What is the "Institutional Approval" process at Northwell?

The Institutional Approval (IA) process was implemented on August 1, 2015, and applies to all clinical research studies submitted for IRB review (regardless of IRB used) on or after that date. The IA process is an internal compliance check to make sure that each study has completed certain compliance steps which minimize risks to patients and the health system.

The IA process is NOT the same as IRB approval. Obtaining IRB approval is one step in the IA process. Enrollment cannot begin to a research study at Northwell Health without both IRB Approval AND Institutional Approval.

What are the steps that make up the Institutional Approval process?

Not every project requires every step in the IA process. However here is a list of the possible steps that could apply:

Always required:

1. IRB Review and Approval (whether using Northwell IRB or an External IRB like WIRB, BRANY, etc)

May be needed, depending the study:

1. IT Security Review (if the study will collect electronic PHI)
2. Research Pharmacist review (when a study involves an investigational drug)
3. Clinical Trials Office (CTO) review for Industry sponsored research (to ensure that consent language matches the contract, and that the CTA has been executed)
4. Grants Management Office review for grant funded research (to ensure funding agreement is in place)
5. Radiology review (when radiology services will be used, to ensure feasibility)
6. Core Lab Services (when core lab services will be used, to ensure feasibility)
7. Biosafety review (when a study involves the use of certain biological agents or toxins)
8. Biorepository services/Tissue Donation Program (TDP) – (to ensure feasibility)

Are there any types of studies for which IA does not apply?

Yes. The following types of studies do not require Institutional Approval, but may require IRB approval.

- Humanitarian Use Device (HUD) – requires IRB approval
- Emergency Use of a Test Article - does not require IRB approval but may need IRB acknowledgment in order to obtain investigational drug/device from manufacturer.
- Studies found to be "Exempt" under 45CFR46 – requires IRB approval

How do I apply for Institutional Approval?

Regardless of the IRB you plan to use, submit to the Northwell HRPP office first, through IRBmanager. This will start the IA process. Submission instructions can be found here. You do not need to contact the IA reviewers; the staff of the Northwell HRPP office will contact the IA reviewer(s) and provide them with the study materials to review. The IA process runs parallel to the IRB process. Once all IA reviewers have approved (including IRB approval), the project is eligible for Institutional Approval.

Who is responsible for notifying the reviewers of the different segments for which I need approval?

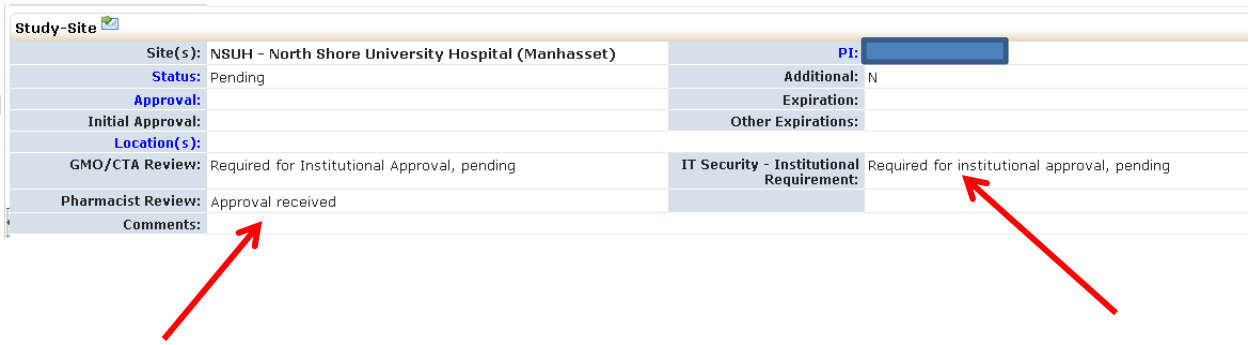
Staff in the HRPP office send out an initial notification to each institutional reviewer required, based on the information provided in the IRBManager initial application. However, it is helpful for the process if the investigators reach out and work directly with the owner of each IA step to move the study toward final approval.

Will I receive a separate Institutional Approval Letter?

Yes. You cannot begin enrollment to your project until you have received BOTH a letter of IRB approval, and a separate letter of Northwell Institutional Approval.

How do I know what steps of the institutional approval process are needed for my study?

On the main study screen in IRBManager, you can find a listing of the parts of the Institutional Approval needed for your study. Unnecessary segments will not be visible on your study profile. Required segments will be visible with a status.



Segment Complete

Segment Incomplete

Who do I contact to inquire about the approval for each step of the IA process?

IA Step	Contact Name	Email	Phone Number
IRB (Northwell/External)	Philip Dong	pdong@northwell.edu	516-465-2545
IT Security	Scott Lynch	slynch6@northwell.edu	516-465-2716
Pharmacy	Ji-Eun Kim	Jkim31@northwell.edu	516-321-2128
Clinical Trials Office	Jen Cano	Jcano@northwell.edu	516-881-7067
	Victoria Speziale	vspeziale@northwell.edu	516-881-7067
	Yashoda Ashraf	yashraf@northwell.edu	516-881-7067
Grants Management Office	Tiffany Chapman	Tchapman@northwell.edu	516-465-2541
Radiology	Angela Hoang	Ahoang1@northwell.edu	516-562-0457
Core Lab	Laurel Tria	ltria@northwell.edu	516-719-1161
	Munira Mulani	Mmulani@northwell.edu	516-719-1158
Biosafety review	*contact IRB office*	irb@northwell.edu	516-465-1910
Biorepository/TDP	Gila Klein	GKlein@northwell.edu	516-562-1264