

## Executive Summary for GIM 10 Revisions

On August 25, 2011, the Department of Health and Human Services issued the final regulation related to individual conflicts of interest in federally funded research, entitled “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.” The 2011 rule substantially modifies the definitions, thresholds, and requirements for disclosing, reviewing, managing and reporting financial relationships between research personnel and outside entities. This required UW to make significant changes to the current University policy (GIM 10), while still balancing the requirements of the State Ethics Code. Many of the revisions to the University policy will apply to PHS Funded Research only, as is required by the 2011 rule. Such revisions appear in italics below.

The revisions to GIM 10 will be implemented on August 24, 2012.

The revisions made to GIM 10 include:

- **Reduction in the SFI threshold:** The de minimis threshold for SFI disclosure is now \$5000. This reduces the non-human subjects disclosure threshold from \$10,000 and removes the zero threshold for clinical trials.
- **Definition of Significant Financial Interests (SFI):** SFI is now defined as financial interests which meet the disclosure threshold and are related to an investigator’s *institutional duties*.
- **Definition of Financial Conflicts of Interest (FCOI):** An FCOI is an SFI that could directly and significantly affect the design, conduct or reporting of research or a Technology Transfer Transaction. Investigators and Innovators will make required disclosures of SFI and travel. The Office of Research will review the disclosures to determine if an FCOI is present.
- **Definition of Investigator:** Investigator is now defined as anyone, regardless of title or position, responsible for the design, conduct or reporting of the research. This may include but is not limited to the Principal Investigator, project director, co-principal investigator, Senior/Key Personnel, post-doctoral fellows, graduate students, trainees, staff members or University employees without an academic appointment.
- **Inclusion of Travel:** Sponsored and Reimbursed Travel must now be disclosed in certain circumstances.
- **Disclosure requirements:** There are now different disclosure requirements for investigators participating in PHS Funded Research, investigators participating in non-PHS funded research and innovators involved in Technology Transfer Transactions.

- *PHS Funded Research:*
    - *Investigators must disclose ALL SFIs at the time of application or within 30 days of acquisition*
    - *Investigators must disclose the occurrence of all Sponsored or Reimbursed Travel within 30 days of its occurrence.*
    - *Travel must be included as part of an SFI, if when it is aggregated with other financial interests, the aggregation meets the disclosure threshold.*
  - *Non-PHS Funded Research and Technology Transfer Transactions:*
    - *Investigators or Innovators must disclose SFI related to the research application or technology transfer transaction at the time of application.*
    - *Travel must be included as part of an SFI, if when it is aggregated with other financial interests, the aggregation meets the disclosure threshold*
- ***Determination of Relatedness:** The Office of Research will examine all SFI and travel disclosures from Investigators participating in PHS Funded Research and make the determination of relatedness for each research application. (Previously, the Investigator has made this determination.)*
  - ***Training:** All investigators participating in PHS Funded Research must complete the PHS FCOI training prior to engaging in any research related to any PHS Funded grant or contract and at least every four years.*
  - ***Public Accessibility:** The Office of Research will maintain a publicly accessible website that will publish certain information concerning identified FCOIs held by Senior/Key Personnel.*
  - ***Retrospective Review:** The University is now required to conduct a retrospective review for PHS Funded Research when there is non-compliance with GIM 10. If bias is found, then a report must be submitted to the PHS Awarding Component. The report will address the impact of the bias on the research project and the actions the University has taken, or will take, to eliminate or mitigate the effect of the bias.*