

**NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
(NIAID)
Appendix 1 Version 2.0**

Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees Involved
in Data and Safety Monitoring

The following lists examples of COI and represents the minimum standards for identifying potential COI. Divisions may add additional examples as needed. This list is not all-inclusive and may be used as a template. This document should be used in conjunction with processes outlined by your Division/Center. All of the following apply to the individual, their spouse, dependent children, other relatives with whom they have a close relationship, and household members.

Professional

- Serving as a director, officer or other decision-maker for a commercial collaborator of the human subjects research.
- Having served within the past 5 years or anticipating 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.
- Serving as an officer, member, owner, trustee, director, expert advisor, or consultant of an organization with a direct role or stake in the study under review.
- Having other personal or outside relationships with the commercial sponsor of the human subjects research (prohibited activity for NIH employees).
- Serving as part-time, full-time, paid or unpaid employee of any organizations: (a) that are involved in the study 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 under review, or (c) whose products or services would be directly and predictably affected in a major way by the outcome of the study.

Note: In the case of an ISM, the individual may be permitted to be an employee of the organization(s) participating in the clinical trial under review.

- Having 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.
- Involvement as a plaintiff, defendant, or expert witness in litigation related to the interventions or products being tested, or in competing products or interventions.

Proprietary

- Royalties paid to the DSMB member, his/her spouse, dependent children, other relatives with whom s/he is deemed to have a close relationship or household members, that derive from intellectual property or tangible materials relevant to the development and commercialization of any product being reviewed; being personally named as an inventor on or having a spouse, dependent children, or household members or relatives with whom they are deemed to have close personal relationships 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.
- Owning or controlling 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 of his/her own or having a spouse, dependent children, or household members or relatives with whom are deemed to have close personal relationships 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.

Financial

- Having significant financial interests, for example:
 - Holding stock in excess of \$5,000 in any single entity whose study is under review.
 - Receiving honoraria from a commercial sponsor of the human subjects research. This excludes honoraria and travel expenses provided by NIAID to DSMB, SMC members and ISM.
 - Having financial interests or assets of his/her own or those of his/her spouse, dependent children, or household members in organizations with which the individual with data safety monitoring responsibilities is connected.
 - Receiving payments based on the research recruitment or outcomes; as consultant/advisor to a commercial sponsor; or accepting payment from the human subjects research sponsor.
 - Receiving any funding, payment or compensation in any form from the commercial sponsor.
 - Having financial interest above the applicable de minimis in a company with a similar competing product to the product or agent under study.

Other:

- Additional financial interests or relationships not listed above that may represent a conflict. Other interests or relationships, which would cause a reasonable person to question the individual's impartiality in the oversight or evaluation of the study, should be disclosed.

References:

SOP 21: Conflict of interest requirements for researchers and research staff.

https://ethics.od.nih.gov/procedures/SOP_21_v3_10-21-14.pdf

SOP 21 Appendix A

https://ethics.od.nih.gov/procedures/SOP_21_Appendix_A_NIH_Guide_to_Avoiding%20COI_10-17-14.pdf

NIH Policy Manual 2400-04 Managing Conflict of interest and the introduction of bias

<http://oma1.od.nih.gov/manualchapters/ethics/2400-04/>

45 CFR Part 94 Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf