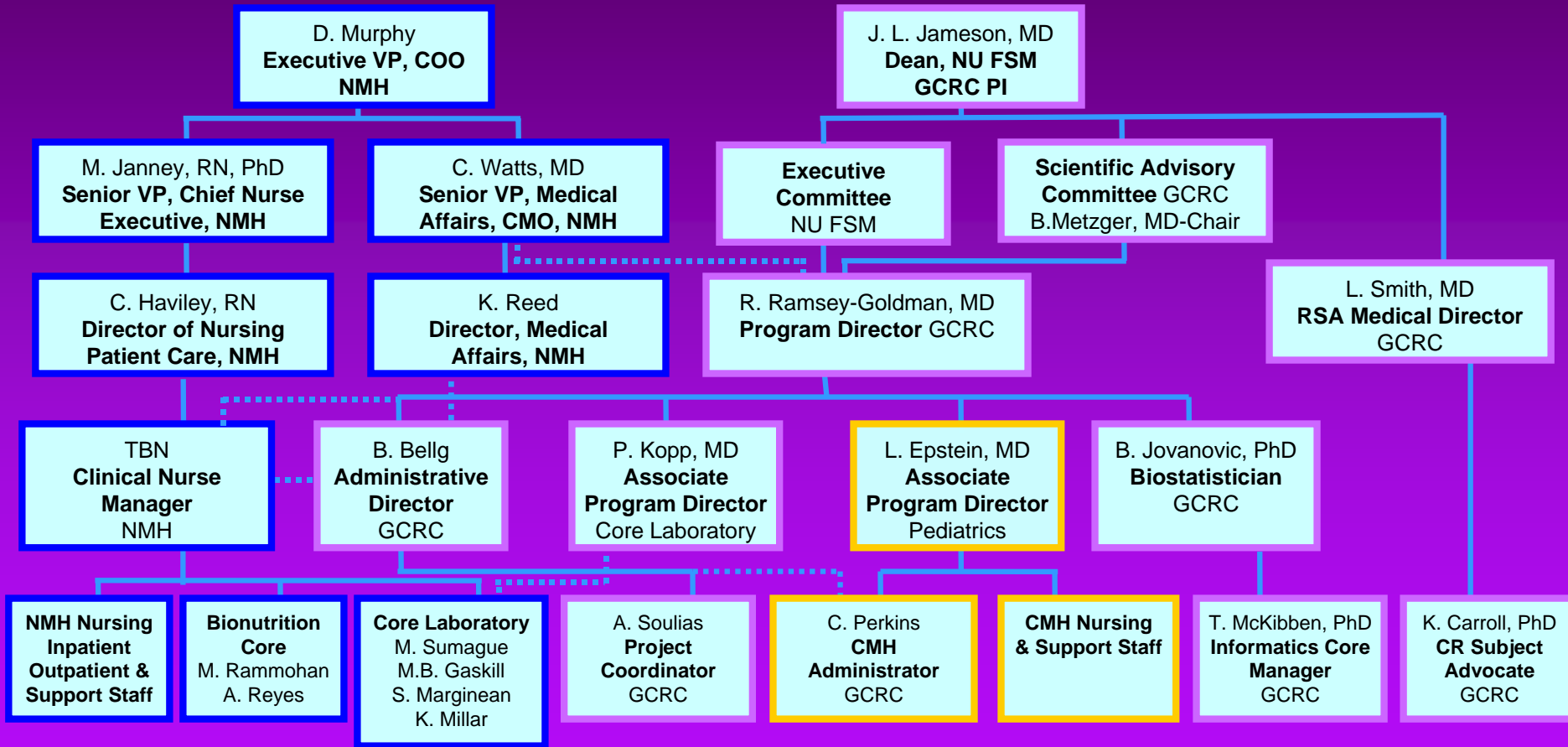


General Clinical Research Center (GCRC)

Resources available through the GCRC

- Inpatient and outpatient research services, with 24/7 research nursing support for every level of acuity of care
- GCRC resources are provided without charge to investigator-initiated research projects, including those with NIH or other federal funding, foundation, or industry support
- The GCRC can provide services for pilot projects or other internally funded initiatives
- Industry-sponsored projects are charged for GCRC services on a cost recovery basis

GCRC Organizational Structure



Who uses the GCRC?

- NU investigators, investigators from other institutions with a NU co-investigator
- A PI may be an MD, PhD, RN, or other healthcare professional
- The GCRC supports investigators working in many disciplines (In 2006, 124 protocols from 19 Departments or Divisions)
- The PI or a co-investigator must be on the staff of Northwestern Memorial Hospital, and have admitting privileges and responsibilities for the protocol
- The GCRC gives priority to NIH-funded research

What does the GCRC need to begin reviewing a study?

- GCRC application
- A copy of the full protocol, investigator's brochure, other study documents
- GCRC Data Safety and Monitoring Plan (DSMP)
- All documents submitted to the IRB
- Before submitting an application, it is recommended that the PI or Coordinator contact the GCRC to discuss the research study

General Clinical Research Center (GCRC)

Important Note ✨

- Unlike many offices, the GCRC prefers that a study should be submitted to the IRB before or concurrently with the GCRC submission
- A study can be submitted to and approved by the GCRC while the IRB is still reviewing it, but the study cannot be initiated on the GCRC until it has received IRB approval
- The GCRC is a clinical unit at both NMH and CMH, and HIPAA approvals and compliance are required

Who needs to sign the GCRC forms for a new study before they are submitted?

- The Principal Investigator

Where are the GCRC forms submitted?

- The complete packet should be submitted to the GCRC administrative office
- Submit one set of hard copies (with original PI signature) and electronic files via email
- The office address is 676 Saint Clair, Suite 14-027B, Chicago, IL, 60611

What happens to my study once it is submitted to the GCRC?

- It is reviewed by the Scientific Advisory Committee (SAC)
- The PI or Co-Investigator attends the SAC meeting to provide a brief overview of the study, and answer any questions the Committee may have
- Protocol reviewed for:
 - Science
 - Utilization of GCRC
 - Safety
 - NIH requirements

How long does it take for the GCRC to approve a new study?

- The SAC meets on the second Thursday of each month
- Studies must be submitted at least two and a half weeks before the meeting
- The SAC usually provides their response within two weeks of the meeting time

General Clinical Research Center (GCRC)

Important Note ✨

Once a study is approved by the GCRC, copies of everything submitted to the NU IRB should also be submitted to the GCRC. This includes annual reviews, revision forms, adverse event forms, and any other notifications sent to the IRB.

Under federal guidelines, copies of these records must be maintained on the GCRC for all center protocols.

General Clinical Research Center (GCRC)

Center Developments in 2008



NU has received a highly competitive score for a 2008 U54 cooperative agreement application under the NIH Institutional Clinical and Translational Science Award (CTSA) program and plans to enhance clinical research infrastructure under this program and the NU Clinical and Translational Sciences (NUCATS) Institute, Philip Greenland, MD, PI and Director. This includes the continuation and expansion of all services currently supported through the GCRC, restructured in the Center for Clinical Research (CCR) in the NUCATS Institute.

Watch for news and updates in 2008!

Who do I contact for GCRC information?

- Call the Administrative Director, Barbara Bellg, at 312-926-3192, or email her at: b-bellg@northwestern.edu
- GCRC forms and instructions can be found at: www.feinberg.northwestern.edu/gcrc/
- The website also includes other important information, including core information, and staff contacts. Be sure to take a look!