

To Members of the Research Community:

Please be advised that as of February 1, 2009, the HIC will eliminate the need for the principal investigator to seek out a primary reviewer from among Committee members prior to protocol submission to the HIC. This change is timed to coincide with the anticipated implementation of the electronic-IRB protocol submission process, and is intended to aid in streamlining the overall protocol submission and review process.

As the first step in this new process, we will accept either paper applications at the HIC office or electronic applications via the COEUS eIRB system (when this option is ready). New protocols submitted will then be assigned to an HIC regulatory reviewer, who will review the submission for clarity, completeness, and regulatory compliance. This staff member will work with the Principal Investigator to create a version of the protocol that is ready for submission to the full Committee or for expedited review. Specific details of this change in procedure are as follows:

- Note that this new system eliminates the submission deadlines previously used by the HIC. That is, new protocols may be submitted any day of the week, once the necessary complete materials are assembled by the investigator (and any required pre-review, such as by the PPRC or the YCC PRC, has been completed). In this system, the time previously spent in review by a Committee member will be offset by the time spent in regulatory review within the HIC office. It is expected that the net result will be a shorter time interval between submission and final approval.
- For protocols requiring full Committee review, the Committee primary reviewer will be assigned to the protocol after the regulatory review, at the time the new protocol is assigned to a Committee meeting agenda. This will be done within the HIC office and will match availability and skill set of the reviewer to the protocol. A major impetus for the changes was controlling the number of people who had to interact with the principal investigator in the electronic system, and had to "sign off" on a new protocol before the protocol could be submitted to the HIC. Another focus is to improve the quality of protocols that come to full Committee so that there would be significantly fewer changes required by the HIC after Committee or expedited review, and thus faster overall approvals.
- The role of the primary reviewer will continue to focus on ethical and scientific issues, to interact with the principal investigator as necessary, and to seek consultation from experts if needed. The primary reviewer will continue to present the protocol to the full Committee, leading the discussion that focuses on ethical concerns, risk-benefit questions, and other substantive issues for full Committee consideration. A similar role for a secondary reviewer will also continue.
- We also thought it important to have a primary reviewer available to a principal investigator during the early development of a protocol if an investigator so desired. That service will continue to be an option for the investigator and we encourage any investigator to use it. The HIC staff will coordinate the early assignment of a primary reviewer should one be requested.

We expect that this change will lead to a substantial improvement in the quality of protocols presented to the HIC for review, as well as a significant decrease in the time Committee members must spend in fulfilling the primary review responsibilities, and the overall time for review and approval of protocols. We will apply the new system to all new protocols, both paper submissions and those submitted via the new electronic system.

Please share with the HIC your questions or concerns. We are continuing to examine and revise processes in an attempt to increase efficiency while maintaining or enhancing quality of review. We hope that you are pleased with these changes.

Best regards,

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