PROPOSED CHANGES TO THE INSTITUTE’S CONFLICT OF INTEREST POLICY

April 24, 2012
The U.S. Department of Health and Human Services (HHS) has issued a final rule that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94).

Institute Policy is being revised to meet these new requirements.
Review: Major Areas Addressed in the Revised Institute COI Policy

- Definition of Significant Financial Interest (SFI)
- Extent of Investigator Disclosure
- Investigator Training
- Reporting of Reimbursed or Sponsored Travel
Significant Financial Interest (SFI)

- Threshold lowered to $5000 from $10,000. (fees, equity, or a combination of both)
- Includes any equity interest in non-publicly traded entities
- Any reimbursed sponsored travel
- Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an Institution of higher education.
- Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
Investigator Disclosure

- All SFIs related to Investigator’s “institutional responsibilities” instead of “related to research.”

- Institution is responsible for determining whether SFIs relate to US Public Health Service-funded research and are financial conflicts of interest (FCOI)
Investigator Training

- **FCOI training required** for Investigators before engaging in US Public Health Service-funded research, every four years thereafter, and immediately under designated circumstances.
Reporting of any reimbursed or sponsored travel related to a US PHS Investigator’s institutional responsibilities

- “Sponsored Travel” = that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available.

- This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
Updates

- Clarification: Travel reporting requirements applied only to Investigators with US Public Health Service-funded research (e.g. from NIH)
  - See www.compliance.gatech.edu/conflicts-of-interest-gt/faq-sponsored-travel for FAQ

- All references to faculty disclosures of conflicts of interest or the like have been updated to reflect use of the new Conflict of Interest Online System.
  - See www.compliance.gatech.edu/conflicts-of-interest-gt/ for link to the System