

Completing a New Study Submission in eIRB+

Create the “New Study” in eIRB+

- Go to the main page for eIRB+ and log-in.
- Once in the system you will be brought to your inbox.
- On the left side of the page toward the top select Create New Study to open the Basic Information screen.

NU Institutional Review Board Office

Hello, Priya Tripathi

My Inbox Home IRB

Create New Study
Report New Information

Submissions
Meetings
Reports
Library
Help Center

My Inbox My Studies

My Inbox

Filter ID Enter text to search for Go Add Filter Clear All

ID	Name	Date Created	Date Modified	Owner	State	Full Study Title	Root Study Exp. Date
STU00207784	18-133 Amin - AbbVie M16-766	6/11/2018 1:45 PM	9/19/2018 3:51 PM	Puylear, Kevin	Modifications Required	A Multicenter, Randomized, Open Label, Efficacy Assessor-Blinded Study of Risankizumab Compared to Secukinumab for the Treatment of Adult Subjects with Moderate to Severe Plaque Psoriasis who are Candidates for Systemic Therapy	
STU00009100-MOD0015	Modification #15 for Study E1217-Aspire	9/18/2018 1:23 PM	9/18/2018 1:25 PM		Pre-Submission	Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) Study	8/16/2019
IRBSITE000000028-MOD0002	Modification #2 for Site For (xIRB) 18-069 Opal - NIH SCA 1 & SCA 3	9/13/2018 2:23 PM	9/13/2018 2:24 PM		Pre-Submission	Site For Clinical Trial Readiness for SCA1 and SCA3	8/7/2019
SITE000000011-MOD0001	Modification #1 for Site For (xIRB) 17-170 Carvill - Pediatric Epilepsies	7/20/2018 11:57 AM	9/13/2018 12:49 PM		Pre-Submission	Site For (xIRB) 17-170 Carvill - Pediatric Epilepsies	5/31/2019
STU00205344	17-097 Stulberg - Mesh Suture	5/23/2017 1:51 PM	9/13/2018 12:16 AM	Linn, Lisa M.	Modifications Required	Mesh Suture for Abdominal Wall Closure	
SITE000000354-MOD0001	Modification #1 for Site For (CIRB) 17-065 Paller - Eli Lilly 11F-MC-RHCD	9/7/2018 8:57 AM	9/7/2018 8:57 AM		Pre-Submission	Site For (CIRB) 17-065 Paller - Eli Lilly 11F-MC-RHCD	4/30/2019
STU00208323	18-167 Colavincenzo - Eli Lilly 14V-MC-JAHO (BRAVE-AA1)	8/28/2018 4:39 PM	9/5/2018 3:40 PM		Pre-Submission	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Operationally Seamless, Adaptive Phase 2/3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Severe or Very Severe Alopecia Areata	
SITE000000499-MOD0001	Modification #1 for Site For (xIRB) 17-147 Prickett - STRC-106-16-01 BARRIERS	9/5/2018 10:59 AM	9/5/2018 11:05 AM		Pre-Submission	Site For (xIRB) 17-147 Prickett - STRC-106-16-01 BARRIERS	7/31/2019
SITE00000176-MOD0002	Modification #2 for Site For (CIRB) Paller - (AD Biomarkers)	6/11/2018 3:37 PM	6/19/2018 4:54 PM	Willston, Dyna	Discarded	Site For (CIRB) Paller - (AD Biomarkers)	#ERROR#
SITE00000362-MOD0002	Modification #2 for Site For (CIRB) Paller - (Ichthyosis)	6/11/2018 1:47 PM	6/19/2018 4:47 PM	Willston, Dyna	Discarded	Site For (CIRB) Paller - (Ichthyosis)	#ERROR#

10 items < page 1 of 1 > 25 / page

Basic Information

In order for eIRB+ to generate a new study submission (and create an STU number), you must also complete the sections indicated with the red asterisk in the Basic Information section.

Throughout the submission, selecting “Continue” should save changes, however, make sure to click “Save” periodically to ensure that all your information to date is saved.

- Enter the study title as listed on the protocol.
- Create the study short name (refer to above instructions for format).
- Enter a brief description of the study briefly (no longer than 1 paragraph) summarizing the main question the research is designed to answer, all primary objectives of the study and the methods that will be used in the study (This can be pulled directly from the protocol).
- Choose the best selection, Social Behavioral or Biomedical, which best describes the type of study you are entering.

Basic Information

1. * Title of study:

2. * Short title:

3. * Brief description: ?

4. * Which selection best describes your study?

☐ Social Behavioral

☐ Biomedical

[Clear](#)

5. * Principal investigator:

Priya Tripathi

6. * Will an external IRB act as the IRB of record for this study? Note: Once you answer this question and save/continue past this page, you will NOT be able to change this answer.

☐ Yes ☐ No [Clear](#)

7. * What kind of study is this?

☐ Single-site study (Regardless the number of locations or sites, the NU IRB will serve as the IRB only for NU)

☐ Collaborative study (Each site will conduct a portion of the study and the NU IRB will either serve as the IRB of record for all participating sites or defer review to another, external IRB)

☐ Multi-site study (More than one site will conduct the entire study and the NU IRB will either serve as the IRB of record for all participating sites or defer review to another external IRB)

[Clear](#)

8. * Attach the protocol:

Document	Category	Date Modified	Document History
<div><input type="button" value="+ Add"/></div>			

- Choose the name of the Principal Investigator by clearing your name and typing in the text box. Registered users will populate as the name is being typed. Select the PI by clicking on the name when it appears.
- Answer the question of whether an external IRB will act as the IRB of record for the study. Once you select the correct option and save, you will not be able to revise your selection. (If you are selecting “Yes” to this question, please move to the “IRB SUBMISSION PROCESS: EXTERNAL IRBs” section of this handbook to complete the submission.)

6. * Will an external IRB act as the IRB of record for this study? Note: Once you answer this question and save/continue past this page, you will NOT be able to change this answer.

☐ Yes ☐ No [Clear](#)

7. * What kind of study is this?

☐ Single-site study (Regardless the number of locations or sites, the NU IRB will serve as the IRB only for NU)

☐ Collaborative study (Each site will conduct a portion of the study and the NU IRB will either serve as the IRB of record for all participating sites or defer review to another, external IRB)

☐ Multi-site study (More than one site will conduct the entire study and the NU IRB will either serve as the IRB of record for all participating sites or defer review to another external IRB)

[Clear](#)

- Select the type of study as Single-Site, Collaborative Study, or Multi-Site study
 - Single site: regardless the number of locations/sites, the NU IRB will serve as the IRB only for NU

- Collaborative study: each site will conduct a portion of the study and the NU IRB will either serve as the IRB of record for all participating sites or defer review to another external IRB
- Multi-site study: more than one site will conduct the entire study and the NU IRB will either serve as the IRB of record for all participating sites or defer review to another external IRB
- Attach the protocol and local protocol addendum (if applicable) by selecting “Add” to open the attachment window. Browse to the protocol file on the R: drive to upload it to the application.
- Select “Continue” in the bottom right corner.

2. * Short title:

3. * Brief description: ?

4. * Which selection best describes your study?

☐ Social Behavioral

☒ Biomedical

[Clear](#)

5. * Principal investigator:

Puneet Opal [...](#)

6. * Will an external IRB act as the IRB of record for this study? Note: Once

☐ Yes ☐ No [Clear](#)

7. * What kind of study is this?

☐ Single-site study (Regardless the number of locations or sites, the NU IRB will

☐ Collaborative study (Each site will conduct a portion of the study and the NU IRB

☐ Multi-site study (More than one site will conduct the entire study and the NU IRB

[Clear](#)

8. * Attach the protocol:

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

Add Attachment - Mozilla Firefox

https://eirbplus.northwestern.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomDataType

Add Attachment

1. * File to attach:

[Choose File](#)

2. Name: (if not supplied, the file name will be shown) ?

3. Version number:

* Required

[OK](#) [OK and Add Another](#) [Cancel](#)

****Please note:** At any time while completing a new study submission in eIRB+, if you are unable to complete a required field in one section you can still navigate to other sections of the application using the drop-down navigation pane at the top of the application. You can then come back later to fill in incomplete sections.

You Are Here: 18-182 Opal - Biohaven BHV4157...

« Back Save Exit Hide/Show Errors Print Jump To ▾

Basic Information

1. * **Title of study:**

A Phase III, Long-Term Randomized, Double-Blind, Placebo-Controlled Trial of

2. * **Short title:**

18-182 Opal - Biohaven BHV4157-206

3. * **Brief description:** ?

Hereditary Spinocerebellar Ataxias (SCA) are disorders of spinocerebellar pathology that are characterized clinically by progressive ataxia and are attributed to various autosomal dominant genetic mutations. Ataxia, itself, is a symptom of loss of control of voluntary body movements and can involve unsteady gait, dysarthria, and clumsiness, potentially progressing to the stage of difficulty with swallowing and breathing. In patients with SCA, atrophy of the cerebellum and sometimes brainstem may be apparent on brain imaging.

4. * **Which selection best describes your study?**

☐ Social Behavioral

☒ Biomedical

[Clear](#)

5. * **Principal investigator:**

Puneet Opal

Basic Information

Funding Sources

Study Team Members

Study Scope

Local Site Documents

Sites

You can also click “Exit” to leave the study application. You can come back and complete the rest of the submission at any time by clicking “Edit Study” on the main study page.

My Current Actions

Edit Study

Printer Version

View Differences

Assign Primary Contact

Add Comment

Discard

Notify PI to Submit

Manage Study Access

RSS Link: RSS00208457 Incomplete

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested → Clarification Requested → Modifications Required

History

Activity	Author	Activity Date
Study Created	Tripathi, Priya	9/20/2018 11:58 AM

Sources of Funding and Other Support

- If the study is sponsored, included grant funded, you will need to indicate “yes” for Question 1 and enter the InfoEd number (e.g., SP0054321) that corresponds to the grant or contract funding the sponsored study. If you cannot locate InfoEd number, contact the finance teams and/or research administrator who works with the contract to obtain the information.
- If there is more than one funding source for the study, you can select multiple InfoEd records (funding sources) for a study.

- If the study is not externally sponsored, or if project is sponsored, but did not go through Northwestern University (e.g., SRALab or Lurie Children's is managing the grant), please select "no" to the question.
- For Question 2, this information can be found on the second page of the New Project Intake Form. If it is missing, contact the study coordinator to obtain the information.

Study Team Members

Study Team Members

1. Internal Personnel

Identify each additional person involved in the design, conduct, or reporting of the research: ?

[+ Add](#)

Name	Roles	Involved in Consent	E-mail	Phone
There are no items to display				

2. External Personnel

Identify each external person who will interact with participants or have access to identifiable data for whom NU IRB will have oversight responsibility such as Interns/Volunteers, research staff covered by an IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA). Do not list research staff from other institutions that have their own IRB approval.

[+ Add](#)

Name	Institution	Roles	Involved in Consent	E-mail	Phone	Training Date
There are no items to display						

- To add team members who are a part of Northwestern, click "Add" in the upper left corner at item 1.
 - Type the first or last name in the box associated with item 1 and click select for the name you are entering. If the study team member's name does not appear in the list, please contact the individual to make sure that they are registered for eIRB+. If they are not eIRB+ registered and/or need to complete CITI training, please see the "COMPLETING CITI TRAINING" and "REGISTERING IN EIRB+" sections at the beginning of the Handbook for next steps.
 - Select the role in research (Co-Investigator or Study Team Member) for item 2.
 - Select whether or not the team member will be involved in the consent process at item 3.
 - Click "OK" once you have finished adding study team member or "OK and Add Another" until you've finished adding team members.

Study Team Members

1. Internal Personnel

Identify each additional person involved in the design, conduct, or report

Name	Roles	Involved in Consent
There are no items to display		

2. External Personnel

Identify each external person who will interact with participants or have a

Investigator Agreement (IIA). Do not list research staff from other institution

Name	Institution	Role
There are no items to display		

Back

Add Study Team Member - Mozilla Firefox

https://eirbplus.northwestern.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomD...

Add Study Team Member

1. * Study team member: ?
2. * Role in research: (check all that apply)
 - ☐ Co-Investigator
 - ☐ Study Team Member
3. * Is the team member involved in the consent process?
 - ☐ Yes
 - ☐ No
 - [Clear](#)

* Required

OK OK and Add Another Cancel

- To add a team member who is not affiliated with Northwestern (external personnel), click “Add” under item 2.
 - Enter the first name, last name, Institution, Email Address, Telephone Number, Training Date, select the Role in research and select whether or not the team member will be involved in the consent process at item 4.
 - Training documents (i.e. CITI or NIH human subjects training) are to be uploaded later on in the “Supporting Document” section of the application for each external study team member.
- Once all study team members are entered, select “Continue” in the bottom right corner.

Study Team Members

1. Internal Personnel

Identify each additional person involved in the design, conduct, or report

Name	Roles	Involved in Consent
ZsaZsa Brown	Study Team Member	yes
Cynthia Poon	Study Team Member	yes
Karen Williams	Study Team Member	yes

2. External Personnel

Identify each external person who will interact with participants or have a

Investigator Agreement (IIA). Do not list research staff from other institution

Name	Institution	Role
There are no items to display		

Back

Add NU External Team Members - Mozilla Firefox

https://eirbplus.northwestern.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomD...

Add NU External Team Members

1. * First Name:
- * Last Name:
- * Institution:
- Email Address:
- Telephone Number:
2. * CITI Training Date:
- Note: For each external Study Team member, please attach documentation of completed CITI training in the 'Other Attachments' section of the Documents page.
3. * Role in research: (check all that apply)
 - ☐ Co-Investigator
 - ☐ Study Team Member
4. * Is the team member involved in the consent process?
 - ☐ Yes
 - ☐ No
 - [Clear](#)

* Required


OK OK and Add Another Cancel

****Please note:** If you have any questions or are unclear about a study team member’s role and/or whether they are involved in the consenting process, please make to sure contact the study team for clarification.

Study Scope

- The answers to these questions can be found in the study protocol.
- If you select “No” to either selection, then subsequent study application pages will not appear (i.e. if you select that no drugs are involved with the study, then the “Drugs” section of the study application will not appear when you select Continue).
- Select “Continue” in the bottom right corner once completed.

Study Scope

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? 

☒ Yes ☐ No [Clear](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

☐ Yes ☐ No [Clear](#)

Drugs

Drugs

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:


 Add

Generic Name	Brand Name	Investigational Drug Code Name	Attachment Name
--------------	------------	--------------------------------	-----------------

There are no items to display

2. * Will the study be conducted under any IND numbers?

☐ Yes ☐ No [Clear](#)

3. Attach files: (such as IND or other information that was not attached for a specific drug) 

 Add

Document	Category	Date Modified	Document History
----------	----------	---------------	------------------

There are no items to display

- If there is a study drug(s), click “Add” under item 1.
 - In the box that pops up, within the comment field under “Select the drug”, you can begin to type the name of the study drug. If is listed on a pre-populated list, it will appear for selection.
 - If you cannot find the drug in the pre-populated list, enter it in the appropriate field below the selection box.
 - In item 2, attach files related to this drug (e.g. Investigator’s Brochure, package insert).
 - Select “OK” once finished or “OK and Add Another” if the study has multiple study drugs.

Drugs

1 * List all drugs, biologics, foods, and dietary supplements to be used in the study.

+ Add

Generic Name	Brand Name	Investigational Drug Code Name
There are no items to display		

2 * Will the study be conducted under any IND numbers?

☐ Yes ☐ No [Clear](#)

3 Attach files: (such as IND or other information that was not attached to the study)

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Back

Add Drug - Mozilla Firefox

https://eirbplus.northwestern.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomDrug

Add Drug

Add Drug Information

1. Select the drug:

If you cannot find the drug in the list above, enter its information here:

Drug name:

Investigational Drug Code Name (if no brand or generic name available):

2. Attach files related to this drug:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Attachments may include a copy of the package insert, investigator brochure, product labeling, or verification of any IND number.

* Required

OK OK and Add Another Cancel

- If the study is not conducted under an IND (and an NU investigator does not hold an IND exemption), this page is complete and select “Continue” in the bottom right corner.
- If the study is conducted under an IND, click “Add” under item 2.
 - If an NU investigator holds the IND, enter the appropriate information into the box that pops up.
 - If the study is a sponsored study where the sponsor holds the IND, you can find this information in the study protocol or from the sponsor contact, and enter the appropriate information into the box that pops up.
- If the NU investigator or study sponsor provides any documentation related to the IND (e.g. acknowledgement of IND submission, study may proceed letter, IND exemption letter), upload it to item 3 by clicking “Add”.
 - A letter is required when an NU investigator holds the IND or received an IND exemption.
 - A letter is not required when an industry sponsor holds the IND, but if provided you may include.
- Once all study drug information is entered, select “Continue” in the bottom right corner.

Devices

Devices ?

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. * Device exemptions applicable to this study: ?

- ☐ IDE number
- ☐ HDE number
- ☐ Claim of abbreviated IDE (nonsignificant risk device)
- ☐ Exempt from IDE requirements
- [Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device) ?

Document	Category	Date Modified	Document History
There are no items to display			

- If there is a study device(s), click “Add” under item 1.
- In the box that pops up, within the comment field under “Select the device”, you can begin to type the name of the study device. If it is listed on a pre-populated list, it will appear for selection. If you cannot find the device in the pre-populated list, you can enter the name in the same box.
- Attach files related to this device (e.g. device manual, Instructions for Use, or informational brochure).
- Select “OK” once finished or “OK and Add Another” if the study has multiple study devices.

Devices ?

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:

Device	Humanitarian Use Device
There are no items to display	

2. * Device exemptions applicable to this study: ?

- ☐ IDE number
- ☐ HDE number
- ☐ Claim of abbreviated IDE (nonsignificant risk device)
- ☐ Exempt from IDE requirements
- [Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device)

Document	Category
There are no items to display	

[Back](#)

Add Device - Mozilla Firefox

https://eirbplus.northwestern.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomDataTypes/...

Add Device Information

1. Select the device: ?

If you cannot find the device in the list above, enter its information here:

Device name:

Is this a humanitarian use device (HUD)?

☐ Yes ☐ No [Clear](#)

2. Attach files related to this device:

[Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

Attachments may include a copy of investigator brochure and the product labeling/device instructions.

* Required

[OK](#) [OK and Add Another](#) [Cancel](#)

- Under item 2, select whether any device exemption types are applicable (e.g. IDE, HDE, non-significant risk device, or IDE exempt).
- If no device exemption types are applicable to the study, or if non-significant risk device, or IDE exempt, then you are done with this page and select “Continue” in the bottom right corner.
- If the study is conducted under an IDE or HDE, click “Add” under item 3.

- If an NU investigator holds a type of device exemption, enter the appropriate information into the box that pops up.
- If a sponsored study where the sponsor holds a type of device exemption, you can find this information in the study protocol or from the sponsor contact, and enter the appropriate information into the box that pops up.
- If the NU investigator or study sponsor provides any documentation related to the device exemption determination (e.g. acknowledgement of IDE submission, IDE approval letter, abbreviated IDE letter, IDE exemption letter), upload it to item 4 by clicking “Add”.
 - A letter is required when an NU investigator holds the IDE/HDE.
 - A letter is not required when an industry sponsor holds the IDE/HDE, but if provided you may include.
- Once all study device information is entered, select “Continue” in the bottom right corner.

Consent Forms and Recruitment Materials

Documents for Research to be Performed at Northwestern

1. Consent forms: ?

+ Add			
Document	Category	Date Modified	Document History
There are no items to display			

2. Recruitment materials: (add all material to be seen or heard by potential participants, including ads) ?

+ Add			
Document	Category	Date Modified	Document History
There are no items to display			

3. Supporting Documents: (any study-related documents not attached elsewhere)

+ Add			
Document	Category	Date Modified	Document History
There are no items to display			

- Upload all consent forms, including NU IRB consent forms for external sites containing site-specific edits, if applicable (item 1) and NU recruitment/retention material (item 2).
 - Updates to a previously approved consent form (not a clean consent form being submitted for a new study) should be uploaded from the R: drive as a tracked changed document (section 1 of the attachment window below). However, after uploading the file, be sure to remove the “(tracked changes)” portion of the file name (section 2 below). This is done because the IRB displays the name provided here on the approval letter, and revising the file name will ensure that the approved consent form will not read in tracked changes and create confusion for someone retrieving it at a later date.

Documents for Research to be Performed at Northwestern

1. Consent forms: ?

+ Add

Document Category

There are no items to display

2. Recruitment materials: (add all material to be seen or heard by potential subjects)

+ Add

Document Category

There are no items to display

3. Supporting Documents: (any study-related documents not attached elsewhere)

+ Add

Document Category

There are no items to display

◀ Back

Add Attachment - Mozilla Firefox

https://eirbplus.northwestern.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomDataTypes/...

Add Attachment

1. * File to attach:

18-182 BHV4157-206... Choose File

2. Name: (if not supplied, the file name will be shown)

18-182 BHV4157-206_MainConsent_09-06-2018

3. Version number:

Required

OK OK and Add Another Cancel

- NU recruitment material consists of documents seen by the public/potential study subjects that requires and contains all Northwestern University required recruitment elements (i.e. content can be controlled by NU study staff and is used specifically at NU). For instance, a study-wide website run by the study sponsor would not be included in this section (but would be included in Supporting Documents).
- Recruitment materials not seen by the general public (i.e. doctor to doctor letters) do not need to be submitted to the IRB for review and can be omitted from the study application.

Supporting Documents

- Upload all remaining study documents that will be used to conduct the research that require IRB review. This includes but may not be limited to the following documents:
 - All materials seen by the public/potential study subjects not defined as “recruitment materials” in the Consent Forms and Recruitment Materials section (i.e. surveys, questionnaires, ID cards, instruction booklets, unmodified recruitment items part of a Central Recruitment Campaign, etc.)
 - If included as appendices to the study protocol, each document must still be individually uploaded here.
 - Radiation dosimetry form and memo (see Supporting Documents section of Essential Regulatory Documentation for more information)
 - SRC Committee approval letter
 - External personnel CITI training certificates
 - Data collection forms (for chart review studies)

Sites

Sites

1. Please specify study site(s):

☐ Northwestern University (NU) – Evanston

☐ Northwestern University (NU) – Chicago

☐ Northwestern University (NU) – Qatar

☐ Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Childrens)

☐ Clinical Research Unit (CRU)

☐ Northwestern Memorial HealthCare (NMHC) and/or its affiliates

☐ Shirley Ryan AbilityLab (SRALab)


☐ Robert H. Lurie Comprehensive Cancer Center and/or its affiliates

2. If the research will be conducted at International Sites, Schools, (Preschools, Primary Schools, and/or Secondary Schools), or any other locations, please specify these below:

Add						
Site	Contact	Phone	Email	External IRB Review	Rely on NU IRB	Location
There are no items to display						

- The site information is found on the Intake Form.
- “Northwestern University (NU) – Chicago” will always be a selected site for all studies we process in NUCATS.
 - Sites should include “Robert H. Lurie Comprehensive Cancer and/or its affiliates” if the study has been approved by the cancer center. The cancer center approval letter is uploaded into Supporting Documents.
- If there will be any external sites (i.e. non-NU affiliate sites) then include those sites by clicking “Add” in the second part of this section. The following information must be entered:
 - Site name, type (international, school or other) and location
 - Site contact information (name, email, phone)
 - Whether NU IRB is IRB of record for the site
- External sites are typically applicable when completing a New Study Submission when NU is a Data Coordinating Center, or DCC (data from external sites is sent to NU for collection and analysis).
- External sites may also be study sites that choose to rely on Northwestern as the IRB of Record. External study sites are typically designated when completing a New Study Submission
- Select “Continue” in the bottom right corner once completed.

Final Page and RSS

The RSS Form is the final page of the new study submission. Prior to forwarding any submission to the PI, the RSS form must be complete. If you are unsure how to answer a question, the blue help circles  have useful clarifying information.

1.0 Cancer Research

RSS: Cancer Research

The Research Supplemental Submission (RSS) collects information about each project submitted to the Northwestern IRB. This information is not used in the course of the IRB review. **All projects submitted to the Northwestern IRB should now confirm whether they are cancer-relevant, according to the NIH definition.** The remainder of the RSS is required for Feinberg-affiliated PIs or projects where research will take place at NMHC or one of its affiliate sites.

* 1. Is this a cancer-relevant human subjects research study? Please view the help text to see if the study is cancer-relevant: ?

☒ Yes ☐ No [Clear](#)

* 1a. Is this an Emergency Use or single patient IND study?

☐ Yes ☐ No [Clear](#)

* 1b. Is this an investigator-initiated study? If yes, you must obtain Lurie Cancer Center approval BEFORE you submit this project to the IRB. This may include Disease Team endorsement or acknowledgement, as well as Scientific Review Committee approval or acknowledgment. For questions regarding what is required for your specific project, please contact the Lurie Cancer Center Protocol Review & Monitoring System staff at: SRC.CCSG@northwestern.edu

☒ Yes ☐ No [Clear](#)

You will not be able to submit this project to the IRB until the 'Related NOTIS Submission' below has an SRC Approval Date. You can check the SRC status any time in the 'Cancer Research - SRC' tab in the study's workspace.

* 1c. Related NOTIS Submission

The Lurie Cancer Center requires cancer-relevant studies to be tracked in the Northwestern Oncology Trial Information System (NOTIS). Please use the [...] chooser button and follow the instructions to select or create the corresponding NOTIS record. Failure to select the correct record could delay IRB project approval. Please contact notis-support@northwestern.edu for all NOTIS-related questions. **NOTE:** If you connect this IRB submission to the wrong NOTIS record below, you will have to contact notis-support@northwestern.edu to correct it in the NOTIS system. The relationship between this IRB record and the NOTIS record is reflected below, but is maintained in the NOTIS system.

...

The remainder of the RSS is REQUIRED for this submission. If you do not see the RSS questions below, the study's primary contact should execute the 'Manage Study Access' activity on the study to add you to the guest list. (If this is a modification, they should do so on the root study.)

1. Question 1 asks if the research study is cancer-relevant.
 - a. Help text will assist with determining if a study is cancer-relevant

2.0 Operational Data

RSS: Operational Data

For help with this form, please send an email to navigator@northwestern.edu. Be sure to include 'RSS Operational Data Form Help' in the subject line of your email.

* 1. Will you or your study team access or collect Protected Health Information (PHI) from NMHC?

☐ Yes ☐ No [Clear](#)

* 2. Does your research include the use of students, residents, or fellows at the Feinberg School of Medicine as participants? If so, please be aware that you must seek prior approval. For additional guidance please see this document. Please contact Dr. Marianne Green at m-green@northwestern.edu for more information.

☒ Yes ☐ No [Clear](#)

* 2a. If your research includes the use of students, residents, or FSM fellows, please attach documentation supporting approval you have received from FSM (e.g. correspondence from Dr. Marianne Green indicating compliance with their policy):

[None] [Upload](#)

1. Question 1 has to do with the collection of PHI from NMHC. Will any Protected Health Information (per HIPAA definition) be accessed or collected as part of the study? This includes but is not limited to patient names and other identifiers, addresses, dates of service, etc.
 - a. Yes: the data for the study will include PHI
 - b. No: the data for the study will be completed de-identified or will contain only aggregate counts
2. Question 2 asks about the use of students, residents, and fellows at FSM as participants.
 - a. If the research includes the use of students, residents, or FSM Fellows,

documentation supporting approval from FSM (e.g. correspondence from Dr. Marianne Green indicating compliance with their policy) must be attached.

3. Community Engagement in Research

Please answer the following questions about community participation in your research. If you need assistance with this section or to learn about resources to support community engagement in your research, contact the Center for Community Health (cch-consult@northwestern.edu). Be sure to include 'RSS CCH Data Form Help' in the subject line of your email.

5a. In which of the following ways will non-academic organizations (including clinical sites affiliated with Northwestern) or community partners (e.g. community or faith-based organizations, foundation, government, social service organization) participate in this research? *Select all that apply.*

- ☐ Participating on an advisory board or other governing body for the study
- ☐ Designing the study proposal or protocol (e.g. assessing feasibility, design of study questions, etc.)
- ☐ Developing the intervention (e.g. drug, device, framework, approach, technology, etc.)
- ☐ Providing a location or space for research recruitment, data collection or intervention delivery
- ☐ Recruiting participants, including obtaining consent
- ☐ Delivering study intervention
- ☐ Acquiring/collecting specimens or data, including permission to use electronic data
- ☐ Analyzing data
- ☐ Interpreting findings
- ☐ Assisting with dissemination activities
- ☐ N/A - No organizations, including clinical sites and community partners, will participate in this research in any capacity
- ☐ Other, please specify:

3b. Reminder: Please ensure that all study team members, including those affiliated with community partner organizations, who are engaged in research activities (for example, consenting subjects and/or accessing identifiable participant data) are included in the study team member list in the IRB application for this study. Please direct any questions about the study team member list to the Northwestern University Institutional Review Board office (<https://irb.northwestern.edu/eirb-support>). The Center for Community Health (cch-consult@northwestern.edu) can advise organizations without their own IRB about how to establish a Federal-wide Assurance (FWA) and can provide community-friendly Human Subjects Protection Training in English and Spanish.

Add

Organization Name	Zip Code	City and Country
There are no items to display		

3. Question 3 asks about Community Engagement in the research.
 - a. The answer will *typically* be “N/A – No organizations, including clinical sites and community partners, will participate in this research in any capacity.”

2.0 NMHC

1. The NMHC affiliation selected for Question 1 should reflect what is provided on study documents, including the 1572 and Consent form.

RSS: Northwestern Memorial HealthCare (NMHC)

For help with this form please contact Delores Purnell Crump at dpurnell@nm.org, or call (312) 926-1719. Be sure to include 'RSS NMHC Data Form Help' in the subject line of your email.

* 1. Northwestern Memorial HealthCare (NMHC) Site(s):

- ☐ Northwestern Memorial Hospital (NMH)
- ☐ Northwestern Medical Group (NMG)
- ☐ Northwestern Lake Forest Hospital (NLFH)
- ☒ Other NMHC Affiliate

* a. If other, please specify:

2. If there is a 1572 for the study, Question 2 will be completed.

2. Please enter information for each investigational drug included in the study (i.e. drugs that have been given an IND number by the FDA):

+ Add

There are no items to display

3. Indicate if equipment, hardware or software will be brought to NMHC for the study. This should be confirmed by the study coordinator or PI for the study.

* 3. Will equipment, software and/or hardware be brought to NMHC for this study?

☒ Yes

☐ No

☐ Unknown at Time of Submission

[Clear](#)

* a. If Yes to question 3, describe the equipment:

* b. If Yes to question 3, indicate the NMHC Department where equipment will be housed:

* c. If Yes to question 3, do you anticipate any IT involvement in this project (e.g. hardware, software, etc.)?

☐ Yes ☐ No [Clear](#)

4. Question 4 discusses the type of patient being seen for the study. For example, for studies where patients will receive overnight infusions at the CRU, "Inpatients" would be selected.

* 4. Indicate the patient type at NMHC:

☐ Inpatients

☐ Outpatients

☐ Medical Students/Residents

☒ Pediatrics

☐ Emergency Department

☐ Bedded Outpatients

☐ Specimen Collection/Processing

☐ NM Staff

☐ Mathews Center for Cellular Therapy (MCCT)

☒ Other

* a. If Pediatrics checked, specify the age:

* b. If other checked, specify:

5. For any additional service locations being used, indicate this here. For example, if the study has an investigational drug being stored at the pharmacy, select "Investigational Pharmacy"

★ 5. Indicate the ancillary service areas where the research will be conducted:

<input type="checkbox"/>	Blood Center
<input type="checkbox"/>	Clinical Research Unit (CRU)
<input type="checkbox"/>	Diagnostic Testing Center (DTC)
<input type="checkbox"/>	Emergency Department
<input type="checkbox"/>	GI Lab
<input type="checkbox"/>	Hematology/Oncology
<input type="checkbox"/>	Infectious Diseases Clinic
<input type="checkbox"/>	Interventional Radiology Laboratory/Pathology
<input type="checkbox"/>	Intensive Care Unit
<input type="checkbox"/>	Mammography/Breast Center (Lynn Sage)
<input type="checkbox"/>	NMDTI
<input type="checkbox"/>	OB/GYNE/SCN
<input type="checkbox"/>	Investigational Pharmacy
<input type="checkbox"/>	NMG Clinic
<input type="checkbox"/>	Radiology/MRI/Nuclear Med/CT
<input type="checkbox"/>	Surgery/Operating Room
<input type="checkbox"/>	Transplant
<input type="checkbox"/>	EP
<input type="checkbox"/>	Catheterization Lab
<input type="checkbox"/>	Mathews Center for Cellular Therapy (MCCT)
<input checked="" type="checkbox"/>	Other

★ a. If other checked, please specify:

6. Indicate that you agree with Northwestern's liability policies by selecting the "I Agree" box

6. I understand that most third-party insurance carriers, including Medicare and the Illinois Department of Public Aid, will not cover investigational/experimental services. Accordingly, I acknowledge Northwestern Medicine may not be held liable for absorbing the cost of research charges, without the expressed written authorization of the Hospital.

Per Northwestern Medicine Policy 5.0034, I understand the Hospital reserves the right to conduct periodic audits to ensure compliance with established policies and procedures and I agree to support the Hospital with these efforts in a timely manner and make available all required records. Additionally, I understand that failure to comply with all applicable federal/state laws and Northwestern Medicine policies/procedures related to this research may include disciplinary action up to and including termination of research at the Hospital.

★ I agree: ☐ Yes ☐ No [Clear](#)

3.0 Data Security

The section will be completed if the PI is a Feinberg School of Medicine faculty member collecting health information on research participants. If completing this section, you will need to complete a Data Security Plan form (DSP). The DSP documents the methods used to record, store, and transmit subject study data in order to protect PHI.

RSS: Data Security

For questions about the 'Data Security' section of the form, please contact FSMIT-policy@northwestern.edu. Be sure to include 'RSS Data Security Form Help' in the subject line of your email.

- * 1. Attest that all sections of the Data Security Plan are complete, using the following Data Security Plan template. If not, attach a document explaining why this project is not Human Subjects Research, or otherwise not applicable:

☐ Yes ☐ No [Clear](#)

Data Security Plan template:

<http://www.feinberg.northwestern.edu/it/policies/information-security/data-security-plans.html>

- * 2. Upload the Data Security Plan (or Not Human Subjects Research justification) for this study. Please do NOT attach the protocol. If you do not yet have a Data Security Plan, use the template linked above to develop one for this project.

[None] [Upload Revision](#)

Technology Resources

Please address all questions and requests for IT resources required (e.g., storage and storage estimates, backup storage, archiving storage, granting access to data) of the Data Security Plan to FSMHLP@northwestern.edu.

Data Security Plans

Please address all questions, request for clarification and all other forms of assistance regarding Data Security Plans to FSMIT-policy@northwestern.edu.

Example Data Security Plans

<http://www.feinberg.northwestern.edu/it/policies/information-security/data-security-plans.html>

You will see the following at the bottom of the RSS Form:

Click Finish to exit the form.

1. Important! To send the submission for review, click Submit on the next page.

[Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print](#) [Jump To](#) [Finish](#)

- Click the "Finish" button to exit the form. This will not submit the study application; it will only bring you back to the main study page in eIRB+.
- Once ready to be submitted for review, on the main study page click "Notify PI to Submit".
- You will be directed to a text box, where a message may be entered. Please use the following template language for all submissions forwarded to the PI:

Hello Dr. (PI's last name),

The submission is complete and ready to submit.



Thank you,

(Your first name)

- After you click "OK", an email will be generated notifying the PI to submit the study to the NU IRB. The PI will not be able to submit until the RSS is complete.

 Deborah Welch
NMHC Endorsement: STU00202923

To  Priya Tripathi

Cc  NM Investigational Drug Service (NM);  Jane Regalado

 Message  IDS Fee Worksheet_v4_09 05 14.pdf (58 KB)  Investigational Drug Order Form1.doc (30 KB)



Office of Research
541 North Fairbanks, 13th Floor
Chicago, Illinois 60611

Study: STU00202923

PI: Cindy Zadikoff

Title: RESTORE: A clinical study of patients with symptomatic neurogenic orthostatic hypotension to assess sustained effects of droxidopa therapy

Dear Cindy Zadikoff:

Thank you for submitting the above titled research project. You have indicated that Northwestern Memorial Hospital (NMH), Northwestern Medicine Group (NMG), or Northwestern Lake Forest Hospital (NLFH) will be a project site, and therefore the Northwestern Memorial HealthCare (NMHC) Office of Research (OOR) has reviewed and endorsed this study in eIRB.

NMHC Office of Research endorsement of this study is contingent upon the following:

1. The submission of a completed Research Budget Form in Study Tracker. Once the NMHC budget has been approved in Study Tracker, the NMHC research account number will be your IRB STU number. Instructions for completing the budget in Study Tracker can be found at:

<http://nucats.northwestern.edu/resources-services/data-informatics-services/software-tools/nitro-study-tracker-formerly-enotis>

This study has been identified as a Medicare Qualifying Clinical Trial (MQCT), the NCT number from ClinicalTrials.gov must be entered into Study Tracker prior to the release of the research account number.

2. An **electronic Study Participant Research Voucher (eSPRV)** must be completed and submitted in Study Tracker **by the close of business on the day of the research service(s) being rendered**. Submit an eSPRV for all research services.

3. Fulfillment of Investigational Pharmacy requirements as follows:

- Complete the Investigational Drug Services (IDS) Fee Worksheet
- To ensure that ordering and transcribing orders for investigational drugs for outpatients occur in a way that maximizes patient safety, prevents delays in the filling of prescriptions, and adheres to JCAHO standards for medication management, please complete the **Investigational Drug Order Form** (attached) and return to the

 Deborah Welch
NMHC Endorsement: STU00202719

To  Priya Tripathi



Office of Research
541 North Fairbanks, 13th Floor
Chicago, Illinois 60611

Study: STU00202719

PI: Amy Paller

Title: An Open Label Multi-Center Extension Study to Evaluate the Long-term Safety of Zorblisa™ (SD-101-6.0) in Patients with Epidermolysis Bullosa

Dear Amy Paller:

Thank you for submitting the above titled research project. You have indicated that Northwestern Memorial Hospital (NMH), Northwestern Medicine Group (NMG), or Northwestern Lake Forest Hospital (NLFH) will be a project site, and therefore the Northwestern Memorial HealthCare (NMHC) Office of Research (OOR) has reviewed and endorsed this study in eIRB.

NMHC Office of Research endorsement of this study is contingent upon the following:

- If there are any Northwestern University employees listed as Authorized Personnel that need access to NMHC's facilities or Systems to conduct research, the individual(s) may need to complete the **NMHC Access Program**. If individuals on your team need to complete the NMHC Access Program or you are uncertain, please contact the NMHC Office of Research at (312) 926-1719 to receive further guidance and instructions.

Please contact me if you have any questions or need additional clarification about the instructions and/or forms enclosed in this email.

We wish you success in the conduct of your research study at NMH.

Thank you.

Deborah Welch
Research Compliance Coordinator
Office of Research
Northwestern Memorial HealthCare

541 N. Fairbanks Court, Suite 1337
Chicago, Illinois 60611
312.926.2244