

**\*\*\* School of Medicine Memorandum \*\*\***

April 20, 2012

TO: School of Medicine Faculty

FROM: Harry Greenberg, M.D.  
Senior Associate Dean for Research

Dear Colleagues,

As many of you know, new requirements regarding conflict of interest (COI) in research funded by the Public Health Service were enacted into law last summer (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>). These regulations will become effective on August 24, 2012 and will primarily impact our funding from NIH however, please note they apply to all PHS agencies. These new regulations are extensive but the most important changes include:

- The threshold at which a personal financial relationship or interest is deemed significant will be decreased from \$10,000 in the current policy to \$5,000 in the 2012 revision. If that financial relationship or interest is related to a faculty member's institutional responsibilities and it is determined to have the potential to have a direct and significant effect on the research, or the research on the financial interest, then an FCOI (Financial Conflict of Interest) exists.
- When a FCOI exists, institutions must assure the NIH that they have managed the FCOI related to a specific PHS funded project before an award can be accepted for that project and any monies spent. This assurance needs to be updated annually and as new FCOIs occur.
- Institutions must also provide assurance of FCOI management for all subrecipients identified on the project.
- The institution, not the faculty member, must determine whether a faculty member's outside interests overlap with/are related to their institutional responsibilities and if so, if they are related to their research/scholarship responsibilities (and specifically to PHS funded research). If that is the case the institution must determine whether an FCOI exists, rather than allowing the faculty member to make this determination.
- Almost all travel reimbursements must be reported to the institution.
- The amount of information that must be reported to the NIH if a FCOI exists is significantly increased.
- Institutions must make readily accessible to the public certain information concerning FCOIs that overlap with PHS funded awards.
- A requirement is now in place requiring that all investigators (including subrecipient investigators) complete training on COI before engaging in any PHS-funded research; training must be completed every four years thereafter.
- If noncompliance with regulations is found, a series of significant review procedures are required to take place.

In order to comply with these new federal regulations, a number of changes and improvements to our COI system have been or are in the process of taking place. The COI training video is currently being updated and a web-based travel reporting instrument is under construction. The Stanford policies on conflict of interest and commitment have been substantially updated, reviewed, and approved by the faculty senate and will go into effect in late August, 2012. The electronic Outside Professional Activities Certification System (OPACS) has been simplified and better integrated with the SeRA and eProtocol systems.

We have worked hard to try to minimize the burden the new regulations will place on our faculty. However, there will be some changes that will require a bit more planning ahead by our faculty. When submitting a proposal to NIH or another PHS agency the approval of your institutional official in the Research Management Group (RMG) indicates that Stanford University has complied with all requirements for disclosure. In order for RMG to provide this approval, Principal Investigators and other participating faculty **must** complete a Proposal Development & Routing Form (PDRF) to document that all requirements related to the submission of that proposal have been met.

**PLEASE NOTE:** your institutional representative (RMG) **cannot** submit the proposal to the NIH or other PHS agencies until all PDRFs have been completed and approved by the participating faculty on any specific grant. Additionally, any participating subrecipient must provide documentation of compliance by completing Subrecipient Commitment Form (F33) before the proposal is submitted. Hence, you are reminded of RMG's internal deadline for providing a complete and final proposal. Most proposals to NIH are submitted electronically through [Grants.gov](http://Grants.gov). RMG requires the complete and final proposal a minimum of 4-business days in advance of the sponsor's deadline to allow time to review, submit, and receive validation from the [Grants.gov](http://Grants.gov) system confirming the transmittal of the proposal without errors and the acceptance of the proposal by NIH. When the proposal is received with fewer than 4-business days in advance of the deadline, RMG **cannot** guarantee timely submission of the proposal. Additionally, the PI assumes the risk of missing the sponsor's deadline or not clearing the NIH system validation process.