



EMORY

Office of Research Administration  
Conflict of Interest Review Committee

To: All Investigators & Research Staff  
From: Brenda J. Seiton, JD, Assistant Vice President for Research Administration  
CC: Sarah Putney, JD, Director, IRB  
RE: Institutional Conflict of Interest Policy for Human Subject Research  
Date: June 14, 2011

Effective March 1, 2011, Emory has a new Institutional Conflict of Interest Policy for Human Subject Research. The policy is required for re-accreditation of the Emory Institutional Review Board by the Association for the Accreditation of Human Research Protection Programs. The policy will apply to human subject research as defined by IRB policies. The policy covers both financial interests of Emory and personal financial interests of Institutional Leaders - those responsible for the review, approval, and oversight of human subject research. ***The investigator COI policy (Emory Policy 7.7) remains unchanged.***

ICOI Review will be required for human subject research protocols with the following types of Institutional Financial Interests:

(1) *Equity in non-publicly traded company that is received through an Emory license agreement:* When Emory receives equity in a non-publicly traded company that has licensed Emory technology and the company is a sponsor, provider of study material (drug, device, software, etc.), financial supporter, or holder of an FDA IDE/IND and the licensed technology is the subject of the research protocol, the protocol will be forwarded to the COI Review Office.

(2) *Receipt of cash gift that exceeds \$500,000 annually:* When a Department or a Unit receives a cash gift that is more than \$500,000 and the donor is a sponsor, provider of study material (drug, device, software, etc.), financial supporter, or holder of an FDA IDE/IND and the study is performed by faculty in that Department or Unit, the protocol(s) will be forwarded to the COI Review Office.

(3) *Receipt of royalties or licensing fees that exceed \$100,000 annually:* When Emory receives royalties or licensing fees for technologies being tested or evaluated in Human Subject Research, the protocol(s) will be forward to the COI Review Office.

The IRB Applications have been revised. A new question about Emory technology is now included on the SmartForms under the Conflict of Interest Section. Additionally, OTT will be reviewing IRB reports to identify whether any Emory technology or Emory companies are involved with the studies. Department/Unit IRB approvers will have the list of donors providing more than \$500,000 to the Department or Unit. One of the most useful tools to manage an Institutional Financial Interest is to use an external IRB. **If you are aware that your proposed research has one of the above Institutional Financial Interests, please contact Brenda Seiton at 712-0046 as soon as possible.**

Institutional Leaders must recuse themselves from reviewing, approving, or making decisions on any human subject research protocols involving technologies in which s/he has a financial interest and/or companies that are sponsors, providers of study material or financial support, or holders of IDE/IND if his/her personal financial interest in those companies/technologies meets the following thresholds:

(1) Equity in a non-publicly traded company;

(2) Consulting fees, advisory board fees, remuneration, honoraria, or gifts that exceed \$100,000 annually;

(3) Holding a fiduciary role in a company; or

(4) Receipt of royalties or licensing fees that exceed \$100,000 for technology that is the subject of the protocol.

If the Institutional Leader cannot recuse him/herself, then s/he must divest the financial interest that creates the conflict. If s/he does not wish to take the divestment route, s/he can appeal to the Provost/EVP Health Affairs & VP for Research Administration.

The full policy can be found on the Emory Policies website and the COI Review Office website: [www.coi.emory.edu](http://www.coi.emory.edu) If you have any questions about this new policy, please do not hesitate to contact the COI Review Office at 404-712-0046 or [COI-Office@listserv.cc.emory.edu](mailto:COI-Office@listserv.cc.emory.edu)