



UW-GCRC Update

UW-Madison: General Clinical Research Center

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2006 GCRC Protocol Submission Deadlines

Deadlines for submitting protocols are listed below. All submissions should be electronic. See the UW-GCRC website, <http://www.medsch.wisc.edu/uwgcrc/forms.html>.

- Thursday Feb. 2, 2006
- Thursday March 2, 2006
- Thursday March 30, 2006
- Thursday April 27, 2006

(Email completed forms to dgale@biostat.wisc.edu)

Cancer Research Active At the UW-GCRC

The University of Wisconsin Comprehensive Cancer Center (UWCCC), whose leaders like Dr. George (Terry) Bryan were instrumental in bringing a General Clinical Research Center (GCRC) to Madison 20 years ago, continues to be a strong presence at the UW-GCRC in 2006.

A total of 14 oncology investigators serve as principal investigators on more than 50 approved protocols on the GCRC. The type of research studies on the GCRC range from protocols examining new treatments for solid tumor cancers (breast, stomach, colon,

bladder, pancreas, brain) to skin cancers such as melanoma, cancers of the blood, and to sarcomas (cancer of connective tissue, including bone, cartilage, fat, muscle, and blood vessels).



Clinical Trials Active at UWCCC

Phase I Trials on the GCRC

For example, Dr. George Wilding, Director of the UWCCC, collaborates with experienced investigators in the Phase I Program that has 14 trials on the GCRC. Currently conducting Phase I trials are: Drs. Anne Traynor, Kyle Holen, Douglas McNeel, Daniel Mulkerin, Lynn van Ummersen, and Howard Bailey.

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You Should Know...

- **The UW-GCRC recently raised its support for lab tests and other ancillary costs for all federally-funded clinical studies that come to the unit.** In a letter to all investigators now using the GCRC, Program Director Dr. Marc Drezner in December noted that while support for one inpatient day remains at \$100 and an outpatient visit at \$33, the total that any one study may receive is now \$10,000 in ancillary coverage for inpatient studies and \$8,500 for outpatient studies. The intent is more support to clinical studies funded by NIH and other federal agencies. The new ancillary support began Dec. 1, 2005 and goes through Nov. 30, 2006.

For all federally-supported grants, the GCRC also pays for the hospital room, research nursing, and outpatient visit space. While the current NIH award to

the GCRC is only \$1,660,000 per year, the University of Wisconsin Hospital and Clinics Authority, the UW School of Medicine and Public Health, and the UW Medical Foundation contribute additional funds to provide the needed \$3 million budget for clinical research at the GCRC.

- **Feng-Chang Lin, MA, is now part of the UW-GCRC Informatics and Statistics team, and available for statistical consulting with GCRC investigators, or those planning to submit GCRC protocol applications.** Lin began at the Center on Jan. 23, and works under the direction of Jason Fine, PhD, Director of the GCRC Biostatistical Core. Lin's email is lin@biostat.wisc.edu, and his phone number is 263-8495. His office hours in E5/640 CSC are Mondays from

10-5, Tuesdays from 9-10:30, Wednesdays from 12:30-3:30, Thursdays from 9-10:30, and Fridays from 9-4.

Lin replaces Abhik Bhattacharya, MS, who served the GCRC and its investigators for nine years, and also had a key role in helping the GCRC team with website and grant applications. Bhattacharya accepted a full-time position with the Center for the Study of Cultural Diversity in Healthcare, which is in the UW School of Medicine and Public Health.

- **Nithya Madhavan assists Dr. Yoram Shenker, the Research Subject Advocate for the GCRC.** The student assistant works with GCRC study coordinators to set Data and Safety Monitoring reviews that occur annually. Contact her at nithya@biostat.wisc.edu.

GCRC Cancer Research (from p. 1)

The Phase I Program investigates potential new therapies for cancer, often conducting trials of new agents for the first time in humans. Such studies offer patients the opportunity to take part in experimental research that may have shown positive results in early studies, or even in animal studies. Phase I studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

"It's important to have a setting like the GCRC," says Dr. Wilding, "in which we can try new treatments under controlled conditions and with a highly-trained and experienced research staff who help ensure the precision and accuracy of research data. Such nurses, right in a hospital setting, allow experimental treatments to be as safe as possible."

UW-GCRC and Oncology Studies

While the oncology studies on the GCRC only made up 30% of the total census in 2005, the expertise of the GCRC nurses in oncology is impressive. Team Leader Mary Gillitzer, RN, who oversees oncology studies, has 19 years as a research nurse on the GCRC. She is often the lead non-MD reviewer on new GCRC cancer protocols, meets with research study groups to prepare for research on the GCRC, and oversees GCRC nurses who work with the cancer subjects. However, all GCRC nurses on the D6/6 unit in UW Hospital and Clinics have ex-

pertise in oncology research, are chemotherapy-certified, and update their certification every year. "Oncology studies and treatments become more sophisticated every year," notes Ms. Gillitzer, "and it's very important to integrate old experience with new knowledge on a continuing basis."

Types of Oncology Studies

The Cancer Center investigators who bring patients to the GCRC specialize in different areas of oncology. They may have NIH grants (for which the GCRC provides nursing and hospital rooms at no cost to the study), or contract with pharmaceutical companies to test new treatments (with the company paying for all nursing, tests, and room charges). In nearly all research treatments, there is no charge for the research portion to patients part in studies.

In addition to collaborating on Phase I team studies, oncology investigators are also principal investigators on their own studies. Other oncology PI's include: Drs. James Cleary, Joseph Connor, Jason Gee, Kyle Holen, Douglas McNeel, Daniel Mulkerin, H. Ian Robins, Joan Schiller, and James Stewart.

Oncology Contributions

Dr. Minesh Mehta, Chair of Human Oncology, is not only a PI on 4 approved protocols on the GCRC, but also served as chair of the Medical School Dean Philip M. Farrell's committee last summer to seek a new Program Director for the GCRC. Drs. Paul Sondel, a pediatric oncologist, Howard Bailey, human oncology, and Anne Traynor, medical oncology, serve as volunteer members of the GCRC Advisory Committee,

which reviews all GCRC protocol applications. Dr. Wilding serves on the GCRC Long-Range Planning Committee and also served on Dr. Mehta's GCRC search committee last summer.



Dr. Sondel directs an NIH melanoma protocol on the GCRC, which he has recently requested be extended to children. The GCRC also supports children's cancer studies, with what is known as a scatter-bed nurse who serves as a research nurse on the pediatric oncology floor.

Dr. Bailey, formerly associate director of the GCRC, directs an NIH study on chemoprevention of skin cancers in organ transplant recipients, looking in this highly susceptible group for prevention strategies that might work in the general population as well. Dr. Traynor is PI on 3 studies, two of which involve new treatments for non-small cell lung cancer.

"The GCRC/UWCCC collaboration is advantageous for both groups," says GCRC Program Director Dr. Marc K. Drezner. "Our unit and staff are able to provide support and expertise on the more complicated and risky new oncology studies, and the Cancer Center, its investigators, managers, and coordinators bring not only GCRC activity but also their expertise to our Center and nursing staff."

Lunch & Learn on Feb. 22

Wednesday, Feb. 22 at noon is the next Lunch & Learn in G5/119 for the update from the Office of Clinical Trials staff. The programs are co-sponsored by the GCRC and the UW's Clinical Investigator Preparatory Program.



UWCCC Fellows and Dr. James Stewart