Managing Conflicts of Interest when Research Involves Human Participants

As stated in Principle 6 of Cornell Policy 1.7 regarding Human Participant Research:

Protecting the rights and welfare of human research participants is of the utmost importance and a requirement of all research personnel and the university. Of particular concern, therefore, are external commitments and financial interests that compromise or appear to compromise the rights and well-being of human research participants. The university scrutinizes the roles in such research of research personnel who have external commitments and financial interests with a sponsor or with an external entity that is related to, or can be affected by, the research.

The university has instituted a rebuttable presumption that research personnel who are involved in the design, participant selection, informed consent process, or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. In other words, the default position is that participation in human participant research by conflicted research personnel is not allowed. However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research. In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk.

A Conflict Management Plan, approved by the Financial Conflict of Interest Committee, with terms and conditions appropriate to the conflict, must be implemented to ensure the integrity of Cornell research, appropriate protections for students, and compliance with University policies. Information on management plans is available at https://www.oria.cornell.edu/COI/mgmtplaninfo/

Consistent with the principle stated above, the conflict management plan must also include additional protections for human participants. The Cornell Institutional Review Board (IRB), which is responsible for ensuring that the interests of research participants are protected, has the final authority in determining the conditions under which such research is allowable. Such research can be conducted with the restrictions listed below. In exceptional cases, the FCOI Committee and the IRB may elect to waive some of these restrictions if they believe that these conditions will not be in the best interests of research, the institution and the human participants:

1. The conflicted researcher may not serve as the PI for the research. Another individual who does not report to the researcher and does not have a financial interest in the company must serve as the PI.
2. The researcher may not be involved in the consenting, advising or data collection processes with participants.
3. In some instances, including clinical trials, the data may need to go through an independent review by a third party approved by the FCOI Committee.
4. During the consenting process, participants must be informed of the researcher’s relationship with the entity and, if appropriate, of the steps that are being taken to protect their interests and in the integrity of the research.

The Conflict Management Plan must be implemented before research personnel can participate in the design or conduct of the research, enrollment of participants, or analysis of the results.