IRB Determination Request Process:

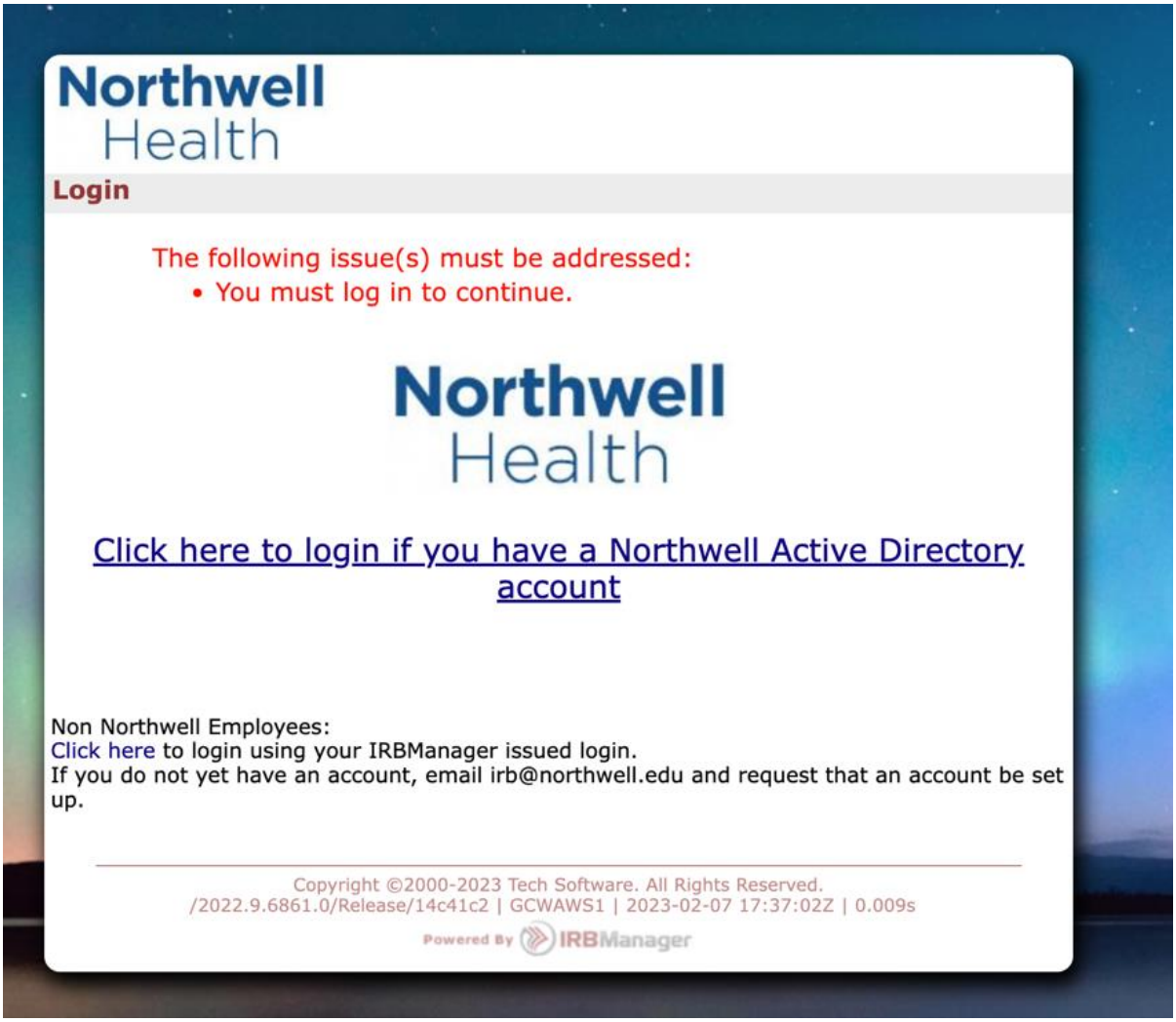
Prior to contacting Dr. Husk or accessing any patient charts for your data, you should complete the following steps to obtain an IRB exemption for your Quality Improvement Project (QIP).

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.

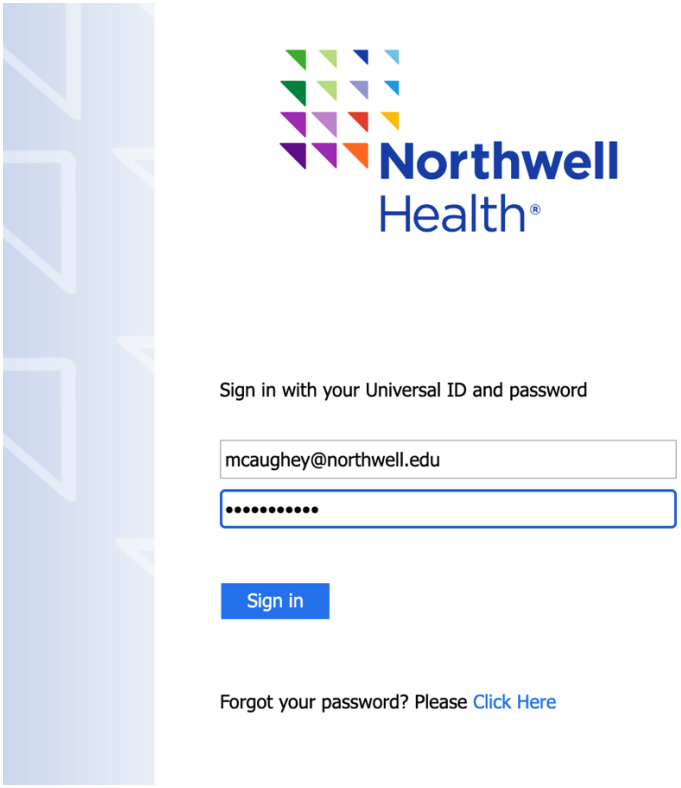
The Committee will review your proposal and then decide whether or not your project can be granted “exempt status” from needing a formal IRB. As a result, this preliminary process is distinct from submitting an actual IRB.

Step 1:
Go to this website:
https://northwellhealth.my.irbmanager.com/Dashboard/PortalHome.aspx

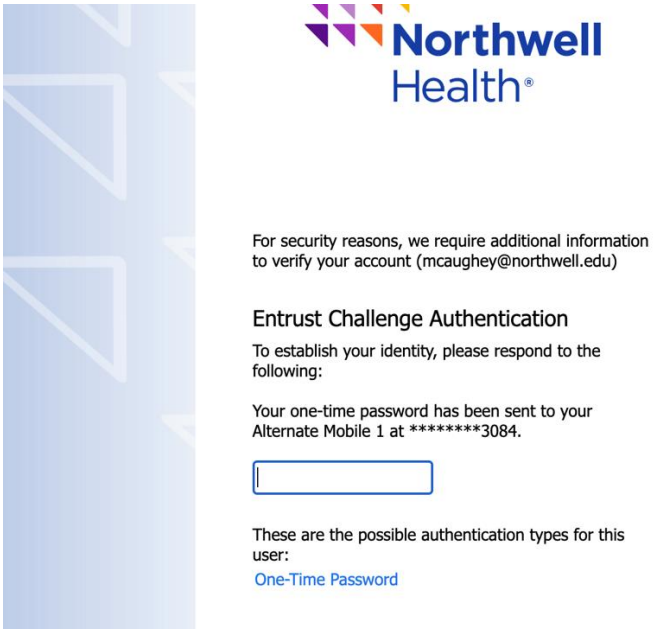
Step 2:
When you see the below screen, click on “click here to login if you have a Northwell Active Directory Account”



Step 3:
Sign in with your normal Northwell username and password.



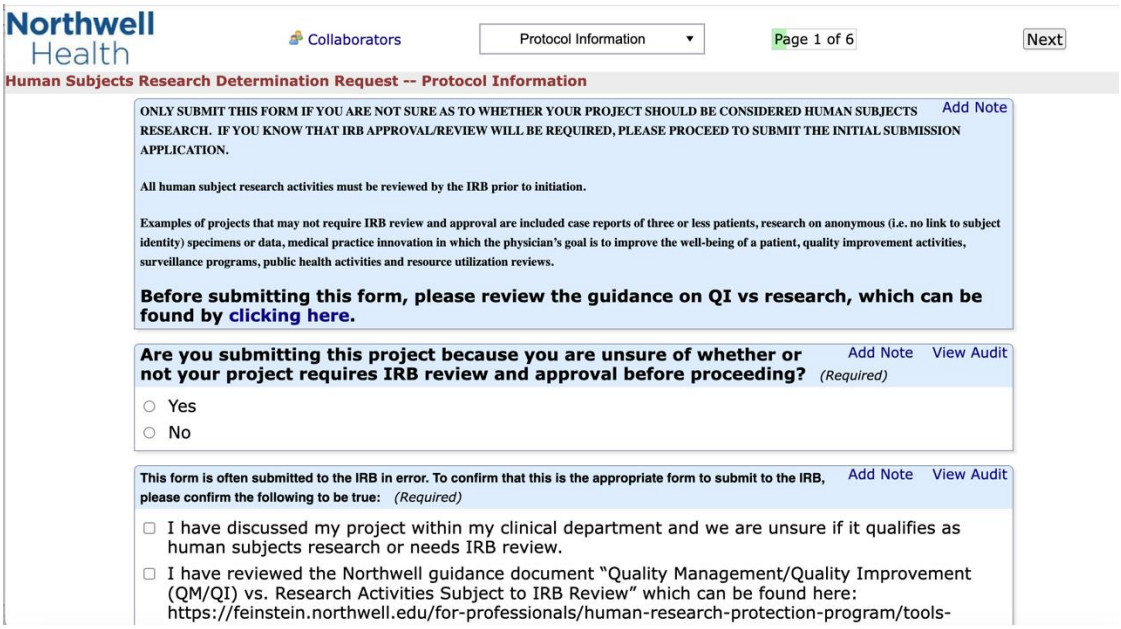
Step 4:
Complete second factor authentication with the security code sent to your phone.



Step 5:
In the top left corner, click on “click here to submit a Human Subjects Research Determination Request” (underlined link).

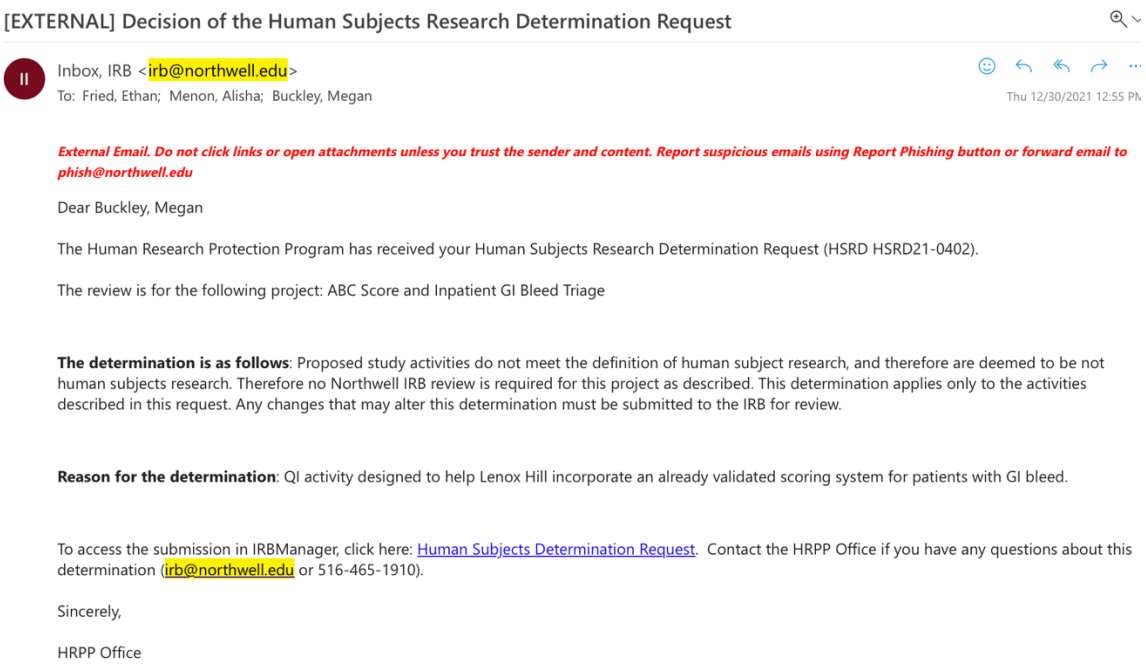
****DO NOT click on the option below to “submit a new study to the IRB.”**
You will ONLY need to submit a new study to the IRB if you are not granted exempt status from the Human Subjects Determination Request.

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.



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.