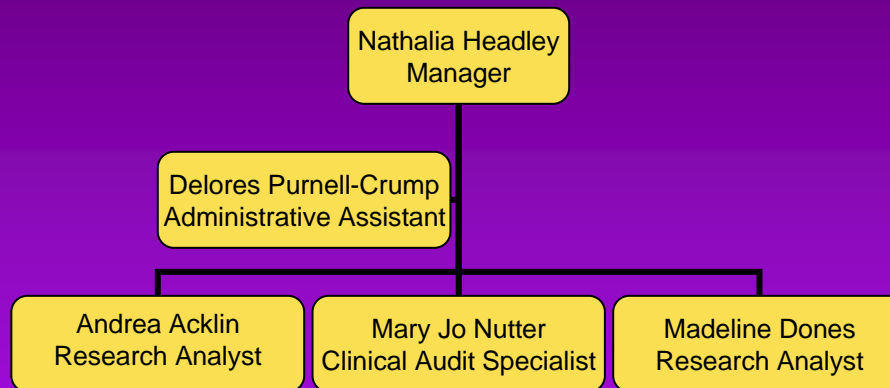


Northwestern Memorial  
(NMH)  
Office of Research

# NM Office of Research Staff



# NMH Office of Research Purpose & Functions

- The NMH OOR is the central research administration office at Northwestern Memorial Hospital
- Our main purpose is to assist all individuals who engage in clinical research at NMH
- We also monitor ongoing research at NMH to ensure compliance with all federal, state and local regulations

# NM Office of Research

- The OOR reviews all IRB applications for studies involving Northwestern Memorial [NM]. NM is a large entity that includes:
  - Inpatient units at Feinberg
  - Prentice Women's Hospital
  - Stone Institute of Psychiatry
  - General Clinical Research Center [GCRC]
  - NMH outpatient clinics, including the HIV Clinic, the Prentice Ambulatory Care Clinic (PAC clinic), the Breast Center, and the Northwestern Memorial Physicians' Group

# NM Office of Research

- Studies that involve NM are those in which the study is being conducted at NM, in whole or in part
- In addition, these include studies that utilize any NM department including:
  - Laboratory Services
  - Radiology
  - MRI
  - Nuclear Medicine
  - Pharmacy
  - Cardiology
  - Emergency Room
  - Surgery
  - Transplant
  - Wellness Institute
  - Pathology

# NM Office of Research

- If the study involves the use of NM staff, patients, or medical records, the OOR must review and sign off on the IRB application prior to submission to OPRS.
- New Project submissions that are in paper format be sure to submit the NPSF, protocol, consent form and HIPAA documents in duplicate. The OOR will contact you if we require additional documents that are specific to the study.

# Additional Forms Required by NM

- NMH Classification of Charges (budget form) which clearly identifies all study-related charges at NMH.
- NMH research protocol review form which identifies whether the study is a Medicare Qualifying Clinical Trial [MQCT].
- These forms may be obtained from the NMH OOR website.

# Requirements for Inpatient Studies

- NM requires that a Research Admitting & Registration form be completed for every research patient that is admitted to a bed. Fax this form to the OOR at 6-0051 and to NMH Admitting & Registration at 6-8111. This form may be obtained from the NMH OOR website.
- This form enables NM to identify the patient as research, so the bills will be held until the research charges can be appropriately separated from the standard of care charges.

# Research Accounts

A research account must be set up for any study requiring research services from NMH including:

- All studies that involve research out-patient procedures
- Studies that involve the NMH Pharmacy or NMH laboratory services
- Contact Madeline Dones at extension 6-2720 to set up a research account

# The NM Pricing Catalog

- Prices for research tests and procedures may be found in the pricing catalog.
- Professional fees are not included in the NM research price. NMFF will bill for these fees. Please contact Margaret McGready at 695-0436 for any questions regarding the professional fees.
- Use it to identify procedure codes for the study and to complete the NMH budget form.
- Contact the OOR regarding services that are not included in the Pricing Catalog.
- Use this tool to prepare the study budget.
- Available on the NMH OOR website.

# Investigational Device Studies

- NM requires many extra steps and procedures for research studies that involve investigational devices.
- No investigational device study may begin at NMH until all requirements have been met.
- Contact Nathalia Headley at 6-2249 in the OOR for specific instructions regarding IDE studies at NMH.

# Equipment

- For studies involving equipment, certain Indemnification and Lease Agreements must be in place before any equipment may be brought into the hospital.
- Electrical equipment must be evaluated and approved by NMH Bio-Medical Engineering.
- Please notify Nathalia Headley, extension 6-2249, as soon as it is known that equipment will be brought in for a research study.

# Research Drug Studies

- NMH requires that an investigational drug data sheet (IDDS) must be completed for all studies involving investigational drugs (IND) using the services of NMH Investigational Pharmacy.
- Investigational Drug order form must be completed for each outpatient prescription.
- The IDDS and Investigational Drug Order forms with instructions to complete the forms may be obtained from the OOR upon request.
- Questions regarding pharmacy dispensing and set-up fees for the NMH Investigational Pharmacy? Contact Jane Regalado at 926-7470.

# The NMH Access Program

- The Health Care Workers' Act requires that all persons having access to the hospital must undergo a (i) criminal background check (ii) a mini physical exam at our Corporate Health that includes current rubeola, rubella and TB tests, (iii) orientation, (iv) privileging, and (v) annual safety quiz.
- The NMH Access Program allows NU research staff to meet the statutory requirements, to obtain identification badges in order to access the hospital, and to obtain access to Power Chart, NMH's electronic medical record.
- For information about the NMH Access Program, please contact Andrea Acklin at extension 6-0488.

# NMH Access Program

- Forms
  - Agreement of Research Staff Members
    - Complete and return to OOR
  - Corporate Health Form
    - Take this with you when you have your appointment with NMH Corporate Health
    - Return completed form to OOR
  - Criminal Background Check
    - Complete and return to OOR

# NMH Access Program

- Additional requirements
  - Online hospital mini orientation
  - Online safety training test
  - Online Corporate Integrity test
  - Online Power Chart training
- Annual requirements
  - TB testing
  - Online safety training test
  - Online Corporate Integrity test

# Additional FYI's to Assist You in Your Research at NMH

- Please refer to <http://www.nmh.org/nmh/research/plogin.htm> for specific detailed instructions for conducting research at NM
- Fax the IRB approval letter, IRB approved consent and IRB approved HIPAA documents to the NMH OOR at 6-0051 once IRB approval has been obtained.

# More FYI's

Contact the NMH OOR at 6-1719 for:

- Grant/contract submissions
- To establish a case rate for studies involving inpatient admissions
- To obtain research policies & procedures
- To report scientific misconduct at NMH
- To report serious adverse events

# And More FYI's...

Contact the NMH OOR at 6-1719 for:

- Questions regarding HIPAA
- Questions about Humanitarian Use Devices, Compassionate Use, and Emergency Use.
- Medicare Qualifying Clinical Trials
- For any questions you may have regarding research at Northwestern Memorial

# NMH Office of Research Website

- <http://www.nmh.org/nmh/research/plogin.htm>
- Please contact Andrea Acklin at [aacklin@nmh.org](mailto:aacklin@nmh.org) if you experience any problems accessing the website

# NMH OOR Contact Information

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