

Financial Conflict of Interest (FCOI) Policy for Holly Westfall PhD

INTRODUCTION

The purpose of this policy is to prevent potential bias resulting from any Financial Conflict of Interest (FCOI) by individuals who have direct influence in the allocation and use of public funding in the conduct of research. The following FCOI policy applies to research and initiatives funded by US Public Health Service (PHS) grants wherein **Holly Westfall PhD** is the recipient of public funding. The policy aligns with requirements within regulation 42 CFR Part 50 – Subpart F with the goal of promoting objectivity and transparency in research.

This FCOI policy defines the requirements and processes for investigators or individuals participating in PHS-funded research to identify and properly disclose any FCOIs. In addition, it outlines activities related to management, enforcement, and reconciliation for all appropriate studies.

DEFINITIONS

- **Holly Westfall PhD:** Referred to as "HWP."
- **Investigator(s):** The Principal Investigator (PI)/Project Director and any other individuals, regardless of title or position, who are responsible for the design, conduct, or reporting of PHS/NIH-funded research, or proposed for such funding, which may include, for example, collaborators or consultants.
- **Institutional responsibilities:** An Investigator's professional responsibilities on behalf of HWP, including but not limited to activities such as research, research consultation, teaching, professional practice, and committee memberships.
- **Financial interest:** Anything which has monetary value, and if the value is readily ascertainable.
- **Financial Conflicts of Interest (FCOI):** Situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research related to the PHS-funded activity.
- **FCOI Manager:** HWP's designated official for managing the FCOI process related to a specific PHS grant.
- **Significant Financial Interest (SFI):** A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:
 - An SFI exists if the value of any remuneration received from an entity (other than HWP), in the twelve months preceding the disclosure and the value of any equity interest in an entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or

other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

FCOI TRAINING

In compliance with federal regulations, all HWP Investigators who are planning to participate in or are participating in Public Health Service (PHS) funded research are required to review this FCOI policy and complete the NIH's online FCOI Training module:

- Prior to engaging in research related to any PHS/NIH-funded grant.
- At least every four (4) years.
- Immediately, if:
 - HWP revises its FCOI policy that affects requirements of Investigators.
 - An Investigator is new to HWP.
 - An Investigator is not in compliance with the policy or management plan.

Upon completion of the training, a certificate of completion must be sent to the FCOI Manager. Investigators should also retain a copy for their records.

DISCLOSURE, REVIEW, AND MONITORING REQUIREMENTS

Disclosure The Principal Investigator of a Research Project will identify all Investigators required to disclose SFIs (and those of the Investigator's spouse, partner, and dependent children) related to PHS-funded activity, which meet the definition of SFI. The Principal Investigator and FCOI Manager will be responsible for ensuring disclosures of any new (e.g., marriage, purchase, or inheritance) or increased financial interests are completed:

- No later than at the time of application for PHS-funded research.
- At least annually during the period of award.
- Within 30 days of discovering or acquiring a new SFI.

Review and Monitoring Prior to expenditure of funds, the FCOI Manager will solicit and review Investigator disclosures to determine whether a potential FCOI exists related to an investigator's institutional responsibilities.

If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to manage, reduce, or eliminate specific SFI to prevent the potential to compromise or bias professional judgment or objectivity regarding the design, conduct, or reporting of research, the FCOI manager will introduce an FCOI management plan. The plan may outline terms, conditions, and restrictions, if any, to ensure compliance with this policy.

Investigators must formally agree to the proposed management strategies. All management plans are required to be signed by the Investigator. Compliance with the management plan will be monitored by the FCOI Manager.

REPORTING REQUIREMENTS

The FCOI Manager is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the sponsor:

Initial report Prior to HWP's expenditure of any funds under a PHS/NIH-funded research project, HWP will provide to the sponsor an FCOI report regarding any Investigator SFI, if found by HWP to be a financial conflict of interest, in accordance with the regulation. In cases in which HWP identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds, HWP shall not submit an FCOI report to the NIH.

During on-going PHS/NIH-funded research projects Whenever, during the research project, a new Investigator discloses SFI or an existing Investigator discloses a new SFI, HWP will:

- Review the disclosure of SFI.
- Determine whether it is related to research.
- Implement a management plan in interim.
- Submit a report of FCOI within 60 days after its determination that a new FCOI exists.

Annual Report For any FCOI previously reported to the sponsor, HWP shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan. Further, HWP will notify the sponsor promptly:

- If bias is found HWP will notify and submit a mitigation report to the sponsor. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and HWP's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, HWP will submit FCOI reports annually.
- If an Investigator fails to comply with HWP's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research HWP will take corrective action.

MAINTENANCE OF RECORDS

Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential FCOI, shall be retained by the FCOI Manager for three (3) years from the date the final expenditure report is submitted to the sponsor or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual.

Whenever HWP identifies an SFI that was not disclosed timely to the sponsor, HWP will complete a retrospective review within 120 days of discovery of noncompliance to determine whether any PHS-funded research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research. Updated FCOI will be submitted to the sponsor. Required retrospective review elements are outlined in 42 CFR 50.605(a)(3)(iii).

Additionally, in any case in which the sponsor determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a vaccine, drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by HWP as required by this subpart, HWP will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the PHS-funded research and to request an addendum to previously published presentations under PHS Funded research.

SUBRECIPIENT REQUIREMENTS

When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), HWP shall establish a written agreement (e.g., subaward contract) which confirms that the investigators of the subrecipient institution will comply with this policy or provide certification that their organization is compliant with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

If an SFI is identified by the sub-award recipient, they are required to notify the PI and FCOI Manager of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

PUBLIC ACCESSIBILITY REQUIREMENTS

HWP will publish the institution's policy on its public website. HWP will respond to all written requests for information within one calendar month and then release the required information about such SFI containing the minimum elements as provided by regulation.

Records of Investigator SFI Disclosure forms will be retained for a minimum of three years from the date the final expenditure report is submitted to the sponsor.