

**Implementation of New Federal Regulations Regarding Objectivity in Research:
How These Impact the Application for and Award of Grants and Contracts**

Effective Date: August 24, 2012

Impact on Application Process:

- Each person who is responsible for the design, conduct or reporting of the research ("Investigator") must have disclosed, **prior to submission of the application**, any Significant Financial Interests (defined below) using the on-line U.Va. financial interest disclosure system. Note: the definition of "Investigator" as it pertains to FCOI is more narrow than the NIH definition for Senior/Key personnel. Please contact your grant administrator in the SOM Office of Grants and Contracts for guidance.
- NAMING ANY PERSON AS INVESTIGATOR, WHETHER AT UVA OR ELSEWHERE, ON ITEM 5, PAGE 2, OF THE GOLDENROD, TRIGGERS THIS DISCLOSURE REQUIREMENT. However, Subcontractor investigators do not need to provide disclosures prior to application submission.
- For Public Health Service applications, each subcontracting site, prior to application submission, must provide a completed assurance that it has its own PHS-compliant FCOI policies in place, or that it will adopt U.Va.'s policy. This assurance is provided using the UVA External Entity FCOI Certification form, available here: <http://www.medicine.virginia.edu/research/offices/research/research-forms-and-documents/>.

Impact on Award Process:

- For Public Health Service applications, an institutional official will determine whether any Investigators' Significant Financial Interests are related to the research in the proposal. This typically will be done during the just-in-time phase of application review.
- If there is relatedness, the matter will be referred to the University's Conflict of Interest Committee, which will determine whether there is any potential or actual conflict of interest. Any conflicts must be resolved prior to an award being accepted.
- No subcontract may be made under an award until any potential or actual conflicts of interest pertaining to the subcontractor's Investigators have been resolved.
- Each Investigator must complete required U.Va. training in research objectivity prior to engaging in Public Health Service funded research and no less than every four years thereafter.

Significant Financial Interests are defined by the following criteria:

1. Financial interest of the Investigator (or the Investigator's spouse and dependent children) that relates to the Investigator's institutional responsibilities
2. Consists of any combination of income or equity in a publicly traded company that exceeds \$5,000
3. Consists of income from a non-publicly traded company that exceed \$5,000
4. Consists of any equity in a non-publicly traded company, regardless of value
5. Intellectual property rights that result in income, unless such income is received through U.Va.
6. Any reimbursed or sponsored travel, unless the payor is a domestic governmental entity, an institution of higher education, or a teaching hospital, medical center or research institute associated with an institution of higher education