



UW-GCRC Update

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 March 31
- Thursday April 28
- Thursday June 2
- Thursday June 30
- Thursday July 28
- Thursday September 1

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

GCRC Applications Now Electronic

The University of Wisconsin-General Clinical Research Center (UW-GCRC) officially launched its electronic submission process effective March 2005. Investigators requesting GCRC support should follow the rules below for submitting protocols and other required documents.

If the study is not supported by federal funds, or sponsored by industry funds, the investigator should first contact Paulette Sacksteder, GCRC Administrative Director, at 263-3271. Because of funding cutbacks, there is limited help for non-NIH funded protocols, and the GCRC wants to save the researcher time and money if the study cannot be supported.

The UW-GCRC application should be sent

electronically, with only a minimal number of paper copies required. Follow the ELECTRONIC and PAPER COPIES directions below. You can access the GCRC website with all the needed links and documents at: <http://www.medsch.wisc.edu/uwgcrc/index.html>

For monthly submission deadlines, be sure to check the 2005 dates, which are listed at the left.

Electronic Directions

Please email GCRC Protocol Manager Danielle Gale (dgale@biostat.wisc.edu)

and attach the following required documents.

1. The GCRC Addendum to the HSC Application (on the GCRC website)



Danielle Gale - Protocol Manager

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You Should Know...

- **GCRC now has limits in covering tests for NIH-funded projects.** While the UW-GCRC covers room and nursing costs for NIH protocols, there is now a limit on coverage for ancillaries (lab tests, chest X-rays, etc). Because NIH cut our GCRC budget by 50%, the maximum net ancillary support is now \$33 for each outpatient visit, and \$100 for each inpatient day. If you have questions, contact Danielle Gale (2-3005 or dgale@biostat.wisc.edu).
- **Non-industry studies without NIH funding will have no ancillary**

support awards, so no request should be made. Because of possible space and funding limits, non-NIH investigators submitting studies to the GCRC should contact Administrative Director Paulette Sacksteder (3-3271, pasacksteder@wisc.edu) before taking the time to complete all the GCRC application forms.

- **Industry-supported studies are subject to the same rules as in past years.** Industry protocols must be submitted, reviewed, and, if approved, the sponsor funds must pay all the

GCRC charges for room costs, nursing, and ancillary costs.

- **Kalpa Gunawardena, BS, a student office assistant, is now working at the UW-GCRC.** She is assisting Dr. Yoram Shenker, the Research Subject Advocate, to schedule data and safety monitoring reviews of all GCRC protocols. Dr. Shenker does annual reviews, so you may be receiving an email or call from her. Kalpa is also working with Administrative Director Paulette Sacksteder.

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2. Data and Safety Monitoring Plan (DSMP) (on the GCRC website)
3. The Institutional Review Board (IRB) Initial Review application, with draft consent form(s) and any other attachments provided to the IRB or, if applicable, the most recent Change of Protocol application, as submitted to the IRB. These forms can be accessed from the GCRC website. [For studies already approved by the IRB, include the IRB Notice of Action – Approval, the IRB-stamped consent form(s) and HIPAA authorization with the "original" copy.]
4. The most current sponsor protocol/grant application.
5. Other pertinent materials [e.g., draft orders, PI biosketch (if investigator is new to the GCRC), RSP budget, etc.]

These can all be submitted as separate

"files," and do not have to be incorporated into one. Adobe Acrobat/Reader (pdf) and Word (doc, rtf) files are recommended.

Limited Paper Copies

Please submit one (1) unstapled, single-sided "original" of all the above (with signatures on the DSMP and IRB application) and 10 double-sided copies of the same. If the study has already received IRB approval, please include a copy of the IRB Notice of Action – Approval, the IRB-stamped consent form(s) and HIPAA authorization with the "original" copy.

If you have any attachments that you are NOT able to submit electronically, please separate those documents with a clip and indicate that they were not included in the electronic application. Please keep these to less than 20 pages, and deliver to Danielle Gale in D6/621.

New Items on the GCRC Application

Please check the GCRC Addendum to the IRB Application for some important new sections, which are based on items approved at recent GCRC Advisory Committee (GAC) meetings. The new addendum is attached as a Microsoft Word document to this *Update* email, and also appears on the website.

First, see a yellow highlighted section under 7. Inpatient Studies. As voted on by the GAC, any visit expected to be 10 or more hours in length needs to be a GCRC inpatient admission. Inpatient subjects should be admitted to the GCRC the night before the study visit.

Second, the Data and Safety Monitoring Plan (#11) has been recently updated on the GCRC website and has additional items that are important for our reviews and upcoming competitive renewal in 2006 to the NIH's National Center for Research Resources (NCRR). Please be sure you always use the website versions of the GCRC Addendum and DSMP.

More to Know...

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- **NIH tracks the number of peer-reviewed publications resulting from GCRC support, and whether authors cite the UW-GCRC.** Please cite the UW-GCRC in your papers. State: "Supported by grant M01 RR03186 from the General Clinical Research Centers Program of the National Center for Research Resources, National Institutes of Health." Provide a copy of each publication to the UW-GCRC office, D6/621 in the Clinical Science Center.

UW-GCRC Spotlight

Suzi Pertzborn's face is well known to UW-GCRC investigators, coordinators, and many throughout UW Hospital and Clinics. She began work at the GCRC in 1985 by helping to write the first competitive grant for the NIH-supported clinical research center. Before the GCRC, she worked in the Comprehensive Cancer Center.

Suzi handles GCRC census reporting, assists the Administrative Director, and she can find answers to almost any GCRC question. She's in D6/621; you can contact her at 263-5377 or email her at pertzbor@biostat.wisc.edu.

"The variety and the people I meet are my favorite part of being in the GCRC. There is never a dull moment, and often many lively ones," Suzi says. Besides census, she works on the Annual Report to NIH, and oversees the summer and mentored medical student grants, as well as the Clinical Research Feasibility Funds (CReFF) awarded by the UW-GCRC to junior faculty investigators.



Suzi Pertzborn — Office Manager