

DEPARTMENT: Clinical Operations Group - Research	POLICY DESCRIPTION: IRB Handling Conflicts of Interest in Research
PAGE: 1 of 3	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.IRB.010 (formerly CSG.IRB.010)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy pertains to all Company-affiliated facility-run Institutional Review Boards (IRBs).
NOTE: that there may be institutional obligations pertaining to conflicts of interest that are outside the scope of this policy, especially for HHS funded studies.

PURPOSE: To provide guidance on how to assure protection of human subjects in the presence of potential conflicts of interest with investigators or IRB members.

POLICY:

1. Identifying Potential Conflicts of Interest

- a. IRB Member Conflicts: IRB members are determined to be conflicted when:
 - i. they have a proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement;
 - ii. they are involved in the design, conduct, or reporting of the research;
 - iii. they are in a subordinate role to the Investigator (i.e., employee, student, etc.); or
 - iv. they have any other interests that would impair their ability to make fair and impartial judgments about an application.
- b. Investigator Conflicts: There are numerous stakeholders (i.e., NIH, FDA, research sponsors, trade associations, institutions, etc.) that define and require reporting of investigator conflicts of interests for various reasons specific to the activity. The general process is that the investigator reports significant financial interests (defined with different thresholds by NIH and FDA) to their Institution (for NIH-funded studies) or the Sponsor (for FDA-governed clinical investigations) or both (for NIH-funded and FDA governed clinical investigations). The Institutional Official and/or Sponsor determines if the significant financial interest could affect the research (be it human subject protections, data integrity or other aspects of the research) and if so, works to eliminate or manage that conflict and report it accordingly to the federal agencies. The role of the IRB is solely to assist the institution in determining if any conflict of interest affects the protection of human subject in research and if so, assist in the management plan. The IRB only receives information pertaining to conflicts of interest as defined by these various stakeholders. The IRB is not responsible for creating or reporting such information in regulatory required reports (i.e., FDA's 21 CFR 54 or PHS reports) unless otherwise assigned to do so by the Institution.

2. Determining A Potential Conflict Of Interest As Affecting Human Subject Protection

- a. The IRB must consider whether the specific conflicts of interests (perceived or otherwise) may adversely affect the rights and welfare of subjects. The "reasonable person" test should be utilized in making this determination.
- b. In the absence of an IRB opinion or a financial interest, individuals may self-determine that a conflict of interest exists that may adversely affect the rights and welfare of subjects. This may be in cases where they feel that their decision is being altered by other personal factors

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such as loyalty to colleagues, business competition with investigators, personal agendas or fear of IRB decisions impacting their non-IRB work.

3. Eliminating or Managing the Conflict Of Interests Potentially Affecting Human Subject Protection

- a. If a conflict of interest is eliminated, then further management is not necessary.
- b. Managing IRB members conflicts of interest: For a conflicted IRB member whose role is limited only to voting on the study, the risk must be managed via the following without exception:
 - i. The conflicted member(s) may not serve as the primary reviewer, expedited reviewer, determiner of exempt status or consultant for the given research activity.
 - ii. During convened meetings, the conflicted member(s):
 - 1. May provide information germane to the discussions but must leave the meeting room during deliberations and voting; AND
 - 2. Are not counted towards a quorum, thus a quorum must be re-validated after they leave in order to vote; AND;
 - 3. Documentation of such absence must be in the minutes.
 - iii. Other protections for Conflicts of Interests affecting IRB Members include:
 - 1. The Use of and Relationship With Institutional Review Boards Policy, COG.RSH.004, forbids facility representatives from using their authority to unduly influence how individual IRB members vote and that any violation of this policy should be immediately reported to the Institutional Official, the Facility Ethics and Compliance Officer, the Corporate Responsible Executive for Clinical Research or the Ethics Line. Depending on the severity and circumstances, the outcome of such investigations could range from requiring education to disciplinary action.
 - 2. The IRB Membership and Training Policy, COG.IRB.002, states that individuals (or their immediate family) with an equity interest in the institution may not serve as voting members of the IRB or in the carrying out of day-to-day operations of the review process.
- c. Managing Investigator Conflict of Interest
 - i. It is up to the IRB, not the Clinical Investigator, to make the final determination as to if an actual, potential or perceived conflict of interest is significant enough (or of the mitigation plan worked in conjunction with the Institutional Official or research Sponsor is sufficient enough) to require additional steps to be taken to minimize the potential for bias or harm; however, the IRB would usually support any efforts volunteered by the investigator.
 - ii. In the event the conflict cannot be eliminated, in order for the study to be approvable, the IRB must be assured that the potential conflict of interest is managed to the point that any potential effects to human subject protections are minimized. The circumstances of the protocol, the subjects and the nature of the conflict will determine the best management plan for the conflict, some examples include:
 - 1. Disclosing the potential conflict of interest during the Informed Consent process.

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- 2. Having another non-conflicted person perform informed consent interviews or collect data.
 - 3. Establishment of a more sufficient monitoring plan.
4. **Non-compliance/non-adherence to this policy**
- a. The IRB (or designee) shall assist the Institution in any retrospective review they are required to do for DHHS or other funded studies when notified of any of the following:
 - i. that an Investigator failed to disclose (or inaccurately disclosed) to the IRB a significant financial interest that is determined by the Institution (or IRB if assigned to do so by Institution) to constitute a financial conflict of interest;
 - ii. that the IRB failed to review or manage such a financial conflict of interest; or
 - iii. that the Investigator failed to comply with a financial conflict of interest management plan.
 - b. The IRB shall be involved, as necessary, in the Institution’s drafting of any corrective and preventative action plans.
5. **Confidentiality**
- To the extent permitted by law, all Statements, letters, other records and information submitted will be maintained confidentially by the IRB and IRB members. Statements, other records and information, however, may be made available to any federal agency funding research upon written request of the agency, and otherwise as required by law.

REFERENCES:

- 1. IRB Related Definition and Common Acronyms Policy, [COG.IRB.001](#)
- 2. Clinical Operations Group Research Policies in the COG.IRB series (COG.IRB.001 through COG.IRB.011)
- 3. Use of and Relationship With Institutional Review Boards Policy, [COG.RSH.004](#)