

Occasionally, researchers have financial interests that create the potential for bias. This is referred to as a conflict of interest. The possibility of profiting from a study's outcome may affect a researcher's judgment in protecting subjects' rights and welfare, as well as in other aspects of research conduct.

University of Michigan conflict of interest policies are designed to safeguard students, patients, and the public trust in unbiased research, as well as to help ensure compliance with state and federal policies and regulations. Together with IRBs, the University's conflict of interest committees—the Medical School Conflict of Interest Board (or MEDCOI) and the University Office of Research Conflict of Interest Committee—work with researchers to manage conflicts of interest.

Information about potential conflicts is shared within the eResearch application. All study team members (except administrative staff) must indicate, when accepting their roles in eResearch, whether they have any research-related outside interests or relationships with non-UM entities. For example, a scientist serving as a consultant to a study sponsor has a related outside relationship. Each study team member's answer to the outside interest question can be viewed by clicking his or her name in the study team list or in section 1.3 of the application.

If a study team member answers yes to the outside interest question, the COI Committee must determine whether the related interest represents a conflict of interest. Some related interests do not create a conflict. In these instances, the Committee communicates the finding to the IRB at the time of COI Committee determination. If there is a conflict that requires management, the COI Committee creates a plan to address it.

Some conflicts can be managed solely by means of the conflicted researcher's disclosure—to members of the study team, subjects, the IRB, and/or in publications—of his or her outside interest. For example, a financial relationship valued at less than \$5,000 is typically handled by disclosure alone. In these instances, the Committee communicates its finding to the IRB as part of COI Committee determination.

Other conflicts require further management such as restricting the conflicted researcher from participating in the informed consent process. The COI Committee outlines management steps in a formal document called the conflict management plan. This plan can be accessed in eResearch either on the investigator's detail page or under the **Documents** tab.

The primary goals of a conflict management plan are to reduce or eliminate the potential for bias and to eliminate any real or perceived coercion or other issues affecting subjects' informed decision to participate. The COI Committee completes its work using the online M-Inform system. Clicking the "View Management Plan" link within an eResearch application opens an M-Inform window in which management plans are listed. To open a management plan document, click the name of the plan.

Contact a University of Michigan conflict of interest committee or the IRB for more information about

U-MIC TRANSCRIPT Conflicts of Interest in Human Subjects Research

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