STANDARD OPERATING PROCEDURE ON THE HANDLING OF NONCOMPLIANCE

I. Introduction

Under institutional authority and, in some cases, pursuant to Federal regulations (42 CFR 50 et seq., 21 CFR 54 et seq.), Penn State 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 Committee is responsible for investigations into alleged noncompliance, and for findings of noncompliance, and is supported by the Office for Research Protections in this process.

II. Applicability

The following policies apply to all research activities of faculty, staff, students and others who are subject to the disclosure requirements of Penn State Policy RP06, “Disclosure and Management of Significant Financial Interests”.

III. Definitions

A. Allegation of Noncompliance is an unproven assertion of noncompliance.

B. Noncompliance is defined as failure to comply with Federal regulations, COI policy, a COI management plan or the determinations or requirements of the COI 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, COI policy, a COI management plan or the determinations or requirements of the COI 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 Penn State. 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 COI 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 PIAF/AIAF 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;
IV. Procedures for Handling Alleged Noncompliance

A. COI staff may become aware of alleged noncompliance during review of disclosures or other information submitted by researchers or other administrative offices, or as a result of an allegation made by a third party.

B. When alleged noncompliance comes to the attention of COI staff, the staff will review the information to determine whether it is valid. If it is valid, then COI staff will undertake an inquiry and determine if the alleged noncompliance appears to be serious or continuing.

C. After conducting an inquiry, if COI staff are able to determine that the alleged non-compliance is non-serious and non-continuing:
   1. The issue will be resolved by COI staff or other staff designated by the COI Official, researchers, department heads, deans and monitors.
   2. COI staff 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:
      a. Required correction of omissions and/or errors in the COI disclosure;
      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 COI staff 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 Official 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, COI staff shall not impose any of the more serious remedial measures available to the COI Committee under section (IV)(F)(7) of this document.

4. The researcher must reply to COI program 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 is serious or continuing, the matter will be referred to the COI Committee.

D. If, after conducting an inquiry, COI staff determines that the alleged non-compliance may be serious or continuing, COI staff or other staff designated by the COI Official will present the information to the COI Official.

E. If the COI Official believes that the alleged noncompliance is neither serious nor continuing, COI staff or other staff designated by the COI Official will resolve the matter according to items (IV)(C)(1)-(5), above.

F. If the COI Official determines that the alleged noncompliance may be serious and/or continuing:
   1. COI staff or other staff designated by the COI Official may undertake a further inquiry.
   2. If the related research involves human participants, COI staff or other staff designated by the COI Official 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 Program 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

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participants.
3. COI staff or other staff designated by the COI Official will document and compile the information and present the findings to the COI Committee. The Committee will receive copies of any existing management plan(s), disclosures, and any communications and discussions concerning the alleged noncompliance from the inquiry phase.
4. The Committee will review the findings at its next appropriate meeting. The researcher(s) alleged of noncompliance will be invited to attend the Committee meeting to discuss the alleged noncompliance with the Committee.
5. The Committee may ask for further investigation if necessary.
6. The Committee will make a determination regarding whether there was serious and/or continuing noncompliance.
7. If serious or continuing noncompliance is found to exist, the Committee 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 on research ethics, the number of hours of which to be determined by the Committee based on the severity of the noncompliance;
   b. A requirement that the researcher(s) work with the ORP to organize a COI information session for their department or college;
   c. Required disclosure to a broader audience than previously required under the existing management plan, if any;
   d. Increased monitoring, (e.g., quarterly instead of semi-annually);
   e. Referral to the IRB if, as a result of the finding of noncompliance, any part of the noncompliance or remedial measures is/are related to the protection of human participants;
   f. Suspension of funds on sponsored research projects pending resolution of the noncompliance matter;
   g. Reporting of the noncompliance to external agencies where required, such as research sponsoring agencies.
8. If serious or continuing noncompliance is found to exist, and the Committee determines it may rise to the level of research misconduct as defined in Penn State policy RP02, the Committee will follow steps for reporting such possible misconduct according to the requirements of policy RP02 or any other pertinent policies.
9. If, in the course of investigating or evaluating alleged noncompliance with COI policies, COI staff or the COI Committee receive or discover other information which may form the basis of a potential research misconduct matter, the staff or Committee will follow steps for reporting such possible misconduct according to the requirements of policy RP02 or any other pertinent policies.