The Research COI Policy and process changes that will be fully implemented on August 24, 2012, are currently available for preview via your WUSTL Key at http://coi.wustl.edu. The following outlines some of the details of the key changes.

**DISCLOSURE**

- Individuals will not need to resubmit a Financial Disclosure Statement due to the changes in the policy and processes until their current disclosure is up for renewal or their personal financial interests have changed.

**Who:** The population of individuals (“covered individuals”) required to disclose has been expanded. The following individuals will be required to disclose:
  - **All faculty** with an academic appointment of instructor or higher on tenure or non-tenure tracks;
  - **Individuals, who by definition, have independent responsibility** for the design, conduct, or reporting of research at WU: Principal Investigator (PI)/Project Director (PD), Co-Investigator, Key Personnel, Mentors and Fellows on individual fellowship grants, Mentors identified on institutional training grants;
  - **Any other individual**, who regardless of title or position, has or may have independent responsibility for the design, conduct, or reporting of the research. The PI/PD is responsible for making the determination of who meets this definition, which may include: Collaborators/consultants, Research/Staff Scientists, Trainees/Students, and Individuals who do not have an appointment at WU, but have the above role/designation related to research being conducted at WU.

**What:** The following outlines the financial interests that must be disclosed:
  - Covered individuals must disclose all personal financial relationships related to their institutional responsibilities (not just those related to their research or clinical care activities, as previously required);
  - A >$0.00 threshold for disclosure will continue to be used uniformly for all individuals (as previously required);
  - For PHS/NIH funded individuals (**only**), there will be a new additional requirement to disclose travel paid for or reimbursed by an outside entity. Elements required to be disclosed are:
    - The dates of travel
    - Destination
    - Entity that paid for the travel
    - Purpose of the trip
    - Was travel paid for your spouse and/or dependent child(ren) by the entity?

**When:** Covered individuals must update their Financial Disclosure Statement:
  - at least annually;
  - within 30 days of acquiring a new financial interest (which includes travel for individuals involved in PHS funded research); or
  - when they initiate new research projects.
Quick Reference Guide
Research COI Policy and Process Changes

How: The existing web-based disclosure system will continue to be utilized:
  o The web-based Financial Disclosure Statement has been revised to reflect these changes and is currently available via the Research Gateway.
  o Individuals required to disclose travel will receive an emailed each month and be prompted to disclose any material travel using a spreadsheet included in the email, which can be emailed back to the Conflict of Interest Review Committee (CIRC) for review. This disclosure process for travel will be piloted during the next 12 months in order to assess a long term solution.

Review of Financial Interests
  o The Disclosure Review Committee has been renamed the Conflicts of Interest Review Committee (CIRC) to more accurately reflect its role at WU.
  o The CIRC will continue to review all financial disclosures to 1) assess whether a financial interest is related to an individual’s research activities and then 2) determine if a financial conflict of interest exists.
  o The threshold for review of financial interests and management of any financial conflicts of interest will be specific to the source of research funding. For research funded by PHS/ NIH, the $5,000 threshold (as established by the regulations) will be used. For all other research the current $10,000 threshold will be utilized for review and management.

Management of Financial Conflicts of Interest
  o The standards/guidelines for managing financial conflicts of interests have been revised and include additional information about what is considered when identifying and managing financial conflicts of interest.

Monitoring
  o For PHS/NIH funded individuals, adherence to the Research COI Policy and processes will be monitored for compliance (as required by federal regulations).
  o Individuals who do not have PHS/NIH funding may also be monitored for compliance.

Education
  o All individuals who complete a disclosure statement must complete COI education within the next 12 months or prior to the start date of any new, competitive, or non-competitive awards supporting research activities, whichever occurs first. For example, if your research funding is due to start September 1, 2012, the education must be completed prior to September 1st, to prevent delays in the award set-up.
  o Renewal of the education will be required every four years.
  o The web-based education module is available via the Research Gateway, under Education and Features Programs, select FCOI Education.

Public Reporting
  o The PHS/NIH regulations outline an option for institutions to post all COI information on a publicly available website, or to make the information available upon written request. For PHS/NIH funded individuals, WU will respond to written requests initially and re-evaluate at a later date whether to publish the information on a website, which will allow more time to effectively assess and communicate this change in process.

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