

# Institution Responsibilities

The University must certify in each application for funding that we:

1. have an up-to-date written, and enforced administrative process to identify and manage FCOIs related to all PHS funded research;
2. will promote and enforce investigator compliance and training;
3. shall manage FCOIs and provide initial and ongoing reports to PHS;
4. will make information available to PHS upon request relating to any investigator disclosure of SFI, whether or not it resulted in determination of an FCOI;
5. will make information concerning FCOIs held by investigators available within 5 business days of receipt of a written request; and
6. will insure that all subrecipient institutions and investigators are in compliance with the PHS regulations.

The Responsibilities of the Director of the Office of Research Administration are to:

1. act in good faith to assist the University in implementing this policy;
2. convey to the V.P. for Research the concerns they, or others, have with this policy;
3. review all disclosure forms and conflict management plans and forward to the V.P. for Research with comments on any case which still appears to present a conflict. Such comments should include actions recommended by the director to manage or remediate the conflict(s).
4. submit all financial conflicts on the Commons prior to the expenditure of any funds on the award and within 60 days of the disclosure of any new conflict of interest.
5. make available information on FCOI held by NIH investigators to any requestor within 5 business days of receipt of a written request.
6. insure that all subrecipient institutions either have a PHS-compliant conflict of interest policy or agree to abide by UA's policy.
7. Require subrecipients to provide investigator financial interest disclosures and management plans to UA in sufficient time for UA to meet its reporting requirements.

Record Retention and Reporting Requirements for Funded Proposals

1. All disclosure forms will be kept in the award file for 3 years from the filing of the final expenditure report.
2. For all identified conflicts of interest, records of the institution's review of, and actions taken to manage the conflict (management plans) will be kept for 3 years from the filing of the final expenditure report.
3. For each identified FCOI, reports will be submitted to NIH through the eRA Commons FCOI module. The following information will be submitted:
  - a. Award ID #
  - b. PI Name
  - c. Name of individual with FCOI
  - d. Name of entity with which the FCOI exists
  - e. Nature of the FCOI
  - f. Amount of FCOI (within specified ranges)
  - g. Description of how the financial interest relates to the NIH-funded research and the basis for the determination that the interest conflicts with the research
  - h. Key elements of the management plan
  - i. Information concerning FCOIs held by Investigators will be made available to any requester within five business days of a written request.
  - j. All FCOIs will be updated annually and submitted to NIH through the eRA Commons when annual progress reports are submitted.

## Subrecipient Monitoring

1. Subrecipients will indicate in their Letter of Intent if they have an NIH-compliant COI policy.
  - a. Subrecipients with an NIH-compliant policy will certify that all subrecipient investigators have submitted a significant financial interest disclosure form.
  - b. Subrecipients without an NIH-compliant policy will be required to submit to UA copies of disclosure forms for all participating investigators.
2. When a proposal is funded the subrecipient institution will certify in the research agreement that all participating investigators have submitted disclosure statements and that all FCOI's have been forwarded to UA. The information must be submitted with the subaward agreement and prior to the expenditure of any funds.
3. Updated FCOI's and any changes in management plans must be submitted to UA 10 days prior to the deadline for submission of the annual progress report, and within 10 days of any change.

## Noncompliance

### Retrospective Review:

When a significant financial interest is identified that was not disclosed or managed in a timely manner, the director of the ORA will, within 60 days, review and make a determination of an FCOI and report it to NIH. Within 120 days of the determination of noncompliance, a retrospective review of the investigator's activities and project will be conducted to determine bias in the design, conduct or reporting of the research. The director of ORA, the V.P. for Research, and others as deemed necessary will conduct the review. If warranted, an updated FCOI report will be submitted to NIH.

The retrospective review will include:

- Award #
- Award title
- PI of award
- Name of investigator with the FCOI
- Name of entity with which investigator has a conflict
- Reason for retrospective review
- Methodology used for review – composition of review panel, documents reviewed
- Findings and conclusions

### Mitigation Report:

If bias is found through retrospective review, UA will notify the NIH awarding component through the eRA Commons and submit a Mitigation report within 45 days which will include:

- Key elements documented in the retrospective review
- Description of the impact of the bias on the research project
- Plan of action to eliminate or mitigate the effect of bias