IRB FREQUENTLY ASKED QUESTIONS

INFORMED CONSENT REQUIREMENTS FOR DRUG AND DEVICE CLINICAL TRIALS AMENDED BY FDA

The U.S. Food and Drug Administration (FDA) published its final rule, revising the current regulations that govern the informed consent process for clinical studies of products regulated by the FDA.

The final rule requires that a statement be included on informed consent forms for all applicable drug and device clinical trials that informs study subjects that a description of the clinical trial will be available on www.ClinicalTrials.gov.

The UNMC and Joint Pediatric IRBs will implement the final rule by mandating that the following paragraph be placed in the "How will information about you be protected?" section, at the end of the HIPAA/Confidentiality statements.

> "A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

The final rule became effective on March 7, 2011; however the FDA will not enforce the requirements until March 7, 2012. This requirement will be required for all new submissions submitted to the Office of Regulatory Affairs (ORA) as of July 1, 2011. However, for studies that were submitted prior to July 1, 2011, this change will not be mandated. If you would like to make the change to an ongoing study, it can be done at the time of Continuing Review without submitting a Request for Change.

IRB OFFICE STAFF CHANGES

Joan Johnson, the IRB Office Assistant, has accepted another position on campus. We want to thank Joan for her years of service and wish her the best in her new position.

In the interim, phone calls to the main line will automatically be redirected to someone in the ORA. However, there may not always be someone at the front desk. If you stop by the office and need assistance, please ring the bell.

WHAT IS AN HRPP?

HRPP stands for Human Research Protections Program, which is comprised of many different components. Many think the IRB is the only element of the HRPP; however the term

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WHAT IS AN HRPP? *continued*

includes all aspects of the human subjects protection, such as Sponsored Programs Administration (SPA), Pharmacy & Therapeutics Committee (P&T), Scientific Review Committee (SRC), Biosafety, Conflict of Interest Committee, etc.

As the UNMC and Joint Pediatric IRBs move closer to AAHRPP Accreditation, HRPP will be used more frequently. The name of this IRB Frequently Asked Questions bulletin will also be changing in the future to incorporate the use of HRPP.

CAN I RECRUIT FOR MY STUDY BY SENDING OUT AN INSTITUTIONAL MASS DISTRIBUTION EMAIL ?

UNMC HRPP policy #3.5 "Subject Recruitment" prohibits advertisement distribution via mass email unless an exception is granted. Exceptions must be approved by the IRB with appropriate justification.

It is acceptable to advertise for a study in UNMC Today or other similar institutional publications. If you are interested in recruiting subjects from the UNMC/TNMC, UNO and/or CH&MC campus, the ad must be listed on the IRB application as a recruitment tool and IRB-approved prior to use.

If you have any questions, please contact Kevin Epperson at 559-2587 or kjeppers@unmc.edu.

CONDUCTING STUDIES THAT INVOLVE BOTH CHILDREN AND ADULTS: DECIDING WHICH BOARD TO SUBMIT TO AND WHICH APPLICATION TO USE

It's easy, right? The subjects of the research are kids, so the pediatric application is used and using adult subjects would indicate the use of the adult application. But what about the times when you will have both ages groups in a study?

Think in terms of majority. If the study is looking at teenagers, ages 13-19, one would expect that the majority would be considered pediatric subjects, with perhaps a few adult subjects (over 19 years of age). In that case, the pediatric application would be utilized, along with Addendum Y: Research Involving Adults as Subjects Participating in a Pediatric Trial. This example would be reviewed by the Joint Pediatric IRB, which meets on the 4th Tuesday of each month. The schedule of meetings and deadlines can be found on the IRB website (www.unmc.edu/irb) under "Pediatric IRB".

Similarly, if an investigator is enrolling college students, there may be the occasional 18 year old that may be interested in participating. Therefore, the PI would complete the adult application, accompanied by Addendum D: Research Involving Children. This study would be reviewed by the UNMC IRB, which means on the 1st and 3rd Thursday of each month (other than January and July). The schedule of meetings and deadlines can be found on the IRB website (www.unmc.edu/irb) under "Schedule".

If you have additional questions, please contact Shirley Horstman at 559-8561 or shorstman@unmc.edu.

A BREAKDOWN OF THE SUFFIXES USED IN THE IRB#

FB: Full Board - The study must be reviewed by the convened IRB and is subject to the federal regulations.

EP: Expedited - The study does not have to be reviewed at a convened meeting. The review is done by one or more IRB members and is subject to the federal regulations. NOTE: "Expedited" does not imply that it will be reviewed faster or that the review and approval criteria are less stringent.

EX: Exempt - Certain categories of research are considered exempt from the federal regulations. The determination is made by the ORA.

IRB Frequently Asked Questions
June, 2011
Volume 1, Issue 4

This Bulletin is produced by the Office of Regulatory Affairs, Institutional Review Board at the University of Nebraska Medical Center.

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