

Disclosure and Management of Conflicts of Interest

OVERVIEW

A robust policy on disclosure and management of relevant affiliations and relationships, and of financial interests, is essential for a scientific organization such as the Health Effects Institute – Energy (HEI-Energy). HEI-Energy has set out the following policies for disclosure of such ‘conflicts’ – whether actual or perceived, financial or otherwise – and the management and use of this information in inviting peer-reviewers and advisors, forming committees, and crafting appropriate roles for committees and their members.

ENERGY RESEARCH AND REVIEW COMMITTEES:

In selecting members for its Energy Research and Review Committees, HEI-Energy uses disclosure procedures that are similar to those used by the U.S. National Academies. In addition to a letter informing prospective members of HEI-Energy’s policies and expectations, HEI-Energy uses a two-part form for disclosure of interests. The first part focuses on relationships and affiliations that senior scientists often have with one or more organizations; its major goal is to make such activities known to HEI-Energy so that HEI-Energy may take this information into consideration – along with myriad other factors – when seeking expert advice. The second part focuses on ‘conflict of interests’ – generally financial in nature – that may be relevant to the member’s work with HEI-Energy. Committee members are asked to update such information on a periodic basis. Individuals employed by HEI-Energy sponsors may not serve as members of Energy Research or Review Committees. HEI-Energy strongly discourages members of its Energy Research and Review Committees from applying for HEI-Energy funds as a principal investigator (PI) or co-PI during the term of their committee service. Should a committee member apply for funding, the policies described below apply.

REVIEW OF APPLICATIONS FOR NEW STUDIES:

HEI-Energy typically reviews applications for new research in a two-step process: Applications are first reviewed by individuals or a panel of experts and then by the Energy Research Committee. For these purposes, HEI-Energy’s procedures for managing conflicts of interest are similar to the guidelines set forth by the U.S. National Institutes of Health. Members of HEI-Energy’s sponsor community are given an opportunity to comment on a draft of the request for application (RFA), but they may not apply for support or participate in application review and funding decisions.

HEI-Energy invites external reviewers who do not have a conflict of interest with the proposal(s) they are asked to review. A conflict can occur in a number of ways, including:

- when the reviewer is named on the application in a major professional role;
- the reviewer (or close family member) would receive a direct financial benefit if the application is funded;
- the PI or others on the application with a major role are from the reviewer’s institution or institutional component (e.g., department);
- during the past three years the reviewer has been a collaborator or has had other professional relationships (e.g., served as a mentor) with any person on the application who has a major role;
- the application includes a letter of support or reference letter from the reviewer; or
- the reviewer is identified as having an advisory role for the project under review.

In addition, HEI-Energy screens external reviewers for potential conflicts of interest with other applicants

who have submitted a proposal under the same RFA. Note that a similar policy applies to members of the Energy Research Committee when reviewing applications.

In some situations, it may not be possible for members of review panels or Energy Research Committee to avoid all possible conflicts of interest as outlined above. In such cases, the panel or Energy Research Committee members who have a conflict of interest are not assigned to review the application(s) in question and are asked to leave the room during discussion of those application(s). They also do not score or vote on the application(s) at issue and refrain from commenting on them during the overall discussion, and in the case of the Energy Research Committee, from all deliberations regarding recommendation of applications for funding. If several Energy Research Committee members are recused from the overall discussion of applications for such reasons, HEI-Energy invites external consultants to join the Committee to fill in the missing areas of expertise.

SITE-VISITS AND REVIEW OF STUDY PROGRESS:

HEI-Energy uses the same general procedures as those outlined above when seeking experts for site-visits to investigator laboratories or for review of a study's progress. In occasional cases, however, the most appropriate expertise for certain aspects of a study may be found in employees of HEI-Energy's sponsors; in such cases, HEI-Energy utilizes their expertise for site-visits and review of study's progress.

REVIEW OF FINAL REPORTS:

Final reports from HEI-Energy-funded investigators are reviewed in a two-stage process: first a peer review by outside subject-matter experts and then by the Energy Review Committee. HEI-Energy uses the same general principles as outlined above for such reviews and for preparation of commentaries. For studies that are particularly large and complex or have direct regulatory significance, HEI-Energy may organize a special panel to review the study; the same procedures apply for selection of panel members. Individuals associated with HEI-Energy's sponsors may be asked to serve as external reviewers, if they have unique expertise relevant to the study.

SPECIAL REPORTS:

For members appointed to panels charged with the preparation of a special report or communication (generally to review the scientific literature in a certain area or to evaluate important research by scientists not sponsored by HEI-Energy), HEI-Energy adopts the same policies for disclosure of conflicts of interest as for the appointment of Energy Research or Review Committee members. HEI-Energy also subjects the reports prepared by such panels to peer-review, using the same general procedures for conflicts as described above for external reviews. However, panel reports may be sent for review to individuals whose work has been reviewed in the report or who have expressed specific views on the work being reviewed by the panel.

SPECIAL COMMITTEES:

In appointing members to special committees or workgroups that advise HEI-Energy on its science and technical efforts but have no role in selecting, overseeing, or reviewing studies, HEI-Energy may appoint some members who are current or former employees of HEI-Energy's sponsors or other companies, or who represent other groups with acknowledged interests (such as trade associations or public interest groups).

HEI-ENERGY FUNDED INVESTIGATORS:

HEI-Energy requires investigators to disclose any potential conflicts of interest. Investigators should report financial relationships with entities in the exposure science or environmental health areas that could

influence, or be perceived to influence, the research described in the final report. Investigators should disclose interactions with any industry, government, or nonprofit entity that could be considered broadly relevant to the work described, in addition to the disclaimer about HEI funding (language provided by HEI in its contract with the investigator's institution). Investigators should report all sources of revenue paid (or promised to be paid) directly to them or their institution on their behalf over the past 36 months greater than \$3,000. They should disclose any personal fees (monies paid to them for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony) and non-financial support (for example reagents or equipment, travel costs, etc.). They should also report any patents, whether planned, pending or issued, broadly relevant to the work, as well as any other relationships or activities, including investment interests (stocks, bonds, and other financial instruments and investments, including partnerships).

Sample disclaimer:

"In accordance with Health Effects Institute policy and my ethical obligation as a researcher, I am reporting that I [have a financial and/or business interests in] [am a consultant to] [receive funding from] (delete as appropriate) a company that may be affected by the research reported in this final report. I have disclosed those interests fully to Health Effects Institute, and I have in place an approved plan for managing any potential conflicts arising from [that involvement]."

or:

"This research is co-sponsored by [company A] and may lead to the development of products which may be licensed to [company B], in which I have a business and/or financial interest. I have disclosed those interests fully to Health Effects Institute, and have in place an approved plan for managing any potential conflicts arising from this arrangement."

If there is no disclosure, HEI will publish the following statement: *"No potential conflict of interest was reported by the authors."*

ROLE OF THE HEI ENERGY BOARD OF DIRECTORS:

The HEI Energy Board has the ultimate authority for appointment of members to the Energy Research or Review Committees. When considering prospective members, the Board ensures that the member has provided full disclosure and that the conflicts, if any, can be managed.

The Board is also responsible for approval of scientific studies as well as research or special reports. The Board generally defers to the scientific expertise, judgment and decisions by the Committees; however, in giving its approval the Board pays close attention to the processes used by HEI-Energy and its committees, including the steps taken to avoid and manage conflict of interests.

Disclosures and decisions in these and other situations are a matter of professional judgment, and it is not possible to describe all potential scenarios. HEI-Energy relies on its committee members and reviewers to declare to HEI-Energy the existence of any real or apparent conflict of interest. If a committee member or reviewer feels unable to provide objective advice for any other reason, he/she is expected to recuse him/herself from the review of that application(s) or report(s). For any questions, please consult with HEI-Energy's Director or President.