedded within the submission forms for BRANY IRB. Answer the appropriate questions within the **Register New Study**, **SBER Study Application**, **Research Application**, or **501-Site Application xForms**.

**Foreign Language Translations of Materials Already Approved by BRANY IRB in English**

Translated materials must be accompanied by a certificate of translation/affidavit of accuracy (sample Certificate of Accuracy is attached). Translations should be performed by a certified translator, or an individual reasonably believed by the IRB to be competent to provide them. The translator should be an individual who is bilingual and fluent in both English and the language of the Non-English Speaking Subject. The translator's credentials should be included in the documentation.   The documentation should reference the protocol number, researcher and title of the protocol.

Translated, already published, standard clinical or other validated questionnaires/ materials will be accepted by the IRB without a certificate of translation (e.g., Beck Depression Scale, SCIDS, materials published by recognized entities, regulatory agencies, or advocacy groups).

**Note:** BRANY IRB can require, under certain circumstances, documents be translated by a certified translator (e.g. Informed Consent Form for a research study that is greater than minimal risk).

## Research Conducted Outside of the U.S.

When research is conducted outside of the United States, documentation of a local review must be obtained and provided to BRANY for consideration. Local approval may come from an IRB, an ethics committee, the Ministry of Health, or another entity that is unrelated to the research. The documentation should acknowledge and address the cultural appropriateness of the study procedures or acknowledge that local regulations do not apply to the study activities. It is strongly recommended that this process be started early.

**When Research is Approved by BRANY’s IRB**

An initial approval notice including, when applicable, copies of both the “red-lined” and the final versions of each document consent/assent document. Approved study materials will also be included with the initial approval notice. All approved documents will be sent to the Principal Investigator.

*The footer of the approved informed consent document will be stamped with the BRANY approval stamp.*

The IRB approval (and expiration dates, when applicable) will be inserted into the final approved version of the informed consent by BRANY’s IRB administrative staff; copies of this consent must be used by the research staff to obtain informed consent from subjects. The PI may then begin recruiting subjects for the study. *Note: Only current IRB approved documents can be used for the recruitment of subjects.*

Once approved, the PI is charged with the responsibility of keeping the BRANY IRB and appropriate agencies informed of (i) any unanticipated problems involving risk to subjects, (ii) changes in research activities, (iii) any non-compliance with regulations or IRB requirements, and (iv) termination or suspension of IRB approval.

## Non-Personnel Modifications / Amendments

**To make a modification submission:**

1. Log into *IRBManager* (<https://brany.my.irbmanager.com>)
2. Find the Study Details page by entering the BRANY # in the **Find Study** box on the upper right or by selecting it from the active studies list at the bottom of your home screen
3. Once on the Study Details page, click Start xForm under the BRANY logo.
4. Select and complete the appropriate Modification Request xForm:
	* For biomedical research studies: 01-Modification/Request for IRB Review
	* For SBER studies: [SBER Modification/Request for IRB Review](https://brany.my.irbmanager.com/xForms/StartForm.ashx?Form=5a9ea3f1-e9e4-4b7e-9187-a45ab48a7355&FormVersion=26906415-89a7-4d6c-a887-ead9e360645b&FormOwner=11602bcb-212e-4154-a169-bcae1a06ab17)

**IMPORTANT NOTE: Clicking SUBMIT when the form is in the data entry stage means the form has been submitted to the PI** for review and sign-off**. The PI will receive an email alert with a direct link to the form so that s/he can login, view, and enter password to submit to the IRB for review.**

## Changes to Study Personnel

All changes in research personnel must be approved by BRANY. Submissions should be made as follows:

* xForm: 02-Study Staff Changes (not PI)
* For each key personnel to be added, include:
	+ evidence of completed training in human subject protections (per NJH’s requirements)

Note: Conflicts of interest should be reported as usual to NJH. BRANY will obtain COI management plans directly from NJH.

## Continuing Review

It is the responsibility of the Principal Investigator to ensure that the IRB approval does not lapse. Continuing review and re-approval of research must occur on or before the date when IRB approval expires. A study’s BRANY IRB approval will expire at 11:59 PM on the last date for which the research is approved. Research activity may be performed until 11:59 PM on the expiration date for the study.

*BRANY’s IRBManager* will send email notifications to researchers about continuing review obligations beginning approximately 45 days prior to the date the study’s IRB approval will expire. If no renewal or study closure form is received in response, the system will send additional notifications at 30 and 15 days prior to expiration of IRB approval.

Enrollment of new subjects and/or performance of research, including data analysis with identifiable data, beyond the IRB approved project period are prohibited by Federal regulations.

Submissions should be made using one of the following forms:

Renewal

* For biomedical research studies: 11-Continuing Approval Application
* For SBER studies: SBER Continuing Approval Application

Annual Status Report (for non-expiring studies)

* 12-ANNUAL STATUS REPORT

Study Closure

* For biomedical research studies: 04-Study Status Change (Closed/Enrollment Closed)
* For SBER studies: SBER Study Status Change (Closed/Enrollment Closed)

**The regulations do not permit any grace period**. **Therefore, failure to either submit a request for renewal or a notification of study closure will result in lapse of IRB approval, after which no research activity may occur.** In such instances, the researcher will receive an expiration notice, and this will be reported to the IRB for consideration of whether such failure represents minor, serious, or continuing non-compliance as these terms are defined in the BRANY IRB Standard Operating Procedures

**Events Requiring Prompt Reporting to the IRB and Reporting Timelines**

The following types of events require prompt reporting to the BRANY IRBs:

* Event (including **unanticipated problems** during a study) that caused harm to one or more subjects or others, placed one or more subjects at increased risk, **and** was unexpected, **and** was related to the research procedures. Examples may include breach of confidentiality from inadvertent information disclosure or unintentional loss of records.
* Protocol deviations – an unintentional or accidental change to the IRB-approved protocol
	+ Major deviations are those that placed one or more subjects at increased risk, affected the rights and welfare subjects, or have the potential to recur without intervention.
	+ Minor deviations are those that did not place one or more subjects at increased risk or did not affect the right and welfare of subjects. (Minor deviations are reported in aggregate to BRANY IRB at continuing review or with notification of study closure, using the [Minor Deviation Log](http://www.brany.com/wp-content/uploads/2018/07/54.minor-deviation-log-20139201.doc).)
* Changes to the protocol made without prior IRB review and approval to eliminate apparent immediate hazard to a research subject
* Complaint of a subject that indicates unexpected risks or that cannot be resolved by the research team
* Interim findings or reports that indicate an unexpected changes to the risks or potential benefits of the research, in terms of severity or frequency
* Publication in the literature that indicates an unexpected change to the risks or potential benefits of the research.

Researchers may submit events requiring prompt reporting via the following form:

* **16-Reportable Event xForm**

Event reporting must be in accordance with the timelines below:



**Does BRANY offer any training on their version of IRBManager**

BRANY provides access to various [training options](https://www.brany.com/irb-manager/) to learn more about *IRBManager* on their website.

* Webinar – IRBManager Basics (46 minutes, with voice)
* Weblet – Where do I find Approval Documents (no voice)
* Weblet – How to submit a Continuing Review (no voice)
* Weblet – How to find my study in *IRBManager* (no voice)
* Weblet – How to start a XForm in *IRBManager* (no voice)

Once you have access to *IRBManager*, you will have quick access to the webinar/weblets (and PDF’s) from your Home page, under Useful Links in the left menu.

These can also be accessed on BRANY IRB’s website here:

<https://www.brany.com/irb-manager/>

SAMPLE CERTIFICATE OF ACCURACY

ON LETTERHEAD

NAME OF RESEARCH CENTER

ADDRESS

Phone:

CERTIFICATE OF ACCURACY

DATE:

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, translated into Spanish version XXX of the main informed consent form for study protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The researcher for the research is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. BRANY IRB number is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

At the college level I studied in Spanish, at the graduate level in English, and can read, write and speak both English and Spanish.

I hereby certify this translation is to the best of my knowledge and ability, consistent in content, style and level of readability with the IRB approved document.

Respectfully submitted,

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INSERT NAME

TITLE