



**Yale University School of Medicine - Yale New Haven Medical Center
Human Investigation Committee
Protocol-Related Conflict of Interest (COI) Policy**

*All investigators and key study personnel must be familiar with this policy and sign the Protocol Application Form to indicate compliance with this policy. Those who answer “yes” to any question below must also complete, sign and submit a [Protocol-Related Conflict of Interest Disclosure Form](#) (“Protocol COI Form”) when submitting an application to the Human Investigation Committee (“HIC”) for protocol **approval** or **reapproval** or when amending a currently approved protocol by adding a new investigator or key study person to the study team or whenever there is a real or apparent protocol-related conflict of interest. Investigators and key study personnel must certify that they have read the policy by signing the application for approval or reapproval in the space provided. If an actual or potential conflict develops after submission of the protocol to the HIC, the investigator or key study person must complete and submit an additional Protocol COI Form to the HIC at that time.*

Introduction:

All members of the Yale University research community should be sensitive to the potential impacts of financial interests and/or non-financial relationships with commercial sponsors or other external entities on the conduct of research and the participation and protection of human research subjects. In compliance with federal regulations, guidance and University policy, the HIC considers such relationships and determines whether they might influence or appear to influence the outcome of a research project involving human subjects, the objectivity of the investigator during the performance of such a project, or the investigator’s interactions with research subjects who participate in the project. Accordingly, the HIC solicits and reviews relevant information regarding the financial interests of all investigators and key study personnel participating in a protocol involving human research subjects prior to approving or re-approving that protocol.

Definitions:

“**Key study personnel**” means those persons involved in the design, conduct, and/or the data analysis of the research involving human subjects.

“**Financial interests**” that may be considered to be conflicts include, but are not limited to, the following: ownership of stocks, bonds, options, patent or royalty interests, receipt of consulting, honoraria or speaking fees, salary, subject accrual rewards and/or penalties, loans, lectureships, memberships on boards of directors or scientific advisory boards.

The Role of the HIC:

The HIC is the primary authority at the Yale School of Medicine responsible for ensuring that human research subjects are protected in accordance with federal regulations, University policies, and ethical principles. One of the primary responsibilities of the HIC is to ensure that human research subjects receive all information needed to provide informed consent. The HIC's consideration of investigators' financial interests is intended to ensure 1) that the informed consent process provides the subjects with the

facts necessary to make a knowledgeable and sound decision as to whether they wish to participate in the study, and 2) that no conflict exists that would otherwise compromise the protection of human subjects.

The HIC's consideration of investigators' financial interests as they relate to human subject research complements, but does not supplant, the deliberations of the Provost's Committee on Conflict of Interest (the "COI Committee"), which is responsible for reviewing the financial disclosures of all faculty members in accordance with the University Policy of Conflict of Interest and Conflict of Commitment.

Role of Investigators and Key Study Personnel:

For all protocols submitted to the HIC, including new protocols and those submitted for reapproval, each participating investigator and key study person must read this Protocol-Related Conflict of Interest policy. Each participating investigator and key study person who answers "no" to all of the questions below must sign the Protocol for Research Application Form or the Request for Reapproval Form in the space noted on the form as "COI signature". A signature in this space indicates that no actual or perceived COI exists. Individuals who answer "yes" to any of the questions listed below are required to complete and sign a Protocol COI Form and submit it to the HIC as part of the application package or request for reapproval. Investigators and key study personnel affiliated with Yale are reminded of their separate obligation to complete the annual disclosure form required by the University Policy on Conflict of Interest and Conflict of Commitment.

Before the HIC meeting at which a protocol is scheduled for consideration, the HIC Chair will review the Protocol COI Form, if one is submitted, to determine if there are related actual or potential conflicts. The Chair will evaluate such conflicts and, if necessary, provide a summary to the Committee. The Committee will determine (1) whether the conflict is permissible in the context of the protocol, and, if so, (2) whether the conflict warrants disclosure to potential subjects as part of the informed consent process. The HIC Chair will share relevant information with the Provost's Committee on Conflict of Interest, which may make additional findings and recommendations regarding actual and potential conflicts of interest. Note again, however, that completion and submission to the HIC of this protocol-specific form *does not* relieve investigators of their responsibility to make disclosures to the COI Committee as outlined in the University Policy.

Note**In the Protocol-Related COI process, the confidentiality of investigators and key study persons will be respected. Financial disclosure forms will be kept in confidential files, and information will be shared only on a need-to-know basis.

Instructions for Investigators and Key Study Personnel

For new protocols: Each participating investigator and key study person must read the following Protocol COI questionnaire. Investigators and key study personnel who answer "yes" to any of the questions must submit a completed Protocol-Related Conflict of Interest Disclosure Form to the HIC with the HIC Protocol Application. Those who answer "no" must sign the Protocol Application Form in the space noted as "COI Signature".

For re-approval of current protocols: Each participating investigator and key study person must read the questionnaire. Investigators and key study personnel who answer "yes" to any of the questions must submit a completed Protocol-Related Conflict of Interest Disclosure Form with the HIC Request for Reapproval Form (Form 5). Those who answer "no" must sign the Request for Reapproval Form in the space noted as "COI Signature".

Note: For the purposes of this disclosure, "real financial interests" include, but are not limited to, the following: ownership of stocks, bonds, options, patent or royalty interests, receipt of consulting, honoraria or speaking fees, salary, subject accrual rewards and/or penalties, loans, lectureships, memberships on boards of directors or scientific advisory boards.

Reminder: All Yale affiliated Investigators are required to file an Annual Conflict of Interest Disclosure Form with the University's Conflict of Interest Committee.

Please see: <http://www.yale.edu/provost/html/coi.html> for information.

Investigators and Key Study Personnel: If you answer "yes" to any of the following you must complete the Protocol-Related Conflict of Interest Disclosure Form and submit it with the Protocol Application or Request for Reapproval.

1. Are you or any family member (spouse, child, domestic partner) the inventor of any item (drug, device, program, method, etc.) being evaluated in this research project?
2. Do you or any family member (spouse, child, domestic partner) have:
 - a) Any financial interest in or relationship with the sponsor of this research project?
 - b) Any financial relationship with the manufacturer of any item (drug, device, program, method, etc.) being evaluated in this research project?
 - c) Any other financial interest or relationship with a competitor of the sponsor of this research project that might be affected by this research project?
 - d) Any other financial interest or relationship that might be affected by this research project?
3. Do you or any family member (spouse, child, domestic partner) have any non-monetary incentives or interests that may affect or be affected by the conduct of this research project and that may affect the protection of the human subjects involved in this research project? Examples may include serving as an officer, director or other fiduciary role of an advocacy group or running for public office. *Do not include the rewards that are traditional to academic life such as publication and career advancement.*
4. Does the arrangement with the sponsor include financial bonus payments related to speed of enrollment or any milestones?
5. Will a company in which you have an interest receive materials from this research project?
6. Do you plan to pay referring physicians or other persons a "finder's fee" or present them with a "gift-in-kind"?
7. Do you know of any real or apparent institutional conflict of interest (e.g., Yale University ownership of a sponsoring company) that might compromise this research project?

Please reference the HIC website, <http://info.med.yale.edu/hic/> for further information regarding the HIC guidelines and policies regarding Protocol-Related Conflict of Interest Disclosure.

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