

## Review Process for New Adult Clinical Trials

Earlier this year, a biostatistics pre-review process was implemented for all adult clinical trials requiring review by the convened (full) SRC. By enabling the SRC biostatistics reviewers to identify issues and obtain study team responses prior to the meeting, there has been a significant reduction in deferrals and conditions by the convened SRC related to biostatistics issues.

This same type of pre-review process will be expanded on October 3, 2011 to include departmental comments from the following additional departments:

- Research Nursing
- Research Pharmacy
- Quality Assurance For Clinical Trials (QACT)
- Institutional Clinical Trial Offices, if applicable
- OHRS (consent form pre-review)

Previously, the departmental comments and OHRS pre-reviews had been provided to study teams with the minutes from the SRC meetings and it is after study teams submit responses to these comments that the protocol is routed to the IRB. By expanding the pre-review process to enable study teams to submit their responses to these comments before the SRC meeting, a protocol that is approved by the SRC without condition will be moved up to an earlier IRB meeting. The goal is to routinely route such protocols to the IRB meeting the following Tuesday (1 week) from the SRC meeting. (However, for the first few weeks of implementation it may be 1-2 weeks depending on the size of the IRB agendas). Additionally, we anticipate that an earlier IRB meeting will translate into reduced time to activation.

**Updated Routing Process:** Effective October 3rd, OHRS will begin routing adult clinical protocol submissions to research nursing, research pharmacy, QACT and clinical trial offices, if applicable, for review.

### Process and Timeline:

- As soon as a complete new protocol submission has been received by OHRS, OHRS staff will route the submission to biostatistics, research nursing, research pharmacy, QACT, clinical trials office and OHRS for comment;
- the reviewers will provide their comments (if any) to OHRS within 10 business days;
- the assigned OHRS HRC will promptly forward the comments to the study teams;
- study teams should respond to the comments within 5 business days; and,
- the study team responses to the comments will be included in the materials submitted for review by the SRC and IRB.

**DFCI initiated studies:** Please note that the pre-review by the DFCI Clinical Trials Office is no longer required prior to a new protocol's submission to OHRS. This CTO review will be obtained as part of the updated routing process described above.

**DF/HCC initiated multi-center studies:** Please note that approval by the Multi-Center Coordinating Committee (MCC) should be obtained prior to submitting a new protocol to OHRS. Please submit the documentation of MCC review and approval with your submission. DF/HCC initiated multi-center studies that are submitted without this documentation will be returned. For more information about the MCC review process, please visit the MCC website at: <http://www.dfcc.harvard.edu/clinical-research-support/quality-assurance-office-for-clinical-trials-qact/multi-center-trials/> or contact Alyssa Gateman, Deputy Director, Quality Assurance Office for Clinical Trials at (617) 632-3731.

If you have any questions about this new process, please do not hesitate to contact Amanda Hammond, Deputy Director, Office for Human Research Studies at (617) 632-3030.