INVESTIGATOR CONFLICTS OF INTEREST MANAGED BY THE DUKE UNIVERSITY SCHOOL OF MEDICINE (DUSOM) CONFLICT OF INTEREST COMMITTEE

11/22/2023

This policy statement applies to conflict of interest (COI) management required by the DUSOM COI Committee or determined in the Duke Office of Scientific Integrity – Conflict of Interest (DOSI-COI), and describes how the DUHS IRB and DOSI-COI work together to ensure institutional conflict of interest requirements are implemented appropriately.

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 study personnel. In addition, the DOSI-COI conducts reviews of real and potential conflicts of interest for these personnel. DOSI-COI will issue a management plan for conflicts that meet institutional criteria for management.

A management plan always requires disclosure of the conflict of interest in the consent form. Other possible management strategies could include restrictions on being PI, restrictions on obtaining consent, data management restrictions, or other requirements as determined by DOSI-COI or the DUSOM COI Committee.

The DUHS IRB will be copied on all management plans issued by DOSI-COI. In addition, all agendas for convened IRB meetings will be screened by designated IRB staff for potential conflicts that may or may not have been identified by the investigator.

Conflict of Interest Pertaining to Investigators

All investigators must follow the DUSOM COI policy for reporting financial conflicts of interest to the institution. Investigators much report their personal investment in, or other financial relationship with, a company related to their research. DOSI-COI will determine the management strategy for the financial interests of the investigator. The IRB will be informed of the results of this evaluation.

The consent form must include disclosure of any potential conflict of interest as required by DOSI-COI. The IRB may not limit or reduce the conditions imposed by DOSI-COI, but may impose additional conditions in accordance with regulatory criteria for approval of the research. The IRB has the final authority to decide whether the interest and its management, if any, and its form of disclosure allow the research to be approved.

NIH requires grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought." That subpart promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator.

If the Conflict of Interest status of an individual changes during the course of a study, the individual is required to declare this to DOSI-COI. The individual is also responsible for ensuring that any affected research studies are updated.

IRB Review

A. New Studies:
Investigators submitting new studies for which they or any member of key personnel have been issued a conflict of interest management plan should ensure that all applicable COI requirements are reflected in the submission.

For new studies undergoing full board review, the management plan will be made available to the IRB members in iRIS. The consent form must contain any required disclosures, and any required restrictions on the conflicted investigator (such as not personally obtaining consent) should be reflected in the study submission. Requirements that are 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 any member of key personnel has been issued a management plan, either for a personal conflict of interest or an institutional conflict of interest, the IRB cannot approve or give contingent approval to the research until the IRB has evaluated the financial interest and the COI Committee's management plan. The IRB has the final authority to decide whether the interest and its management allow the research to be approved. The convened IRB will make this determination for studies requiring full board review. This determination may be made by the expedited reviewer for studies that do not require full board review.

B. Studies That Have Already Received IRB Approval:
When conflict of interest is newly identified for approved studies, the investigator must submit an amendment to add disclosure language and any other conditions required by DOSI-COI. Conflict of interest may be reviewed either by the expedited procedure or referred to full board.

When reviewed by the full board, the COI management plan will be made available to the convened board in iRIS. The convened IRB will review the financial interest and the management requirements in order to decide whether the conflicting interest

and its management allow the research to continue to be approved. When reviewed by the expedited procedure, the expedited reviewer will have access to the management documents and will determine whether the conflicting interest and its management allow the research to continue to be approved. At any time, the expedited reviewer may request that a submission involving a COI change be scheduled for review at a convened IRB meeting.

C. Failure to Comply:

Failure of Key Personnel to comply with the requirements of the DOSI-COI 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.

Previous Version Date(s): 10/1/2008, 6/7/2011, 11/8/2011, 7/25/2014, 3/3/2016, 6/5/2019, 3/17/2021