Institutional Review Board
McGiffert Hall, 2nd Floor
5751 S. Woodlawn Avenue
Chicago, Illinois 60637

2 April 2012

To whom it may concern,

Previously, the practice of the IRB office was to stamp approved consent forms “approved” with each submission approval, including with the approval of amendments that did not seek to alter previously approved consent forms and for which previously approved consent forms continued to remain approved. The consent forms were stamped with the approval date of that submission (new protocol, amendment, or continuing review). With the transition from one electronic submission system (IRBWise) to another (AURA-IRB), this practice is being changed.

Effective April 2, 2012 with the launch of AURA-IRB, consent forms will be stamped “approved” with the approval date of the date they are originally approved, and subsequently will only be re-stamped “approved” with an updated approval date at time of renewal, when the entire study is re-approved. If an amendment is submitted that does not involve a change to an existing consent form, any previously approved consent form that remains approved will retain the “approved” stamp with the date it was originally approved and/or most recently renewed.

Please share this letter with pharmaceutical sponsors and any other interested parties, as applicable.

If you have any questions about this procedure, please contact me or the Director of the IRB, Millie Maleckar, at 773-702-1472 or mmalecka@bsd.uchicago.edu.

Sincerely,

Nell Thompson, CIP
Associate Director of IRB Operations
BSD/UCH Institutional Review Board
Office of Clinical Research
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