MISSISSIPPI STATE UNIVERSITY CONFLICT OF INTEREST REVIEW COMMITTEE	Handling of Noncompliance (01-04) *Approved 04-10-2013*

I. Introduction

Under institutional authority and, in some cases, pursuant to Federal regulations (42 CFR 50 et seq., 21 CFR 54 et seq.), Mississippi State University is responsible to maintain and enforce a policy on financial conflicts of interest in research. Under these policies, the University is required to obtain information from researchers on outside financial or business interests, review the information for potential conflicts of interest, manage identified conflicts where possible, eliminate conflicts where management is not possible, and report existing conflicts to sponsors as required by sponsoring agency rules and regulations. The University may suspend research and/or impose remedial measures on Investigators who fail to disclose interests where required, or who fail to comply with their approved management plan. The Conflict of Interest Review Committee is responsible for Investigations into alleged noncompliance, and for findings of noncompliance, and is supported by the Vice President for Research and Economic Development and the Vice President for Agriculture, Forestry and Veterinary Medicine in this process.

II. Definitions

Allegation of Noncompliance – is an unproven assertion of noncompliance.

Noncompliance – is defined as failure to comply with Federal regulations, FCOI policy, an FCOI management plan or the determinations or requirements of the Conflict of Interest Review Committee.

1. Non-serious and non-continuing noncompliance involves isolated incidents, e.g. an unintentional mistake, an oversight or a misunderstanding. The issue is not serious or continuing in nature.
2. Serious noncompliance is an action or omission taken by an Investigator, that is noncompliant with Federal regulations, FCOI policy, an FCOI management plan or the determinations or requirements of the Conflict of Interest Review Committee, and that any other reasonable Investigator would have foreseen as increasing the potential for bias or perceived bias in research, or otherwise compromising the integrity of research at MSU. 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. An existing knowledge of FCOI policies on the part of the same researcher(s) as evidenced by 1) past compliance, or 2) efforts to mitigate the present alleged noncompliance;
    c. A failure to disclose information relating to financial or business interests which was clearly requested in a grant/contract application or award;
    d. Signature(s) on Financial Interest Disclosure forms relating to disclosure of significant financial or business interests;
    e. Changes in relationships with companies or research personnel that are inconsistent with the original research plan;
    f. Communications with the researcher(s) during the course of investigating the noncompliance.
3. Continuing noncompliance is a pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, FCOI policy, an FCOI management plan or determinations or requirements of the Conflict of Interest Review Committee.

III. Procedures

1. Allegations of noncompliance will be reviewed by the COI manager to determine the appropriate course of action.
2. The COI manager will review the information to determine whether the allegation is valid. If the allegation can clearly be determined to be not valid, the allegation will be dismissed. If the allegation appears to be valid, the COI manager will undertake an inquiry and determine if the alleged noncompliance appears to be serious and/or continuing.
3. If, after conducting an inquiry, the COI manager is able to determine that the alleged non-compliance is non-serious and non-continuing:
    1. The issue will be resolved by the COI manager in conjunction with other personnel as appropriate, such as: researchers, department heads, deans, etc.
    2. The COI manager will document the outcome in writing, including any remedial measures required. This documentation may be in the form of email communications with the researcher(s) or notes to the file. Remedial measures for non-serious or non-continuing noncompliance can include:
        i. Required correction of omissions and/or errors in the Financial Interest Disclosure form;
        ii. A request to the researcher(s) to fulfill obligations under the management plan and/or FCOI policies;
        iii. A reminder to the researcher(s) to adhere to management plan requirements and FCOI policies in the future;
        iv. A meeting between the COI manager and the researcher(s) to explain FCOI requirements and policies;
        v. Issuance of a letter to the researcher(s) signed by the Conflict of Interest Review Committee Chair outlining the findings and any remedial measure(s), sent to the researcher(s), and others as deemed appropriate.
    3. In response to finding non-serious or non-continuing noncompliance, the COI manager shall not impose any of the more serious remedial measures available to the Conflict of Interest Review Committee under section (6)(v)(1-7) of this document.
    4. The researcher must reply to notifications of noncompliance to acknowledge the noncompliance and agree to any remedial measures, if applicable.
    5. If, during the inquiry of a non-serious or non-continuing noncompliance, it is determined that the noncompliance may be serious or continuing, the matter will be referred to the Conflict of Interest Review Committee.
4. If, after conducting an inquiry, the COI manager determines that the alleged non-compliance may be serious or continuing, the COI manager will refer the allegation to the Conflict of Interest Review Committee Chair.
5. If the CIRC Chair believes that the alleged noncompliance is neither serious nor continuing, the COI manager will resolve the matter according to items (3)(2)(i-v), above. A summary record must be provided for review to the CIRC within 30 working days of the Chair's determination.
6. If the CIRC Chair determines that the alleged noncompliance may be serious and/or continuing:

1. The allegation may be referred to a Noncompliance Subcommittee for further inquiry. The Noncompliance Subcommittee will consist of the CIRC Chair, Vice Chair, COI Manager, and another member of the CIRC named by the Chair. At least three members of the Noncompliance Subcommittee must participate to conduct business.
2. The Investigator against whom the allegation of noncompliance is directed will be invited to the Noncompliance Subcommittee meeting to address the allegations and answer questions.
3. The Noncompliance Subcommittee may determine via unanimous vote that the allegation of noncompliance has no basis in fact and the matter will be dismissed.
4. If the allegation is not dismissed, the following actions will be taken:
    i. If the Noncompliance Subcommittee determines (via majority vote) that the alleged noncompliance is neither serious nor continuing, the COI manager will resolve the matter according to items (3)(ii)(1-5) above.
    ii. If the Noncompliance Subcommittee determines (via majority vote) that the alleged noncompliance is serious and/or continuing, the matter will be referred to the CIRC for inclusion on the agenda of the next scheduled meeting.
    iii. CIRC members will receive a written report regarding the findings of the Noncompliance Subcommittee including recommendations and any supporting materials.
    iv. The Investigator against whom the allegation of noncompliance is directed will be invited to the CIRC meeting to address the allegations and answer questions.
    v. The CIRC may, via majority vote, accept the Noncompliance Subcommittee's recommendations, impose additional sanctions outlined, or dismiss the allegation while reserving the right to require corrective actions to prevent future problems.
5. If serious and/or continuing noncompliance is found to exist, the CIRC will determine if remedial measures are necessary to encourage future compliance with FCOI policies and/or management plans. Examples of remedial measures include, but are not limited to:
    i. Required training on research ethics, the number of hours of which to be determined by the CIRC based on the severity of the noncompliance;
    ii. Required disclosure to a broader audience than previously required under the existing management plan, if any;
    iii. Increased monitoring;
    iv. Reporting of the noncompliance to external agencies where required, such as sponsoring agencies.
6. If the related research involves human participants, the COI manager will notify the IRB that the COI Program has received an allegation of noncompliance, and that it will keep the IRB informed of developments in the inquiry and determination as appropriate. The COI Manager will notify the IRB if, after the inquiry and determination of noncompliance, any part of the noncompliance or remedial measures is/are related to the protection of human participants.
7. If serious or continuing noncompliance is found to exist, and the CIRC determines it may rise to the level of research misconduct as defined in MSU OP 80.02, the Committee will follow steps for reporting such possible misconduct according to the requirements of MSU OP 80.02 or any other pertinent policies.

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Conflict of Interest Review Committee Chair Date