



**POLICY STATEMENT REGARDING
CORRECTIVE ACTIONS DECLARED BY THE
DUKE UNIVERSITY SCHOOL OF MEDICINE (DUSOM)
CONFLICT OF INTEREST COMMITTEE**

10/01/2008

This policy statement applies to corrective actions required by the DUSOM Conflict of Interest (COI) Committee or determined in the DUSOM Research Integrity Office (RIO), and describes how the DUHS IRB and DUSOM RIO work together to see that corrective actions are implemented as required. The DUSOM COI Committee meets periodically to review real and potential conflicts-of-interest, as defined by the DUSOM COI policy, concerning Duke investigators and other Duke personnel. In addition, the DUSOM RIO conducts reviews of real and potential conflicts of interest for these personnel. As a result of reviews by both the DUSOM COI Committee and DUSOM RIO personnel, the DUSOM COI Office issues plans for the management of putative conflicts of interest. These management plans may involve submissions to the DUHS IRB.

The DUHS IRB will be copied on all management plans issued by the DUSOM COI Office that involve Human Subjects Research and will be made aware of issued management plans using either of the two processes below. In addition, all agendas for IRB meetings will be screened by the IRB staff person responsible for COI issues, for potential conflicts that may or may not have been identified by the investigator.

A. New Studies:

For new studies that have not yet received DUHS IRB review, if a management plan is issued by the DUSOM RIO to any key personnel on that study, the management plan will be made available to the IRB members as a discussion item in eIRB. All study documents that are affected by the management plan, such as the consent form, must contain any required disclosures, or other language required by the RIO, at the time of submission to the IRB. Any language that is missing at the time of IRB review will be required by the IRB as a condition of approval.

For the purposes of this policy, “Key Personnel” for a research study are research personnel who are directly involved in conducting the research with human subjects through an interaction or intervention for research purposes, or who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study.

If DUHS or anyone at DUHS has a financial interest associated with the research, the IRB cannot approve or give contingent approval to the research until the convened IRB has evaluated the financial interest and the COI Committee's management plan. The convened IRB has the final authority to decide whether the interest and its management plan, if any, allow the research to be approved.

B. Studies That Have Already Received IRB Approval:

The convened IRB will review the financial interest and the management plan in order to decide whether the conflicting interest and its management allow the research to continue to be approved. The only exception to this would be if the financial interest (or the financial interest after divestment) does not meet the criteria for disclosure.

Investigators with recently issued management plans will be contacted by the IRB staff person responsible for COI issues, and asked to submit an amendment for any known studies affected by the conflict. Submissions must be made via amendment either in paper or through the eIRB, depending on the original study's status as a paper or electronic file. The management plan will be made available to the convened board as a discussion item in eIRB.

If the requested submission(s) has/have not been received by the DUHS IRB office within one month, the DUHS IRB office will send an e-mail notification to the Principal Investigator, co-Principal Investigator, if applicable, and study coordinator, with a copy to the Administrative Director of the RIO, the Senior Chair of the IRB, the Principal Investigator's Department/Divisional Chairperson(s), and the Institutional Official (IO) or designee, School of Medicine. This e-mail will contain wording substantially the same as the wording in Attachment 1. If no response is received by the IRB office within 2 weeks of this notice, a second notice will be sent to the individuals above that contains wording substantially the same as the wording in Attachment 2. The IRB will send all appropriate notifications to federal regulatory departments/agencies promptly upon issuance of the second e-mail.

C. Failure to Comply

Failure of Key Personnel to comply with the requirements of the DUSOM RIO as expressed in its management plans could result either in termination of the study, or in suspension of some or all study activities by either the DUHS IRB or the IO in keeping with the DUHS IRB Policy on Allegations and Findings of Noncompliance.

ATTACHMENT 1 – FIRST E-MAIL NOTIFICATION

FIRST NOTICE

The purpose of this e-mail is to notify you that the Duke University Health System Institutional Review Board (DUHS IRB) has not received any/part of the submissions requested on [date] and required by the management plan issued to you by the DUSOM Research Integrity Office for your relationship with [company]. This is related to your study entitled:

“insert study title” IRB #[insert]

Please complete these submission(s) immediately. If the submission(s) has/have not been received by the DUHS IRB office within 2 weeks of issuance of this notice, your study will be placed on administrative suspension on **[specify exact date]**.

Upon receipt of a suspension notice, you must immediately cease all study activities, including enrollment, interventions, data collection, and data analysis. In addition, the DUHS IRB will notify all appropriate federal agencies/departments, including OHRP, FDA and NIH, that your study has been placed on administrative suspension.

A copy of this e-mail is being provided to the Administrative Director of the COI Office, the Vice Dean for Clinical Research, Associate Dean for Research Support Services, Senior Chair of the IRB, the DUSOM CTQA Office, and your Departmental/Divisional Chair(s).

ATTACHMENT 2 – SECOND E-MAIL NOTIFICATION

SECOND NOTICE

The purpose of this e-mail is to notify you that your study entitled:

“insert study title” IRB #[insert]

has been placed on administrative suspension by the Duke University Health System Institutional Review Board (DUHS IRB). You must immediately cease all study activities, including enrollment, interventions, data collection and data analysis, until further notice from the DUHS IRB.

If cessation of certain study activities, such as study drug administration or safety monitoring, would directly affect subject safety or are in the subject’s best interest, please e-mail Dr. John Falletta (falle001@mc.duke.edu) and Jody Power (power008@mc.duke.edu) to request permission to continue those study activities. The e-mail must contain the following information:

- (1) a description of the specific study activities to be continued;
- (2) an explanation as to how those activities directly affect subject safety or are in the subject’s best interest;
- (3) an explanation for why submissions required by the DUSOM COI Office were not completed in the required time period; and
- (4) a timetable for when the required submissions will be completed.

The DUHS IRB will promptly report this administrative suspension to all appropriate federal agencies, including, but not limited to, OHRP, FDA and NIH.

A copy of this e-mail is being provided to the Administrative Director of the COI Office, the Vice Dean for Clinical Research, Associate Dean for Research Support Services, Senior Chair of the IRB, the DUSOM CTQA Office, and your Departmental Chair or designee.