Dear Research Staff and Administrators,

The faculty updates were sent to faculty earlier this week from Dr. Stadler, Associate Dean for Clinical Research. It highlights concurrent and centralized routing, IRBWise, and the research related injury policy. It does not offer many details, thus this communication to you.

As most of you know, in April 2008, the administrative functions of the Office of Clinical Research and the Institutional Review Board we merged into one joint operation. In December 2008, the majority of the OCR staff moved to McGiffert House so that the staff would be physically closer together. The Office of Clinical Research is now divided into two major divisions, one of which is further subdivided:

1) Research Operations and Conduct
   a. Training & Education; Informatics Support; Regulatory Knowledge Support
   b. Quality Assurance & Oversight; Research Billing & Oversight; Device Oversight;
2) Human Subject Protection- The Institutional Review Board

Over these last few months we have worked to identify opportunities to streamline the protocol review and approval process; increase institutional knowledge of the research conducted within the BSD; and allow the combined resources of the OCR to provide more consistent assistance to all investigators. The following changes have resulted.

To realize the benefits of the office merger, we will begin concurrent and centralized routing of all clinical research documents March 2, 2009. We encourage all research groups to begin as soon as possible so that issues can be identified and resolved quickly. In addition, in working with the members of the Chicago BioMedicine Policy Board as well as members of the Institutional Review Board, crucial changes are being implemented in regards to the IRB Policy concerning research related injury. Finally, the IRB is in the process of implementing a new electronic protocol submission process to streamline the protocol review process and to eliminate the need for paper based IRB submissions.

Concurrent and Centralized Routing (CCR)

Rationale

Historically, the IRB has been the only repository for institutional knowledge of clinical research. Its primary role is to protect human subjects involved in research and to ensure compliance with applicable regulations and guidelines. Therefore, many requirements concerning the conduct of research, including research billing requirements, standards for Good Clinical Practices, investigator responsibilities for IND/IDE trials, and other regulatory requirements fall outside of its purview. Within the review and approval process, the primary role of the OCR was to review industry sponsored clinical trials, which meant that many protocols, including those that have federal funding or those without external funding, were not being reviewed for compliance with other regulatory

requirements. Our expectation is that by taking a more comprehensive approach to the review and approval process, institutional policies and standards will be more consistently applied to all clinical research and this will remove some of the burden that had been placed on the IRB. Our solution is to implement concurrent and centralized routing for the protocol review and approval process for all clinical research, regardless of funding.

Process

Concurrent and centralized routing (CCR) requires the submission of the IRB documents at the same time as the budgets, schema, and contract (as applicable). This allows protocols to be considered in their entirety both by the IRB and the Regulatory Group rather than separately as in our previously model. If this concurrent model is not feasible for individual groups, submission of the budget/ contract prior to the IRB documents is acceptable, but not vice versa. For protocols that were not previously reviewed by the Research Operations and Conduct Group in the OCR, please see the attachment labeled "Submission Documents" for information on what should be submitted with the IRB documents. Additionally, this review process will require all clinical research protocols to comply with the "Identification and Distinction of Clinical Trial Participants Charges" policy, also known as the Schema Review policy.

We have been piloting this process and haven't found any significant problem to date; however, this is a work in progress. Your feedback will be very important. Please don't hesitate to contact us with questions or concerns. We hope to have all submissions routed centrally and concurrently by May 1, 2009.

Research Related Injury Policy

The Clinical Research Policy Board has recently approved a Chicago BioMedicine policy, "Treatment of Research Related Injuries". This policy defines what treatment will be provided by University of Chicago at the Medical Center as the result of a research-related injury. The policy further defines what is required for studies offering therapeutic intent, for studies involving healthy volunteers, and for studies sponsored by commercial industry. The IRB has approved revisions to its "Research Related Injury" policy to reflect this Medical Center Policy. Separate communication from the Institutional Review Board reflecting these modifications and the impact of these modifications on the consent form process is forthcoming.

Electronic IRB Submission Process- IRBWISE

Over the past few years, the administrative offices of the Institutional Review Board have been in the process of evaluating and customizing an online electronic IRB submission and review process. IRBWise is a web based IRB submission platform that is currently being piloted by faculty within the Departments of Pediatrics and Neurology. This web based system will allow paper free submissions of all IRB submission materials. In addition, Principal Investigators

and research staff will have online access to all of their IRB submissions, approved study documents, and historical data. The Office of Clinical Research and the Institutional Review Board will continue to provide updates on the progress of IRBWise implementation.

While we know there will be implementation challenges for each of these processes at the local level, especially during these times of significant institutional change, we are prepared to work with faculty and staff as needed to ensure these processes are efficiently implemented. During this transition time, we will strive to ensure that study activation is not hindered. The early pilot protocols have been through the concurrent review process more quickly and we anticipate that ultimately this will be faster than the current process. Similarly, we have had conversations about this plan with many research administrators and anticipate that we can move forward without significant hurdles.

Should you have any questions about these issues please don't hesitate to contact me bmartell@bsd.uchicago.edu or 4-9799 or Millie Maleckar mmaleckar@bsd.uchicago.edu or 4-1742.

Sincerely,
Bethany Martell