NIH Policy Manual

3014-202 - Board Member Financial Conflicts of Interest

Issuing Office: OD/OIR/OHSRP **Phone:** (301) 402-3713

Release Date: 8/13/2020 ? **Technical Revision Date:** 2/04/2022 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** NIH Human Research Protection Program (HRPP) policies have been revised to comport with the revised HHS Common Rule (45 CFR 46) and to reflect the newly consolidated IRB structure within the NIH Intramural Research Program. This policy describes the requirements for identification and management of real or perceived financial conflicts of interest of NIH Institutional Review Board (IRB) members and IRB consultants, and prevention of these real or perceived conflicts from interfering with the research review process.
2. **Filing Instructions:**
    - **Insert:** NIH Manual Chapter 3014-203, dated 08/13/2020
    - **Implementation Date:** 3/1/2021
3. **PLEASE NOTE:** For information on:
    - The current policies can also be found at: https://irbo.nih.gov/confluence/display/ohsrp/Policy.
    - Content of this chapter, contact the issuing office listed above.
    - NIH Policy Manual, contact the Division of Compliance Management, OMA, on 301-496-4606 or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

1. To identify and manage real or perceived financial conflicts of interest of NIH Institutional Review Board (IRB) Chairs and members, and to prevent these real or perceived conflicts from interfering with the research review process.

B. Scope

1. This policy applies to all NIH IRB Chairs, primary members, alternates, and nominees, (Chairs, primary members, alternates and nominees will be referred to as “members” throughout the remainder of this policy, unless a requirement is specific to one group) regardless of the level or type of research reviewed by the NIH IRB(s).

2. This policy applies to consultants selected to advise the NIH IRB (IRB consultants), who are not IRB members.
3. This policy applies to the Office of Human Subjects Research Protections (OHSRP) including the Office of IRB Operations (IRBO).
4. This policy applies to the NIH Ethics Offices.
5. This policy applies to the Deputy Director for Intramural Research (DDIR).

C. Policy

1. In accordance with federal regulations on the protection of human subjects, no NIH IRB member may participate in the review of, or voting upon, an action in which the member has conflicting interests. (45 C.F.R. § 46.107 and as applicable 21 C.F.R. § 56.107; see also Policy 3014-201 IRB Membership and Composition.)
2. IRB consultants selected to advise the IRB may not consult on any action in which they are conflicted.
3. The NIH is committed to a policy that does not allow IRB members to participate in official matters that affect their personal financial interests and will ensure that they do not have a financial interest which could raise concerns about the integrity of the program or the IRB review and approval process.
4. In addition to the requirements of 45 C.F.R. § 46.107 and 21 C.F.R. § 56.107, IRB members who are Federal employees are also subject to the government-wide ethical conduct requirements in the context of their IRB service and cannot, therefore, participate personally and substantially in any particular matter that will affect their personal financial interests, as well as their imputed financial interests, which include the interests of the member's spouse, minor child(ren), other household members, any organization in which the employee serves in a fiduciary capacity, a general partner, or any entity with which the employee is negotiating for, or has an arrangement for, prospective employment. (18 U.S.C. § 208)

    a. In addition, Federal employees are prohibited from participating in specific party matters involving persons and organizations with which they have a "covered relationship." For example, a Federal employee has a covered relationship with family members and their employers, and any entity the employee has served within the last year as an employee or other fiduciary, a consultant, or a contractor. (5 C.F.R. § 2635.502)

5. IRB Members will comply with the conflict of interest (COI) clearance requirements described in this policy.
6. The IRBO will ensure that the COI clearance process has been completed prior to any submission for approval to the OHSRP Director or designee, of an initial appointment or re-appointment of an IRB member(s).
7. To maintain the independence of NIH IRBs, generally, the OHSRP Director or designee will not appoint IRB members (or allow them to continue to serve as an IRB member) who have, or who acquire, certain financial interests that may be affected by the work of the NIH Intramural Research Program (IRP).

a. In the case of interests in Substantially Affected Organizations (SAOs) (e.g., a biotechnology or pharmaceutical company), such interests include: 1) aggregate interests in one or more publicly-traded Substantially Affected Organizations (SAOs) valued in excess of $15,000; 2) aggregate interests in one or more SAO sector funds valued in excess of $50,000; and 3) interests in privately-held SAOs, regardless of the market value.
b. Notwithstanding the above limitations, in consultation with the NIH Ethics Office (NEO) Director, the DDIR has the authority to review and determine that a specific SAO will not be affected by the work of the NIH IRP (e.g., because the IRP does not do research on the types of products made by the SAO) and need not, therefore, be included in the aggregation analysis.

8. Review of NIH Federal employee IRB member financial disclosure filer designations will be done annually by the IC Ethics Offices.

    a. For non-federal IRB members and non-NIH Federal employee members, the certification forms will be collected by the IRBO at the time of initial appointment, reappointment, and annually.

9. The IRB COI clearance process will be managed consistent with current regulations and NIH policies for confidentiality. Information considered in connection with COI clearance for IRB members will be reviewed on a need to know basis and withheld from disclosure to the extent permitted by law.

D. Definitions

OHSRP has developed a comprehensive glossary of definitions that describe the terms listed below. The glossary can be found at the following link: NIH IRP HRPP Policy Glossary.

Note: There *may be more than one definition per term*, so please review terms carefully to make sure they match the terms listed below. Qualified terms are indicated with a parenthetical qualification. When reviewing a definition, be sure that you are reviewing the appropriate definition that links to this policy. To further assist the reader, each term in the glossary cites the relevant policy number(s) indicating where the term is utilized.

1. Appearance of Conflict of Interest
2. Conflict of Interest
3. Non-NIH Federal Employees
4. NIH Federal Employees
5. Non-federal IRB Members
6. Sector Fund
7. SAO Sector Fund
8. Substantially Affected Organization (SAO)

E. Responsibilities and Requirements

1. **The Office of IRB Operations (IRBO)**

    a. The Office of IRB Operations (IRBO) Director or designee must ensure that real or perceived conflicts of interest are identified and managed with respect to board membership and assignment of reviewers, consistent with applicable procedures, and for confirming that IRB consultants do not have conflicts of interest relevant to the research under review.

        I. The IRBO must ensure that the COI clearance process occurs when a potential IRB member is nominated, or is reappointed to the IRB, or as part of an annual COI review.

    b. The IRBO must ensure that the process for submission and management of conflicts is completed prior to the nomination or renewal of a member.
    c. The IRBO must disseminate the roster of IRB members to the NIH Ethics Office (NEO) annually, or upon request, to aid the IC Ethics offices in their annual review of the financial disclosure filing status of members and the COI clearance of IRB members.

2. **NIH IRB Members**

    a. NIH IRB members must identify any real or perceived conflicts of interest at the time of initial appointment, renewal of membership, annual COI review, or when a current IRB member has changes to his or her financial interests, and at each IRB meeting in which the member participates.
    b. All NIH IRB members must comply with NIH Ethics clearance procedures:

        I. NIH federal employees must comply with NIH ethics procedures as directed by their IC Ethics Office. This includes NIH federal employees who are only financial disclosure report filers because of IRB membership.
        II. Non-NIH federal employees IRB members must complete and submit the *Certification Form for IRB Members Who are Non-NIH Federal Employees and Non-Federal Members* (*Appendix 1*) upon nomination, and annually thereafter to the IRBO.
        III. To better understand what constitutes a conflict, all IRB members must read the "*A Guide to Avoiding Financial and Non-financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH*".

3. **Consultants to the NIH IRB**

    a. To better understand what constitutes a conflict, IRB consultants must read A Guide to Avoiding Financial and Non-financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH.

b. IRB consultants must identify any real or perceived conflicts of interest at the time of selection by the IRBO, and if conflicted may not serve as a consultant to the NIH IRB (see C.2. above).

4. **The NIH Ethics Office (NEO) and IC Ethics Offices**

a. The NIH Ethics Office (NEO) must:

I. Provide ethics policy guidance to the DDIR, OHSRP and IRBO;
II. Provide advice and consultation to the DDIR regarding specific SAO determinations;
III. Maintain and distribute to the IC Ethics Offices the list of SAOs determined by the DDIR not to be affected by the work of the IRP; and
IV. Disseminate the roster of IRB members to IC ethics offices annually, or upon request, to aid IC Ethics offices in completing their annual filing status and COI reviews of NIH IRB members.

b. The IC Ethics offices must:

I. Perform COI clearance of employees within their IC when they are nominees or members of the NIH IRB;
II. Serve as a point of contact for questions about filing requirements and COI from employees within their IC; and
III. Notify the IRBO of member COI clearance status.

5. **The DDIR**

a. The DDIR must:

I. Upon request, review and make determinations about specific SAOs as described in C.7.b. above.
II. Upon request, and after consultation with the NEO, determine that a specific SAO is not affected by the work of the NIH IRP because the IRP does not do research on the types of products made by the SAO.
III. Re-evaluate the list of these SAOs annually.

6. **OHSRP**

a. The OHSRP must:

I. Serve as a resource to the IRBO, and outside organizations, for questions about this policy, and
II. Coordinate requests for determinations about specific SAOs as described in E.4. above.

F. References

1. **Federal Regulation**
    - 45 C.F.R. § 46
    - 21 C.F.R. § 56
2. **NIH Policies**
    - NIH Ethics Policies
3. **Guidance and Resources**
    - A Guide to Avoiding Financial and Non-financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH

Appendix 1: Certification Form for IRB Members Who are Non-NIH Federal Employees and Non-Federal Members

August 2020

To be completed by non-NIH Federal employees who do not file financial disclosure reports and all non-Federal IRB members.

IRB members who are Federal employees are subject to the government-wide ethical conduct requirements in the context of their IRB service and may not, therefore, participate personally and substantially in any particular matter that will affect their personal financial interests, as well as their imputed financial interests, which include the interests of the member's spouse, minor child(ren), other household members, any organization the employee serves in a fiduciary capacity, a general partner, or any entity with which the employee is negotiating for or has an arrangement for prospective employment (18 U.S.C. § 208). In addition, Federal employees are prohibited from participating in specific party matters involving persons and organizations with which they have a covered relationship, including family members and their employers, and any entity the employee has served within the last year as an employee or other fiduciary, a consultant, or a contractor (5 C.F.R. § 2635.502).

Furthermore, per federal regulation, no Institutional Review Board (IRB) may have a member participate in the IRB's review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (see 45 C.F.R. § 46.107(e)).

To maintain the independence of NIH IRBs, NIH will not appoint IRB members (or allow them to continue to serve) who hold a financial interest in: one or more publicly-traded Substantially Affected Organizations (SAOs)* with an aggregate market value exceeding

$15,000; one or more SAO sector funds** with an aggregate market value exceeding $50,000; or any privately-held SAOs, regardless of the market value.

The individual with an identified eligibility to serve question may resolve it by one of the following mechanisms: 1) reducing the value of the holding below the value limits described above; or 2) choosing not to serve or resigning from the IRB. Accordingly, any nominee (or member) with an identified conflict will not be appointed to an IRB (or be allowed to continue to serve) until the question is resolved. The nominee/member can also notify the IRB Chair that he or she does not wish or is unable to resolve the conflict and therefore will be unable to serve.

If you are unable to sign this form, please contact the IRBO immediately. In addition, if after signing this form, the holdings of the nominee/member change such that you are no longer able to certify to this form, you should notify IRBO immediately.

Name of IRB Member:

IRB Name:

Home Institution/Employer (if any):

I certify that I am in compliance and do not have personal or imputed SAO or SAO sector fund interests above the value limits stated above. I also certify that I have received and read the Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Human Subjects Research at NIH.

_____ _____

(Signature) (Date)

* Under 5 C.F.R. § 5501.109, a SAO is generally defined as a pharmaceutical, biotechnology and medical device manufacturing company; or other organization with similar interests or involvement. For additional information on SAOs, please see https://ethics.od.nih.gov/sao-intro.

** Any sector mutual fund that states in its prospectus the objective of concentrating its investments in the securities of substantially affected organizations.