

Conflicts Of Interest (COI) in Human Subjects Research Frequently Asked Questions

Who does this policy apply to?

All University faculty, staff, and students (including full-time and part-time faculty and staff, visiting faculty, postdoctoral scholars, undergraduates, graduate students, postdoctoral fellows and all research team members) who are in a position to *influence or commit University resources*.

Research team members include the principal investigator and any other person who is responsible for the design, conduct or reporting of human subjects research.

Who is in a position to influence or commit University resources?

Anyone who can impact decision-making or offer advice on purchasing, hiring, or anything involving University funds or facilities.

What is the difference between actual and potential or perceived conflicts of interest?

An actual Conflict of Interest arises in a situation where financial or other personal or professional considerations compromise an individual's objectivity, professional judgment, professional integrity, and/or ability to perform his or her responsibilities to the University. Perceived or potential COI exist in situations where an individual member of the University community, a member of the individual's family, or a close personal relation has financial interests, personal relationships, or professional associations with an outside individual or organization, such that his or her activities within the University could appear to be biased against the University by that interest or relationship.

When should I fill out a conflict of interest disclosure?

As soon as the situation comes up and before beginning the activity in question. Also, on an annual basis, certain employees of the University, whether they are engaged in activities that might create the perception of or potential for a COI or not, are required to fill out a COI Disclosure Summary. An e-mail notification will provide instructions when it is time to complete the annual disclosure on line. COI Disclosure Summaries may be updated in the system at any time.

Who decides if I have a conflict of interest?

Once you've completed your disclosure summary, a review will determine whether an actual, potential, or perceived COI exists. If the review determines that an actual, potential, or perceived COI exists, the reviewer refers the matter to the Committee on Oversight of Individual Financial Conflicts of Interest in Research with Human Subjects, also known as the Campus COI Committee, which will decide what conditions or restrictions, if any, should be imposed by the University to manage, reduce or eliminate such conflicts. The Campus COI Committee may also draft a Mitigation Plan for submission to the UMass Conflict of Interest Committee, also known as the System Committee.

If I have a conflict of interest, can I still take part in the research?

If the COI requires review by the System COI Committee and they require a Mitigation Plan, then a mitigation letter must be signed. The IRB will make the final decision about whether or not you may proceed with the research.

I have a draft consulting agreement with Company X. What should I do now?

Contact the Office of Technology Management. They will review the agreement and may suggest adding the UMMS Intellectual Property Rider. You may also want to consult an attorney to represent your interests. In addition, if the agreement is for human subjects research you should contact us!

Can I be a paid advisor for Company X while being a PI on a research study sponsored by Company X?

You generally cannot be a paid advisor while working on a study sponsored by the same company.

When is a mitigation plan needed and who drafts it?

If the Campus COI Committee determines that an actual, potential, or perceived COI exists, they may suggest the addition of mitigating language to the IRB consent form, or in some cases will draft a Mitigation Plan in order to ensure the reduction, mitigation, or elimination of any conflict. The Mitigation Plan will then need to be approved by the medical school dean and System COI Committee. You must sign and return the mitigation letter in order for the IRB to make a determination whether to move forward with the research.

Can my office or department get training on the Conflict of Interest Policy?

Yes. Please contact coi@umassmed.edu to set-up a training session.