



OneFifteen Recovery

Financial Conflict of Interest (FCOI) Policy

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Author: Larry Pliskin, Nick Mills

Contact: Nick Mills (nmills@onefifteen.org)

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SCOPE:

Company Wide. This Financial Conflict of Interest policy (Policy) of OneFifteen Recovery (“OneFifteen”) covers all projects conducted with government funds granted to OneFifteen and is applicable to all employees, subrecipients, consultants, and any other covered organizations or persons involved in governmental awards.

PURPOSE:

Under this Policy, OneFifteen 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 harm patients, the reputation of OneFifteen, the government agency providing the funding, and/or external partners. As OneFifteen 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 Governmental Awards. 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).

GENERAL:

No research, sponsored program, or technology transfer activities occurring at OneFifteen shall be adversely affected by the financial interests of OneFifteen personnel carrying out those activities. **Prior to participating in research, a sponsored program, or any technology transfer activity, OneFifteen personnel having a potential conflict of interest shall disclose the details to OneFifteen.** An official designated by OneFifteen shall be responsible for reviewing such disclosures and instituting an adequate plan to manage any potential financial conflicts of interest. The current official for this purpose is the OneFifteen Chief Compliance Officer. Guidelines consistent with the regulations have been provided to the OneFifteen Chief Compliance Officer to determine whether an Investigator’s SFI (defined below) is related to the PHS-funded research and, if so related, whether the SFI is an FCOI. The ultimate goal of this Policy is to protect the integrity and credibility of activities related to research and technology transfer and to maintain public trust and confidence in OneFifteen and its employees.

DEFINITIONS:

For purposes of this Policy, the following definitions shall apply:

Conflict Management Plan (“CMP”): the document specifying the actions to be taken to manage a Financial Conflict of Interest.

External Partner: a consultant, subcontractor, or subrecipient performing work under a Government Award who is not employed by OneFifteen.

Government Award: government 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 OneFifteen receives directly from government agencies or indirectly from pass-through entities. Government Awards do not include procurement contracts, payments for health care services provided under government healthcare programs (e.g., Medicare, Medicaid), or Medical Education and Research Costs (MERC)).

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

Immediate Family Member: a spouse, domestic partner, child or step-child, parent or step-parent, sibling or step-sibling.

Investigator:

(1) For PHS-funded research: 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.

(2) For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.

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



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).

Research: a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.

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

Significant Financial Interest (SFI):

(1) 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 appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 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. 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;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) 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 also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that 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 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. Details of this disclosure shall include, at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this Policy, the CCO will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does **not** include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 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; or income from service on advisory committees or review panels for a Federal, state, or local government agency, 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.

POLICY:

It is the policy of OneFifteen to comply with the Financial Conflict of Interest Rules ("FCOI Rules") to ensure that the work performed under Government Awards is carried out in a manner that is free from any bias which may result from financial conflicts of interest. **All Investigators for Government Awards must disclose any Significant Financial Interests (SFI) to OneFifteen.** Investigators must disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's responsibilities for OneFifteen no later than:

1. at the time of application for PHS-funded research;
2. at least annually during the period of award;
3. and within 30 days of discovering or acquiring a new SFI.

The OneFifteen designated official shall, prior to OneFifteen's expenditure of funds: review all Investigator SFI disclosures; determine if any SFIs related to PHS-funded research; determine if an FCOI exists; and develop and implement management plans, as needed to manage FCOIs. The foregoing includes:

1. when there is an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI;



2. within 60 days whenever OneFifteen identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by OneFifteen; and
3. when it involves a subrecipient Investigator, including monitoring Investigator compliance with management plans until completion of the project.

If OneFifteen determines that an SFI constitutes a Financial Conflict of Interest (“FCOI”), OneFifteen will establish and monitor a Conflict Management Plan (“CMP”) to manage or eliminate the conflict of interest. The OneFifteen Chief Compliance Officer (“CCO”) will be the conflict of interest official responsible for managing the conflict of interest process for Government Awards. No Government Award funds may be expended unless the CCO has determined that no FCOI exists or that any FCOI is manageable in accordance with the terms of a CMP that has been adopted and implemented in accordance with the procedures set forth in this Policy.

Duty to Cooperate:

If the CCO requests additional information from an Investigator to assess whether an 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 CMP is implemented in connection with an SFI, the Investigator must comply with the CMP. Compliance with the requirements of this Policy is a condition of employment with OneFifteen for employed Investigators and a condition of participating in Government Award projects as an External Partner. Failure to comply may result in appropriate sanctions.

Education:

Investigators must complete training regarding this policy and the applicable regulations at the following times: (i) upon becoming an Investigator for OneFifteen; (ii) before performing work under a Government Award; (iii) when this policy is revised to alter the responsibilities of an Investigator; (iv) and at least every four years.

Informing Investigators and Public Posting of Policy:

Each Investigator shall be informed of OneFifteen’s FCOI policy, of the Investigator’s disclosure responsibilities under the OneFifteen FCOI policy, and of the Federal applicable regulations, including 42 CFR Part 50, subpart F. This Policy will be posted on OneFifteen’s public Website.

Information concerning identified FCOIs held by senior/key personnel (as defined by 42 CFR 50.605(a)(5)(i)-(iv)), shall be publicly accessible prior to the expenditure of funds. The information will:

- Include the minimum elements as provided in the regulation;
- Be posted on a Public Website or made available within 5 calendar days of a written request;



- Be updated, at least annually (Website only, but any response to a written request should include the updated information);
- Be updated, within 60 days of a newly identified FCOI (Website only, but any response to a written request should include the updated information); and
- Remain available for three years from the date the information was most recently updated.

Reporting of Financial Conflicts of Interest for PHS-Funded Projects:

The CCO shall send initial, annual, and revised FCOI reports, including all reporting elements required, to the NIH for OneFifteen and its subrecipients (if any), as follows:

- before the expenditure of any funds under a PHS-funded project;
- within sixty days of identification for an Investigator who is newly participating in the project;
- within sixty days for new, or newly identified, FCOIs for existing Investigators
- at least annually (at the same time as when OneFifteen is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- Following a retrospective review to update a previously submitted report, if appropriate.

The CCO shall notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation (42 CFR 50.605(a)(3)(iii)).

The CCO shall notify NIH promptly if an Investigator fails to comply with the OneFifteen FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research and take corrective action for noncompliance with the OneFifteen FCOI policy or the management plan.

If the CCO subsequently identifies a Financial Conflict of Interest, the CCO will report all Financial Conflicts of Interest that have not been eliminated to the PHS-awarding component and will ensure that an appropriate Conflict Management Plan has been implemented. The report will include the elements required under the PHS FCOI Rules. For subsequently identified FCOI's, the CCO 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 CCO also will provide an annual FCOI report that addresses the status of any previously reported FCOI's and CMP's related to an ongoing PHS-funded project.



External Partners:

Any individual or organization acting as a consultant, subcontractor, or subrecipient (“External Partner”) to OneFifteen on a PHS-funded award must either: (1) have a FCOI policy that meets the requirements of the PHS FCOI Rules or (2) follow this policy.

Organizations with their own FCOI policy will certify that the policy meets the requirements of the PHS FCOI Rules by submitting an External Partner Financial Conflict of Interest Disclosure form or registering with the Federal Demonstration Partnership (FDP) Clearinghouse ([FDP link](#)) before submission of the Government Award. The CCO will verify registration with the FDP Clearinghouse before submission. The contract with OneFifteen will contain language requiring compliance with the organization’s FCOI Policy.

Individuals and organizations without their own FCOI policy are required to follow this Policy. The contract with OneFifteen will contain language requiring compliance with OneFifteen’s FCOI Policy.

Subrecipient Requirements

Where applicable, establish, via a written agreement, whether the subrecipient will follow the OneFifteen FCOI Policy or the FCOI policy of the subrecipient.

- If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
- If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows OneFifteen to report identified FCOIs to the NIH as required by the regulation.
- Alternatively, if applicable, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable OneFifteen to identify, manage and report identified FCOIs to the NIH.

Procedure:

This procedure is for use by OneFifteen employees and External Partners that do not have their own FCOI policy.

1. Before the expenditure of funds under a Government Award, Investigators must complete the training on OneFifteen’s Government Awards FCOI Policy. All external investigators must complete FCOI training required under the policy. Training can be completed using the NIH FCOI tutorial found at: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.
2. Training must be documented by submitting the Government Award FCOI Training Certification



form to the OneFifteen CCO. The required training is valid for four years; however, Investigators are required to certify annually that they understand and have complied with their responsibilities under OneFifteen's Government Awards FCOI Policy.

3. After the training is completed, the Investigator will complete the Government Award FCOI Questionnaire. This survey must be completed no later than the time of application for a Government Award and before any funds are expended. It also must be updated as required by this Policy.
4. The principal investigator/project director will complete the Government Award Approval form, which requires verification that those meeting the definition of Investigator and External Partners have been informed of the requirement to comply with this Policy.
5. The Investigator must report and update their Government Award FCOI Questionnaire when he/she is a recipient of sponsored travel. The Investigator will 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 relevant travel.
6. If the CCO determines a FCOI exists, he/she will create a draft CMP. The draft CMP will be presented to the Research Compliance Oversight Committee (RCOC) for consideration and approval. The RCOC will act as the Conflict of Interest Committee for purposes of Government Awards.
7. The actions taken by the RCOC will be documented in the RCOC meeting minutes. The CCO will ensure that CMP's are properly implemented and will monitor compliance with CMP's on an ongoing basis. The RCOC will review the status of established CMP's at intervals determined by the RCOC and indicated in the CMP, and will have oversight responsibility for the enforcement of CMPs and compliance with this policy.
8. Each Investigator under a CMP must comply fully and promptly with the CMP, and each person identified in the CMP as having responsibility for monitoring compliance with the CMP must carefully and fully monitor that compliance.
9. For PHS-funded projects, OneFifteen will disclose the FCOI and CMP to the PHS-awarding component before the expenditure of any federal funds.
10. For PHS-funded projects, OneFifteen will make FCOI information available to those who submit a request by sending an email to lpiskin@OneFifteen.org or by writing to OneFifteen at the address below. Responses will be sent within five business days.
11. OneFifteen will maintain records related to FCOI and the related CMP for the longer of at least three years after:
 - a. For at least 3 years from the date the final expenditures report is submitted to the PHS (NIH);
 - b. Other dates specified in 45 CFR 75.361, where applicable; or
 - c. the date required to be in compliance with OneFifteen's Record Retention policies.



12. RCOC will regularly evaluate compliance with this Policy and will review the effectiveness of OneFifteen's conflict of interest management program, including a review of the implementation and effectiveness of these procedures.
13. As part of OneFifteen's Corporate Compliance Program, it has established adequate enforcement mechanisms and under such program, provides for employee sanctions or other administrative actions to ensure Investigator compliance.
14. This Policy requires the CCO to complete and document retrospective reviews within 120 days of OneFifteen's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the applicable federal regulation.
15. To ensure that in any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is 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 OneFifteen, as required by the regulation, OneFifteen shall require the Investigator involved to:
 - a. Disclose the FCOI in each public presentation of the results of the research, and
 - b. To request an addendum to previously published presentations.

OneFifteen's Procedure for External Partners with their own PHS Rule policy:

1. The principal investigator/project director will complete the Government Award Approval form, which requires them to inform any External Partner if they need to comply with FCOI Rules.
2. Prior to any application submitted by OneFifteen for a Government Award, OneFifteen must receive confirmation the External Partner has a FCOI policy that meets the PHS FCOI Rules.
3. The External Partner shall submit the External Partner Financial Conflict of Interest Disclosure to OneFifteen to verify they have a FCOI.

Contact information:

Nick Mills, Chief Financial Officer
OneFifteen
6636 Longshore Street, Suite 200
Dublin, Ohio 43017
Phone: (216) 212-1267
Email: nmills@OneFifteen.org