

FREQUENTLY ASKED QUESTIONS

- 1) What is the purpose of the revised UA policy on financial conflict of interest?** The revised UA policy stems from recently revised federal regulations (HHS/PHS) designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of its funded research will be free from bias by investigator financial conflict of interest. The regulations were promulgated by HHS/PHS in 1995. The 2011 regulations amend the 1995 regulations by increasing accountability, adding transparency, enhancing regulatory compliance and effective institutional management of investigators' financial conflicts of interests, as well as strengthening compliance oversight at the federal level.
- 2) What are the major changes to the revised UA policy?** The UA policy incorporates changes from the recently revised federal regulations. The major changes include:

 - A lower financial disclosure threshold (from \$10,000 to \$5000) for payments and equity interests (Note: this threshold is \$0 when the study involves human research participants);
 - Exclusion of income from government agencies or institutions of higher education for seminars, lectures, teaching, or service on advisory or review panels;
 - A new requirement for conflict of interest training for investigators (required every four years);
 - Increased transparency for travel reimbursement;
 - New public accessibility requirements.
- 3) May an institution implement a conflict of interest policy that goes beyond the federal regulations?** Yes, as long as the institution's policy meets the minimal requirements of the federal regulations.
- 4) To whom does the revised UA policy apply?** Any UA investigator involved in the design, conduct, or reporting of sponsored activities funded, or proposed for funding, by outside entity. The revised policy applies to each grant or cooperative agreement (including non-competing continuations) with a Notice of Award issue date subsequent to 8/24/12.
- 5) What is HHS/PHS?** The Department of Health and Human Services (HHS) is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services. The Public Health Service (PHS) is the primary division of HHS. The operating divisions of HHS include:

 - Administration for Children and Families (ACF)
 - Administration for Community Living (ACL)
 - Agency for Healthcare Research and Quality (AHRQ)
 - Centers for Disease Control and Prevention (CDC)
 - Centers for Medicare and Medicaid Services (CMS)
 - Food and Drug Administration (FDA)
 - Health Resources and Services Administration (HRSA)
 - Indian Health Service (IHS)
 - National Institutes of Health (NIH) – which consists of 27 institutes and centers
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
- 6) Does the UA policy apply to other non-governmental agencies/organizations?** Yes. In addition to HHS/PHS and NSF, the following agencies/organizations have adopted the HHS/PHS regulations:

FREQUENTLY ASKED QUESTIONS

- American Heart Association
 - American Cancer Society
 - American Lung Association
 - Susan G. Komen Foundation
 - Arthritis Foundation
 - Alliance for Lupus Research
 - Lupus Foundation of America
 - Juvenile Diabetes Research Foundation (JDRF)
- 7) Does the UA policy apply to all grants and contracts awarded by HHS/PHS?** No; the regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Phase I applications. The policy explicitly applies to research grants, career development grants, center grants, individual fellowships, infrastructure awards, institutional training grants, program projects, research resources awards, conference grants, and all NIH “S” awards such as NIH S06 (Minority Biomedical Research Support) awards.
- 8) Who are “senior/key personnel”?** The principal investigator or project director and any other person identified as senior/key personnel within the grant application, progress report, etc. This includes, but is not limited to, study coordinators, recruitment coordinators/schedulers, interviewers, statisticians, data analysts who are responsible for the design and conduct of the activity.
- 9) Does “investigator” include UA post-doctoral fellows?** Yes, if they are funded by the sponsor and they are considered responsible for the design, conduct, or reporting of the funded activity.
- 10) Does “investigator” include UA graduate students working on federally-funded research?** Yes, if they are considered responsible for the design, conduct, or reporting of federally-funded research.
- 11) What is meant by the “design” of research?** The planning of the scientific strategy to test a research proposal.
- 12) What is meant by the “conduct” of research?** The execution, management, or supervision of a research study. This is typically done by the PI and co-investigators, but may also be performed by post-docs and graduate students who have significant roles in collecting and analyzing data, as well as supervising junior researchers or technicians. For studies involving human subjects, this includes anyone who is responsible for obtaining informed consent.
- 13) What is meant by the “reporting” of research?** The authorship of publications or reports to be submitted to the sponsor related to the research. This includes anyone who will likely present the study data at national/international meetings.
- 14) What is a Significant Financial Interest (SFI)?** A SFI is anything of monetary value or potential monetary value, whether or not the value is readily ascertainable, that meets the PHS thresholds and that reasonably appears to be related to or is in the same field of expertise as the investigator’s institutional responsibilities. This includes the sum of any paid compensation, ownership in companies, and leadership positions (e.g., consulting fees, honoraria, stocks, stock options, or other

FREQUENTLY ASKED QUESTIONS

ownership interests, patents, copyrights, licensing agreements, and royalties from such rights).
Please refer to the UA policy for exclusions.

15) Do I have to disclose my UA salary? No. You are not required to disclose your salary or other income received from UA, including salary received from external sources through sponsored research agreements administered by UA on your behalf. *Please refer to the UA policy for other exclusions.*

16) What are some examples of SFIs? Examples of SFIs include but are not limited to:

- Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization; or salary received outside of UA.
- Stock or stock options in a company that is developing, manufacturing, or selling products or providing services used in an investigator's teaching, research, administrative, or committee responsibilities.
- Receipt of income from any organization other than UA for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from prior employers and other universities.
- Travel reimbursements made to, or on behalf of, the investigator, by a for-profit or non-profit entity where the combined monetary value is greater than \$5000 for all categories. *Excludes federal, state, or local government, a U.S. institution of higher education or an affiliated medical center, hospital, or research institute.*

17) What are “institutional responsibilities”? These include activities such as teaching, research, research consultation, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

18) What if I don't have any financial interests or activities to disclose? If you receive research support from an external sponsor, you must still complete and submit the Statement of Financial Interest at least annually.

19) If I disclose a financial interest on my statement, will it automatically be considered a conflict of interest? No. Some financial interests are of such low value and/or limited duration that they do not meet the definition or threshold of disclosable financial interests, or are so small or inconsequential that the research support from the sponsor can be accepted with no further action. Furthermore, almost all disclosed financial interests and resulting conflicts of interest can be reduced, eliminated, or managed so that the research project can be accepted and funded by the proposed sponsor.

20) Am I required to disclose mutual funds and retirement accounts? Not unless you have a controlling interest in the investment decisions made in these vehicles.

FREQUENTLY ASKED QUESTIONS

- 21) What are the requirements for disclosing my travel expenses?** You must disclose any reimbursed or sponsored travel related to your institutional responsibilities. This disclosure requirement also applies to your spouse and dependent children. The disclosure should include a description of the purpose of the trip, sponsor/organizer, destination, and duration. *Travel to scientific meetings and to present one's research to colleagues and other interested parties are an integral part of the scientific research enterprise and affords many important opportunities for forging relationships and collaborations among researchers.*
- 22) What are the exceptions to disclosing travel expenses?** You are not required to disclose travel reimbursed/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 research institution affiliated with an institution of higher education. *This exception does not apply to professional societies.*
- 23) Do I need to report any entity which directly paid for my travel expenses to an airline or hotel?** Yes, if the aggregated amount for support from an entity exceeds the \$5000 threshold.
- 24) If I paid my own travel costs and the entity reimbursed me directly, then would I still need to disclose this?** Yes. You should report any travel expenses related to your institutional responsibilities that were either:
- Reimbursed to you or
 - Sponsored by an entity on your behalf (i.e., travel expenses that were paid directly on your behalf, thus not reimbursed to you) and
 - The aggregated amount of support from the entity sponsoring the travel exceeds \$5000.
- 25) Does the revised policy apply to foreign institutions and international organizations?** Yes. The policy applies to any institution (i.e., foreign or domestic) that applies for or receives PHS or NSF funding through a grant or cooperative agreement as either a prime awardee institution or a sub-recipient institution.
- 26) How do I disclose my financial interests?** By completing the Statement of Financial Interest form and submitting it to the UA Office for Research Compliance. You may mail the form via campus mail to Box 870127 or submit a scanned copy of the form via email to rscompliance@fa.ua.edu.
- 27) Are electronic/digital signatures accepted on the form?** No. Currently, the form requires your 'true' (handwritten) signature.
- 28) When must I disclose my financial interests?**
- Your initial disclosure should be made prior to submitting a grant or contract application for a proposed project in which you plan to participate.
 - On an ongoing basis:
 - At least once per year.
 - Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a *new or increased* SFI. This is done by filing an amended Statement of Financial Interest.

FREQUENTLY ASKED QUESTIONS

- Immediately if you are a new investigator at UA. The disclosure must be on file with the Office for Research Compliance prior to joining an ongoing UA study or submitting a new grant or contract application.

29) How is a “new” SFI defined? A new SFI is a different type or nature of SFI (e.g., royalty payment vs. consulting fee) than what had previously been disclosed *from the same source* that meets or exceeds the threshold. In addition, a “new” SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) *from a different source* (e.g., Company A vs. Company B).

30) Am I required to monitor the day-to-day changes in value of publicly traded stock or other similar interests with fluctuating value? No. Generally, the annual filing of your Statement of Financial Interest will be sufficient to allow you to disclose updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

31) Do I need to file a separate statement/disclosure for each grant/contract? No.

32) Do I need to file a statement for renewals or non-competing continuations? No, statements are filed annually and updated within 30 days of discovery of a chance current the financial interest.

33) Do I need to complete training even if I am not supported by NIH? Yes, training is required once every four years for all UA investigators, regardless of funding source. An NIH tutorial titled “Financial Conflict of Interest (FCOI)” is currently being used as the training module for UA investigators. A link to the training is available on the website at http://osp.ua.edu/site/RC_Col.html.