

IRB Determination Request Process:

Prior to contacting Dr. Husk or accessing any patient charts for your data, you should complete the following steps to obtain an IRB exemption for your Quality Improvement Project (QIP).

Most QIPs will not be considered “research” and thus will not need a formal IRB. There are occasionally exceptions, however, depending upon the exact nature of your project. For this reason, you must formally propose your project to the Human Subjects Research Committee via a Human Subjects Research Determination Request.

The Committee will review your proposal and then decide whether or not your project can be granted “exempt status” from needing a formal IRB. As a result, this preliminary process is distinct from submitting an actual IRB.

Step 1:

Go to this website:

<https://northwellhealth.my.irbmanager.com/Dashboard/PortalHome.aspx>

Step 2:

When you see the below screen, click on “click here to login if you have a Northwell Active Directory Account”

Northwell Health

Login

The following issue(s) must be addressed:

- You must log in to continue.

Northwell Health

[Click here to login if you have a Northwell Active Directory account](#)


Non Northwell Employees:
Click [here](#) to login using your IRBManager issued login.
If you do not yet have an account, email irb@northwell.edu and request that an account be set up.

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/2022.9.6861.0/Release/14c41c2 | GCWAWS1 | 2023-02-07 17:37:02Z | 0.009s

Powered By IRBManager

Step 3:

Sign in with your normal Northwell username and password.




Sign in with your Universal ID and password

[Sign in](#)

Forgot your password? Please [Click Here](#)

Step 4:

Complete second factor authentication with the security code sent to your phone.



For security reasons, we require additional information to verify your account (mcaughey@northwell.edu)

Entrust Challenge Authentication

To establish your identity, please respond to the following:

Your one-time password has been sent to your Alternate Mobile 1 at *****3084.

These are the possible authentication types for this user:

[One-Time Password](#)

Step 5:

In the top left corner, click on “click here to submit a Human Subjects Research Determination Request” (underlined link).

****DO NOT click on the option below to “submit a new study to the IRB.”**

You will ONLY need to submit a new study to the IRB if you are not granted exempt status from the Human Subjects Determination Request.

Health

My Studies

Actions

- [Click here to submit a Human Subjects Research Determination Request.](#)
- Click here to submit a new study to the IRB
- Click here to submit an Application for Emergency Use to the IRB
- Click here to submit an interventional study for review by the Clinical Research Unit (NOT FOR IRB)

Studies (5 Active)

- You are associated with **5 active** Studies
- You are the CC Recipient for **3 active** and
- You are the Co-Investigator - No Consen

xForms (16 Active)

- You have **16 unsubmitted** xForms.
- You have **0 xForms** waiting for the PI, D
- There are **1 xForms** awaiting your attent

Events (1 Open)

Only show events where I am:

- You have **1 Exempt New Submission** ev

You have **1 Total Open** events

Step 6:

Complete the following 6-page PDF application answering questions as pertinent to your project. If you cannot complete this entire document in one sitting, you can always save it and come back to it later to finish and submit electronically.

Northwell Health

Collaborators Protocol Information Page 1 of 6 Next

Human Subjects Research Determination Request -- Protocol Information

ONLY SUBMIT THIS FORM IF YOU ARE NOT SURE AS TO WHETHER YOUR PROJECT SHOULD BE CONSIDERED HUMAN SUBJECTS RESEARCH. IF YOU KNOW THAT IRB APPROVAL/REVIEW WILL BE REQUIRED, PLEASE PROCEED TO SUBMIT THE INITIAL SUBMISSION APPLICATION. [Add Note](#)

All human subject research activities must be reviewed by the IRB prior to initiation.

Examples of projects that may not require IRB review and approval are included case reports of three or less patients, research on anonymous (i.e. no link to subject identity) specimens or data, medical practice innovation in which the physician's goal is to improve the well-being of a patient, quality improvement activities, surveillance programs, public health activities and resource utilization reviews.

Before submitting this form, please review the guidance on QI vs research, which can be found by clicking here.

Are you submitting this project because you are unsure of whether or not your project requires IRB review and approval before proceeding? [Add Note](#) [View Audit](#) (Required)

Yes

No

This form is often submitted to the IRB in error. To confirm that this is the appropriate form to submit to the IRB, please confirm the following to be true: (Required) [Add Note](#) [View Audit](#)

I have discussed my project within my clinical department and we are unsure if it qualifies as human subjects research or needs IRB review.

I have reviewed the Northwell guidance document "Quality Management/Quality Improvement (QM/QI) vs. Research Activities Subject to IRB Review" which can be found here: <https://feinstein.northwell.edu/for-professionals/human-research-protection-program/tools->

Step 7:

You will wait normally no longer than 2-3 weeks while the Human Subjects Research Committee reviews your determination request proposal.

They will send you an email confirming both receipt of the determination request proposal and whether or not it has received exempt status. If you do not hear back from them within 3 weeks, you can always reach out by contacting: irb@northwell.edu

[EXTERNAL] Decision of the Human Subjects Research Determination Request



Inbox, IRB <irb@northwell.edu>

To: Fried, Ethan; Menon, Alisha; Buckley, Megan



Thu 12/30/2021 12:55 PM

External Email. Do not click links or open attachments unless you trust the sender and content. Report suspicious emails using Report Phishing button or forward email to phish@northwell.edu

Dear Buckley, Megan

The Human Research Protection Program has received your Human Subjects Research Determination Request (HSRD HSRD21-0402).

The review is for the following project: ABC Score and Inpatient GI Bleed Triage

The determination is as follows: Proposed study activities do not meet the definition of human subject research, and therefore are deemed to be not human subjects research. Therefore no Northwell IRB review is required for this project as described. This determination applies only to the activities described in this request. Any changes that may alter this determination must be submitted to the IRB for review.

Reason for the determination: QI activity designed to help Lenox Hill incorporate an already validated scoring system for patients with GI bleed.

To access the submission in IRBManager, click here: [Human Subjects Determination Request](#). Contact the HRPP Office if you have any questions about this determination (irb@northwell.edu or 516-465-1910).

Sincerely,

HRPP Office

Additionally:

- Please review the document about what constitutes “Quality Improvement Versus Research in Health Care” prior to submitting your determination request. This document has helpful information about what distinguishes the two.
- If you have any questions about the Human Subjects Determination Request proposal, please reach out to your Chief Residents. They can likely show you examples from their prior QIP that received an exempt status to help guide you.