ATTACHMENT 1
IMPACT OF UPDATED PHS FCOI REGULATIONS

**UMN Investigators who receive PHS awards.** The Office of Institutional Compliance (OIC) changed this spring’s Report of External Professional Activities (REPA) form to accommodate the change for our own researchers. Almost all researchers have already filed their REPAs (and those who didn't are being hunted down..) UMN’s 1,480 PIs, Co-i’s, and other key personnel working on active PHS awards or who submitted PHS proposals within the last twelve months have also received notifications reminding them that they need to take updated FCOI training before the new regulations go into effect on 8/24/12. If they fail to take this training, their PHS funding will have to be suspended at the time they receive their next PHS notice of award (obviously, we want to avoid this ever happening.) SPA, OIC and Research Associate Deans are working together to continue to remind these investigators of the need to do their training throughout the summer. We are also sending notices to any new researchers who submitted PHS proposals after the original notice went out.

**UMN Investigators who receive PHS subawards.** If UMN will be a subrecipient to another entity on a PHS award, a PI or department may receive a form from the prime grantee asking us to certify whether we will use our own Financial Conflict of Interest (FCOI) policy or whether we will use the prime recipient's policy. The answer is always that we use our own FCOI policy. UMN does not agree to use any other entity's FCOI policy, forms, or procedures. If the other entity requires an institutional signature, please send this form to your GA and SPA will sign it for you.

**Consultants, Collaborators and Service Providers on our PHS Awards.** We have determined that it is unlikely that the new FCOI rules apply to collaborators or consultants, or service providers (other than subrecipients) because they are unlikely to meet the PHS definition of "investigator" as someone “responsible for the design, conduct or reporting of the research.” In most cases, these types of individuals may be performing research, but they are not responsible for it - they are turning over their results to one of our investigators and our investigator is then responsible for when/how to use that input. If a PI feels that a particular consultant/collaborator/service provider does meet the test of “investigator” then that person or entity must follow the same process as a subrecipient.

**UMN Subrecipients.** See webpage at: [http://www.ospa.umn.edu/PHSFCOIT.html](http://www.ospa.umn.edu/PHSFCOIT.html). Effective with proposals with subawards submitted by SPA on or after August 24, 2012, UMN subrecipients will need to notify us at time of proposal whether they have their own PHS-compliant FCOI policy or whether they will use the University of Minnesota’s conflict of interest policy and process. If a subrecipient has its own policy, they must follow that. If the subrecipient must use UMN’s policy, disclosures of significant financial interest must be on file at SPA before UMN can submit our proposal to a PHS agency and annually thereafter, or whenever reportable interests change. Any positive disclosures will be reviewed by UMN's Conflict of Interest program at the Just-in-Time stage or at whatever later time the subrecipient notifies the University of a potential conflict. If the subrecipient is using UMN’s policy, any positive disclosures must be reviewed prior to the subrecipient expending any funds (e.g., before the subaward being issued.) In addition, subrecipient personnel meeting the definition of “investigator” (see above) and using the University of Minnesota conflict of interest policy must take the University of Minnesota on-line FCOI training prior to a subaward being issued.

6/26/2012