



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 30
- Thursday July 28
- Thursday September 1

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

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

GCRC Statisticians Can Aid Studies

The UW-GCRC Biostatistics/Informatics group offers an added dimension to clinical studies on the D6/6 unit in UW Hospital & Clinics. The biostatistics services, free to NIH-supported clinical investigators with GCRC studies, include consultation in preparation for a GCRC submission, or analysis and other services during a study.



Jason Fine, DSc — Biostatistics

Jason P. Fine, DSc, is the GCRC Director for both the biostatistics and informatics areas. He serves as chief biostatistics reviewer and consultant to the pre-review committee and to the GCRC Advisory Council (GAC), which examines and the science, including statistical accuracy, of all submitted protocols.

Abhik Bhattacharya, MS, GCRC Informatics Core Manager, is responsible for the overall operation of the computer system, which consists of a variety of work stations, microcomputers, and data management and analysis software. He is also responsible for instructing and assisting clinical investigators in the use of the system; responding to queries from users about study design and statistical analysis; ensuring adequate hardware and software maintenance; archiving completed studies, and performing tape backups.

What Services are Available?

“Even before studies are submitted,” says Bhattacharya, “we can provide consultation on

(Continued on page 2)

You Should Know...

- **The Board of Research Advisors meets quarterly as a forum for input and improvements to UW-GCRC clinical services.** Board members are Dona Alberti, Rhoda Arzoomanian, Mary Baliker, Mary Beth Benson, Nichelle Cobb, Gayle Love, Rebecca Marnocha, Tracy Ohrt (for Sanjay Asthana), Kathleen Roberg, Teresa Smith, and Judy Van Kirk. If GCRC users have questions or suggestions, they can contact any member to add an item to the agenda.
- **NIH judges GCRCs on both the number of peer-reviewed articles its investigators get published, and whether the article cites the GCRC that supported the research.** 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."
- **You can register with a Visa or Mastercard for the 2005 “Short Course in Clinical Research” on July 19, 20, 21 by calling 265-2955.** Or, you can ask for more information about the program for medical and graduate students, residents and fellow, or faculty and academic staff. The program is jointly sponsored by the UW Medical School Office of Continuing Medical Education, UW Clinical Investigator Preparatory Program (CIPP), and Howard University College of Medicine, Washington, DC.

Biostatistics (Continued from page 1)

study design, calculation of sample size, database setup, and other preliminary statistical expectations. We did this for more than 75 studies in the last 3 years.”

Studies that seek help must be Category A (NIH or other investigator-initiated studies) or Category B (investigator-initiated research and standard-of-care studies). Since the GCRC statisticians are federally-funded, they cannot provide free consultation to industry research studies.

Once a study is approved for implementation on the GCRC, Fine and Bhattacharya can review and advise on study progress in the statistical area. The



Abhik Bhattacharya, MS — Biostatistics

GCRC biostatistics/informatics group does not have the resources to serve as a study’s statistician.

What Statistics Are Most Important?

When a principal investigator submits a study for GCRC review, the biostatistical review will concentrate primarily on the following: (1) study design, (2) sample size and (3) data analysis plan.

“Statistics is not an isolated part of a protocol,” says Fine, “it is our goal to see that the statistics of a study, such as the data analysis plan, can support the science of the study.”

To contact the UW-GCRC statistics group, call or email: Dr. Fine at 5-9167 (fine@biostat.wisc.edu) or Abhik at 3-8495 (abhik@biostat.wisc.edu).

Q&A with Biostats

What does a GCRC Biostatistician do?

Biostatisticians can help starting with study design, power calculation, data analysis, database management and publication.

How can I use Biostatistical help before my study is GAC approved?

A PI can seek help on design and sample size issues. Biostatisticians will also look to see if your study has an appropriate data analysis plan.

When a Biostatistician reviews my protocol, what are they looking for?

They look to see whether there exists a sound statistical analysis plan to answer the research question.

If my statistician says that my study is strong enough, does it matter if the GCRC biostatistician disagrees?

If there is a disagreement, for instance, in power calculations, the GCRC will ask for further review and discussion by study personnel.

UW-GCRC Spotlight...Mary Jane

Mary Jane Williams, RN, BSN, MPH, sees her Nurse Manager role as ensuring the integrity of clinical research on the GCRC unit, promoting excellence in patient care within the research setting, and overseeing a successful hospital unit.

“It’s a difficult balance,” says Mary Jane, who came to the UW-GCRC in 2003 from a career in nursing and research at St. Vincent Hospital in Little Rock, Arkansas. “As a nurse, patient care is foremost, but a research nurse must be aware of the importance of the detail and precision needed for research data. Sloppy data collection can invalidate otherwise good research.”

Williams oversees 22 nursing staff and is responsible to the hospital for budget, census, and administration. She and all the nurses are employees of UW Hospital and Clinics, but are paid by the federally-funded GCRC grant.

“Our goal is to partner with researchers to deliver high quality data and excellent patient care,” says Williams. “To accomplish this goal, we must work operationally with multiple hospital and

medical school departments to consistently deliver quality care and research.”



Mary Jane Williams, RN, BSN, MPH

Several months ago, GCRC nurses collaborated on a GCRC Mission Statement. The mission is as follows:

The University of Wisconsin General Clinical Research Center (UW-GCRC) offers access to a unique environment for medical science researchers to conduct quality, cost-effective research. The infrastructure supports a full spectrum of patient-oriented scientific inquiry on healthy subjects and patients with disease. Research is conducted in an atmosphere of profound respect for the individual research subjects and is guided

by Good Clinical Practice (GCP), federal regulations and UWHC policies that protect patients in clinical research protocols.

Says Mary Jane Williams, “We believe in this mission, and have the opportunity to work with many different UW departments to realize both its words and its spirit. And the most satisfying part of the GCRC is working with other healthcare providers who share our passion for quality patient care and dedication to the most precise delivery of research data.”