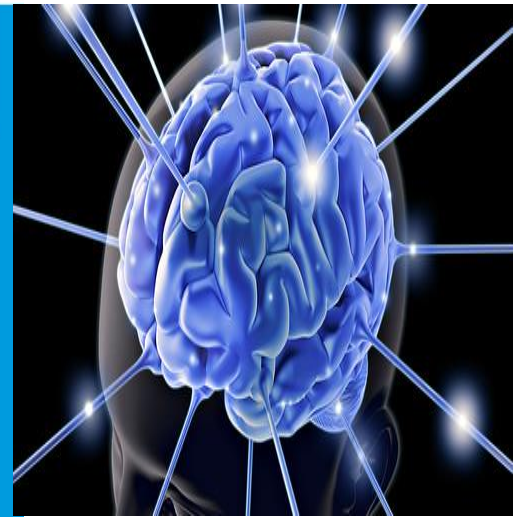


# Clinical Research Site Profile

## Department of Neurosurgery

As one of the largest neurosciences programs in the country, we have a vast repertoire of diagnostic, clinical and research expertise to treat the entire spectrum of neurological conditions with both surgical and nonsurgical treatment options

[neurosurgeryresearch@northwell.edu](mailto:neurosurgeryresearch@northwell.edu)



### Qualifications Summary

One of the largest Neurosurgery departments in the nation with over 30 neurosurgeons, 10 neurocritical care doctors, 16 neurosurgery residents and fellows. We have an experienced research team and operate clinical trials that are both federal and industry sponsored

### Clinical Research Interest

Our site has an interest in federal and industry sponsored trials for:

Brain tumors • Neurotrauma • Trigeminal nerve stimulation for balance disorders • Acute subdural hematomas • Subarachnoid hemorrhage • Concussion • Neurovascular (carotids, endovascular coiling) • Epilepsy • Surgery for epilepsy • Intracerebral hemorrhage (ICH) • Stroke • Degenerative spine • Spasticity • Surgery for pain • Traumatic brain injury

### Protocol Experience

We have participated in Phase II and Phase III trials in all types of study designs: multi-center, randomized, single and double blinded. We also have experience with NIH and Investigator-Initiated Studies

### Site Research Team

11 experienced investigators, 1 research director, 1 research nurse, 4 research coordinators, 4 research assistants, 1 biostatistician, and 1 research pharmacist

### Site Performance

Our site has a low number of lost to follow up and early withdrawal of less than 5%. We follow protocol specific guidelines for data entry and query resolution. We aim to complete data entry 7-10 days after study visit has occurred

We have consistently performed well on industry-sponsored audits as well as QA reviews by our Office of Research Compliance

## Department of Neurosurgery

(516) 253-7753

[neurosurgeryresearch@northwell.edu](mailto:neurosurgeryresearch@northwell.edu)

---

### **Betsy Moclair, RN, CCRC** **Director, Clinical Research**

North Shore University Hospital  
300 Community Drive  
Manhasset, NY, 11030

Feinstein Institutes for Medical Research  
350 Community Drive  
Manhasset, NY, 11030

Northwell Health Brain Tumor Center  
Center for Advanced Medicine  
450 Lakeville Road  
Lake Success, NY, 11042

Northwell Health Neurosurgery  
805 Northern Blvd, Suite 100  
Great Neck, NY, 11021

Neurosurgery Administrative Office  
1554 Northern Blvd, Suite 209  
Manhasset, NY, 11030



[neurosurgeryresearch@northwell.edu](mailto:neurosurgeryresearch@northwell.edu)

## **Research Trainings and Certifications**

All investigators and research staff are required to be trained in Good Clinical Practice. This is completed through CITI ([www.citiprogram.org](http://www.citiprogram.org)). Our research staff is IATA certified and our research director is a certified research coordinator through the Association of Clinical Research Professionals

All new research hires go through internal research training via a fundamentals research class and are able to learn through e-learning modules. They shadow experienced coordinators and are assigned a mentor

## **Research Support Services**

We have the ability to use central IRBs for our industry-sponsored trials. Our institution has central research support services that we are able to utilize: Office of Clinical Research, Office of Research Compliance, Human Research Protection Program, Clinical Trials Office, and Center for Research Informatics

## **Office of Clinical Research Support**

The Office of Clinical Research (OCR) offers a wide range of clinical research and trial management support across Northwell Health. Our office will review, negotiate and complete Confidential Disclosure Agreements (CDAs), sometimes called a Non-Disclosure Agreements (NDAs). We facilitate clinical research trials and studies by providing regulatory support, new trial feasibility assessments, recruitment strategy and retention tips, and clinical research professional coaching and mentoring

## **Clinical Trials Office**

The CTO manages all clinical trial contracts, budgets and billing. Our office will review, negotiate and complete Master Clinical Trial Agreements (MCTAs), Clinical Trial Agreements (CTAs), sometimes called Clinical Study Agreements, and Data Use Agreements (DUAs)

## **Technology Experience**

A vast amount of experience in many EDC systems: Medidata Rave, IBM clinical development, eCaseLink, InForm, iMedNet, Axiom Fusion, etc. Northwell Health also utilizes Florence to digitize and manage study binders, workflows, documents, and data to provide remote access to our sponsors. Research staff is also experienced with using IWRS/IVRS, electronic diaries, and central readers

## **Facilities**

On-site resources include refrigerated centrifuge, -70 and -20 freezer (continuous temperature monitoring with alarms), MRI, CT, Dexa. Our sites have access to locked medication cabinets with thermometers, and locked storage for research binders. There is an ability to utilize research pharmacists for more complex trials. There is also experience with the utilization of both local and central core labs. All of our laboratories are both CLIA and CAP certified. All of our equipment is biomed inspected.

## **Department of Neurosurgery**

**(516) 253-7753**

[neurosurgeryresearch@northwell.edu](mailto:neurosurgeryresearch@northwell.edu)

---

### **Betsy Moclair, RN, CCRC Director, Clinical Research**

North Shore University Hospital  
300 Community Drive  
Manhasset, NY, 11030

Feinstein Institutes for Medical  
Research  
350 Community Drive  
Manhasset, NY, 11030

Northwell Health Brain Tumor Center  
Center for Advanced Medicine  
450 Lakeville Road  
Lake Success, NY, 11042

Northwell Health Neurosurgery  
805 Northern Blvd, Suite 100  
Great Neck, NY, 11021

Neurosurgery Administrative Office  
1554 Northern Blvd, Suite 209  
Manhasset, NY, 11030