


CHAPTER Administrative	CHAPTER 01	SECTION 002	SUBJECT 95
SECTION Operations		DESCRIPTION Financial Conflict of Interest in Public Health Services Funded Research	
WRITTEN BY Lisa Ruddy, BS, CHES Quality Improvement Coordinator	REVISED BY		AUTHORIZED BY  Lauren Emmons, ACSW CEO

APPLICATION:

<input checked="" type="checkbox"/> CMH Staff	<input type="checkbox"/> Board Members	<input checked="" type="checkbox"/> Provider Network	<input checked="" type="checkbox"/> Employment Services Providers
<input type="checkbox"/> Employment Services Provider Agencies	<input checked="" type="checkbox"/> Independent Contractors	<input type="checkbox"/> Students	<input type="checkbox"/> Interns
<input type="checkbox"/> Volunteers	<input type="checkbox"/> Persons Served		

POLICY:

Lapeer County Community Mental Health (LCCMH) promotes objectivity by ensuring the design, conduct and reporting of funded research is free from bias resulting from financial conflicts of interest.

STANDARDS:

- A. This policy applies to Investigators and subrecipient Investigators participating in, or planning to participate in, the design, conduct, reporting or proposing Public Health Services (PHS) funded research according to 42 CFR Subpart F.
- B. Each investigator is provided with a copy of this LCCMH Financial Conflict of Interest Policy.
- C. Each Investigator (individuals responsible for the design, conduct or reporting of the research, including but not limited to the Project Director, Project Evaluator, and consultants) must disclose all significant financial interests (SFIs) relevant to the research responsibilities.

CHAPTER Administrative	CHAPTER 01	SECTION 002	SUBJECT 95
SECTION Operations		DESCRIPTION Financial Conflict of Interest in Public Health Services Funded Research	

- D. LCCMH reviews all Investigator SFI disclosures, determines if the SFI relates to PHS-funded research, and if a financial conflict of interest (FCOI) exists.
- E. LCCMH develops and monitors management plans to manage FCOIs.
- F. LCCMH complies with the FCOI reporting requirements of the PHS.
- G. LCCMH makes all FCOIs publically available on the LCCMH website or through a written request.

PROCEDURES:

- A. Each Investigator completes FCOI training:
 - 1. Prior to engaging in research related to any PHS-funded grant
 - 2. At least every four years
 - 3. Immediately if LCCMH reviews the FCOI policy affecting the requirements of Investigators, an Investigator is new to the agency, or the Investigator is not in compliance with the policy or management plan
- B. Disclosure, Review and Monitoring Requirements
 - 1. Each Investigator will disclose SFIs (and those of their spouse and dependent children) related to their agency responsibilities using LCCMH Financial Conflict of Interest Attestation Form #396.
 - a. No later than at the time of application for PHS-funded research
 - b. At least annually during the period of award
 - c. Within 30 days of discovering or acquiring a new SFI
 - 2. LCCMH CEO and Corporate Compliance Officer review all SFI disclosures, determines if any FCOIs exist, and develops a plan to manage FCOIs when:
 - a. An Investigator discloses a new SFI
 - b. LCCMH identifies a SFI that was not disclosed timely by an Investigator or not previously reviewed by LCCMH

CHAPTER Administrative	CHAPTER 01	SECTION 002	SUBJECT 95
SECTION Operations		DESCRIPTION Financial Conflict of Interest in Public Health Services Funded Research	

3. LCCMH Corporate Compliance monitors Investigator compliance with management plans and reports findings to the CEO.

C. Reporting Requirements

1. LCCMH submits the agency's and subrecipients' FCOI reports to the PHS as required:
 - a. Prior to the expenditure of funds
 - b. At least annually
 - c. Within 60 days of a new Investigator starting on the project
 - d. Within 60 days of a new or newly identified FCOI for a current Investigator
 - e. Following a retrospective review to update a previously submitted report, if needed
2. LCCMH will notify the PHS and submit a Mitigation report if bias is found with the design, conduct or reporting of PHS-funded research.
3. LCCMH will notify the PHS promptly and take corrective action if an Investigator does not comply with LCCMH's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.

D. LCCMH will maintain FCOI-related records in accordance with 45 CFR 75.361 and at least three years after the date of the final expenditures report is submitted to the PHS.

E. Investigators who do not comply with this policy will be subject to disciplinary action, up to and including termination.

F. LCCMH will complete a retrospective review within 120 days of determination of noncompliance for:

1. SFIs not disclosed timely or not previously reviewed
2. Whenever a FCOI is not identified or managed in a timely manner and to document reviews consistent with the regulation

CHAPTER Administrative	CHAPTER 01	SECTION 002	SUBJECT 95
SECTION Operations		DESCRIPTION Financial Conflict of Interest in Public Health Services Funded Research	

- G. If the Department of Health and Human Services determines a PHS-funded research project has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by LCCMH as required, LCCMH will require the Investigator to:
1. Disclose the FCOI in each public presentation of the results of the research
 2. Request an addendum to previously published presentations
- H. LCCMH requires a written agreement with all subrecipients which establishes whether the subrecipient will follow LCCMH FCOI policy or the FCOI policy of the subrecipient.
1. LCCMH obtains a copy of the subrecipient FCOI policy to ensure compliance with the regulation, if applicable.
 2. Subrecipients will report identified FCOIs to LCCMH:
 - a. Prior to the expenditure of funds
 - b. At least annually
 - c. Within 30 days of a new Investigator starting on the project
 - d. Within 30 days of a new or newly identified FCOI for a current Investigator
 3. Subrecipients who do not have their own FCOI policy will follow the LCCMH FCOI policy. LCCMH will review subrecipient Investigator disclosures and identify, manage, and report FCOIs to the PHS. Failure of subrecipient to comply with LCCMH FCOI policy may result in contract termination.
- I. Identified FCOIs of senior / key personnel are publically accessible prior to the expenditure of funds on the LCCMH website. This information:
1. Is available within five days of a written request
 2. Is updated at least annually on the website (responses to written requests will include the most up-to-date information)

CHAPTER Administrative	CHAPTER 01	SECTION 002	SUBJECT 95
SECTION Operations		DESCRIPTION Financial Conflict of Interest in Public Health Services Funded Research	

3. Is updated within 60 days of a newly identified FCOI on the website (responses to written requests will include the most up-to-date information)
4. Will remain available for three years from the date the information was most recently updated

DEFINITIONS:

Financial Interest: anything of monetary value or potential monetary value held by the Investigator, their spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI): a Significant Financial Interest (SFI) related to a research program or project which could directly and significantly affect the design, conduct or reporting of research.

Significant Financial Interest (SFI): a financial interest consisting of one or more of the following interests of the Investigator, their spouse and/or dependent children that reasonable appears to be related to the Investigator's institutional responsibilities:

1. 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 the 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 interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
2. Regarding 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 (and/or the
3. Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
4. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

CHAPTER Administrative	CHAPTER 01	SECTION 002	SUBJECT 95
SECTION Operations		DESCRIPTION Financial Conflict of Interest in Public Health Services Funded Research	

Investigator: a Program Director (PD) or Principal Investigator (PI) and any other person who is responsible for the design, conduct or reporting of PHS-funded research, or proposed for such funding. This may include collaborators or consultants.

Subrecipient: LCCMH subcontractors, sub-grantees or sub-awardees at other institutions for PHS-funded research.

REFERENCE:

42 Code of Federal Regulations Part 50, subpart F (42 CFR 50.603, 604 b-i, 605)

LR