NIH IRB Member Evaluation of Investigator COI: What IRB Members Need to Know

A Conflict of Interest (COI) occurs when a government matter, including clinical research, will have a direct and predictable effect on the financial interests of an individual or the individual's spouse, minor children, general partner(s), or certain other organizations in which the individual serves as an officer, director, trustee, general partner or employee, and any entities with which the individual is negotiating for, or has an agreement regarding, prospective employment.

Covered Research Protocols (CRPs) include those that involve: (1) investigational drugs and devices; (2) a research question about a commercially available drug or device; and (3) involve collaborations with a substantially affected organization (SAO)[1] or other for-profit entities when the entity is receiving data or specimens from the NIH for the purpose of developing a product. Most interventional protocols will be CRPs unless the intervention does not involve the criteria listed above. **Non-Covered Protocols** include NIH protocols that do not meet the definition of a covered protocol.

Review of a Covered Research Protocol Prior to Review by the IRB

- The NIH PI first determines if the protocol meets the definition of a CRP. If so, it is submitted for further review by their IC Deputy Ethics Counselor (DEC) at initial and continuing reviews, as well as for amendments when there is addition of a new investigator or statistician, change or addition of SAO or IND/IDE, or the protocol becomes a CRP.
- The DEC reviews the submitted financial holdings of those NIH investigators who are ethics filers engaged in human subjects research (HSR) as well as those involved in analysis of primary endpoint data whose role has potential to bias research results (e.g., study statistician, epidemiologist), even if they are not otherwise engaged in HSR. NIH investigators or statisticians working on a CRP who are not NIH ethics filers complete a COI Certification provided to the DEC. (Non-NIH site investigators on the CRP must follow the COI policies of their home institutions. However, they must certify to the NIH that they are not conflicted with the SAO related to the CRP, or they are not able to serve on the study staff for this protocol.)
- If there is an actual or apparent COI, the IC Ethics office will work with the employee, the NIH PI, NIH Ethics Officials and/or the Office of the General Counsel, Ethics Division, to identify an appropriate remedy under applicable law. Remedies may include: complete or partial divestiture of one or more conflicting financial interests; disqualification from participation in the research; or a waiver is issued by the NIH Director to permit participation. (Such a waiver is very rare and explained further in SOP 102.) Federal law precludes disclosure of these reviews such that the IRB will not be informed of how specific COIs have been mitigated. IC level leaders (Director, Deputy Director, Scientific Director, and Clinical Director) undergo increased scrutiny and are subject to additional regulation.
- In addition, if at the time of protocol submission, the PI indicates that any investigator engaged in the protocol is listed as an inventor for any intellectual property (for example a drug, device, or assay) that is the object of this investigation, the protocol is referred for administrative review by the Conflict of Interest Committee (COIC). The COIC Chair or designee may collect additional information regarding the intellectual property and associated royalties (if any), and the COIC will review this information within the context of the protocol. The COIC determination is conveyed to the IRB and the affected investigator and includes one of the following recommendations to the IRB: no measures are recommended (no COI); disclosure in consent form is recommended without additional measures; or disclosure in the consent along with additional measures as described.

IRB member review of a Covered Research Protocol at the time of IR, CR or submission of a relevant amendment

- ✓ Check the eIRB system to confirm that DEC review occurred and, if applicable, review COIC recommendations.
- ✓ IRB members must ensure that consent forms for CRPs have language that is appropriate for the given situation. **NIH consent templates on the IRBO website** have recommended consent language for various circumstances in the section of the consent template labeled *CONFLICT OF INTEREST (COI).*

IRB member COI during conduct of the meeting: If the investigator is an IRB member and present at a convened meeting when their study is being reviewed, the investigator must be recused during consideration of their study but may provide information about the study if requested by the IRB. If this occurs, the IRB needs to ensure that quorum is maintained. IRB members can also recuse themselves if they feel they are conflicted and cannot provide an unbiased review, even if they are not a study team member.

[1] An SAO is a biotechnology or pharmaceutical company, a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products.