Compliance is a new buzz word on campus. UNMC has a new Office of Compliance reporting to the Vice Chancellor of Academic Affairs. Being in charge of compliance is a big job, so several questions occurred to me, “Compliance of what?” and “If you see non-compliance, what is the procedure to follow?”

According to Sheila Wrobel, UNMC Compliance Officer, the compliance program will focus on laws and regulations that impact academic medical centers, including human and animal subjects research protection, grants management, privacy and security, safety and environment, employment, and intellectual property and integrity. Currently, there are existing compliance mechanisms in place with subject matter experts in all of these areas. The goal of an overall program will be to ensure that adequate measures are in place to address high risk areas and ensure that compliance related policies and procedures are consistently implemented across campus.

The Compliance Office is using the Federal Sentencing Guidelines and the Department of Health and Human Services model compliance plans as reference tools to develop the compliance program. The following compliance initiatives are underway:

- A compliance committee with representatives from each of the colleges and supporting departments has been established. The committee will assist the Compliance Officer with developing the compliance program, including providing feedback on policies and procedures and implementing compliance monitors to assess the effectiveness of the program.
- A compliance hotline will be introduced soon to provide staff with another channel to communicate compliance concerns if they do not feel comfortable discussing them directly with departmental staff. While staff will be encouraged to identify themselves, calls to the hotline may be made anonymously.
- A conflict of interest committee has been created to develop a process to ensure that potential conflicts of interest are properly disclosed and managed pursuant to Public Health Service and National Science Foundation regulations.
- A research billing Work Out is being conducted with representatives from UNMC, UMA and NMC to ensure that patients who are research subjects are properly identified and services associated with clinical trials are properly billed to third party payors and to the grant.
- A compliance website that provides links to specific functional compliance areas is located at: http://appt.unmc.edu/compliance.

Staff who have concerns about compliance with laws, regulations and UNMC policies and procedures should discuss their concerns with supervisory personnel in their department. Or, they may contact the department that has responsibility to manage the program on campus, i.e. the subject matter experts. Third staff may contact the Compliance Officer or call the compliance hotline when it is established. Staff are encouraged to bring compliance concerns forward so they can be investigated and addressed.

If you have any questions please feel free to call Sheila Wrobel at 9-6767 or swrobel@unmc.edu
There have been some recent changes in the process of applying for CRC grant funding and nursing support of which I would like everyone to be aware.

1. The Research Support Fund was renamed the “CRC Grant Fund”.
2. The deadline for submitting for financial or nursing support is now 3 weeks in advance of the meeting. This is being done to make it possible to communicate with the investigator so if revisions are needed this can be done prior to the full committee meeting thus expediting the process through committee.
3. There is a new application on-line that you can download. It is interactive and has a few changes. Please use the new application from this point forward.
4. Julie Petsche, RN is a new coordinator in the CRC.

Feel free to come see us anytime and if there is anything we can do to be of assistance just give us a call.

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**Coordinators Corner**

The following story from Charleston.net. Amid mounting concerns that drug companies aren’t telling people everything they know about their products, the pharmaceutical industry in October revealed plans to post the results of its clinical trials on the internet.

The Pharmaceutical Research and Mfg’s of America made clinicalstudyresults.org available to the public October 1, 2004 for free. It is the industry’s most extensive effort thus far to give patients and doctors information in its unpublished clinical trials.

Even so, the plan may not satisfy those who have been pushing for greater disclosure of drug company-funded clinical trials. The entire story can be found on http://www.charleston.net/stories/090804/bus_08drugs.shtml

**Setting up Grant Accounts** accurately is extremely important. Grant accounts must be set up on “S” accounts rather than “C” accounts. If you are unclear about how to go about doing this call the CRC and we will show you. 9-8555

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**NIH Updates Evaluation Criteria**

October 12, 2004

NIH announced changes in its research grant review criteria. The changes are intended to better accommodate interdisciplinary, translational, and clinical projects. A side-by-side document comparing the changes with the criteria in use since 1997 is available at http://grants.nih.gov/grants/peer/comparison_evaluation.doc

Beginning with reviews in the summer of 2005, reviewers will be instructed to use the updated review criteria as the basis for evaluating research grant applications & for assigning a single, global score for each scored application. The score should reflect the overall impact that the project could have on the advancement of science. An application need not be strong in all categories to be judged likely to have a major scientific impact.

For more information and frequently asked questions go to: http://grants.nih.gov/grants/peer/peer.htm#documents.
The Biostatistics Section of the Department of Preventive and Societal Medicine provides biostatistical support for CRC investigators and protocols. The Section includes four faculty biostatisticians (Dr. James Lynch, Section Chief, and Drs. James Anderson, Jane Meza, and Julie Stoner) and three Master’s degree-trained biostatisticians (Elizabeth Lyden, Susan Puumala, and Lynette Smith). Fred Ullrich, Eugene Boilesen, Mary Morris, and Alison Lahners provide computing and research support. Section faculty and Master’s-trained biostatisticians are available to collaborate on protocol development including study design, sample size considerations, plans for safety and efficacy monitoring, and plans for data analysis. They are also available to collaborate on developing internal or external funding applications, including NIH applications. Drs. Lynch and Meza serve on the CRC Scientific Advisory Committee that reviews each CRC protocol and Research Grant Fund application and encourage biostatistical input in the early stages of project development to facilitate the review process.

In addition to providing biostatistical support, Biostatistics Section members can also assist with the operational aspects of clinical research, such as developing plans for data collection and management. They may include scanned or keyed data entry, paper or web-based data-capture forms, and protocol-specific databases, as well as monitoring study conduct.

The Section’s role in clinical research is illustrated by its activities on the NIH-funded multicenter clinical trial, “Low-Dose Doxycycline Effects On Osteopenic Bone Loss,” led by Dr. Jeffrey Payne of the UNMC College of Dentistry. Drs. Lynch and Stoner collaborated with Dr. Payne to develop the funding application and the protocol, including the statistical design of the clinical trial. Ms. Lahners, with computing support from Mr. Boilesen and Mr. Ullrich, oversees data collection and quality assurance and is responsible for data computerization using paper data-capture forms (developed in collaboration with trial investigators), scanned data entry, and a protocol-specific database. Ms. Lahners also completes and submits MedWatch reports of serious adverse events. To ensure the quality of data collection and computerization, audits both of capture forms (through on-site audits) and of computerized data are overseen by Ms. Morris. Drs. Stoner and Lynch prepare annual reports, including interim quality assurance, safety, and efficacy analyses for the trial’s independent data and safety monitoring board and will perform the statistical analysis of the trial’s results.

Statistical Support

We're on the web!
www.unmc.edu/crc

CRC Phone Numbers
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