BRANY IRB

Guidance and Guidelines for Weill Cornell Medical College Researchers

For Submitting New Studies to BRANY IRB

BRANY Services

BRANY IRB (IRB00000080; 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
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Jennifer Mosby
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A full list of BRANY IRB Contacts are available here.

Submitting to BRANY IRB

All submissions must be submitted using the ***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 (if possible; temporarily during the COVID-19 pandemic, digital signatures or sending the form from a password-protected email address will be accepted), and submit via email to sabramov@brany.com. After it 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 the PI and study personnel that will need access to *IRBManager* will need to complete this process. It is not necessary for ALL personnel to obtain a user account.

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 WCM faculty member. Voluntary faculty cannot serve as PIs, but may serve as co-investigators.

In addition, employees of New York Presbyterian Hospital/Weill Cornell Medicine (only pharmacists, nurses, dieticians) can serve as PIs on protocols, except clinical trials that include an intervention with human subjects. However, medical residents cannot serve as PIs, but may serve as co-investigators.

Meetings and Timelines

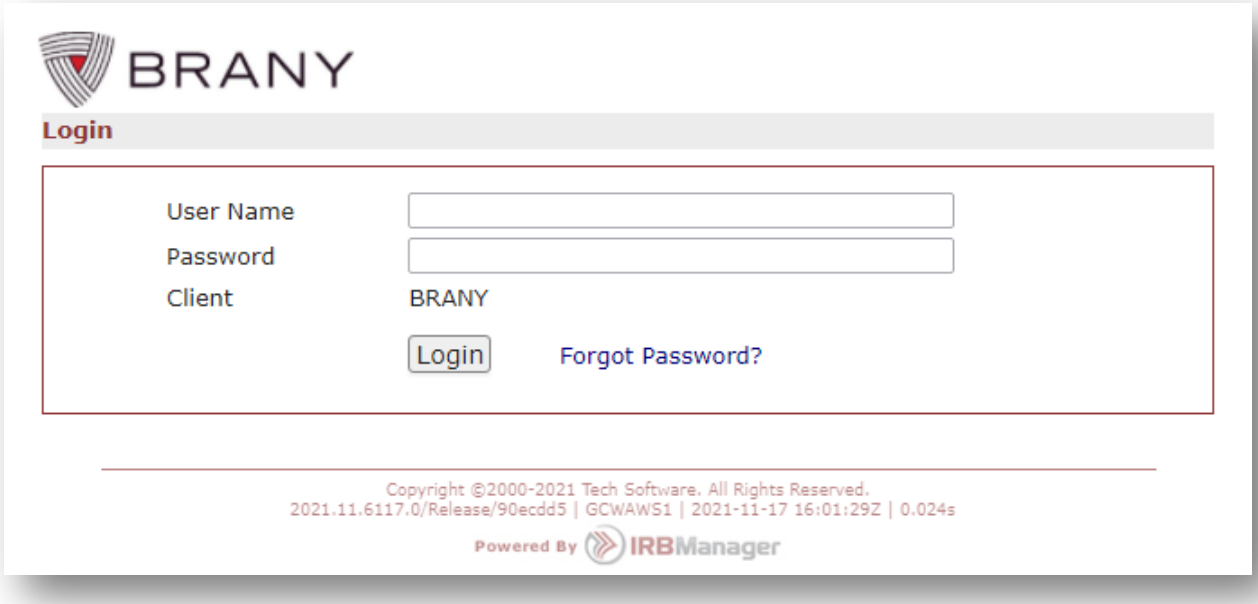
- BRANY's IRBs continuously review submissions that qualify for expedited review.
- Expected turnaround time for a submission qualifying for expedited review is 5 – 7 days from receipt of a complete submission.

- 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.
- **For 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 WCM liaisons 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 Status 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 IRB's Forms and Downloads website: https://www.brany.com/forms-and-downloads/
- BRANY's website with information on *IRBManager:* https://www.brany.com/irb-manager/
- BRANY's direct portal for *IRBManager:* https://brany.my.irbmanager.com/

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



Initial Review

On your *IRBManager* home page, click on the link under **Actions** beneath the BRANY logo on the upper left: **START NEW STUDY/Obtain BRANY ID#**

- Select and complete the xForm called: **Register New Study**
  This xForm is used to introduce a new study into *IRBManager*. Once this xForm is complete, your study will receive a BRANY ID# so you can login to *IRBManager* and complete a **Research Application** xForm.

  Other required documents:
  - BRANYPlus reliance memo indicating approval to submit to BRANY IRB
  - Curriculum Vitae of the Principal Investigator
  - Current clinical license for Principal Investigator, if applicable
  - Completed BRANY User Access Form for anyone associated with the study that needs an *IRBManager* access – if not already on file with BRANY IRB
  - Research Protocol
  - Informed consent and assent documents, as applicable
  - 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.

Informed Consent

Use the WCM site specific version of BRANY IRB's consent form template for submissions to BRANY IRB. The template is available here:
https://research.weill.cornell.edu/integrity-compliance/human-subjects-research/institutional-review-board-irb

Consent forms for studies reviewed by BRANY IRB must 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. 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 consent does not exempt an investigator from obtaining informed consent. Investigators may apply for a waiver of documented consent using the following xForm:

- The **Request for Waiver of Documentation of Consent** is embedded within the submission forms for BRANY IRB. Answer the appropriate questions within the xForm.

Waiving or Altering Elements of Consent for Minimal Risk Research

Investigators may apply for a waiver or alteration of consent using the following xForm:

- 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 xForm.

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, investigator 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).

Short Form consents can be requested via *IRBManager*. Log into your study details page, and start and complete xForm **#03 – Short Form Consent Request.** Guidance for appropriate use of Short Form Consents can be found on BRANY IRB's web site here:

- Short Form Guidance

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.

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 ID # 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 xForm: 01-Modification/Request for IRB Review

   IMPORTANT NOTE: Clicking **SUBMIT** when the xForm is in the **data entry stage** means the xForm 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 WCM's requirements)
  - BRANY financial disclosure forms, study-specific:
    - FORM 01: Conflict Disclosure Statement
    - FORM 02: Conflict Report Form (only if answered "YES" on Form 01)

Note: Disclosed conflicts of interest will be reported by BRANY IRB staff to WCM. BRANY will obtain any required COI management plans directly from WCM, as applicable.

Continuing Review and Annual Status Reports

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.

IRBManager will send email notifications to investigators 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 xForms:

Continuing Review

- 11-Continuing Approval Application

Annual Status Report (for non-expiring studies)

- 12-ANNUAL STATUS REPORT

Study Closure

- 04-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 investigator 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 BRANY IRB:

- 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.)
    -
- 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.

Investigators may submit events requiring prompt reporting via the following xForm:

- **16-Reportable Event xForm**

Event reporting must be in accordance with the timelines below:

Reporting Timelines

UPIRTSOS (Unanticipated Problems)	Report per occurrence within 5 days
Serious Adverse Events (Local)	Report per occurrence within 5 days
Unanticipated Adverse Device Events (UADEs)	Report per occurrence within 10 days
Complaints	Report per occurrence within 5 days
Major Deviations	Report per occurrence within 10 days
Minor Deviations	Report in aggregate with continuing review or study closure

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 stamp will be inserted into the final approved version of the informed consent by the IRB administrative staff; copies of this stamped consent must be used by the research staff to obtain informed consent from subjects. The PI may then submit BRANY approved documents in WRG via the Initial Submission form. The PI may not begin recruiting subjects for the study until all items in SASP listed as required for study initiation are marked as approved. *Note: Only current IRB approved documents can be used for the recruitment of subjects.*

Once approved, the Investigator 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.

Does BRANY offer any training on *IRBManager*?

BRANY provides access to various training options 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 investigator 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,

INSERT NAME
TITLE