Oklahoma State University Conflict of Interest Committee		
Handling Noncompliance with COI Policies/Procedures	COI COP 100-113	COI- 01
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1. Introduction

The Oklahoma State University (OSU) Conflict of Interest Committee (COIC) works to ensure that all research and instructional activities involving the COI disclosures and federally required trainings are in compliance with all federal regulations, state laws, and guidelines, as well as applicable University policies. Reports of noncompliance will be directed to the appropriate COI staff and to the Conflict-of-Interest Committee for investigation and corrective action. Complaints regarding the COI process or the disclosure of information may or may not involve noncompliance with COI policies or federal regulations and will be handled as potential incidents involving nondisclosures or management plans. This document outlines the procedures that will be used for reporting and investigating any noncompliance with pertinent federal regulations, laws, guidelines, OSU policies and procedures.

2. Definitions

2.1 Noncompliance is defined as conducting research in a manner that is not compliant with federal regulations, state laws, guidelines, OSU COI policies and procedures or the decisions of the OSU COIC. Noncompliance can range from inadvertent errors, inattention to detail, inadequate training and supervision of research staff, to more serious violations that pose a risk to both the Investigator and the University.

2.2 Minor noncompliance represents isolated incidents such as (but not limited to) unintentional mistakes, oversights, or misunderstandings.

2.3 Major noncompliance is a pattern of intentional, willful noncompliance with applicable federal regulations, state laws, and/or guidelines. These include but are not limited to failure to abide by Conflict-of-Interest disclosure requirements, Conflict-of Interest management plans requirements, and any requirements that a reasonable Investigator would have foreseen as increasing the potential for bias or perceived bias in research, or, otherwise compromising the integrity of research at OSU. Information which can be used to evaluate the seriousness of noncompliance includes, but is not limited to:

a) A history of noncompliance by the same researcher(s).
b) A failure to disclose information relating to financial or business interest which were clearly requested in a grant/contract application or award.
c) Signature(s) on Conflict-of-Interest Disclosure forms relating to disclosure of significant financial or business interests.
d) Changes in relationships with companies or research personnel that are inconsistent with the original research plan.
e) Communications with the researcher(s) during the course of investigating the noncompliance.

2.4 Continuing noncompliance is defined as a pattern of repeated actions or omissions taken by an investigator or research personnel that indicates a lack of ability or willingness to comply with

federal regulations, state laws, guidelines, OSU policies and procedures, or the determinations and requirements of the Conflict-of-Interest Committee (COIC).

3.0 Reporting Allegations of Noncompliance

3.1 Allegations of noncompliance may be submitted to the Assistant Vice President for Research, Conflict-of-Interest Committee members, COI Office personnel, or the Office of University Research Compliance (URC) either verbally or in writing. In addition, reports of noncompliance may be submitted *via* the EthicsPoint confidential reporting system used by OSU. The identity of the individual making the report will be kept confidential to the extent possible.

4.0 Processing the Allegation of Noncompliance

4.1 Screening and Initial Review of the Allegation
The Conflict-of-Interest Manager (COIM) screens the allegation to determine if a conflict exists and has not been disclosed. If a conflict is discovered, the COIM determines the source of funding, if any, and if there are any issues pertinent to other research review committees (IACUC, IRB, IBC, RSC, Laser Safety).
The COIM, in consultation with the Assistant Vice President for Research, will review the allegation to allow an initial determination of the nature and severity of the alleged noncompliance. This may involve discussion with the research team and the complainant (if not anonymous) and others as needed. The COIM will document and compile the information into a summary report. noncompliance may often be the result of communication difficulties; therefore, the COIM will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study. All the actions taken will be documented.

4.2. Determinations
After the initial review, the COIM and the Assistant Vice President for Research will determine whether:

a) The allegation was false or failed to constitute the instance of noncompliance by the Researcher.
b) The allegation, if true, is of minor noncompliance.
c) The allegation, if true, is of major noncompliance.

4.2.1 False allegation
If the COI Manager and the Assistant Vice President for Research determine that the allegation of noncompliance is false, the matter will be documented, if appropriate, the COIM or Assistant Vice President for Research will communicate the decision to the complainant (if her or his identity is known). The Conflict-of-Interest Committee will be informed at the next convened meeting.

4.2.2 Minor noncompliance
If the allegation is determined by the COIM and the Assistant Vice President for Research, that the allegation is a minor noncompliance, the researcher will be notified in writing. In addition, the COIM and/or Assistant Vice President for Research will discuss the issue and develop an action plan with the researcher. The final action plan will be forwarded to the researcher via letter or e-mail. The Conflict-of-Interest Committee will be informed at the next meeting convened. The action for minor noncompliance can include:

a) Required correction of omissions and/or errors in the Conflict-of-Interest Disclosure form.
b) A request to the researcher(s) to fulfill obligations under the management plan and/or COI policies.
c) A reminder to the researcher(s) to adhere to management plan requirements and COI

policies in the future.

d) A meeting between the COIM and the researcher(s) to explain COI requirements and policies.
e) Issuance of a letter to the researcher(s) signed by the Conflict-of-Interest Committee Chair outlining the findings and any remedial measure(s), sent to the researcher(s), and others as deemed appropriate.

The researcher must reply to notifications of noncompliance to acknowledge the noncompliance and comply.

4.2.3 Major noncompliance

If the allegation is determined by the COIM and the Assistant Vice President for Research, to be a major noncompliance, the COIM, Conflict-of-Interest Committee, and Assistant Vice President for Research will determine if remedial measures are necessary to encourage future compliance with COI policies and/or management plans. Examples of remedial measures include, but are not limited to:

a) Required training in research ethics, the number of hours and courses of which are to be determined by the Conflict-of-Interest Committee based on the severity of the noncompliance.
b) Increased monitoring.
c) Reporting of the noncompliance to external agencies where required, such as sponsoring agencies, and suspension of award, if required. The researcher involved in the allegations, appropriate school or department heads, college research deans, and the institutional officials will be notified in writing if any suspension occurs. Further investigation and review by the convened COIC will determine the length of any suspension.

The CIOC chair may appoint one or more committee members to assist in the gathering of information pertaining to the nature of the allegation. The researcher will be notified of the inquiry by the COIM or the Assistant Vice President for Research and asked to respond in writing to the allegation within 10 workdays. If the researcher needs more time, an extension may be granted by the COIC chair. The COIM will document and compile the information, including the investigator's response, into a summary report. The summary report will be presented to the Conflict-of-Interest Committee at a meeting convened for review. The researcher may be asked by the COIM or COIC chair, to attend the next convened Conflict-of-Interest Committee meeting.

4.3 Review Procedures for Noncompliance

The allegation and inquiry results will be presented at the next scheduled convened Conflict-of-Interest Committee (COIC) meeting. For urgent issues, the COIC chair may convene an emergency meeting of the COIC.

At the convened Conflict-of-Interest Committee meeting, the COIM will present the allegation(s) to the COIC. All Conflict-of-Interest Committee members will receive the investigation report, synopses of any communication with the investigator and any other pertinent information. All members attending the COIC meeting will review all the documents and determine whether:

a) There is an isolated or continuing noncompliance.
b) More information is needed, and determination is deferred to future meetings, pending receipt of additional information.
c) A lack of noncompliance has been found.

4.4 Review Outcomes/Conflict-of-Interest Committee Actions

The convened Conflict-of-Interest Committee makes the final determination whether the alleged noncompliance is major based on the materials compiled during the inquiry. The convened COIC may take a variety of actions depending on the outcome of the review, including, but not limited to, the following:

a) Approve continuation of research without changes.
b) Request minor or major changes in the Disclosures or management plans.
c) Require audits of other active proposals and awards of the investigator.
d) Suspend the use of awards in research and/or instructional activities.
e) Terminate the use of awards in research and/or instructional activities.
f) Recommend further administrative action to the University Administration.
g) Notifying federal agencies of the noncompliance.

The Conflict-of-Interest Committee resolves questions or concerns raised by a researcher regarding the outcome of a specific Conflict-of-Interest Committee noncompliance review through direct communication with the researcher.

The researcher may submit concerns in writing to the Conflict-of-Interest Committee within thirty days of the date the Conflict-of-Interest Committee decision and may request the researcher to attend a convened meeting of the COIC to discuss the concerns.

4.5 Reporting

The Conflict-of-Interest Committee informs the following individuals **internal** to the university of the allegation, the review process, and the findings of the review in writing:

a) Investigator(s) (e.g. PI and/or Co-PIs)
b) Associate Dean(s) for Research
c) Institutional Official and Assistant Vice President for Research
d) Other administrative personnel as appropriate

The Conflict-of-Interest Office will inform any external agencies of any non-compliance issues as required by federal regulations.

REFERENCES

2 C.F.R § 200, *Uniform Administrative Requirements, Cost Principals, and Audit Requirements for Federal Awards.*

U.S. Public Health Services (PHS), 42 C.F.R. § 50 Subpart F (grants and cooperative agreements): "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" https://grants.nih.gov/grants/compliance/42_50_Subpart_F.htm

National Science Foundation: NSF Proposal & Award Policies Guide (PAPPG) (NSF 24-1 or latest version), see Conflict of Interest Policy, Chapter IX.
https://www.nsf.gov/pubs/policydocs/pappg19_1/index.jsp

U.S. Department of Education: 34 C.F.R. § 75.525 AND 34 C.F.R. § 74.42. Food and Drug Administration regulated research:21 C.F.R. § 54.

45 C.F.R. § 75.361, *Retention Requirements for Records.*

Oklahoma State University Policy and Procedures, Conflict of Interest in Sponsored Programs, 4-0130, Research, 12/2020