



# UW-GCRC Update

UW-Madison: General Clinical Research Center

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## 2005 GCRC Protocol Submission Deadlines

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

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

(email completed forms to [dgale@biostat.wisc.edu](mailto:dgale@biostat.wisc.edu))

Cover Photo: Philip M. Farrell, MD, PhD, GCRC Principal Investigator, Dean of UW Medical School

## Skilled Bionutritionists Aid GCRC Studies

The UW-GCRC Bionutrition Unit provides nutrition expertise to investigators whose research protocols involve nutrition assessment or intervention. Lisa Davis, MS, RD, and Kristina Penniston, PhD, RD, staff the Bionutrition Unit. Additionally, clinical nutrition interns prepare research diets for specific protocols. Bionutrition services include the following:



Lisa Davis, MS, RD, - Bionutritionist

post-review of protocols submitted to the GCRC.

**Dietary assessment:** The bionutritionist advises on the use of an appropriate assessment mechanism for your protocol. Some of the tools available include food frequency questionnaires, food records, and diet recalls. The bionutritionist instructs subjects on completion of the assessment tool, and analyzes and prepares documentation for you.

**Protocol design and development:** A research dietitian (also known as a bionutritionist) meets with investigators during the development and implementation of their research protocols and can advise on optimal nutrition methods to enhance the quality of the data obtained. The bionutritionist also participates in pre- and

**Computerized dietary analysis:** Bionutritionists utilize state-of-the-art nutrient analysis software for documenting dietary intake.

**Calculating energy requirements and special nutrition needs:** Your protocol may require

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## You Should Know...

- **The 12:00-1:00 Lunch and Learn on Wed., May 18 is a panel on research admissions and billing from UWHC, UWMF, GCRC, and OCT.** Paulette Sacksteder, GCRC Administrative Director, will moderate a discussion in CSC G5/113. Panel members include: Mary Beth Benson, UWHC Manager of Patient Accounts; Tina Gudenschwager, UWHC Supervisor of Registration; Kathy Boelke, UWMF Director of Patient Business Services; Peggy Munson, Clinical Research Program Manager at the Office of Clinical Trials; and Danielle Gale, GCRC Protocol Manager and Billing Specialist.
- **Register before Friday, June 3, for the 2005 "Short Course in Clinical Research," to receive a 10% discount.** The three-day course on July 19, 20, and 21 is for medical students, residents, and fellows; graduate students; faculty & academic staff, and other interested research personnel. The course, from the UW Clinical Investigator Preparatory Program, is at the new UW-Health Sciences Learning Center, 750 Highland Avenue, next to the north entrance of UW Hospital and Clinics. **See the program and brochure, attached to your email.**
- **All current GCRC investigators will receive new 6-month awards to run June 1 through November 30, 2005.** A GCRC financial and census review will determine new day and/or visit awards, and new ancillary limits. The GCRC Advisory Committee will review changes at its June 20 meeting.

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## Bionutritionist

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the individual calculation of subjects' energy needs for weight maintenance, loss, or gain. Alternatively, your protocol may include subjects with chronic disease, whose nutrient status may be compromised. The bionutritionist conducts detailed nutrition assessments on nutritionally-compromised individuals and performs appropriate calculations necessary to determine energy and/or special nutrition needs.

**Research diets:** Your protocol may require that research subjects be provided meals or snacks with specific energy and/or nutrient parameters. Controlled nutrient

diets are created by the bionutritionist, and weighed and prepared in the kitchen of UW Hospital and Clinics by trained nutrition personnel.

**Nutrition instruction and counseling:** The bionutritionist provides specialized instructions to subjects as needed and nutrition education as required by your protocol.

**Nutrition training:** The bionutritionist provides nutrition education and training to GCRC investigators, staff, and clinical nutrition interns.

*Lisa Davis, MS, RD, is the bionutritionist in charge of providing nutrition services on the GCRC at UW Hospital and Clinics. She has been with the unit since its inception in 1985. To contact Lisa, call 263-8244*

## More to Know...

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- **The GCRC now requires NIH budgets with all protocol submissions.** Starting with the June 2 submission deadline, the UW-GCRC will require a copy of the investigator's NIH budget with all new protocol submissions for GCRC support. Please email this along with other materials to [dgale@biostat.wisc.edu](mailto:dgale@biostat.wisc.edu). Nationwide, most GCRC's require these budgets to avoid duplication of ancillary tests' support already funded in the investigator's NIH grant.

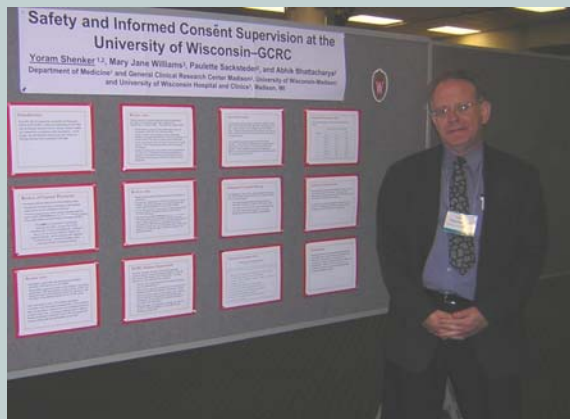
## UW-GCRC Spotlight...Data and Safety Monitoring on the GCRC

All 80 General Clinical Research Centers (GCRCs) in the United States in 2002 were given new funding for a Research Subject Advocate (RSA), and the expectation that scrutiny and oversight of GCRC subjects' safety and study data would be intensified.

From site visits at GCRCs over the past year, it is apparent that the National Center for Research Resources (NCRR) of NIH is paying particular attention to this GCRC safety and data area, the local academic centers' IRBs, and the communication between the GCRCs and IRBs on adverse events and other issues.

Yoram Shenker, MD, the UW-GCRC's RSA, spends 60% of his time at this position. He takes his role very seriously, holding in-person review sessions with all GCRC protocols once each year, of which there are 150 open studies. He rounds twice weekly with the nurse manager on the GCRC to measure subjects' knowledge and studies' compliance with

required documents. The GCRC also surveys all study patients.



UW-GCRC safety program on display at the national meetings, where Dr. Yoram Shenker talked to more than 20 poster visitors.

"It's hard to underestimate the importance of the RSA/IRB role in both the safety of research subjects and for our next competitive renewal application and site visit in 2006," says Dr. Shenker. "Our NIH administrative visit this August 2005 and the formal site visit next year will examine this area closely."

At the April GCRC National Meetings, Dr. Shenker attended the RSA section meetings, as well as presenting a poster highlighting the UW-GCRC patient safety oversight, "Safety and Informed Consent Supervision at the University of Wisconsin GCRC." He noted that the most important takeaways from these sessions were: (1) Subjects' safety is a shared responsibility of everyone involved, including investigators, study coordinators, GCRC nursing personnel, RSA, and IRB (2) Sharing information and learning from experience of other RSAs is very beneficial for our own safety and monitoring programs; and (3) Monitoring and reviewing protocols is a conduit for feedback and improving the science of GCRC protocols.

For more information on Data and Safety Monitoring on the UW-GCRC, and investigator requirements for GCRC protocol submissions, you may access the GCRC website, <http://www.medsch.wisc.edu/uwgcrc/index.html>.