IRB FREQUENTLY ASKED QUESTIONS

IF AN INVESTIGATOR HAS A QUESTION ABOUT THE IRB, IRB POLICIES OR IRB REVIEWS, WHO SHOULD THEY CALL?

The IRB's 6 Administrators (Gail Kotulak, Kevin Epperson, Gail Paulsen, Sue Logsdon, Shirley Horstman and Jenny Kucera) are always happy to respond to questions and provide assistance as needed. Our IRB Administrators can be contacted directly (see contacts list on the IRB website at www.unmc.irb) or through the main desk at 559-6463 or irbora@unmc.edu. The IRB Administrators consult regularly with the IRB Executive Chair, Dr. Ernest Prentice, and the IRB Chair, Dr. Bruce Gordon.

IF A FACULTY MEMBER IS ONLY SIGNING THE IRB APPLICATION AS A FACULTY ADVISOR, DO THEY NEED TO BE CITI TRAINED?

Yes. The certification statement that the Faculty Advisor signs states "My signature certifies that I have reviewed this IRB application and I approve it for submission to the IRB. I assume responsibility for the overall supervision of this research. I will advise the student on the responsible conduct of research including compliance with all applicable federal regulations, state laws, and HRPP policies." The Institution, therefore, requires that CITI certification be maintained to ensure adequate oversight of student research projects.

WHY DOES IT TAKE SO LONG FOR THE IRB TO REVIEW AN APPLICATION?

The IRB's data indicates that the average time for the IRB to generate a review letter following an IRB meeting is three business days. The average time for the investigator to respond to that letter is 21 calendar days. It should be noted that UNMC IRB turnaround times are far better than those at most academic institutions.

WHY ARE IRB DEADLINES SO RIGID?

IRB deadlines are not as rigid for all studies. The IRB deadlines are rigid for full board initial reviews, previously tabled reviews and any Continuing Reviews that are not in standard follow-up. Whenever an investigator submits an IRB application, it must be processed for review, which includes entering information into the IRB database, conducting a pre-review to ensure that sections have not been omitted and signatures are in place. Once that process is completed and the study has been determined to require a full board review, the protocol is assigned to two reviewers who have the principle responsibility for reviewing the application. IRB reviewers obviously need sufficient time to complete their reviews.

If a study is assigned to either exempt or expedited status, they are reviewed by the IRB Administrators and IRB Chairs. While there are no specific deadlines for submission for exempt and expedited studies, there is no guarantee that the process will take less time than a full board review and approval process. Please allow a sufficient amount of time for the IRB process when considering deadlines.

WHY DO WE HAVE TO BE CITI CERTIFIED?

With the wide range of educational backgrounds among our investigators and research staff, CITI provides a baseline level of research ethics training to those conducting research at our institution. CITI is a research ethics training program adopted by the institution in order to help our investigators fulfill their obligation to protect human subjects. If you have any questions regarding CITI certification, please contact Jenny Kucera, IRB Education Coordinator @ 559-6119 or jikucera@unmc.edu.

Please email questions to address in future issues of "IRB Frequently Asked Questions" to Jenny Kucera (jikucera@unmc.edu)

WHAT IS THE DIFFERENCE BETWEEN WITHDRAWAL CRITERIA AND STOPPING RULES?

Withdrawal criteria describe the specific criteria by which the investigator would withdraw **individual subjects** from the research. The criteria will depend upon the nature of the research and the risk level. It may include both medical (e.g., specific toxicity or lack of efficacy) and non-medical (e.g., non-compliance) criteria for withdrawal of a subject from the research.

Stopping rules refer to specific criteria for early termination of the **study**. Reasons for such termination might include statistical evidence of unacceptable toxicity or early demonstration of efficacy or lack of efficacy. Stopping rules are necessary for subject safety.

IF AN INVESTIGATOR OR OTHER STUDY PERSONNEL IDENTIFY NON-COMPLIANCE, WHAT STEPS DO THEY NEED TO TAKE?

Immediately report non-compliance to Sue Logsdon, IRB Compliance Coordinator by completing the Protocol Violation Form. It is particularly important to include a corrective action plan that minimizes the possibility of repetitive non-compliance. Self-reporting is a clear indication that the concept of self-regulation works. If you have questions regarding compliance, Sue can be reached via email at slogsdon@unmc.edu or phone at 559-3779

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