

Financial conflict of interests and human subjects research: overcoming the rebuttable presumption

The American Association of Medical Colleges [Task Force on Financial Conflicts of Interest in Clinical Research](#) has recommended that proposed human subjects research by investigators with significant financial interests undergo intensive review at the institutional level:

With the welfare of research subjects always of foremost concern, an institution should regard all significant financial interests in human subjects research as potentially problematic and, therefore, as requiring close scrutiny. Institutional policies should establish the rebuttable presumption that an individual who holds a significant financial interest in research involving human subjects may not conduct such research. The intent is not to suggest that every financial interest jeopardizes the welfare of human subjects or the integrity of research, but rather to ensure that institutions systematically review any financial interest that might give rise to the perception of a conflict of interest, and further, that they limit the conduct of human subjects research by financially interested individuals to those situations in which the circumstances are compelling.

Several institutions have incorporated a rebuttable presumption in institutional policies (e.g., [UVA](#), [Harvard Medical School](#), [Stanford University](#), [Vanderbilt University](#), [Emory University](#)).

The table below provides guidance on the circumstances under which a financially conflicted investigator might overcome the rebuttable presumption. In reviewing such proposals, the UVA Conflicts of Interest Committee assesses the nature of the proposed research, the opportunity to manipulate study results for financial gain, and whether an effective management plan can be established. Committee recommendations will depend on the specific financial conflict and proposed research, rather than on hard and fast rules.

Activity	Guidance
Site Principal Investigator	Normally, a financially conflicted individual may not participate as site PI. Unique expertise or access to a unique patient population may form the basis for overcoming the rebuttable presumption.
Recruitment, screening, consenting	Normally, a financially conflicted individual may not participate in recruitment, screening, or consenting of research subjects.
Collection of study readouts	Normally, a financially conflicted individual may not collect the data used to evaluate study endpoints. Exceptions might be granted for laboratory assays where the specimens are blinded.
Data entry and cleaning	Normally, a financially conflicted individual may not participate in these activities.
Data analysis	Normally, a financially conflicted individual may not participate in data analysis since analysts generally are not blinded to the study arms.
Writing or presentation of reports	Normally, a financially conflicted individual may participate as a member of a writing group for resulting manuscripts/report, but s/he may not (1) lead the writing group, (2) write the first draft of any manuscript, and (3) be the first or senior author of any resulting publication.
Participation as coordinating investigator (multi-center studies)	Normally, a financially conflicted individual may participate as the coordinating investigator on a human subjects protocol.