



**Yale University School of Medicine - Yale New Haven Medical Center
Human Investigation Committee
Protocol-Related Conflict of Interest Disclosure Form**

Research investigators and study personnel must read [the HIC Protocol-Related Conflict of Interest Policy](#) located at <http://info.med.yale.edu/hic>. Investigators and study personnel who answer “yes” to any of the screening questions set forth in the policy must submit a completed Protocol-Related Conflict of Interest Disclosure form with the [HIC Protocol Application](#) or the [HIC Request for Reapproval](#) (Form 5).

Name of Researcher Submitting Disclosure:

Last Name _____ First _____ MI _____

Department: _____ Phone: _____

E-mail address: _____ Role in Protocol: _____

Check one: Faculty Resident/Fellow Staff Student
 Other (Please specify): _____

Check one: Yale or Yale Affiliate Non-Yale Collaborator

HIC # _____ Protocol Title: _____

This Protocol-Related COI form is submitted in conjunction with the following:

- _____ Initial Approval for a New Protocol
- _____ Continuing Review of Protocol
- _____ Amendment to a Currently Approved Protocol

Funding Source(s): _____ Grant # (If applicable) _____

Principal Investigator: _____ PI's Department: _____

Questions for Yale Affiliated Investigators and Study Personnel

1. Have you filed an annual Conflict of Interest Disclosure Form with the University in accordance with the University's policy on Conflict of Interest and Conflict of Commitment within the past twelve months?

Yes No

If “No,” you must submit the form in accordance with the directions on the following web page. (See: <http://www.yale.edu/provost/html/coi.html>)

Questions for All Investigators and Study Personnel

2. 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?

Yes **No**

If “Yes,” please explain: (Attach additional pages if necessary.)

3. 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?

Yes **No**

b) Any financial relationship with the manufacturer of any item (drug, device, program, method, etc.) being evaluated in this research project?

Yes **No**

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?

Yes **No**

d) Any other financial interest or relationship that might be affected by this research project?

Yes **No**

If you answered “Yes” to any of the above, please explain: (Attach additional pages if necessary.)

For the purposes of this disclosure, “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.

4. 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 publications and career advancement.*

Yes No

If “Yes,” please explain: (Attach additional pages if necessary.)

5. Does the arrangement with the sponsor include financial bonus payments related to speed of enrollment or other milestones?

Yes No

OR _____ **I have not seen the contract with the sponsor.**

If yes, describe the arrangement.

6. Will a company in which you have an interest receive materials from this research project? **Yes No**

7. Do you plan to pay referring physicians or other persons a “finder’s fee” or present them with a “gift-in-kind”? **Yes No**

If yes, describe the arrangement.

8. 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?

If “Yes,” please explain: (Attach additional pages if necessary.)

By signing this disclosure form, I certify that I have read a copy of the [HIC Policy on Protocol-Related Conflict of Interest](#) and the [University Policy on Conflict of Interest and Conflict of Commitment](#) and affirm the accuracy and completeness of the information provided on this form.

(See: <http://grants.med.yale.edu/conflict.html>)

Signature of Investigator or Study Person Submitting Disclosure Form

Printed Name: _____ **Date:** _____

HIC Protocol Number: _____

Retention of Information: The HIC will retain this information in confidential files, and in the case of Yale Affiliated Investigators and study personnel, may refer this information to the University COI Committee.

*******For HIC Use Only*******

Action: _____ **Date** _____

Signature of HIC Chair: _____

Referred to University COI Committee? **Yes** **No**