

**CONFLICT OF INTEREST (COI)
DISCLOSURE FORM
CONFIDENTIAL**

**NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
CENTER FOR CANCER RESEARCH
OFFICE OF SPONSOR AND REGULATORY OVERSIGHT**

NOTE: In this document the term “you” will be used to indicate applicability to you AND your spouse, dependent children, or any household members or relatives with which you currently have close personal relationships.

Instructions:

- Check the appropriate response for each question. If the answer is “yes” to any question, please provide the additional information as requested.
- You must provide a copy of your current detailed curriculum vitae when submitting this disclosure form.

A. PROFESSIONAL

1. Are you

- a. directly involved in the conduct of the study(ies) to be reviewed?
- b. in a direct supervisory relationship with one or more members of the research team; or serving in a data and safety monitoring role while being supervised by an individual who is part of the research team?
- c. involved as a plaintiff, defendant, or expert witness in litigation related to the interventions or products being tested, or in competing products or interventions?

Yes

No

2. Are you serving as a part-time, full-time, paid, or unpaid employee of any organizations

- a. that are involved in the study(ies) under review (e.g., involved in protocol development or supervise a member of the study team)?
- b. whose products or services will be used or tested in the study(ies) under review?
- c. whose products or services would be directly and predictably affected in a major way by the outcome of the study(ies)?

Yes

No

If yes, please identify the organization; describe employment status of you or your family member(s) and indicate what products or services would be affected.

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3. Are you currently serving as
- a. an officer, member, owner, trustee, director, expert advisor, or consultant of an organization with a direct role or stake in the study under review?
 - b. a director, officer or other decision-maker for a commercial collaborator of the human subjects research?

Yes

No

If yes, please provide the name of the organization and the role of you and/or your family member(s).

- c. Within the past 5 years have you served or anticipate serving as a co-author on a scientific paper with the principal investigator (PI) for the protocol under review, even if the subject matter is not addressed in the current study being reviewed.

Yes

No

B. PROPRIETARY

4. Do you
- a. obtain royalties that derive from intellectual property or tangible materials relevant to the development and commercialization of any product being reviewed; or are you personally named as an inventor on patents or patent applications relevant to the product(s) being reviewed in the human subjects research or products in direct competition with the product(s) being reviewed?
 - b. own or control intellectual property rights or other proprietary rights in any of the products being reviewed or in products in direct competition with such products under review?

Yes

No

C. FINANCIAL

5. Do you currently receive any funding, payment, compensation or honoraria, in any form from the commercial sponsor of the human subjects research?

Yes

No

If yes, please provide the name of the commercial sponsor and the type of compensation.

6. Do you
- a. hold stock in excess of \$5,000 in any single entity whose study is under review?
 - b. have financial interests or assets in organizations with which the individual with data safety monitoring responsibilities is connected?
 - c. receive payments based on the research recruitment or outcomes; receive payments as consultant/advisor to a commercial sponsor; or accept payment from the human subjects research sponsor?

Yes

No

If yes, please provide the name of the organization/commercial sponsor and the type of compensation.

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Member certification:

- I/my spouse, dependent children, or any household members or relatives with whom I have currently personal relationships do not have any financial or other interest with any of the collaborating or competing pharmaceutical firms or other organizations involved in the study that constitute a potential conflict of interest.
- I will notify OSRO promptly if a change occurs in any interests or activities during the tenure of my responsibilities that may create a potential conflict of interest.
- I will disclose interests that may create a potential conflict to the DSMB prior to any discussion so that they can be reflected in the minutes along with the determination of the DSMB on how to handle such potential conflict(s).
- I am aware of my responsibilities for maintaining the confidentiality of any non-public information that I receive or become aware of through this activity, and for avoiding using such information for my personal benefit, the benefit of my associates, or the benefit of organizations with which I am connected or with which I have a financial involvement.

Member Name Printed

Signature

Date

This box for OSRO Use ONLY:

OSRO review of eligibility:

I have reviewed the conflict of interest disclosure information provided, in addition to the current curriculum vitae; and find the member **is eligible** to serve as a DSMB member at this time.

I have reviewed the conflict of interest disclosure information provided, in addition to the current curriculum vitae; and find the member **is eligible** to serve as a DSMB member at this time with the disclosure of:

I have reviewed the information provided and find the proposed member **not eligible** to serve as a DSMB member at this time due to an unmanageable potential conflict of interest, which is:

Director, OSRO or designee

Signature

Date