



UW-GCRC Update

2005 GCRC Protocol Submission Deadlines

Deadlines for submitting protocols are listed below. All submissions should be electronic and must be submitted by noon on the deadline date. See the UW-GCRC website, <http://www.medsch.wisc.edu/uwgcrc/index.html>, for more information.

- Thursday September 29
- Thursday November 3
- Thursday December 1

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

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

Medication Management Changes for Inpatients on Monday, Sept. 26

Beginning Monday, Sept. 26, the UW-GCRC will follow the same procedures as other UW hospital units on use of a patient's home medications for GCRC inpatients. The

purpose of these changes is to bring the GCRC to compliance with JCAHO medication management standards. UW Hospital pharmacists will discuss with patients their home medications needed during their hospital research stay, record a complete home medication and allergy list, and then provide the same or equivalent home medications to be given by the GCRC nursing staff as ordered in the patient's orders.

The new process for home medications on the GCRC applies to all current inpatient studies on the GCRC as well as all future studies. There will be no charge to the research studies

or the study participants. This new program applies to all studies on the GCRC, even if a study does not dispense any drugs for the protocol.



"This change on the GCRC is not only an additional safety measure for our studies and their subjects, but also allows us to benefit from the expertise of an excellent pharmacy program," says Mary Jane Williams, RN, BSN, MPH, the clinical nurse manager for the UW-GCRC. "We begin the service for inpatients on Monday, but will expand the service to outpatient subjects in the near future."

Exceptions

The new policy will cover all medications administered to all inpatients on the GCRC, according to Steve Rough, MS, RPh, Director of Pharmacy at UW Hospital and Clinics. One

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IRB/GCRC Set October Pilot for Consent Summary Sheet

The UW Health Sciences Institutional Review Boards (UW-IRB) and the UW-General Clinical Research Center (UW-GCRC) will test IRB's innovative Consent Form Summary Sheet this fall. The objective is a short 1-1 ½ page research project summary that is informative, written in 8th grade language or lower, and able to concisely inform subjects about the essential facts and risks for which the subject has been recruited. The Summary Sheet is an adjunct to the complete Consent Form, not a substitute.

The UW-GCRC, which receives about 7-10 research applications per month, will begin requiring the Summary, along with the current, longer IRB consent form, for its October protocol reviews. The deadline for GCRC October applications is Thursday, September 29 at noon. The Summary Sheet should be included in the electronic copies sent to Danielle Gale, GCRC protocol manager, dgale@biostat.wisc.edu.

If you plan to submit a GCRC protocol application for the October 2005

meeting, or in the future, for more information please go to the IRB Website at www.medicine.wisc.edu/irb. The new Summary Sheet will be located under the "Consent Form" link on the IRB site.

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."

Medication Management

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exception to current inpatient procedures is that there would be no therapeutic substitutions for any of the home medications. All drugs dispensed will be the exact formula as the home medication.

Patients will be allowed to use their own medication of a non-formulary product if an order is written for the medication to be "patient's own" and the pharmacist verifies the integrity of the medication. These medications must be stored securely (locked drawer or under constant supervision) and this will be coordinated by the pharmacists. If a patient does not have his or her own medication, the pharmacy will provide the non-formulary medications as needed to maintain patients' home regimens. To use a patient's own medications, they need to be in the original labeled bottles as provided to the patient and securely stored.

The policy, Mary Jane emphasizes, covers all patients' own medications and has nothing to do with any medications that are part of an investigator's GCRC research protocol. There is no change to how study medications will be provided to patients.

Changes for GCRC Studies

The following is a list of expectations for inpatients starting next Monday, Sept. 26, 2005:

- (1) each GCRC admitting physician or NP will need to order all inpatients' home medications to be continued during their hospital stay, as well as list the patient's allergies, in the GCRC physician admission orders. Blanket orders for "resume home medications" or "continue home medications" will not be allowed,
- (2) orders should be submitted at least 1

day prior to admission to optimize protocol flow,

(3) study personnel need to notify subjects to bring all their home medications in their original containers, and

(4) study personnel should also tell subjects that the hospital pharmacist may call the night before admission to talk about the medication regimens (as listed in the orders) to ensure the list is complete and correct.

The PI of any study should be aware that if there is a discrepancy between the orders and what the patient takes as their home regimen, the pharmacist will call the PI or the delegated prescriber. Therefore, the prescriber or study coordinator phone or pager number must be listed on the orders. In lieu of this, the study prescriber can write in the orders a statement allowing the pharmacist to adjust the medications: "pharmacists to modify admission home meds per medication history obtained by pharmacist." The pharmacist will then have the ability to write clarification orders for the medications without contacting the prescriber.

Discharge Changes

Finally, the discharge physician is responsible for filling out the *Discharge Order and Face Sheet* for patients, as done on any other hospital unit. The medication at discharge must list all home medications so the pharmacist can reconcile the discharge medication orders with the inpatient and at-home medication regimens. The pharmacist will counsel all patients on all new medications prior to their discharge.

If you are confident that the medications will not change during the inpatient stay, you may wish to submit the Discharge Face Sheet at the same time you deliver the admit orders to the GCRC. A blanket

discharge order, "Resume home meds" will NOT be acceptable. Face Sheets not provided the day before would require the prescriber to provide discharge prescriptions to the patient, otherwise the pharmacist will provide these.

If you have questions, please contact Steve Rough, 3-1282 (ss.rough@hosp.wisc.edu) or Mary Jane Williams 3-0201 (mj.williams@hosp.wisc.edu).

You Should Know...

- **The GCRC RSA is available to consult with current or future investigators for any issues related to the consent process, safety, design of Data and Safety Monitoring Plans, or need for a Data and Safety Monitoring Board.** Dr. Shenker's responsibilities include reviewing all new protocols for safety and reporting to the GCRC Advisory Committee at their protocol review meetings, conducting annual Data and Safety Monitoring reviews for GCRC protocols, and chairing the GCRC Data and Safety Monitoring Committee. Contact him at yxs@medicine.wisc.edu for consultation.
- **New studies submitting protocols to the GCRC should make sure that their consent forms specify that the Research Subject Advocate (RSA) and the GCRC Data and Safety Monitoring Committee may potentially request access to subjects' information.**
- **The GCRC Website has the latest information and electronic forms you need to submit a protocol for review.** See <http://www.medsch.wisc.edu/uwgcrc> for submission information and deadlines. Deadlines for 2006 will be posted the week of Sept. 26, 2005.