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 Shiela Wrobel at 9-6767 or swrobel@unmc.edu
Those of you that have budgets to manage may find this piece of information very valuable. The Nebraska Medical Center is increasing the cost of all tests by 10% overall starting July 1. Some tests will increase more than 10%. Look at the new costs before agreeing to new budgets.

If you have left over &/or expired lab tubes they can be donated to Dr. Chambers for use in Afghanistan. Other items could be used as well. Questions call 9-3595.

The coordinators workshop for new coordinators on campus is scheduled for August 30 (9am-3:30pm) and August 31 (8am-1pm). For a copy of the curriculum or to register call Janet at 9-7685.

**NIH Progress Report Notification On-Line**

Historically, the NIH reminded grantees about the submission of a progress report by mailing a pre-printed face page. In August 2002 NIH announced that they will no longer be mailing these out, PI's will need to log on to a new website to obtain the progress report due date information using the Institutional Profile Number (IPF). If you are unsure of your IPF number a companion query is also available at the site to determine the IPF. The website is [http://era.nih.gov/userreports/pr_due.cfm](http://era.nih.gov/userreports/pr_due.cfm). An e-mail reminder is sent to the PI 2 months prior to the due date and approximately 2 weeks after the due date. The progress report will still need to be mailed directly to the NIH awarding institute. Institutions and PI’s registered in the NIH eRA Commons can find due date information in the Status system and have access to pre-populated face pages via Status.

**Clinical Research Symposium**

The Clinical Research Symposium will be held September 13-17, 2004 and January 17-21, 2005. The course is aimed at young or new clinical investigators, including fellows, jr faculty and research staff. Participants will write a sample grant, IRB application & a patient consent form. Ethics of clinical research, the process of informed consent, & basic principles of study design & statistical analysis are covered. Call 9-7685 to get a copy of the schedule or to register.

**CRC Phone Numbers**

559-4837 Jennifer Larsen, MD Director
559-8555 LuAnn Larson, BSN Nurse Manager
559-7685 Clinic