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Conflict of Interest in Human Subjects Research

Conflicts of interest in human subjects research deserve special scrutiny because of their potential to affect the rights and welfare of human subjects. Such conflicts commonly arise when principal investigators or co-investigators conduct research that is sponsored by, or involves a product of, an entity with which they have an external relationship.

Principal investigators (PIs) and co-investigators on a human subjects research application submitted to the JHSPH IRB must inform the IRB about any conflict of interest, whether the study is a new submission or an ongoing project. If it is new, the PI should notify the IRB through the PHIRST application. There is a question in the PHIRST application which asks about conflict of interest. In addition, the PI must complete a “Conflict of Interest in Human Subjects Research” Form describing the potential conflict. If the PI indicates that there is a conflict, the Research Subjects Specialist assigned to process the application will notify the Conflict of Interest (COI) Committee to ensure that the COI Committee is aware of the conflict. If the project is ongoing, the PI should complete the form and submit it to the IRB as an amendment.

The COI Committee will decide whether the proposed activity may proceed, and whether a management plan is required to manage the conflict. Management plans may include, and but are not limited to:

- disclosure in relevant publications and presentations
- disclosure of the conflict in consent forms
- restrictions on the role of the conflicted person in obtaining informed consent, serving as PI of the project, or performing data analysis
- including the name and contact number of a non-conflicted person in the consent document

Other management restrictions may be considered, depending upon the nature of the conflict and the potential impact on human subjects. In some cases, the Committee may decide that a conflict cannot be managed and that the conflicted person may not be involved in the proposed research activity. For example, individuals with significant financial interests (more than \$10,000) associated with a human subjects research project are generally prohibited from directly engaging in the research.

The COI Committee will send its management recommendations to the conflicted individual with a copy to the IRB. The conflict will be presented to the IRB at a convened meeting. The IRB may decide whether to a) accept the COI Committee management recommendations, b) accept the recommendations with additional management measures prescribed by the IRB, or c) conclude that the research cannot proceed with the conflicted individual as part of the study team because of the risk to the human subjects. A study may not go forward without IRB approval of the recommended COI management plan. The IRB will inform the PI and the COI Committee of its decision.



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Faculty who need guidance as to whether a potential conflict of interest exists in their human subjects research project should contact the COI Committee for consultation.