



## **CONFLICT OF INTEREST PERTAINING TO DUHS IRB MEMBERS AND CONSULTANTS**

3/17/2021

DUHS IRB Members and Consultants are responsible for making known any potential or perceived conflicts of interest (COI) concerning protocols reviewed by the IRB. These conflicts could include the IRB member's/consultant's role in any of the following categories of activity with respect to the study in question:

- Acting as Principal Investigator, Co-Principal Investigator or other key personnel
- Personally receiving funding or funded effort from the study, as listed in the study budget
- Acting in a supervisory role over the PI of the study,
- Being involved in research utilizing a competing technology such that the ability to render an objective assessment could be compromised; or
- Being a family member involved in a close personal relationship with a member of the study team (for example, as a spouse or immediate family member)

An IRB member or consultant is considered to have a conflicting interest when the member/consultant or their immediate family has any of the following:

- Involvement in the design, conduct, or reporting of the research with the following exception:

- An IRB member who is listed on an IRB protocol as a member of the study's Key Personnel but whose study-related activities are limited to (i) the performance of commercial services for the investigator (or performing other genuinely non-collaborative services meriting neither professional recognition nor publication privileges), while (ii) adhering to commonly recognized professional standards for maintaining privacy and confidentiality, is not considered to have a conflicting interest on this basis.
- Supervisory role over the principal investigator of the research.
- A conflict of interest management plan issued by the Duke Office of Scientific Integrity – Conflict of Interest (DOSI-COI) overlapping with the research.
- Stock ownership or stock options, equity, or other financial interest related to the research valued at \$5,000 or more.
- Personal compensation of \$5,000 or more related to the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, such as an Advisory Board or Board of Directors, regardless of compensation.

- Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

Board members and consultants should make known any conflict of interest prior to the beginning of the Board's discussion of the protocol under review. They must leave the meeting room prior to the Board's deliberation and vote.

Additionally, IRB members are responsible for self-identifying any conflicting interests before conducting review using the expedited procedure, so as to remove themselves from involvement in the review of the research.

Individuals who are responsible for business development are prohibited from:

- Serving as members or ex-officio members on the IRB.
- Carrying out day-to-day operations of the review process.

Staff members from the Office of Research Administration, the Office of Licensing and Ventures and the Office of Research Contracts are prohibited from serving as voting members of the IRB. Individuals from these offices may provide information to the IRB and attend IRB meetings as guests.

### **COI Query by Chair or Vice Chair**

The chair or vice chair will read or paraphrase the statement below at the beginning of each convened meeting:

*"Does anyone have a conflict of interest with any investigator or protocol that is under consideration today? If you do, you will be expected to leave the room unless the IRB requests you to stay temporarily to answer questions about the study, but you must leave the room during the IRB's deliberations and vote on the protocol."*

*"Should you realize at any time during today's meeting that you have a conflict of interest regarding a protocol under review, please promptly declare it as so."*

This COI query by the chair will be recorded in the minutes, along with any declarations of COI made by the members.

Previous Version Date(s): 6/25/2008, 6/7/2011, 7/1/2013, 5/20/2016, 6/5/2019