



# UW-GCRC Update

## 2005 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/index.html>.

- Thursday December 1
- Thursday December 29
- Thursday February 2, 2006

(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 School of Medicine and Public Health

## GCRC Seeks Grant Renewal Under New NIH Rules in 2006

The University of Wisconsin–General Clinical Research Center (UW-GCRC) will submit its competitive renewal application on June 1, 2006, and hopes to secure a three-year renewal from the National Center for Research Resources of the NIH.

The NIH renewal process, however, has changed dramatically since previous competitive submissions. For example, there will be no site visit or protocol presentations, and only a straightforward listing of protocols that will be using the GCRC during the December 1, 2006–November 30, 2007 grant year.

For investigators using the UW-GCRC, this limited protocol information will mean less work for researchers, time that can be devoted

to moving their projects forward. For each investigator who is using and plans to use the Center in the 2006-2007 grant year, the following will be required under the September 2005 GCRC Guidelines: (1) PI name, degree, and department; (2) SPID number (provided by the GCRC); (3) Complete project title, if supported by an NIH grant (grant number, grant PI, and grant project period; and (4) Other information needed for a successful GCRC application.

For a non-NIH peer-reviewed grant, the listing must include the source of funding, i.e., the American Cancer Society, grant number, grant PI, and grant project period. The GCRC will be contacting current investigators for the

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## Associate Dean Names Carnes, Drezner As Co-PI's for CTSA

Drs. Molly Carnes and Marc Drezner are Co-Principal Investigators for the Clinical and Translational Science Award (CTSA) application that the University of Wisconsin plans to submit to NIH in 2007. The two were named PI's on Oct. 10 by Dr. Paul DeLuca, Associate Dean for Research in the UW School of Medicine.



Marc K. Drezner, MD  
UW-GCRC Program Director

Drs. Carnes and Drezner will lead wide-ranging discussions and planning over the

next two years to help develop a unique University of Wisconsin vision to meet the expectations of NIH for this new program. Dr. Carnes is Director for the UW Center for Women's Health Research, while Dr. Drezner is Program Director for the UW-General Clinical Research Center and Head, Division of Endocrinology, Diabetes, and Metabolism.

"The UW occupies a particularly strong position to successfully compete for a CTSA," says Dr. Drezner. I look forward to working with the diverse group of individuals at our institution to formulate an exciting proposal."

According to Dr. Carnes, "The UW's commitment to multidisciplinary training

and to the study of successful career development of clinical researchers will contribute greatly to a CTSA application."



Molly Carnes, MD  
Director, UW Center for Women's Health Research

### CTSA Article in NEJM

The CTSA program and the NIH rationale is outlined in "Translational and Clinical

Science—Time for a New Vision," which appears in the October 13, 2005 issue of *The New England Journal of Medicine*. The

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## Grant Renewal (Continued from page 1)

above information during the next few months. Other investigators who plan to use the GCRC for protocols starting December 1, 2006 should contact Paulette Sacksteder, GCRC Administrative Director, at 3-3271 or at [pasacksteder@wisc.edu](mailto:pasacksteder@wisc.edu) for more information.

## Reason for Change

A newly-released NIH Request for Application, the Clinical and Translational Science Award (CTSA) program, produced these major changes for the national GCRC program, which has been in existence for more than 40 years. While currently there are 78 GCRCs across the United States, the expected number by 2010 is approximately 60.

## You Should Know...

- **Beginning in December 2005, the GCRC is required to review oncology research protocols as part of its Data and Safety Monitoring program.** While GCRC oncology protocols in the past were only reviewed by the UW Comprehensive Cancer Center (UWCCC) for data and safety issues, this new GCRC review will be a collaborative process with the UWCCC. The GCRC Data and Safety program, which reviews protocols annually, has developed over several years to meet NIH expectations. The addition of oncology programs is expected to be of benefit to subjects, investigators, the GCRC, and the UWCCC. Scheduling will be coordinated with the help of the UWCCC staff.

"We will be working with the UWCCC and its GCRC investigators to assure there is no overlap or duplication of current reviews," says Yoram Shenker, MD, the GCRC Research Subject Advocate

Although the first CTSA applications may be submitted in March 2006, institutions may not submit CTSA and GCRC competitive applications in the same year. Thus, the UW-GCRC will be applying for a three-year GCRC renewal on June 1, 2006, allowing ample time for preparing a CTSA application. In addition, the University of Wisconsin will be applying for a CTSA Planning Grant in March 2006.

The GCRCs, according to NIH, will disappear as separately-funded entities by 2010, and become part of CTSA programs. In addition to the GCRCs, the CTSA will also enfold all current K30s (called CIPP at UW) and Roadmap K12s.

For more information about the CTSA program and RFA, go to <http://grants.nih.gov/grants/guide/notice-files/NOT-RM-05-013.html>.

and chair of the GCRC Data and Safety Monitoring Committee. "Our objective, as outlined by NIH, is to be a protection for subjects, but we also assist investigators to better track and assess the data and safety aspects of their protocols. Non-oncology investigators have found this review program very helpful to their studies." If there are questions about this new oncology review process, Dr. Shenker can be contacted at [yxs@medicine.wisc.edu](mailto:yxs@medicine.wisc.edu).

- **The "Lunch and Learn" noon educational sessions will return in January 2006.** These sessions, held on Wednesdays, are co-sponsored by the UW-GCRC and the Clinical Investigator Preparatory Program (CIPP). Examples of topics include quality assurance in clinical research, budget and billing for research studies, and recruitment strategies. Usual attendees are junior investigators, research managers, and study coordinators.

## Co-PI's for CTSA (Continued from page 1)

article, written by NIH Director Elias A. Zerhouni, MD, discusses NIH's Roadmap for Medical Research, specifying the Roadmap's third theme of concerns from researchers.

"Third, we heard resounding concern from basic, translational, and clinical researchers alike that their interactions were becoming more remote and difficult, that clinical research was increasingly less attractive to new investigators, and that clinician-scientists were moving away from patient-oriented research," says Dr. Zerhouni.

To meet the challenge, he goes on to explain, NIH has the responsibility to dissolve artificial barriers that spring up in any large organization. He then announces the opportunity for institutions to apply for a CTSA, which he sees as responding to the demands of modern translational and clinical research.

"The NIH," he continues, "wishes to provide flexibility and support to institutions who choose to "re-engineer" their own clinical and translational research programs in order to combine a number of existing NIH-funded programs creatively. The NIH is asking applicants to consolidate General Clinical Research Centers, T32 and K12 programs, and other resources, as appropriate."

Finally, Dr. Zerhouni announced the redirection of NIH Roadmap funding from other initiatives to this new CTSA program, so that the GCRC, T32, and K12 program funding can be augmented. According to a NIH-sponsored meeting in Washington, DC, which Drs. Carnes and Drezner attended on October 17, there will be up to \$6 million in addition to the current GCRC, T32, and K12 program funding that could ultimately fund the UW-CTSA, if the application were successful.