

I. Introduction

An institutional conflict of interest (ICOI) includes situations where the financial interests of an institution may affect or appear to affect the integrity of research outcomes. ICOI's are of particular concern when human research participants may actually be, or reasonably appear to be, compromised or injured by the conflicting financial interest. This Standard Operating Procedure (SOP) is intended to provide guidance to the Conflict of Interest Review Committee (CIRC) when reviewing these situations so that research involving human subjects at MSU is conducted without untoward influence resulting from the University's financial interests.

II. Definitions

Human Subjects Research (HSR)— any research that requires review and approval by the MSU Institutional Review Board (IRB).

Institutional Conflict of Interest (ICOI) Involving Human Subjects Research – an ICOI that exists whenever the financial interests of the University might affect, or reasonably appear to affect, the design, conduct, reporting, review, or oversight of human subjects research.

III. Procedures

In assessing and managing ICOIs that involve human research participants, the CIRC shall begin from the default position that either the University's financial interest should be eliminated, or the research should not be conducted at or under the auspices of MSU.

However, the CIRC may approve conducting the research at or under the auspices of MSU if it determines that compelling circumstances warrant proceeding with the research at MSU and that an effective management plan can be implemented to fully protect the welfare of human research participants and the integrity of the research. Compelling circumstances require an assessment of:

1. a description of the research, including its current phase of development and intentions for subsequent phases as prepared by the PI;
2. the level of risk to research participants as determined by the IRB;
3. whether the University is uniquely qualified, by virtue of distinctive resources (e.g., special facilities or equipment, special participant population) and the experience and expertise of its investigators, to conduct the research; and
4. whether the financial interest is of sufficient magnitude that it might affect, or reasonably appear to affect, oversight of research at the University.

If the CIRC determines that there are compelling circumstances for allowing the research to proceed in the presence of the ICOI, a management plan should be designed to effectively address the specific risks to the participants and the actual or perceived risks to the integrity of the research.

In crafting the management plan, the CIRC may in its discretion include one or more of the following strategies among any others it may deem necessary:

1. Disclosure of the ICOI in informed consent processes;
2. Recusal of any conflicted investigator(s) from some aspects of the research project;
3. Designation of a non-conflicted senior individual to monitor the research project;
4. Use of an external IRB;
5. Use of an external Data Safety Monitoring Board (DSMB) or similar review board to evaluate the design and provide ongoing evaluation of the study and reporting of results;
6. Disclosure of the conflict in public presentations and publications, and to all individuals engaged in the design, conduct, or reporting of the research;
7. Disclosure of the conflict to other centers in a multi-center trial;
8. Disclosure to the sponsor of the research.


Conflict of Interest Review Committee Chair


Date