

HAC Policies and Procedures for HAC Members and OHRP Staff

Conflict of Interest

What is the Definition of a Conflict of Interest?

Conflict of interest may be defined as: "A conflict between the private interests and official responsibilities of a person in a position of trust." This definition is not limited to financial conflicts of interest.

What is a Conflict of Interest for an HAC Member, Special Expert or Consultant?

"Conflict of interest" means any situation in which it reasonably appears that a significant financial interest or other personal interest could compromise the integrity of work to be performed for MCG (for instance without limitation: in the design, conduct, or reporting of activities funded or proposed for funding by a sponsor; in the vendor selection process; in hiring or employment decisions; in research approval processes). A conflict of interest includes, without limitation, apparent or actual bias in the work to be performed for MCG, created by an individual's personal relationships, or by an individual's or family member's significant financial interest or other interest in a company that does business with, competes or may compete with the Medical College of Georgia.

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interest); and intellectual property rights (e.g., patents, trademarks, copyrights and royalties from such rights). The term does not include:

- salary, royalties or other remuneration from MCG;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities (in connection with approved outside professional activity);
- income from services on advisory committees or review panels for public or nonprofit entities (in connection with approved outside professional activity); or
- an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: [i] does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and (ii) does not represent more than a 5% ownership in any single entity; or
- other salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next twelve-month period.

EXCEPTION: When the proposed project involves human subjects and approval from the Institutional Review Board, the above monetary thresholds do not apply. In human subject research, the threshold for required conflicts of interest disclosure is any dollar or stock amount above zero.

Can the Conflicts be Research-Related?

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Yes. The conflicts may also be research-related such as conflicts that arise out of an individual's participation in the conduct or oversight of clinical research or non research-related if unrelated to clinical research.

What Should a HAC Member or Consultant do if They Feel That a Conflict of Interest Exists for them Personally or Professionally?

If a HAC member or consultant feels that a conflict of interest may exist, that individual should excuse themselves from the review process.

If the HAC Member does have a Conflict of Interest, Can They Vote on the Protocol?

No. Members may not participate in the vote and must recuse themselves prior to that action if in attendance at the meeting and their attendance at that time does not constitute part of the quorum.

What if the Investigator Feels that a Conflict of Interest Exists Between an HAC Member and the Investigator?

If the investigator feels that a conflict of interest exists, the investigator may request in writing prior to the member assignment that an individual member not be assigned to review the protocol in question. The investigator must fully document the perceived conflict of interest. However, investigators may not select the HAC reviewers.

Can any HAC Member Vote on any Protocol Where their Vote May Represent a Conflict of Interest?

HAC members with a conflicting interest are:

- Excluded from the discussion except to provide information requested by the HAC.
- Required to leave the meeting room for discussion and vote and can not simply abstain from voting
- Not counted towards the quorum.

Who Identifies the HAC Member with a Conflicting Interest for Review by the Convened HAC?

HAC members self-identify a conflict of interest for the review by the convened HAC. If the Conflict of Interest Panel has determined a conflict of interest, the individual is responsible for notifying the appropriate committees.

Who Identifies the HAC Member with a Conflicting Interest for Review by the Expedited Procedure?

HAC members self-identify a conflict of interest for the research under expedited review. If the Conflict of Interest Panel has determined a conflict of interest, the individual is responsible for notifying the appropriate committees.

Does the IRB Withhold Approval Until the Evaluation and Management of the Financial Interest is Complete?

Yes. The HAC withholds approval until the evaluation and management of the financial interest was complete.