

Spring River Mental Health & Wellness, Inc.		Policies and Procedures	
Policy Name:	Financial Conflict of Interest Policy		
Policy Type:	Fiscal		
Department Responsible:	Business Administration		
Purpose:	To understand 42 CFR 50.603 and prevent financial conflicts within the organization.		

Definitions (42 CFR 50.603)

- FCOI – financial conflict of interest is when it can be reasonably determined that the financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- SFI – significant financial interest means 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. These may include:
 - *Publicly Traded Entity* – SFI exists if the value of any remuneration (salary and any payment for services not otherwise identified as salary) from the entity in the 12 months preceding the disclosure and the value of any equity interest (stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
 - *Non-Publicly Traded Entity* – SFI exists if the value of any remuneration received from the entity in the 12 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 (stock, stock option, or other ownership interest).
 - *Intellectual Property Rights and Interest* – including patents and copyrights, upon receipt of income related to such rights and interest.

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:

Spring River Mental Health & Wellness, Inc. (SRMHW) will maintain an up-to-date, written, enforced policy of financial conflicts of interest in compliance with 42 CFR 50.604 and make such policy available on its website. SRMHW will provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with the organization's standards within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new significant financial interest (42 CFR 50.604(3)(3)).

When an SRMHW investigator participates in sponsored or reimbursed travel for another organization, the Investigator will disclose such travel to the designated SRMHW official to determine if the sponsored travel constitutes a FCOI with the PHS-funded research (42 CFR 50.603).

Any Director, as a member of a committee or member of the Board, may **not** vote on a grantmaking or grant administrative issue affecting an organization disclosed on the disclosure form or disclosable if the disclosure form were then updated. The Committee or Board shall be informed, by the Executive Director, of the conflict before the discussion of the issue begins. A Director subject to this paragraph shall be entitled to listen to the general staff presentation of the grant or administrative issue to the Committee or Board and to provide any additional or corrective factual information deemed relevant by that Director. Following presentation of that factual information, the Director will be generally excused from the meeting room during further discussion and final action, although the Board may request the Director to remain for the discussion when the Board determines that would be helpful.

Training Requirements

SRMHW's authorized official will inform each investigator of the organization's policy on financial conflict of interest, the investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations during annual reviews. Each investigator will complete FCOI training prior to engaging in research related to any PHS-funded grant, at least every four years thereafter, and immediately if/when any of the following circumstances apply (42 CFR 50.604(b)(1)-(3):

- SRMHW revises its FCOI policies or procedures in any manner that affects the requirements of investigators;
- A new investigator is hired by SRMHW or

- SRMHW’s Board of Directors find that an investigator is not in compliance with the organization’s FCOI policy or management plan.

Investigators will complete the online training module, print a certificate of completion, and complete the FCOI disclosure form to the executive director. The executive director will submit FCOI training certifications and disclosures to the Board of Directors.

FCOI training will be completed annually, as part of the investigator’s annual review, or more frequently, as required.

Online Training module:

https://grants.nih.gov/grants/policy/foi/tutorial2018/story_html5.html

Conflicts of interest will be reported on the attached Conflict of Interest Disclosure Form.

SRMHW will adhere to the guidelines for submitting FCOI reports to NIH listed in Table 1 below.

Table 1 REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	CONTENT	REQUIRED WHEN?
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.

Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.
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(42.CFR 50.604(h); 42 CFR 50.604(b))

If SRMHW carries out the PHS-funded research through a subrecipient (e.g. subcontractors or consortium members), SRMHW will take reasonable steps to ensure that any subrecipient investigator complies with this policy by (42 CFR 50.604(c):

- Incorporating as part of the written agreement with the subrecipient terms that establish whether SRMHW’s financial conflicts of interest policy or the subrecipient’s FCOI policy will apply to the subrecipient’s investigators;
 - If the subrecipient’s investigators must comply with the subrecipient’s FCOI policy, the subrecipient will certify as part of the agreement that its FCOI is in compliance with 42 CFR 50.604. If a subrecipient cannot provide such certification, the agreement will state that the subrecipient’s investigators are subject to SRMHW’s FCOI policy; and
 - If the subrecipient’s investigators must apply with SRMHW’s FCOI policy, the agreement will indicate that the subrecipient will report all identified financial conflicts of interest to SRMHW within 15 days of signing contractual agreements and prior to the expenditure of any funds.

Disclosure, Review, and Monitoring

FCOI training compliance and disclosures will be reviewed by SRMHW’s executive director for all supervisees. The Board of Directors will review the FCOI training compliance and disclosures for the executive director and corporate finance director (42 CFR 50.604(d)).

Each investigator planning to participate in the PHS-funded research will disclose to SRMHW’s designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research (42 CFR 50.604(e)(1)).

Each SRMHW investigator will submit an updated disclosure of significant financial interests at least annually, in conjunction with their annual review. The disclosure will include any information not previously disclosed and will include the updated value of previously disclosed significant financial interest (42 CFR 50.604(3)(2)).

Sponsored travel other than for the PHS-funded research will be disclosed and will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. A disclosure of the monetary value of the trip may be also be required (42 CFR 50.603).

In the event a financial conflict of interest is determined, a FCOI management plan will be developed within 60 days between the investigator, the executive director, and the Board of Directors, as appropriate. FCOI management plans will be reported as outlined in Table 1. Disclosed FCOIs will be monitored throughout the duration of the PHS-funded research.

Reporting to NIH

SRMHW will provide relevant FCOI reports to NIH based on the guidelines in Table 1.

Whenever SRMHW identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by SRMHW during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so (42 CFR 50.605(a)(3)(iii)):

- Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
- In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by SRMHW to constitute a financial conflict of interest; failure by SRMHW to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, SRMHW shall, within 120 days of SRMHW's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

If the failure of an Investigator to comply with SRMHW's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, SRMHW shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to SRMHW for further action, which may include directions to SRMHW on how to maintain appropriate objectivity in the PHS-funded research project.

PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator (42 CFR 506(a)).

Maintenance of Records

SRMHW will maintain all FCOI records for a minimum of three (3) years from the date the final expenditures report is submitted to NIH (42 CFR 50.604(i)).

Enforcement Mechanisms, Remedies, and Noncompliance

Investigators found to be in noncompliance with SRMHW's FCOI policy and/or any reasonable FCOI management plans will be sanctioned per the employee handbook (42 CFR 50.604(j)).

Retrospective reviews will be completed within 120 days of SRMHW's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever a FCOI is not identified or managed in a timely manner (42 CFR 50.605(a)(3)).

Subrecipient Requirements

SRMHW will incorporate as part of the written agreement with the subrecipient terms that establish whether SRMHW's financial conflicts of interest policy or the subrecipient's FCOI policy will apply to the subrecipient's investigators (42 CFR 50.604(c)):

- If the subrecipient's investigators must comply with the subrecipient's FCOI policy, the subrecipient will certify as part of the agreement that its FCOI is in compliance with 42 CFR 50.604. If a subrecipient cannot provide such certification, the agreement will state that the subrecipient's investigators are subject to SRMHW's FCOI policy; and
- If the subrecipient's investigators must apply with SRMHW's FCOI policy, the agreement will indicate that the subrecipient will report all identified financial conflicts of interest to SRMHW within 15 days of signing contractual agreements and prior to the expenditure of any funds.

Public Accessibility Requirements

SRMHW will make its FCOI publicly accessible on its website (42 CFR 50.604(a)). Prior to expenditure of grant funds, SRMHW will make any identified FCOIs held by senior/key personnel publicly accessible. The information will (42 CFR 50.605(a)(5)(i)-(iv)):

- Include minimum elements described in 42 CFR 50.605;
- Be posted on SRMHW's website or made available within 5 calendar days of a written request;
- Be updated, at least annually;
- Be updated within 60 days of a newly identified FCOI;

- Remain available for three years from the date the information was most recently updated.