

UAH Interim Policy on Promoting Objectivity in Research

The federal Public Health Service (PHS) has issued new regulations designed to promote objectivity in research. 42 CFR §50.601 *et seq.* Specifically, the regulations are aimed at preventing researchers from having a personal financial conflict of interest that could affect the outcome of federally funded research. Several federal agencies are encompassed within the PHS, including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). The PHS regulations require that all institutions receiving agency grants have implementing policies in place by August 2012. The National Science Foundation (NSF) has similar conflict of interest policy requirements. *See Proposal and Award Policies and Procedures Guide, January 2011, Part II Award and Administration Guide, Chapter IV-Grantee Standards, (A) Conflict of Interest Policies.* UAH researchers have grants from the NIH, the CDC, and the NSF, and are thus subject to the requirements of these federal initiatives.

The PHS regulations are slightly more detailed than the NSF regulations, so compliance with the PHS regulations should also result in compliance with the NSF regulations. UAH has adopted the Interim Policy on Promoting Objectivity in Research, which may be found on the UAH Office of Sponsored Programs (OSP) website at http://www.osp.uah/documents/Objectivity_in_Research.pdf. The Interim policy is applicable to researchers whose work is funded by either the PHS or NSF. The UAH Interim Policy has been reviewed by the Staff Senate and is being reviewed by the Faculty Senate. Faculty and staff members affected by the new Interim Policy can comply by filling out the questionnaires that may also be found on the OSP website.

In general, the regulations require all research investigators to disclose to the University any financial interests they or their family members have that could affect their research or sponsored program activities. Disclosure must be made annually and, in addition, on the occurrence of certain events, such as the award of additional funding of a sponsored research project. If a financial interest is disclosed, the University must then determine if it is “significant,” as defined by the regulations. A researcher has a “significant financial interest” if he/she receives remuneration of \$5,000 or more from a publicly or non-publicly traded company. A “significant financial interest” includes an equity interest of \$5,000 or more in a publicly traded company, or any equity interest or executive position in a non-publicly traded company.

If a University researcher discloses a significant financial interest, then the researcher, the researcher’s department chair or center director, and the University’s compliance officer will determine, presumably by consensus, if the interest is “related” to the researcher’s research or sponsored program activities. If the disclosed significant financial interest is regarded as “related,” then this same group must decide whether or not the related significant financial interest creates a conflict of interest or the appearance of a conflict of interest. A conflict of interest exists when a significant financial interest is related to an investigator’s research activities *and* could directly and significantly affect the design, conduct, or reporting of the research or sponsored program activity.

In those instances in which a conflict of interest is found to exist, a written mitigation and management plan is to be developed and implemented. The “conflict of interest” decision and the content of the management plan are subject to the approval of the applicable Dean and the Vice President for Research. In the event that disagreements exist about these matters, the Vice President for Research, when the case reaches his/her level for approval, may appoint a Conflict of Interest in Research Committee to offer advice on the dispute’s resolution.

A researcher’s failure to report a financial interest and/or the failure to manage a conflict of interest in accordance with an approved written mitigation and management plan can, under the applicable regulations, require the Vice President for Research to report the conflict of interest to the appropriate funding agency. Such failures may also result in a recommendation for disciplinary action against the researcher by the Vice President for Research. Any such recommendations would be handled in accordance with existing University policy and procedures.

It is obvious that the federal regulations mandating the University’s new policy are quite complex and burdensome. However, their purpose and intent, when properly understood, are beneficial. No one favors federally sponsored research the results of which are tainted or made vulnerable to question because of the presence of financial conflicts of interest on the part of the researcher.

One aspect of the new regulations appears to reflect a new attitude or trend by federal government sponsors toward academic researchers. In the past, government sponsors were content to simply ask if academic researchers had a financial conflict of interest and were usually satisfied with the answer given. Apparently, this attitude has changed or is in the process of changing. Now, federal research sponsors insist upon disclosure of all financial interests. The decision as to whether or not a particular financial interest constitutes a conflict of interest, or an appearance of a conflict of interest, will be made by others, academic administrators in the first instance, and, ultimately, by the federal research sponsors themselves. As Heraclitus observed some 2500 years ago, “the only constant is change.”