



UW-GCRC Update

2005 GCRC Protocol Submission Deadlines

Deadlines for submitting protocols are listed below. Please, see the UW-GCRC website, <http://www.medsch.wisc.edu/uwgcrc/index.html>, for more information.

- Thursday April 28
- Thursday June 2
- Thursday June 30
- Thursday July 28
- Thursday September 1

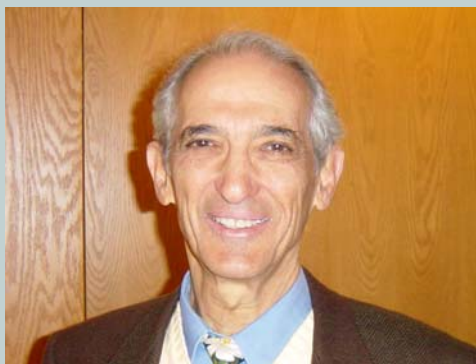
Email completed application to dgale@biostat.wisc.edu

Cover Photo: Philip M. Farrell, MD, PhD, GCRC Principal Investi-

New Members Will Join GAC in May

Eight new members join the Advisory Committee of the UW-General Clinical Research Center (GCRC). The additions bring the GCRC Advisory Committee (GAC) to 21 members, which will allow broad representation for the varied protocols that the GAC reviews.

The new members, who begin 3-year terms at the May 16 meeting, are Drs. Sanjay Asthana (Geriatrics), Howard Bailey (Oncology), Craig January (Cardiology), Peter Rahko (Cardiology), Sterling Johnson (Geriatrics), Paul Sondel (Pediatric Oncology/Oncology/Medical Genetics), Anne Traynor (Oncology), and Terry Young (Population Health Studies; sleep studies).



Theodore Goodfriend, MD — GAC Chair

Current Members

Continuing members are: Drs. David Allen (Pediatrics), David Andes (Infectious

Diseases), Christopher Coe (Psychology), Paul Hutson (Pharmacy), Dean Krahn (Psychiatry/Nutritional Sciences), Marzena Krawiec (Pediatrics/Pulmonary), Kenneth Kudsk (Surgery).

Also, Robert Lemanske (Pediatric Allergy/Immunology), Diane Puccetti (Pediatric Hematology/Oncology), Paul Rutecki (Neurology), James Skatrud (Pulmonary/Critical Care), Sandra Ward (School of Nursing), and Donald Wiebe (Pathology).

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You Should Know...

- **The UW-GCRC Advisory Committee (GAC) meets the third Monday of every month to review new protocols.** If the GAC reviews your protocol on a Monday, you should receive a Notice of Action within 10 days after the Post-Review Committee meets. That memo will include whether your protocol was approved, conditionally accepted, tabled, or disapproved. If approved, there is an AWARD SUMMARY with the score, request, GCRC award, and ancillary (lab tests, etc.) award if yours is an NIH project.
- **The GCRC Pre-Review Committee meets 10 days before the full GAC meeting.** Every Principal Investigator (and coordinator) with a protocol application for that month's GAC is emailed a Pre-Review Memo with concerns, questions, or requests for clarification. The memo's purpose is to speed up reviews and approvals for protocols. If you don't answer the Pre-Review memo before the GAC meeting, the GAC may need to give a conditional approval or table a project.
- **Every outpatient at the UW-GCRC must sign an Assignment of Benefits (AOB) form that gives approval for charges to research, to insurance, or to the patient.** The GCRC is a research unit, but it is also a University Hospital and Clinics nursing unit, and must follow all JCAHO, government, and accounting department policies. Please review this form with your patients, so they are not surprised or concerned about billing issues. We have copies of the AOB form at the GCRC.

New Members (Continued from page 1)

Major Responsibilities

The GAC supervises and reviews all operations of the GCRC, its sample Processing Facility, Informatics Core, and other components; sets general policies; delineates common needs of GCRC investigators; establishes admission policies; and evaluates projects for GCRC use.

To meet NIH GCRC Guidelines, all studies on the GCRC must have GAC approval. In all cases, NIH-funded clinical research must

be given preference. In addition, the GAC determines if a protocol involves significant risk, and, if so, evaluates and approves the required Data and Safety Monitoring Board (DSMB). The GAC also sets the category of inpatient research days and outpatient visits as Category A (research only), B (research and standard-of care, or D (industry-sponsored research).

Under new federal expectations, the GAC oversees the GCRC budget, and approves all competitive and noncompetitive renewal requests to the National Center for

Research Resources (the NIH division under which GCRCs operate).

The GAC meets monthly to review new protocols.

PLEASE CITE GCRC IN PUBLICATIONS

Remember to acknowledge the UW-General Clinical Research Center when you have received support from us. Please state: "Supported by grant M01 RR03186 from the General Clinical Research Centers Program of the National Center for Research Resources, National Institutes of Health."

UW-GCRC Spotlight

The GCRC Nurse Team Leaders have a combined 35 years of clinical research experience, and their expertise ranges from oncology to sleep studies to allergy. Linda Carr, BSN, RN, and Mary Gillitzer, RN, at the GCRC since 1987, are familiar faces to many investigators and their study coordinators, but it's their knowledge and abilities that makes a difference.

"I enjoy getting into the protocols, giving ideas that might make the studies go more smoothly," says Mary, who often reviews cancer protocols in early versions and makes recommendations. Mary also

works with studies in oncology, radiology, nutrition, and Alzheimer's disease. She began her career as a nurse at Stoughton Hospital and started research nursing at UW Hospital in hematology/oncology. "I

like the intensity of clinical research," she says, "and the importance of what we're doing for future patients."

Linda began her career at St. Luke's in Milwaukee as a cardiac nurse in the cardiovascular/thoracic surgery area. "What I enjoy about clinical research nursing," she notes, "is working with patients in a wide variety of medical specialties". Outcomes are important to them and

important to us. I also enjoy helping new investigators and new coordinators to make their projects successful."

Mary and Linda work with the GCRC Nurse Manager Mary Jane Williams, BSN, RN, MPH, who has been at UW Hospital and Clinics since 2003. All the GCRC nurses are UWHC

employees, paid by an NIH grant under a subcontract with the hospital.

Mary and Linda split their hours on the floor, as both working research nurses and mentors to GCRC staff. They both serve on the GCRC Pre-Review Committee, and

attend the GCRC Advisory Committee meetings. Linda is also member of the GCRC Data & Safety Monitoring Committee.

What makes a good research nurse?

"Dedication," says Mary. "Attention to detail" says Linda. They agree that beyond one-word answers are other important criteria: (1) understanding all aspects of the research process, (2) a strong nursing background, (3) flexibility to meet the changing needs of researchers, (4) accuracy of data collection, and (5) making sure the patient is a willing and informed participant

Asked if research nursing is a demanding job, they agree, saying "Yes, but always important and never boring."



Linda Carr, BSN, RN—GCRC Nurse Team Leader



Mary Gillitzer, RN—GCRC Nurse Team Leader