TO: Northwestern University’s Research Community

FROM: Northwestern Conflict of Interest Office (NUCOI)

DATE: December 19, 2012

RE: COI Policy and System Updates Announcement

1. **Travel**
   Effective 1/1/13, the disclosure threshold for travel will be $5,000 rather than zero. This means that Investigators need only disclosure sponsored and/or reimbursed travel (for themselves + spouse and dependent children) that exceeds $5,000 from a single entity in the 12 months prior to disclosure date.

   Investigators are welcome to continue to disclose all travel in the system if they feel it is easier to enter all travel as it occurs, rather than track on their own in order to disclose appropriately when travel from one entity exceeds the $5,000 disclosure threshold.

   This change results from a Notice from the National Institute of Health (NIH) that allows institutions regulatory discretion in applying the $5,000 disclosure threshold to travel.

   Northwestern’s Policy on Conflict of Interest in Research will be updated to reflect this policy change effective 1/1/13.

2. **Proxy Access**
   Effective 1/1/13, the proxy functionality in the FASIS COI system will be available. This means that Investigators may assign appropriate Northwestern administrators as a “proxy” to enter COI disclosure information into the FASIS COI system on behalf of the Investigator.

   Investigators must assign proxies with specific access; either:
   - Full access: if full access is designated, proxies will be able to view and enter information for all questions in the COI disclose; or
   - Travel-only access: if travel-only access is designated, proxies will only be able to view and enter information for the travel disclosure question (i.e., question # 6).

   Any disclosures in which proxies enter information on behalf on an Investigator will be routed to Investigators for approval. Investigators will still have to certify to the accuracy of the disclosure and submit the disclosure.

   Detailed education regarding assigning and administering proxy access is scheduled on both campuses in January – click [here](#) for details.

3. **No-Change Disclosures**
   Investigators will no longer be required to review and click through the entire disclosure when submitting a “no change” disclosure. Effective 1/9/13, when Investigators select “Acknowledge No Change” as a disclosure reason, they will be taken directly to the “Sign and Submit” page (rather than
having to navigate through the six questions). On this page, Investigators will still have the option to review responses to their last disclosure prior to submitting the “No Change” disclosure.

4. **Reiteration of Compliance Requirements**

A friendly reminder of key compliance points for projects funded by sponsors subject to NU’s COI requirements:

- Disclose SFIs
- Complete COI training

Proposal Submission

- FCOI determination made
- FCOI managed, as applicable
- FCOI reported, as applicable

Funding Released

- At proposal stage (for proposals submitted subsequent to 8/24/12): Proposals may not be submitted by OSR if all individuals listed as an Investigator on a project subject to COI requirements have not submitted a disclosure **within 30 days prior to proposal submission date**.

  Federal regulations require that Investigators submit a disclosure prior to submission of an application for funding. Rather than require Investigators to submit a disclosure prior to every single proposal, we allow a 30-day “window” – when an Investigator submits a disclosure (or updates a disclosure with no change), that disclosure is sufficient to meet compliance requirements for any proposal submitted for the subsequent 30 days.

- At award stage (for new awards subsequent to 8/24/12): Award chart strings will not be established, nor funding released, for projects received in which COI disclosures or COI determinations are outstanding.

  COI determinations must be made, COI management plans finalized, and sponsor COI reports submitted, **before project funding is released.** Significant Financial Interests disclosed by all project Investigators must be reviewed relative to research activity to assess whether or not a Financial Conflict of Interest related to the specific research project exists.

- New budget periods subsequent to 8/24/12: Federal draw-down of funds will not occur for active projects in which COI disclosures or COI determinations are outstanding.

  Existing active projects that have new budget periods starting subsequent to 8/24/12 are subject to the new COI requirements. At this stage, compliance requirements identical to those for new awards kick in.

  Accounts may be frozen for continued investigator non-compliance.

  **Industry-sponsored clinical trials:** OSR will not execute clinical trial agreements with sponsors for projects in which COI disclosures or COI determinations are outstanding.