

## USWM, LLC FCOI Policy

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**APPLIES TO:** All USWM employees and External Partners involved in the design, conduct or reporting of PHS Funded Research programs for which USWM is the recipient Institution.

**PURPOSE:** Under this policy, USWM (the “Institution”) strives to ensure that all work performed under Government Awards meets the highest standard of integrity and is free of any real or perceived conflicts of interest that could bias the design, conduct or reporting of research. As USWM must comply with government regulations when making expenditures with Government Awards, this policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Government Awards, specifically PHS Funded Research. It is intended to comply with the requirements of federal regulations, including , but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service (“the PHS FCOI Rules”) as found in 42 CFR Part 50 Part F (titled Promoting Objectivity in Research) and 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the “Financial Conflict of Interest Rules”).

### **DEFINITIONS:**

***Compliance Officer:*** The designated Institutional official responsible for managing the conflict of interest process for PHS Funded Research, including solicitation and review of Investigator disclosures of SFIs.

***External Partner:*** Any Investigator, not directly employed by USWM, including individual consultants, subcontractors, or those employed by other Institutions party to PHS Funded Research for which USWM is the award recipient through an agreement with USWM including subrecipients such as consortium members, sub-awardees, vendors, and contractors.

***FCOI Management Plan:*** The document specifying the actions to be taken to manage a Financial Conflict of Interest.

***Financial Conflict of Interest (FCOI):*** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of a PHS research study or other government funded project.

***Institutional Responsibilities:*** An Investigator’s professional responsibilities on behalf of USWM, which may include, but is not limited to: research, research consultation, teaching, professional practice, institutional and committee memberships, and service on panels such as Institutional Review Boards, Data and Safety Monitoring Boards, or advisory boards.

***Investigator:*** The project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

***PHS Funded Research:*** PHS funded grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that USWM receives directly

from government agencies or indirectly from pass through entities. (PHS Funded Research does not include procurement contracts, payments for health care services provided under government health care programs (e.g., Medicare, Medicaid) or Medical Education and Research Costs (MERC)).

**Public Health Service (PHS):** a division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

**Relevant Family Members:** An Investigator's spouse, domestic partner, or dependent children.

**Remuneration:** Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).

**Senior/Key Personnel:** The PD/PI and any other person identified as senior/key personnel by USWM in the grant application, progress report, or any other report submitted to the PHS by USWM.

**Significant Financial Interest (SFI):**

- (1) A financial interest consisting of one or more of the following interests of the Investigator or their Relevant Family Member that reasonably appears related to the Investigator's Institutional Responsibilities: (i) the value of any remuneration received from a public entity in twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000, or when the Investigator or their Relevant Family Member holds any equity interest (e.g., stock, stock option, or other ownership interest); or (ii) the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or their immediate family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or (iii) intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- (2) Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. The disclosure will include, at a minimum, the following details (i) the purpose of the trip, (ii) the identity of the sponsor/organizer, (iii) the destination and the (iv) the trip duration. (This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.)
- (3) A significant financial interest does not include the following:
  - Salary, royalties, or other remuneration paid by USWM to the Investigator if the Investigator is currently employed or otherwise appointed by USWM;
  - Any ownership interest (e.g., stock, stock options) in USWM held by the Investigator;
  - Intellectual property rights assigned to USWM and agreements to share in royalties related to such rights;

- 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;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; and
- Income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- For employees of an External Partner of USWM (e.g., a contract research or manufacturing organization, analytical lab, or other specialty service provider under agreement with USWM to perform specific fee for service activities related to PHS funded research), salary, royalties, equity or other remuneration paid by the External Partner to individual employees named as Investigators for USWM's PHS funded research.

**POLICY:** It is the policy of USWM to comply with the Financial Conflict of Interest Rules ("FCOI Rules") to ensure that the work performed for PHS Funded Research is carried out in a manner that is free from any bias which may result from financial conflicts of interest.

***The following applies to USWM employee Investigators and External Partner Investigators employed at Institutions without FCOI policies involved in PHS Funded Research for which USWM is the recipient.***

The contract between External Partner Investigators and USWM must contain language requiring compliance with USWM's FCOI Policy.

***Disclosure of SFI:*** Investigators must disclose any Significant Financial Interests (SFI) related to the Investigator's institutional responsibilities that meet or exceed the regulatory definition of SFI to USWM. Investigators must complete or update a disclosure survey at least annually during the period of the PHS Funded Research award period and must disclose any new SFI's within thirty days of discovering or acquiring a new SFI. Investigators also must ensure that the disclosure survey is completed or updated no later than the time of application for an initial PHS Funded Research project. If USWM determines that an SFI constitutes a Financial Conflict of Interest ("FCOI"), USWM will establish and monitor an FCOI Management Plan ("FMP") to manage or eliminate the conflict of interest. The USWM Compliance Officer will be the designated official responsible for managing the conflict of interest process for PHS Funded Research. No PHS Funded Research funds may be expended unless the Compliance Officer has determined that no FCOI exists or that any FCOI is manageable in accordance with the terms of an FMP that has been adopted and implemented in accordance with the procedures set forth in this policy.

***Duty to Cooperate:*** If the Compliance Officer requests additional information from an Investigator to assess whether a SFI constitutes a Financial Conflict of Interest, (including but not limited to documents relating to the SFI), the Investigator must cooperate with the request. If a FMP is implemented in connection with a SFI, the Investigator must comply with the FMP. Compliance with the requirements of this policy is a condition of employment with USWM for employed Investigators and a condition of

participating in PHS Funded Research projects as an External Partner. Failure to comply may result in appropriate sanctions.

**Training:** All Investigators will be informed of the Institution's FCOI policy, the Investigator's disclosure responsibilities, and the applicable federal regulations upon becoming an Investigator for USWM. Investigators will be required to complete FCOI training (i) prior to engaging in research related to PHS Funded Research, (ii) when this policy is revised to alter the responsibilities of an Investigator; (iii) at least every four years; and (v) if an Investigator is found to be not in compliance with the policy or management plan.

FCOI training can either be completed using the NIH FCOI tutorial found at: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> or CITI COI training found at: <https://about.citiprogram.org/en/homepage/>.

FCOI training must be documented by submitting a valid certificate from the listed online programs to the USWM Compliance Officer at [compliance@usworldmeds.com](mailto:compliance@usworldmeds.com).

***The following applies to External Partner Investigators employed by Institutions with their own FCOI policies:***

Any individual or organization acting as a consultant, subcontractor, or subrecipient ("External Partner") to USWM on a PHS-funded award must either: (1) have a FCOI policy that meets the requirements of the PHS FCOI Rules or (2) follow USWM's FCOI policy. External Partners with their own policy will certify that (i) their policy meets the requirements of the PHS FCOI Rules and (ii) that the External Partner Investigator is compliant with the Institution's FCOI policy in response to a written request from the USWM Compliance Officer prior to their inclusion as an Investigator in any application for PHS Funded Research. Upon a PHS Funded Research award and prior to the performance of any services related to PHS Funded Research, the External Partner Investigator's contract with USWM will be executed with language requiring compliance with the External Partner Institution's FCOI Policy, including, without limitation, timely reporting of FCOI in order for USWM to meet its FCOI reporting obligations to the PHS awarding entity, and the requirement of the Institution to cooperate with USWM to develop or oversee an FMP when determined necessary.

**PUBLIC POSTING OF POLICY and FCOIs:** This policy will be posted on a publicly accessible website for USWM. Information concerning identified FCOIs held by Senior/Key personnel will be made publicly accessible. The publicly accessible information will be updated at least annually, within 60 days of a newly identified FCOI, and will remain available for three years from the date the information was most recently updated.

**REPORTING OF FCOI:** Before the expenditure of any funds under a PHS-funded project and within sixty days of subsequently identifying a Financial Conflict of Interest, the Compliance Officer will report all Financial Conflicts of Interest that have not been eliminated to the PHS awarding component and will ensure that an appropriate FMP has been implemented. The report will include the elements required under the PHS FCOI Rules. For subsequently identified FCOI's, the Compliance Officer will conduct a retrospective review to determine whether the PHS funded project was affected by the financial conflict of interest, and if bias is found, will submit a mitigation report to the PHS awarding component. The

Compliance Officer also will provide an annual FCOI report that addresses the status of any previously reported FCOIs and FMPs related to an ongoing PHS-funded project.

**PROCEDURE:**

1. Before the application for any PHS Funded Research, Investigators must have on file with USWM 1) a valid FCOI training certificate with USWM or written confirmation that the Investigator's Institution has an FCOI policy which complies with the FCOI Rules and 2) a disclosure of Significant Financial Interests.
2. Prior to the expenditure of funds for any PHS Funded Research, all Investigators will be informed of the requirement to comply with this policy. USWM employee and External Partner Investigators without their own Institutional FCOI policy will be required to submit all SFIs to the Compliance Officer. Prior to the expenditure of funds to subrecipient Investigators or contracted Institutions with their own FCOI policies, they will be required to disclose FCOI to the Compliance Officer or otherwise verify that there are no FCOIs.
3. Prior to expenditure of funds for the PHS Funded Research, the Compliance Officer will (i) review all Investigator SFI disclosures; (ii) collect additional information from the disclosing individual and/or from other individuals who possess relevant information, if necessary, to understand the nature of the SFI, (iii) determine whether the SFI are related to the individual's research responsibilities at USWM and therefore represent FCOI requiring an FMP. In conducting this review, the Compliance Officer may consider factors such as the value of the SFI, if the SFI could be affected by the PHS-funded research, is an entity whose financial interest could be affected by the PHS-funded research, and/or how the SFI could affect the Investigator's ability to objectively contribute to PHS Funded Research.
4. If the Compliance Officer determines that an FCOI exists, the Compliance Officer will:
  - i. prepare the Public Financial Conflict of Interest Disclosure Form, including the following information, for reported FCOIs such that it can be made publicly available upon request:
    1. Project/Contract number
    2. Investigator's name
    3. Investigator's title and role with respect to the research project
    4. Name of the entity in which the relevant SFI is held
    5. Nature of the relevant SFI (e.g., equity, consulting fees, travel, reimbursement, honoraria, etc.)
    6. Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.); and
  - ii. develop a FMP to include: role and principal duties of the Investigator with the FCOI; how the FCOI Management Plan is designed to safeguard objectivity in the PHS research project; confirm that Investigator agrees with the FCOI Management Plan; and how the FCOI Management Plan will be monitored. The conditions imposed to safeguard objectivity of the PHS research project will be determined on a case-by-case basis but may include disclosure of the FCOI, appointment of an independent monitor, and/or modification of the research plan.

When an Investigator is new to participating in the PHS Funded Research, the above will be completed within 60 days.

5. The Compliance Officer will request updated SFI or FCOI disclosures from all Investigators and Subrecipient Institutions, respectively, on an annual basis during the relevant funding period for a PHS Funded Research project. In addition, Investigators are responsible for reporting any new SFIs for themselves and Relevant Family Members, including any sponsored travel (for the Investigator only), within 30 days of acquiring the new SFI or the dates of such travel. In the event of sponsored travel, the Investigator must disclose the purpose of the trip; the name of the entity that paid for the travel; the travel destination; the duration of the trip; the dates of the travel; and if known, the approximate value of the travel.
6. The Compliance Officer will review SFI disclosures annually and within 30 days of each new report of SFI. If the Compliance Officer determines a FCOI exists, the steps outlined in item 3 are required.
7. Each Investigator under an FMP must comply fully and promptly with the FMP, and each person identified in the FMP as having responsibility for monitoring compliance with the FMP must carefully and fully monitor that compliance.
8. The Institution will disclose the FCOI and FMP to the PHS awarding entity (i) before the expenditure of any federal funds; (ii) within 60 days of identification of an Investigator who is newly participating in the project; (iii) within 60 days for new, or newly identified, FCOIs for existing Investigators; (iv) at least annually; and (v) after a retrospective review to update a previously submitted report if new information is discovered following completion of the review.
9. USWM will promptly notify the PHS awarding entity if:
  - i. Bias is found with the design, conduct, or reporting of the PHS Funded Research, including a Mitigation Report to explain what actions have been or will be taken to mitigate the effects of bias in accordance the regulation. The report will include the Institution name, name of investigator with the FCOI, nature of the SFI(s), and value of the SFI(s).
  - ii. An Investigator fails to comply with the Institution's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS Funded Research. Corrective action will be undertaken by USWM for cases of such noncompliance.
10. USWM will make FCOI information available to those who submit a request by sending an email to [compliance@usworldmeds.com](mailto:compliance@usworldmeds.com). Responses will be sent within five business days.
11. The Institution will submit FCOI reports annually to the PHS awarding entity during any PHS Funded Research award period as required by the PHS awarding entity. Newly identified unmitigated FCOI will be reported to the PHS awarding entity within 60 days.
12. USWM will keep records related to FCOI and the related FMP for the longer of at least three years after:
  - i. the date of creation;
  - ii. the date of termination or completion of the Government Award and submission of the final expenditure report for the Government Award identified in the disclosure statement; or
  - iii. the date of final resolution of any investigation, audit, or similar action involving the records.

**FAILURE TO COMPLY:** Failure to comply with USWM's FCOI policy includes failing to submit a required disclosure, providing false information, omitting required information, failing to maintain confidentiality, failure to carry out duties prescribed by these policies, and refusal or failure to comply with an FMP adopted under these policies. A failure to comply with these policies may result in a decision by the

Compliance Officer to employ any or all of the following disciplinary actions: (1) require retraining on FCOI policies (2) suspend, all or in part, the Investigator's activities related to PHS Funded Research, (3) require permanent replacement of the non-compliant Investigator's responsibilities for the PHS Funded Research, (4) suspend eligibility of the individual to be included as an Investigator for future USWM PHS Funded Research initiatives, and/or termination of employment. NOTE: In addition, USWM will comply with federal financial conflict of interest requirements regarding non-compliance retrospective review and corrective actions).

If the Institution determines that noncompliance has occurred due to (i) failure of the Investigator to disclose an SFI that is determined to constitute an FCOI; (ii) failure of the Institution to review of manage such an FCOI; or (iii) failure of the Investigator to comply with the financial conflict of interest management plan, the Institution will complete a retrospective review within 120 days of the determination of noncompliance. The retrospective review will document at minimum the following: project number, project title, PD/PI or contact PD/PI, name of Investigator with the FCOI, name of the entity with which the Investigator has an FCOI, reason(s) for the retrospective review, methodology of the retrospective review, findings of the review, and conclusions of the review.

If the Department of Health and Human Services determines that an Institution's PHS-funded research project involving clinical research intended to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was *not* managed or reported by the Institution as required by the regulations, the Institution shall require the Investigator involved to 1) disclose the FCOI in each public presentation of the results and 2) request an addendum to any previously published presentations.

**CONTACT:**

USWM Compliance Officer

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