Dear investigators, IRB chairs and staff, protocol coordinators, Clinical Directors:

Attached please find both a new and streamlined Conflict of Interest SOP and a new NIH Guide to preventing conflict of interest. The purpose of this email is to outline how the new system will work.

**What has changed?**

• Assessment of financial conflict of interest is required ONLY for “covered” protocols – those that may lead to the financial benefit or loss of any individual or entity. This includes studies of investigational drugs and devices, studies whose research question involves a commercially available drug or device, studies involving a CRADA or Clinical Trials Agreement, studies involving collaboration with a substantially affected organization, or studies involving intellectual property. NIH research protocols that are categorized as Teaching and Training, or Natural History studies are not covered research protocols, unless they meet the criteria listed above.

• COI review is only required for “covered” individuals—those that may realize financial benefit or loss as a result of participation in the protocol. These are further defined in the SOP.

• Non-Federal employees and NIH employees who do not file a financial conflict of interest report must complete a certification form regarding COI.

**How will this be implemented?**

• All forms are available on the OHSRP website:

<https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

[http://ohsr.od.nih.gov](http://ohsr.od.nih.gov/)  (outside the NIH firewall)

• The PI should determine the employment and financial COI filing status of the covered individuals who participate in their protocol. If the covered individuals are not aware of their financial filing status, the PI should contact his/her Deputy Ethics Counselor (DEC) and inquire about their status. For a list of DECs: <https://ethics.od.nih.gov/decs.pdf>.

• The PI will request that any required certifications be completed by covered individuals.

• The PI will file the personal financial holdings form with the DEC, along with any required certifications.

• NCI/NHLBI iRIS will have the form programmed into the system; NIAID iRIS will continue to use an electronic fillable form (and attach certifications and précis) that is uploaded within iRIS; PTMS users will use an electronic fillable form and attach certifications and précis. The documents can be uploaded into PTMS, with an email asking the DEC to download them and review, or they can be emailed to the DEC.

• DECs for NCI/NHLBI iRIS and NIAID iRIS will document their review as they do now; PTMS DECs will email the clearance to the PI who will upload it into PTMS. (We hope that the form will be programmed into PTMS in 2014.)

**How often must certifications be updated?**

• Certifications are protocol-specific, but only need to be provided once, unless the investigator recognizes a change.

**When does this policy go into effect?**

• As of October 27, 2014, any submissions to the DEC must follow the new policy. This includes initial review, continuing review, and any amendments that increase the “covered” status of the protocol. DEC submissions before October 27, 2014 may use the current process.