

RCOI MANAGEMENT PLANS

Who Needs to Have a Management Plan

Researchers who have or appear to have conflicts of interest or commitment between their outside activities and their research are required to have a management plan in order to eliminate or mitigate these conflicts or appearances of conflict.

What is a Management Plan

A [template management plan](#) can be seen at the link. It describes the actions that must be taken to eliminate or mitigate any conflict of interest or commitment or the appearance of such. If a management plan is required, a notification will be sent from the RCOI Committee and they will work with the researcher to implement and report as necessary.

When is a Management Plan Necessary

A management plan is necessary when there is or appears to be a conflict of interest or commitment between a researcher's outside activities and their UWM research as determined by review of disclosed activities by the RCOI Committee. If it is required, the RCOI Committee will contact the researcher to complete the form and work with them to explain any elements and complete all the necessary approvals.

How to Complete a Management Plan and Remain in Compliance

A template management plan can be found on the [Office of Research Forms and Documents download page](#). The upper portion is information specific to the Investigator and the Investigator's research and possible conflicts, and the remainder of the documents are the requirements to eliminate and/or mitigate any potential types of conflicts. If there are any issues not covered in the management plan, please include them in an additional document when the completed form is sent to the RCOI Committee. Please include any questions or a request to review the management plan with the committee when returning the form.

Once the plan has been agreed upon and reviewed, the Investigator is responsible for all its terms and conditions and must cooperate with UWM's efforts to monitor compliance with the management plan.

Sponsored funding that is related to the management plan will not be available for spending until the management plan is fully completed and approved.

Management plans prohibit participation in human subjects research when a managed entity sponsors the study, or own or license a technology used in the study.

Requesting an Exception to the Restriction on Participation in Human Subjects Research

Researchers may apply for an exception to the restriction on participation in human subjects research. Exception requests are only granted for specific protocols; therefore, every protocol requires a separate, explicit exception.

Protocols that have been determined to be of no greater than minimal risk do not require an exception

and may proceed without one according to the limitations listed on the Management Plan.

For all protocols that are greater than minimal risk, or where the researcher must appeal a limitation for a minimal risk study, the research must work with their Dean's Office to request an exception. If the Dean's Office agrees to support the exception request, they will prepare a memorandum outlining the basis for the exception, and their willingness to participate in additional management actions.

Additional management actions include: disclosure of financial interests to participants, disclosure of financial interests to research collaborators, additional protocol monitoring, restriction of roles in the study, and other management, as determined by the committee.

The Dean's representative will share this memorandum with the RCOI Committee at the next RCOI Committee meeting. After the meeting, the Investigator will be notified of whether or not the exception has been granted.

The IRB has authority to require disclosure of the conflict of interest in the consent form as well as restrict participation in the recruitment of study participants for any study if the IRB determines either is necessary to protect research participants.

Appealing a Management Plan

Faculty members may appeal the VPR's determination to the Faculty Appeals and Grievances Committee. Academic staff members may appeal the determination to the Academic Staff Hearing and Appeals Committee. These committees may then make recommendations concerning the management plan in question to the Provost. The decision of the Provost regarding conflict of interest matters shall be final.

Please note that the appeal process may delay spending on sponsored awards.

Terminating a Management Plan

If the circumstances of a managed outside activity change so that they meet one of the criteria listed below, please contact the [RCOI Committee](#) to request termination of a management plan. Termination of an existing management plan requires explicit action from the UWM RCOI Committee.

Situations that may be cause for termination of a management plan:

- The Investigator is no longer employed by UWM
- The managed entity has dissolved
- The Investigator's relationship with the managed entity has ended
- The Investigator's compensation from the managed entity has fallen below the PHS management threshold