New Director of PRC/CTO

Mark Rupp, MD assumed the role of Medical Director of the Pharmaceutical Research Center (PRC) and the Clinical Trials Office (CTO) January 1, 2002. "I think it's an exciting time with the research enterprise being emphasized institutionally. It has given us the opportunity to elevate clinical research to a new level at UNMC." Dr. Rupp also added that "We are combining the resources of the CTO and PRC in order to work together and we are exploring where we can cooperate and collaborate with the Clinical Research Center (CRC)."

The major strategic goal of the CTO is to increase industry-sponsored clinical trials on campus. The CTO was developed to support clinical trial initiation including regulatory documents. There are several reasons for supporting clinical trials, Dr. Rupp explains that it gives us the opportunity to offer our patients cutting edge treatments, it is a way to translate basic research to clinical practice, it brings the University notoriety in being associated with ground breaking trials and the financial gain can help to fund other research. To accomplish this the CTO has helped to expedite the contract process and is working to market UNMC to bring in the most exciting trials being offered.

The PRC is a place to perform and support a research study. It is in a transitional phase and is currently formulating a new pricing structure and developing a menu of services that will aid investigators and research participants so their visits will be a "one-stop-shop". The PRC has coordinators available to assist with industrial trials. This is where the PRC and CRC are different in that the PRC supports industrial research and the CRC supports investigator initiated research. It is hoped the PRC will be seen as a way to off load research projects from the clinics that are too busy to accommodate these studies. In addition, the PRC will diversify the types of studies in the center to include both in-patient and out-patient protocols.

"A lot of first time investigators are daunted by the regulatory process. In the future we hope the CTO/PRC will be able to help investigators negotiate their way through that process. However, this will be a voluntary choice. We certainly don't want to add to the cost or complexity of the process for experienced and established investigators."

The long term goal is to improve the throughput of research at UNMC/NHS. To get in touch with the Clinical Trials Office please call Cindy Lear at 92174, or to contact the Pharmaceutical Research Center call Muriel Sorbel at 22283.
HIPPAA and Clinical Trials

If the government gets its way, your IRB could be forced into making value judgments on what patient identification data can be disclosed as part of research. The new privacy rules could impair clinical trials, place onerous burdens on IRBs, and restrict the number of health research studies conducted in the United States.

Organizations that oppose the Health Insurance Portability and Accountability Act (HIPPA) of 1996 voiced concern in a letter written to Tommy G. Thompson, secretary of the US Dept of Health and Human Services. The group is calling for substantial amendments to the proposed rules published in the Aug. 14, 2001 Federal Register.

“Our concern with HIPPA is it creates a parallel regulatory structure with much greater liability associated with any breach of the very complicated privacy rules,” says Jennifer Kulynych, JD, PhD, director of the division of biomedical and health sciences research for the American Association of Medical Colleges in Washington DC.

Breaches of the privacy rule could result in civil fines and criminal penalties for researchers, medical schools, hospitals, and others directly involved in maintaining patient health data, Kulynych says.

The final rule says that medical research must protect confidentiality of research subjects by de-identifying protected health information. The rule lists 18 identifiers often listed in medical charts that should be removed for the purposes of research:

A. Names
B. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code, if
1. That geographic unit contains more than 20,000 people.
2. The initial three digits of a ZIP code for all such geographic units contain 20,000 or fewer people is changed to 000.
C. All elements of dates, except year, for dates directly related to an individual, including DOB, admission/discharge date, date of death, and all ages over 89 must be aggregated into a single category of 90 or older.
D. Telephone number
E. Fax numbers
F. Electronic mail addresses
G. Social Security numbers
H. Medical record numbers
I. Health plan beneficiary numbers
J. Account numbers
K. Certificate/license numbers
L. Vehicle identifiers and serial numbers
M. Device identifiers and serial numbers
N. Web Universal Resource Locators
O. Internet Protocol address numbers
P. Biometric identifiers, including finger and voice prints
Q. Full face photographic images and any comparable images
R. Any other unique identifying number, characteristic, or code.

Melissa Bartlett, JD, legislative counsel of the American medical Group Association in Alexandria, VA, and others opposed the HIPAA’s final rule say that research entities already are subject to the common rule, and that research which is subject to an IRB review should be exempt from additional privacy rule requirements.

An example of difficulties that could be encountered may be a study in which serial numbers might be used to identify a patient who used a particular medical device. When a physician reports to a medical device company that there was a defect involved with a particular pacemaker, the manufacturer will be unable to investigate whether similar pacemakers also had a problem unless that serial number was included, Bartlett says.

A chief concern about HIPAA resides in the fact that the rule contains so much ambiguity and complexity that it’s unclear how medical facilities, researchers, and IRB’s may adhere to them, Kulynych explains. The regulation provides for IRB’s to conduct a waiver analysis to see if a particular research project may be exempted however to be eligible for a waiver of authorization, the research has to be of minimal risk and the privacy board or IRB must look at it and decide whether the risk of losing privacy is outweighed by the importance of the research, Kulynych said. “And it is not clear how this is intended to function.”

Excerpts from IRB Advisor Volume 1, NO. 3

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Health Care Cash Fund
Accepting Applications

Grant applications under the Nebraska Health Care Cash Fund are now being accepted until April 2, 2002. Application guidelines can be obtained from the HHS System web site at http://www.hhs.state.ne.us/fin/exchcft.htm or by contacting Charlene Gondring at 402/471-6057 or Sue Medinger at 402/471-0191.

Funding priorities have been established and are available from Sponsored Programs or the CRC.

More information regarding workshops and video conferences on how to complete their application is also available.