

Guidelines for Reviewing Research Conflicts of Interest in Interventional Human Subject Research

In general, there is a rebuttable presumption that conflicted Investigators will not participate in interventional human subject research (HSR) unless there are compelling circumstances. For the purposes of these guidelines, interventional HSR is a research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome.

Compelling Circumstances

The RCOI Administrator may consider compelling circumstances when making a determination about a conflicted Investigator's permitted involvement in interventional HSR. The following factors will be considered when determining whether compelling circumstances exist:

- (1) the nature of the research;
- (2) the magnitude of the significant financial interest and the degree to which it is related to the research;
- (3) the extent to which the significant financial interest could be directly and substantially affected by the research;
- (4) the degree of risk to the human subjects involved that is inherent in the research protocol;
- (5) the extent to which the conflicted Investigator is uniquely qualified to perform a research study with important public benefit, and;
- (6) the extent to which the SFI is amenable to effective oversight and management.

IRB Notification and Review

The Institutional Review Board (IRB) will be notified of conflict of interest management strategies implemented for research overseen by an IRB. It is in the purview of an IRB to review the conflict of interest management strategies associated with IRB protocols and determine whether or not the conflict of interest management is sufficient with respect to the rights and welfare of human research participants.

If the UF IRB determines that additional conflict of interest management is necessary to protect the rights and welfare of human research participants, the IRB will notify the RCOI Administrator in writing.