

Supplemental Procedures Governing Financial Conflicts of Interest in Externally Funded Research

I. Scope

These procedures are supplemental to University Policy 54 and apply to all WCU personnel (faculty and staff) who pursue external research funding. These procedures are intended to comply with Public Health Service (PHS) regulations (42 CFR 50 and 45 CFR 94) and National Science Foundation (NSF) policies regarding the disclosure and management of investigator financial conflicts of interest. For all other external agencies, the institution will comply with that agency's financial conflict of interest policy to the extent the agency's policy is more stringent than these procedures.

II. Disclosures of Significant Financial Interests

Investigators must disclose any significant financial interest (refer to University Policy 54 for definition) to the Office of Research Administration (ORA) prior to the submission of their project to an external agency. This disclosure is separate from the University annual conflict of interest disclosure process. Investigators will complete the Supplemental Disclosure Form and the ORA will maintain the form, for at least three years from the date the final expenditure report is submitted to the external agency. Investigators must update the Supplemental Disclosure Form with the ORA at the following intervals:

- (a) within thirty days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) any new significant financial interest; and
- (b) annually within the period of the award

III. Travel Disclosure for PHS Funded Research

Investigators who receive funding from a Public Health Service agency (includes NIH, CDC, HRSA, etc) must also disclose any reimbursed or sponsored travel to the ORA prior to the submission of their project to the external agency. The ORA will maintain the Disclosure of Reimbursed or Sponsored Travel form, in confidence, for at least three years from the date the final expenditure report is submitted to the agency. Investigators must update the Disclosure of Reimbursed or Sponsored Travel Form with the ORA at the following intervals:

- (a) within thirty days of acquiring a new reimbursed or sponsored travel opportunity; and
- (b) annually within the period of the award

IV. Conflict of Interest Training

Investigators are required to complete an online Conflict of Interest training module through the CITI program. Training must be completed prior to the submission of the research proposal to an external agency. The training must be repeated at four-year intervals and a certificate of completion will be retained in the ORA.

V. Review and Management of Significant Financial Interests

The Director of Sponsored Research or his/her designee, will review the disclosure form to determine whether each significant financial interest relates to the funded research. The Director will determine whether the significant financial interest could directly and significantly affect the design, conduct, or reporting of the externally funded research, thereby constituting a financial conflict of interest. If a financial conflict of interest exists, the Director will notify the researcher's Department head or direct

supervisor for further review and management of the conflict consistent with University Policy 54. The ORA will maintain all records relating to the investigator's conflict of interest review for at least three years after the final expenditures report is submitted to the external agency.

If an investigator fails to timely disclose a conflict of interest or comply with the financial conflict of interest management plan, the institution will, within 120 days, conduct a retrospective review to determine whether any externally funded research was biased in design, conduct, or reporting. For PHS-funded projects, if any bias is found the Institution will notify the PHS awarding agency and submit a mitigation report in accordance with regulations.

VI. Reporting

The ORA will adhere to the following requirements when reporting financial conflicts of interest:

1. **Sponsor Reporting** For PHS funded research, prior to expenditure of federal funds, the institution will provide a report to the PHS awarding agency regarding any investigator financial conflict of interest and the implemented management plan. Any new financial conflicts of interest, which arise during the course of the funded research project, will be reported to the PHS awarding agency within 60 days of the Institution identifying the financial conflict of interest. Upon request, the institution will disclose any reported financial interests to the PHS awarding agency and will permit on site review of all pertinent records. Oversight and reporting for all other external agencies will be completed in accordance with sponsor policies.
2. **Public Requests** The institution will respond in writing, within five days of receiving a request for disclosure of information concerning a financial conflict of interest related to PHS funded research.

VII. Subrecipient monitoring

The University and the subrecipient will execute a written agreement indicating whether the subrecipient will adhere to the University's FCOI policy (Policy 54) or the subrecipient's policy. If the subrecipient's policy will be followed, the subrecipient must certify its policy complies with PHS regulations and the agreement will specify a time period for the subrecipient to report identified financial conflicts of interest to the University. If the subrecipient entity does not have a financial conflict of interest policy, then the subrecipient investigators will be subject to University Policy 54 and the requirements outlined in this procedure.

In the event a subrecipient investigator discloses a significant financial conflict of interest for which the Director of the ORA determines the unit does not have the resources to manage, the University may preclude further collaboration with the entity.

VIII. Enforcement

Investigators who do not comply with the provisions of this procedure may be subject to disciplinary action. The University COI panel will assist in all investigations and enforcement activities as appropriate.