Attention PHS Funded Investigators:

New Mandatory Conflict of Interest Rules Effective August 24, 2012

Date: August 16, 2012
To: PHS Funded Investigators
From: William Grabe, Vice President for Research
Re: New mandatory conflict of interest rules for PHS

Dear Colleagues:

NAU is updating its conflict of interest policy to reflect recent changes in the Public Health Service (PHS) regulations and to be consistent with the Arizona Board of Regents (ABOR) policy for Conflict of Interest (3-901), which was updated in 2011.

The PHS regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The NIH Office of Extramural Research Conflict of Interest Website contains helpful information and resources about the FCOI Regulations. The revised PHS FCOI regulation is effective August 24, 2012 and applies to awards (including noncompeting continuations) with a Notice of Award (NoA) that is issued on or after August 24, 2012.

Changes to the PHS conflict of interest policy include:
- Lower financial disclosure thresholds
- Required conflict of interest training
- New public accessibility requirements regarding investigators' conflicts of interest
- Increased transparency for travel reimbursement
- New requirements regarding reporting of FCOI at subrecipient or subcontractor institutions

Lower financial disclosure thresholds: The new FCOI regulations require the PI and any other individual, who, regardless of title or position, has responsibility for the design, conduct, or reporting of PHS-funded research to separately disclose certain financial interests that exceed the thresholds provided by PHS and that are related to any of their institutional responsibilities. The institution is then required to determine whether the disclosed financial interest could be affected by the research and, if so, whether the financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. Northern Arizona University is presently developing a “user-friendly” online disclosure form that complies with the regulations.
Training requirements: The FCOI regulations also include new requirements for mandatory and ongoing education and training. All PHS-funded researchers will be notified via e-mail regarding required training to comply with the new FCOI rules. All PHS investigators, as defined by the rule, must complete this training prior to expending funds on a PHS-funded project with a Notice of Award issue date after August 24, 2012. NAU’s training requirements will include completion of the NIH conflict of interest tutorial and training via NAU-specific FCOI modules provided through the Collaborative Institutional Training Initiative (CITI), which are currently in development.

New public accessibility requirements: NAU is required to make its policy on Financial Conflict of Interest publicly available via a publicly accessible website, and to make certain information available concerning identified FCOIs via a publicly accessible website or by a written response to any requestor within five business days of a request. At a minimum, NAU must provide the Investigator’s name, title and role on the PHS research project, name of the entity in which the significant financial interest is held, and approximate dollar value of the significant financial interest. Dollar ranges are permissible ($0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Increased transparency for travel reimbursement: Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., 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), related to their institutional responsibilities. Investigators do not have to disclose travel that is reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers. The University is then required to determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

A table summarizing the major differences between the 1995 and 2012 Regulations is available at http://grants.nih.gov/grants/policy/coi/summary_of_major_changes.doc. The NAU Addendum to the OVPR Policy, Conflict of Interest in Sponsored Projects: Promoting Objectivity in Research for which PHS Funding is Sought will be available on August 24, 2012. More information, including information about the on-line disclosure process and NAU’s plan for implementing the regulations will be forthcoming. If you have any immediate questions, please contact Winnie Ennenga, Director of Grant and Contract Services, at (928) 523-8319 or via e-mail to winnie.ennenga@nau.edu or Nanda Gudderra, Associate Vice President for Research, at (928) 523-8594 or via e-mail to nanda.gudderra@nau.edu.

Thank you for your cooperation.

cc: Daniel Kain, Chair, NAU Conflict of Interest in Sponsored Projects Committee
Nanda Gudderra, Associate Vice President for Research and Institutional Official
Wilma G. (Winnie) Ennenga, Director of Grant and Contract Services