



Human Subjects Protection Update Special Communication

OCTOBER 8, 2008

COMMITTEE ON CLINICAL INVESTIGATION

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NEW Pre-Review Process for Protocol Submissions

On November 1, 2008 the Committee on Clinical Investigation will implement a new *administrative pre-review process*. The IRB administrative staff will review the protocol for completeness and consistency and provide the investigator with feedback, questions or concerns to be addressed before protocols are placed on the IRB meeting agenda or provided to a committee member for expedited review. Though this process we hope to make sure protocols are in the "best shape" before IRB review. The following questions and answers will help clarify this new policy.

1. When will this policy become effective?

As of November 1, 2008 any new protocol that is received in the IRB office will undergo a pre-review.

2. Why are you making this change?

We have found that the majority of protocols are submitted with incomplete or inconsistent information. For example, one of the most common issues is that the number of study subjects will be listed differently in part A of the protocol, the body of the protocol and the consent form. Protocols frequently do not adequately describe recruitment plans or fail to include recruitment materials. Informed consent documents often do not include all the required elements. Problems such as these impede the IRB review and approval process and are straightforward to correct in advance. Such pre-review processes have become standard in many institutions and have been effective in streamlining the IRB review. IRB administrative staff can also provide advice as to what will likely be acceptable within IRB policies and provide input on the protocol and consent document prior to being reviewed. The focus of the pre-review will be completeness and consistency of the protocol.

3. Does this mean that once it gets to the IRB or the expedited reviewer, there will be no questions?

No, this does not guarantee there will be no additional questions. It is important to remember that the administrative staff will perform an administrative review. The detailed risk/benefit analysis occurs at the committee level. We want IRB members to devote their time to the ethical evaluation of the research and consent process and the risk/benefit analysis. IRB members are still obligated to question whatever they think needs to be addressed, however we hope the new system will focus their review on the more difficult issues that require their expertise.

4. Does this mean that my protocol will not automatically be placed on the next agenda or given to a reviewer if it is eligible for expedited review?

Protocols will NOT automatically be placed on the next agenda. However, if a well prepared protocol is submitted and is determined to be complete, detailed, and consistent, it may be sent on for committee review without the need for any pre-review feedback. Investigators will be notified one way or the other.

5. What if there is a protocol that I submitted before November 1, 2008 what will happen?

Administrative pre-reviews will not be undertaken for anything submitted prior to November 1.

6. Will this add time to the review process? Do I need to submit things earlier?

The aim of administrative pre-review is improve the efficiency of the review process. We will carefully track the impact of this new process takes and continually evaluate its implementation. We anticipate that any additional time requirements prior to committee review will be compensated by reduced time requirements once the committee or the expedited reviewer has received it. Our current practice is to accept up to 12 protocols per meeting or cut off submissions about 10 days before the meeting date, whatever comes first. We need this amount of time in order to duplicate the protocols and provide members with sufficient time for review. **Only protocols that have completed both the IRB and the investigator parts of the pre-review process by 10 days before the meeting get put on the agenda, providing the agenda is not closed.** You are always welcome to call the office to get an estimate of the number of slots left for a meeting or the potential cut off date, however this information is just an estimate since this is a first come, first served process and we cannot predict what is submitted day to day. It will now be even more important to not wait until the last minute to submit a protocol if you have constraints on time to approval.

7. How long will it take to receive feedback on the administrative pre-review?

Our initial goal is to provide feedback within 72 business hours or less. We recognize this is an ambitious time frame to implement in our office. For the first several months if we cannot provide the review within 72 hours, we will automatically forward the protocol on to the next step in the review process and forgo pre-review. We feel this is an unlikely scenario but we have included this safeguard, while we adjust to the new process. Once we have more experience with the process we will notify you about any modifications.

8. Will the IRB administrator assigned to my department always provide the pre-review?

The goal is for your department IRB administrator to provide the review and feedback. However, given the uncertainty of submissions it may not always be possible. If the number of submissions that would normally be assigned to a particular administrator is excessive, the staff will divide up the work as appropriate in order to be time responsive. All staff are trained to perform this review and can cover each other's departments. This is the same process we use for reports of action after a meeting and the process works well.

9. Will the consent be pre-reviewed?

Yes the consent form will undergo a complete pre-review to make sure all regulatory requirements are included and the consent is in lay language. The administrators will both suggest and make changes as appropriate. You will receive a "marked up" version for your review and approval. Changes and clarifications will then need to be submitted as a response to the pre-review process.

10. How long do I have to submit responses to the pre-review?

The quicker we receive your responses the faster the protocol will be reviewed. It is entirely up to you how quickly to respond. Please understand the protocol will not move forward until we receive your response. It is possible, but we hope

unlikely, that the material you re-submit will not adequately address the pre-review issues. If this were to occur you could receive additional feedback for correction. Obviously, we hope this is an unusual occurrence.

11. Will you use the same process to pre-review continuing reviews and amendments?

Yes, but not immediately. We are initiating this process with the new protocol submissions but will quickly expand to include amendments and continuing reviews. We will provide more information about this in the future.

12. What can you I do to assure a timely submission and review?

Investigators who take the time to carefully prepare and review the protocol to make sure all questions are answered, the protocol is complete and detailed and all information is consistent throughout the protocol will avoid a lengthy pre-review process.

If there are any questions or concerns about this change in policy please contact Susan Kornetsky at 57052. Thank you for your collaborative efforts to achieve a more transparent and efficient IRB review process.