

**Thompson, Nell [BSD] - OCR**

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**From:** Edge, Lisa [BSD] - MED  
**Sent:** Friday, June 26, 2009 3:06 PM  
**To:** Thompson, Nell [BSD] - OCR  
**Subject:** FW: On behalf of Chris Daugherty, IRB Chair

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**From:** Edge, Lisa [BSD] - MED  
**Sent:** Friday, June 26, 2009 1:43 PM  
**To:** 'bsdfaculty@lists.uchicago.edu'  
**Subject:** On behalf of Chris Daugherty, IRB Chair

To all faculty researchers,

As of October 2008, the University Conflict of Interest Assurance and Disclosure forms were revised to reflect the updated University Policy (dated July 2007), and to capture University of Chicago Medical Center Conflict of Interest reporting requirements re: all outside financial interests. As part of this updated policy, researchers were advised that the IRB would be copied on all management plans. These plans are created in conjunction with officials from the BSD and URA and ultimately signed and issued by the University Deputy Provost for Research out of the Provost's Office. However, faculty need to be aware that the IRB does not receive a copy of the disclosure form itself and thus is typically unaware of the specific nature of any given conflict or outside financial interest and the monetary value involved.

Many of these management plans request that the investigator inform the IRB of certain conflict(s) as they pertain to relevant research studies. While the IRB is copied on the management plan, these plans do not delineate which IRB studies are or may be affected. Without further notification from the PI, the IRB is thus unable to determine how a particular conflict may affect any particular study.

The IRB would like to re-iterate at this time that disclosure to the IRB regarding conflict(s) of interest that are related to IRB-approved or proposed research is required by University conflict of interest management plans. The IRB Committees respectfully request that investigators prepare and submit disclosure memos to the IRB giving specifics of the conflict(s) and how they may relate to a particular protocol or protocols when these conflicts are identified in management plans.

In the electronic submission system (IRBwise), investigators are first asked to state whether or not they have a conflict of interest management plan on file by answering the COI section on the "My Account" page. This is to ensure that the IRB has been notified and copied on all management plans. This set of questions need only be answered once, unless a new disclosure is filed with URA, in which case the responses should be updated, as needed. Second, investigators must make a determination *per protocol* as the protocol is being submitted as to whether any conflicts that have been disclosed to URA are pertinent to the specific protocol being submitted. These COI questions appear at the end of the protocol submission screen for each protocol. The PI of the protocol should be aware not only of his or her own potential conflicts but also of any relevant co-investigator conflicts when answering the questions in this section. The COI memo to the IRB should be uploaded, if needed.

The IRB Chair and/or IRB Directors are available at any time to discuss these issues with investigators if there are any questions about determining which of their conflicts of interest may be relevant to IRB approved or proposed research.

Thank you for your attention to this matter.

6/26/2009

Christopher K. Daugherty, M.D.  
Professor of Medicine  
Chair, BSD IRB

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Thank you  
University of Chicago Medical Center