



# Human Subjects Protection Update Special Communication

MARCH 28, 2008

COMMITTEE ON CLINICAL INVESTIGATION

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## **Elimination of Three Year Rewrite Reviews & Changes to Continuing Review Process**

In an effort to improve the IRB review process, several significant changes will take place during the next few months. The changes result from recommendations made during the AAAHRP re-accreditation review process and from an IRB subcommittee charged with improving the IRB's efficiency. The first major change is the elimination of the three year rewrite review process and the strengthening of the continuing review process. This change is effective immediately. The following questions and answers will explain why the change is being made, what this means for investigators and how it will be implemented.

### **1) Why is the three year rewrite requirement being eliminated?**

The three year rewrite policy was originally established as a mechanism for the IRB to perform a detailed review of protocols once the research begins and to allow investigators to periodically update their protocols by incorporating any changes, revisions or new information. Our current regulatory environment requires that an in depth IRB review be conducted on an annual basis or as frequently as requested by the IRB and amendments and revisions must be incorporated into the protocol when they are submitted. Given the changes in our regulatory expectation, the need for three year rewrites has become moot and as such we are eliminating this requirement but will require a more detailed continuing review.

### **2. Now that the three year rewrite is eliminated, how will this impact the continuing review process?**

The IRB has revised the continuing review form to request detailed information in areas pertinent to the ongoing review of human subject protection. Changes in the continuing review form include the following:

- Information about enrollment, whether targeted goals are met and if not, an explanation as to why and any efforts to improve enrollment
- Limiting the summary of enrollment and adverse events to those that have occurred at Children's unless Children's is the coordinating center.
- Investigators will be asked to submit (Part B) of their protocol with each continuing review. All approved changes that may have occurred during the previous year must be incorporated. Executive summaries will no longer be requested or accepted.
- All currently approved consents and recruitment materials must also be submitted with the continuing review.
- Detailed and consistent information about the approved data and safety monitoring plan and whether it has been followed will be required. The IRB will require the submission of all data and safety monitoring reports, coordinating center reports, and any other monitoring reports the PI may have received during the past year. Investigators are currently submitting DSMB reports as they become available. We now ask that investigators only submit data and safety monitoring reports with the continuing review submission unless the report has prompted a request for an amendment, reported unexpected events or require that a protocol or informed consent be modified. In these situations the report should be submitted with the amendment form or unanticipated event report.

**3) When is this policy change effective?**

The policy to eliminate three year rewrites and change the continuing review process is effective immediately. As of this date no additional three year rewrites need to be submitted and the new continuing review forms should be used. The new form may be downloaded from the website

**4) If I have received a three year rewrite notice and have already prepared the three year rewrite what should I do?**

Submit it. We will continue to accept any three year rewrites that you have already prepared and will review it as we have in past.

**5) If I received a three year rewrite request and have not prepared it what should I do?**

You may transition this to a continuing review. Please go to our website and download the continuing review form. Please complete the form and submit it to our office. It would be helpful if you attach a note that specifies you are converting this to a continuing review, however this is not necessary and we will note this in the office.

**6) If I have three year rewrite that was reviewed by the IRB and I received a conditional approval or deferral what should I do?**

Reviews that are in process will not be transitioned to a continuing review. Complete the review process as it was started. If the protocol was conditionally approved, please submit your response and it will be sent to the primary and secondary reviewers for final approval. If the protocol was deferred please submit your response and it will be placed on the next full agenda for review.

**7) The GCRC and Radiation Safety Committee require review three year rewrites, how will this impact them?**

We have communicated with the GCRC and Radiation Safety and they have accepted this change. The GCRC requests that any time there are major changes to the science of the protocol or a need for increased GCRC resources, you should contact them and they will arrange the appropriate review. This should be done outside of any IRB continuing review cycle. The Radiation Safety committee also requires that any change in the use of radioisotopes for research, use of radiological procedures required for the research or changes in the consent regarding radiation exposure be brought to their attention for approval. This should be done as necessary and outside of any IRB continuing review cycle.

**8) My department requires scientific review of three year rewrites, has this changed?**

We have notified all departments that we are eliminating three year rewrites. Most departments only required three year rewrites, when there were major changes being made to the protocol. For the departments requiring three year rewrite review, we working with each department to determine how they would like to handle this. We will update the scientific review section of our website for each department as soon as this information is available. In the meantime, please check with your department if you have any questions.

**9) Is there a new continuing review form?**

Yes, the continuing review form has been modified to include the changes mentioned above. We ask that all investigators use this new form. If you have already completed the old form you may submit it. We will accept old forms only until May 1, 2008 otherwise please be sure to go to the website and download the new form.

**9) Who do I contact for questions and further information?**

Clinical Investigation staff is available to answer any questions or concerns. Please contact the protocol administrator assigned to your department at 57052 for assistance.