Colleagues,

As we talked about at the last GMUN meeting, PHS is changing its financial conflict of interest (FCOI) rules effective August 24, 2012, and this means that the University of Minnesota must correspondingly change our procedures. This change impacts our investigators as well as our subrecipients, and potentially our consultants or collaborators/service providers as well. Attachment 1 of this memo briefly explains the primary impact to each group.

The most significant change you will see are new business processes are related to proposed/current PHS subrecipients. This memorandum focuses on those changes, and all relevant materials can be found at: http://www.ospa.umn.edu/PHSFCOIT.html.

As of August 24th, the University must obtain verification from each proposed subrecipient at time of proposal whether they have their own PHS-compliant financial conflict of interest policy or, if they don’t have their own policy, that they will agree to by our policy. We have identified that the University does business with approximately 600 PHS subrecipients. While we don’t have any idea how many will need to use UMN’s policy, we anticipate that some smaller research entities, small businesses, and foreign entities may have this need. Therefore, we have developed the following new business process:

**Business Process at time of Submission of a New/Renewal PHS Proposal (effective 8/24/12)**

For new and renewal proposals that SPA will submit to any PHS agency on or after August 24, 2012 that includes one or more subawards, please

(a) Check to see if your proposed subrecipient is listed on the FDP Clearinghouse of PHS FCOI Compliant Institutions. This list may be found at: http://sites.nationalacademies.org/PGA/fdp/PAGA_070596. If your subrecipient is on this list, you need only add an annotation following the name of the subrecipient you added in Question 14 of the PRF indicating that they are on the FDP FCOI Compliant list, for example:

> University of Wisconsin (on FDP FCOI Compliant List)

If your subrecipient is on the FDP Clearinghouse, you can stop here. You need do nothing further (e.g., you do not need to send either Form 1 or Form 2 to the subrecipient).

(b) If your proposed subrecipient is not on the FDP Clearinghouse of PHS FCOI Compliant Institutions, send out (well in advance of the proposal deadline) the attached form packet to each of your proposed subrecipients. You may also send your proposed subrecipient the invitation posted on the FCOI web site at http://www.ospa.umn.edu/PHSFCOIT.html to encourage the proposed subrecipient to sign themselves up on the FDP Clearinghouse of PHS FCOI Compliant Institutions if they are eligible. If they do so and inform you that they are now on the list, you may follow Step (a) above to independently verify that their name now appears on the Clearinghouse and annotate the PRF accordingly. It is our hope that over the next few months, the vast majority of our proposed subrecipients will join this Clearinghouse. Otherwise, the baseline form (“Form 1”) must be submitted by ALL PHS subrecipients (signed by their institutional representative). To aid in tracking, please complete Section A: “Proposal Information” of Form 1 before you send it to your subrecipient. The form(s) should
be returned to you. If the subrecipient responds that they are using their own FCOI policy, you need not do anything further – just send SPA the signed Form 1 with the proposal. IF (and only if) the subrecipient marks the box on Form 1 saying "I am using University of Minnesota's COI policy", then each subrecipient individual meeting PHS's definition of an investigator ("individual responsible for the design, conduct or reporting of the research") must ALSO complete and return a Disclosure of Significant Financial Interests form ("Form 2") before our proposal is submitted to a PHS agency.

Please have Form 1 and (only if applicable) Form 2 paperwork completed and returned to SPA by the time the proposal routes to us for signature. Per the regulations, SPA cannot submit a proposal containing a subaward to a PHS agency on or after 8/24/12 unless this process is complete. If you cannot complete this process by the proposal deadline, you will have to update the proposal to show the subrecipient as "To be Named" in your proposal or drop the subaward entirely from the scope of work.

**Business Process at Just-in-Time and at time of Award (effective 8/24/12)**

If the proposed subrecipient is using our policy and any of its investigators has a positive disclosure of financial interests (answers “yes” to any of the questions on Form 2), UMN’s COI Committee must complete its review and if necessary, create a conflict management plan, prior to any funds being expended by the subrecipient. SPA will coordinate with the Office of Institutional Compliance (OIC) to make sure this review occurs, which will be triggered at the Just-in-Time phase. It is critical that SPA/OIC be notified if our PI hears that his/her proposal is going to be funded, so we can launch this review process. SPA will also be on the lookout for positive disclosures if we receive Just-in-Time materials. SPA cannot issue a subaward or a subaward modification until all positive disclosures have been reviewed.

**Business Process for Previously Submitted PHS Proposals and Active PHS Awards**

SPA will, over the summer, be contacting each currently-active subrecipient and all proposed subrecipients (from PHS proposals submitted in the last 12 months) to ascertain whether or not they will be in compliance with the new regulations by August 24, 2012. If any of those entities need to use our policy, SPA will work with them to obtain disclosures and move forward with the review of any positive disclosures. PIs and departmental administrators will be copied on this correspondence.

SPA is working on ways to reduce the burden of complying with these new requirements, and we will inform you when changes to these requirements can be made. You may also want to review the FAQs on the web page listed above as we’ve tried to answer some additional questions there that we think may come up. Please let your GA, your SPA manager, or me know if you have any questions.

Pamela

Attachment 1: Impact of Updated PHS FCOI Regulations
Attachment 2: Forms “Packet” (Forms 1 and 2 and related instructions)