



IRB FREQUENTLY ASKED QUESTIONS



A NOTE FROM THE EXECUTIVE CHAIR OF THE IRB

Your IRB is here to help you. Our mission is to assist our investigators and other research personnel in the protection of the rights and welfare of human subjects. To that end, we are launching an educational initiative titled “IRB Frequently Asked Questions”.

In these educational bulletins distributed by email, we will pose pertinent questions related to IRB submission, review processes and research ethics. Succinct answers will be provided, with links as necessary, to guide you to more detailed information that will help you piece together the IRB puzzle.

We encourage all of you to submit questions to Jenny Kucera, IRB Administrator/Education Coordinator at jikucera@unmc.edu. In addition, we invite you to call the IRB Main line at 559-6463 if you require assistance in the development and submission of your IRB applications/forms.

Ernest Prentice, PhD
Associate Vice Chancellor of Academic Affairs

WHY ARE THE FEDERAL REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS ALWAYS CHANGING?

The regulations have basically not changed since 1981. Interpretation of the regulations by OHRP (Office of Human Research Protections) and the FDA has, however, evolved considerably, resulting in more stringent standards of IRB review and documentation. The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) standards also has imposed additional requirements to strengthen human subjects protection. As the UNMC IRB prepares for accreditation, these standards must be met.

WHO SERVES ON AN IRB?

Members are volunteers who have the necessary medical, scientific or other expertise needed to review a wide variety of research, ranging from complex biomedical protocols to social-behavioral studies. The UNMC IRBs also include community representatives.

IF AN INVESTIGATOR WOULD LIKE TO POST THEIR STUDY ON THE NEW SEARCHABLE CLINICAL TRIALS DATABASE ON THE UNMC WEBSITE, WHAT STEPS MUST BE TAKEN?

For currently active studies, fill out the Request for Change form called "Request for Change (Ads, Educational Items and Personnel Only)" and the required information in the RSS System. The IRB Application will also need to be updated and included with the submission.

For a study that does not have final IRB approval, list it as a recruitment tool on the IRB Application and fill out the required information in the RSS System for IRB review. The posting will not be reviewed, approved or made publicly available until the full protocol is granted final approval and release by the IRB.

For more questions about the UNMC Clinical Trials Database, contact LuAnn Larson at 559-8555 or llarson@nebraskamed.com

CURRENTLY, THERE ARE A TOTAL OF 1818 ACTIVE PROTOCOLS UNDER THE OVERSIGHT OF THE UNMC IRB. THIS INCLUDES 425 FULL BOARD, 461 EXPEDITED, 826 EXEMPT, 50 EXTERNAL AND 56 CENTRAL IRB STUDIES.

WHEN A PROTOCOL IS SUBMITTED FOR IRB REVIEW, INVESTIGATORS SOMETIMES RECEIVE A LENGTHY REVIEW LETTER.

WHY?

When an application does not address all of the information necessary for IRB review, the Board has to obtain that information in order to do a thorough review and ultimately approve the study. Therefore, it is advantageous for the investigator to consult the notes within the educational guide that accompany most questions on an IRB application to ensure that complete information is provided.

WHEN WILL THE UNMC IRB BEGIN UTILIZING AN ELECTRONIC SYSTEM FOR PROTOCOL SUBMISSION?

UNMC IRB is currently working with people at UNMC to develop an electronic system. Most Universities who have such systems contracted with a commercial software vendor to develop their system. The installation and maintenance of a commercially-generated system is extremely expensive.

TO DATE, THERE HAVE BEEN 642 PROTOCOLS SUBMITTED TO THE IRB FOR REVIEW IN 2010.

IF AN INVESTIGATOR DISAGREES WITH AN IRB REQUESTED MODIFICATION, DOESN'T UNDERSTAND THE RATIONALE OR NEEDS CLARIFICATION, WHAT SHOULD THEY DO?

For disagreements, present your views in the response letter to the IRB. If it is something that you don't understand or needs clarification to proceed with addressing the modification, feel free to contact the IRB via email (irbora@unmc.edu) or phone (559-6463). The IRB is very receptive to hearing from any investigator that disagrees or requires clarification with any aspect of the IRB's review. The IRB seeks to help our investigators protect human subjects and facilitate their research.

ARE THE CLINICALTRIALS.GOV AND THE EPPLEY CANCER CENTER SEARCHABLE DATABASES CONSIDERED RECRUITMENT TOOLS THAT NECESSITATE BEING LISTED ON THE IRB APPLICATION?

Yes. Even though registration with clinicaltrials.gov is a requirement for clinical trials and registration with the Eppley Cancer Center database is automatic if reviewed by the SRC, potential subjects, family members and caregivers can search these sites for possible studies which they or their loved one may be eligible. Other internal or external physicians may also access these sites to consider options for their patients, as well.

**IRB Frequently Asked Questions
November, 2010 Volume 1, Issue 1**

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

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