Consumer Wellness Solutions, LLC.
Center for Wellbeing Research
INVESTIGATOR SIGNIFICANT FINANCIAL CONFLICT OF INTEREST POLICY
Applicable to Project Proposals Submitted
to Public Health Service Research

What is required?

To promote objectivity in research, Federal regulations, including 42 CFR Part 50 Subpart F, require institutions to have policies and procedures in place that ensure that Investigators (see definition below) disclose any Significant Financial Interest that may present an actual or potential conflict of interest in relationship to research projects sponsored by the Public Health Service (PHS) research funding, which includes National Institutes of Health (NIH). Any actual or potential conflict of interest in relationship to Investigators' institutional responsibilities must also be disclosed. Such disclosures must be made prior to the submission of a proposal for funding,* and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to the expenditure of any funds on an award. The Center for Wellbeing Research (CWR) requires that disclosure forms be completed for all projects applying for Federal funding. CWR also requires that disclosure forms be completed for non-competing continuation grant applications (renewals).

** If a new reportable significant conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, the filing of a disclosure is also required.*

Who is covered?

"Investigator" means the principal investigator/project director, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding. Senior or Key Personnel means the PD/PI and any other person identified as Senior/Key Personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation. Key Personnel definition in the FCOI Policy is different than the NIH Grants Policy Statement.

What must be disclosed?

Each Investigator shall disclose all significant financial interests: (i) that would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

What is a Financial Conflict of Interest (FCOI)?

Financial Interest means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable. An FCOI is any Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

What is covered?

"Significant Financial Interest" (SFI) means anything in excess or equal to $5,000 of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- Base salary, or other usual remuneration from Consumer Wellness Solutions, LLC. ("RVO Health"); or
- intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights; or

- any ownership interest in the Institution held by the investigator, if the institution is a commercial or for-profit organization; or
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; or
- income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as definite at 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an Institution of higher education; or
- income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as definite at 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an Institution of higher education.

Disclosure Procedures:
(1) When submitting a proposal to any federal funding entity as a prime grantee, all Investigators must affirm that they have read this policy and must disclose any significant financial interests. Investigators should complete the Significant Financial Interest Disclosure (SFID) form (with relevant supporting documentation attached). The completed form and attachments, if any, must be reviewed and approved by the Director of CWR or their designee by the proposal's submission date. Supporting documentation should be submitted in a sealed envelope marked "confidential."

(2) In accordance with federal regulations, a complete disclosure must be made by Investigator(s) prior to submission of the proposal.

(3) In accordance with federal regulations, this policy will be made publicly accessible on the CWR website (https://www.optum.com/business/state-government/public-health/wellbeing-research-center.html).

(4) Prior to the expenditure of funds, CWR will make certain information concerning FCOIs held by Senior/Key Personnel via a publicly accessible website or by a written response to any requestor within five business days of a request. The reportable information includes the following:
- Investigator's name and title,
- investigator's role with respect to the research project,
- name of the entity in which the SFI is held,
- nature of the SFI, and
- approximate dollar value of the SFI.

(5) FCOI reports need to be submitted as of the compliance date and in accordance with the requirements of 42 CFR Part 50 Subpart F. Additional and/or updated reports need to be submitted upon the occurrence of the following events:
- Prior to the expenditure of funds.
- Within 60 days of identification for an Investigator who is newly participating in the project.
- Within 60 days for new, or newly identified, FCOIs for existing Investigators.
- At least annually to provide the status of the FCOI and any changes to the management plan until the completion of the project.

CWR will promptly notify NIH if bias is found with the design, conduct, or reporting of NIH funded research. CWR will also notify NIH promptly if an investigator fails to comply with the Institution's FCOI policy or the management plan appears to have biased the NIH-funded research.

Review Process:
The Director of CWR will designate a senior staff member to conduct an initial review of all financial disclosures made by all Investigators/staff. If the initial determination is made that there may be a potential for conflict of interest covered by this policy, the Director of CWR will review the materials and decide if there is a conflict of interest as defined by this policy.

Guidelines for Determining FCOI:
The designated senior staff member conducting the initial review to determine whether the Investigator's SFI is a FCOI that may reasonably affect the research may consider the following factors:

- Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
- Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
- Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
- Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
- Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
- The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
- Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
- The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
- Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
- Whether other scientific groups are independently pursuing similar questions; or
- Whether sufficient external review of the research conducted, and the reporting of research results exist to mitigate undue bias; or
- Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has an SFI; or
- Whether the project involves a subaward to an entity in which the Investigator has an SFI.

Management Plan:
If it is determined that a conflict of interest exists, then, the Director of CWR or their designee, will request that the Investigator develop, in cooperation with the Director of CWR or their designee, a Management Plan. The Management Plan is for the purpose of proposing appropriate remedies, including, but not limited to:
(1) public disclosure of significant financial interests; or
(2) review of research protocol by independent reviewers; or
(3) monitoring of research by independent reviewers; or
(4) modification of the research plan; or
(5) disqualification from participation in all or a portion of the research funded; or
(6) divestiture of significant financial interests; or
(7) severance of relationships that create actual or potential conflicts of interest.

The Director of CWR shall review and approve the Resolution Plan or require revisions as deemed appropriate. In the process of institutional decision-making, any disclosed Significant Financial Interest, including confidential documentation, may be referred by the Director of CWR to affected RVO Health departments, pertinent advisory committees, the principal investigator on the grant, to the Legal Department, and/or UnitedHealth Group Office of Human Research Affairs (UHG OHRA) staff (CWR's Institutional Review Board [IRB]). Financial Conflict of Interest and the Management Plan will be communicated to any applicable federal granting agencies, such as NIH. Confidential information will not be released by RVO Health to other parties except as required under state laws or federal regulations.

Resolution to conflicts of interest will be incorporated into a Memorandum of Understanding (MOU) between the Investigator(s) and the Institution [signed by the Director of CWR or their designee] prior to expenditure of any award funds. Resolution will include either a reduction or elimination of the SFI. The Director of CWR will moderate this decision and assist with the management process. The Director of CWR may choose a designee to facilitate the process, utilizing RVO Health corporate-level policies for reporting conflicts of interest and having them assessed. To initiate this process, any individuals may contact the RVO Health Compliance Team via the Compliance Email at healthcarecompliance@rvohealth.com. RVO Health Compliance is always available to report a concern regarding a possible violation of law or company policy, including conflicts of interest. CWR's IRB at UHG OHRA may also be consulted in this process.

Required Reporting of Conflict of Interest for DHHS Funded Projects:
Federal regulations require that institutions must notify the National Institutes of Health (NIH) Chief Grants Management officer if there is an identified FCOI for PHS funded projects. Reporting is required prior to any expenditure of funds. The Management Plan, whether the conflict has been reduced or eliminated, must also be reported to that official**.** If there is an FCOI requiring administrative oversight and management, there will be annual report updates for the duration of the research project. FCOI reports must include sufficient information. Including but not limited to the following:

- Project number
- PI
- Investigator with the FCOI
- Name of the entity with which the Investigator has a FCOI
- Type or nature of Financial Interest
- Value of Financial Interest
- Description of how the financial interest relates to the NIH funded research
- Description of the key elements of the management plan, including:
    - Role and principal duties of the conflicted Investigator in the research project
    - Conditions of the management plan
    - How the management plan is designed to safeguard objectivity in the research project
    - Confirmation of the Investigators agreement to the management plan
    - How the management plan will be monitored to ensure Investigator compliance

Conflict of Interest Reported During the Study Period:
If a new reportable FCOI arises at any time during the period from the submission of the proposal through the period of the award, the filing of a disclosure is also required within 30 days of acquiring the SFI. For PHS funded projects, the PHS also requires that disclosure forms be completed for noncompetitive continuation grant applications (renewals). The review and resolution processes will follow the above policies for Review and Resolution and will be completed within 45 days of the filed report. A determination will be made if project expenditures should be suspended before the Resolution Plan is complete. If this is a clinical trial or other human subject research project, the

Human Subjects Review Committee may be notified before a Resolution Plan is adopted, so they may determine if enrollment or other activities shall be suspended, or if any other action needs to be taken.

Policy Enforcement and Sanctions: Remedies for Non-Compliance
Federal regulation requires that institutions include employee sanctions in their policies. Whenever an Investigator has violated this policy or the terms of the Memorandum of Understanding, the Director of CWR or their designee shall recommend sanctions which may include disciplinary action ranging from a letter of reprimand to dismissal and termination of employment. If the violation results in collateral proceeding under Institutional policies regarding misconduct in science, then the Director of CWR or their designee shall defer a decision on sanctions until the misconduct in science process is completed. The Director of CWR or their designee's recommendations on sanctions shall be presented to the Investigator's supervisor who shall enforce any disciplinary action consistent with RVO Health policies. In addition, the Institution shall follow federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with its policy. The sponsor may take its own action, as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

Federal Regulations require the following:

1. Review within 120 days of RVO Health determination of Investigator non-compliance.
2. Determination of other disciplinary action, as necessary.
3. If FCOI is determined but not managed properly by RVO Health, the FCOI must be disclosed in each public presentation of the results of the research and addendums to previously published presentations to which the Investigator contributed.

Investigator Training:
All Investigators will be trained when hired and, training will repeat periodically throughout the Investigator's tenure with the Institution, not less than once every four years. Investigators will complete the Collaborative Institutional Training Initiative (CITI) FCOI module and review this FCOI policy.

Each Investigator must complete training on FCOI and compliance policies prior to engaging in research related to any Federal Granting Agency such as NIH. **Additional training may be necessary in the following circumstances:**

a. Institutional FCOI policies change in a manner that affects Investigator requirements.
b. An Institution finds an Investigator noncompliant with its FCOI Policy or management plan.

Subcontracts:
Investigators at other institutions who subcontract to RVO Health on PHS sponsored projects must certify in the contractual agreement between RVO Health and their institution that their institution is in compliance with FCOI regulations. RVO Health Investigators who subcontract to other institutions must complete an Investigator Significant Financial Interest Disclosure Form in accordance with this policy. This should be completed at the time of the submission, upon subcontract award, and within 30 days of acquiring an SFI.

Other Information:
Records of Investigator financial disclosures and of actions taken to manage significant financial interests shall be retained for a minimum period of three (3) years following termination or completion of the award to which they relate, or until the resolution of any outstanding issues involving those records, whichever is longer.

The Research Program shall submit all original written documentation to the Legal Department for storage; copies will reside with the Research Program as well.

Effective Date:
The policy is effective as of July 13, 2012.
The policy was updated as of February 15, 2022.