

The Investigators' Complete Guide to the HEI Review and Publication Process

PART I: THE REVIEW PROCESS

From Research to Review

During the research phase of an HEI-funded study, the HEI Research Committee and a Staff Scientist work with the investigator to monitor study progress. When the research phase ends, responsibility for the review of the final report passes to the HEI Review Committee, which had no role in reviewing applications, selecting studies to fund, or overseeing the research. A different Staff Scientist oversees the review process and works with the Review Committee and the investigator during review of the Investigators' Final Report.

Review Process and the Review Committee's Role

When the research phase comes to an end, each investigator is required by contract to submit a comprehensive Draft Final Report to HEI. The Final Report is intended to be a complete description of the research conducted; as such, it is more extensive than a standard journal article. The report should describe all components of the research (scientific background, specific aims, methods, and positive and negative results) and discuss the findings. However, to assist investigators in writing their reports and our readers in interpreting them, HEI asks investigators to submit relatively short Core Reports with more material presented in Appendices (see *Part 3: Instructions for Preparing the Final Report* for a description of Core Report length and other components). The overall goal remains the same: to present all results.

The role of the Review Committee is to (1) review the Final Report and provide feedback to the investigator and (2) write an independent assessment of the study (a Commentary or shorter Critique) to be published with the Investigators' Final Report for HEI's sponsors and other interested parties.

Reviewing the Final Report

To assist the Review Committee in its review, the Draft Final Report is sent to several outside reviewers with appropriate technical expertise, including a biostatistician. Outside reviewers and Review Committee members are asked to focus on the following questions:

- Is the research presented consistent with the original statement of work (and any changes in the work plan made jointly by the Research Committee and the investigators)?
- Does the introduction provide adequate background to interpret the study and its findings?
- Are the study design and methods appropriate?

- Do the results follow from the study design and methods and include appropriate statistical analyses? Are they presented clearly?
- Are the interpretation and conclusions adequately supported by the results? Are the caveats appropriately described?
- Do the raw data and their subsequent analyses require more in-depth evaluation?

After the Review Committee's discussion of the Draft Final Report, the Staff Scientist summarizes the Committee's feedback and comments from the outside reviewers in an Initial Review. In most cases, the Committee requests revisions to the report, which are outlined and prioritized in the Initial Review. The Committee may recommend that

- One or more components of the report (study design, description of methods, data to support results, interpretation of results) be clarified, expanded, or otherwise revised.
- Additional analyses be conducted.
- The report be reorganized, including the possibility that some information be put into Appendices, which will be available on the web only and not part of the Core Report.

The Committee sometimes disagrees with some of the investigators' conclusions. In that case, the Initial Review explains the reasons for the disagreement and asks the investigator to reconsider or modify the conclusions. As with submission of a manuscript to a journal, investigators have the opportunity to address or rebut comments from the Review Committee and reviewers. In addition, HEI editors check the manuscript to ensure that all report components are included (see *Part 3: Instructions for Preparing the Final Report*). Notice will be sent at this time to investigators if report components are missing.

Generally, the investigator responds to these comments and submits a Revised Final Report. Submission of this report should be made within a reasonable time frame requested by HEI. The Committee then discusses the Revised Final Report; usually at this stage, the Committee approves the report for publication by HEI. Rarely, the Committee decides not to publish the report. Once the report has been accepted, it will be prepared for publishing by HEI editors. To speed up the process, the investigator is asked to submit the Revised Final Report files in a format suitable for publication (see *Part 2: The Publishing Process* and *Part 3: Instructions for Preparing the Final Report*).

Review Committee's Commentary or Critique

While the accepted Final Report is being edited and prepared for publication, the Review Committee writes a Commentary or shorter Critique that places the study into a broader context of scientific issues, points out its strengths and limitations, and discusses conclusions, interpretations, and implications of the findings. The Staff Scientist sends the Commentary or Critique to the Principal Investigator before it is published so that the investigator has the opportunity to address any inaccuracies in the description of the work performed and respond to the Committee's evaluation.

The Commentary or Critique is written to reach an audience of scientists in various fields of research, technical and nontechnical members of HEI's sponsoring organizations, scientific advisors to decision makers, and other individuals and groups who share concern about the

environment. The Committee's evaluation of the study and its comments on the investigators' discussion of the results are important to ensure the quality of information that HEI provides and to offer alternative interpretations of the results.

All project results and accompanying comments by the Review Committee are widely disseminated through HEI's website (www.healtheffects.org), printed reports, newsletters and other publications, annual conferences, and presentations to legislative bodies and public agencies. HEI research reports are also listed by bibliographical services, such as the National Library of Medicine's Medline/PubMed database, so that they can be found through appropriate search engines and cited.

Release of Withheld Funds

The Research Contract stipulates that HEI hold back funds equivalent to 20% of the total budget of the final year of the study. The Institute releases half of the withheld funds when an acceptable Draft Final Report has been received (i.e., a report that is complete and is suitable to be reviewed). The remainder of the funds is released when the Revised Final Report has completed the review process and been accepted for publication by the Review Committee.

Quality Assurance Audit

HEI conducts an external quality assurance audit for any study that involves human subjects and other studies that have a high potential for use in regulatory decisions. The audit includes an evaluation of the Draft and Revised Final Reports by the auditors. In such cases, a signed statement from the auditors is included in the published report. Publication of the report is contingent on completion of the audit process and the authors' having addressed any concerns identified by the auditors. Please refer to HEI's Quality Assurance and Control Procedures, available at www.healtheffects.org/research/quality-assurance.

Publication of Results Elsewhere

HEI encourages investigators to publish results of research funded by HEI in the open scientific literature. However, HEI retains a nonexclusive license to publish material from research it has funded. The investigator and his or her institution are responsible for notifying other publishers of HEI's rights. Article 17 of the HEI Research Contract specifies

The Recipient (or other author) agrees to grant, and hereby does grant, to the Institute, to the United States EPA, and to other current sponsors of the Institute a royalty-free, nonexclusive, and irrevocable license throughout the world to publish, translate, reproduce, deliver, perform, dispose of, and to authorize others so to do, all copyrightable material produced at any time directly or indirectly from the work under this Agreement now or hereafter covered by copyright.

Article 16 states that investigators are free to present material derived from work conducted under the HEI Agreement in peer-reviewed scientific journals or at meetings of established scientific organizations. HEI does *not* need to review or approve such materials, but investigators are required to inform HEI about the dissemination of the findings — in particular to send HEI electronic files of the following:

- Manuscripts based on all or part of the HEI-funded work when they are submitted to peer-reviewed journals
- Meeting abstracts at the time of submission and final presentations and posters immediately following the meeting
- All journal articles, abstracts, and review articles describing HEI-funded research at the time of their publication

Article 16 further states that HEI “discourages the disclosure of the results of the work performed under this Agreement outside the scientific community until after such results have undergone scientific peer review.”

A statement acknowledging HEI’s support and a disclaimer must appear in all publications resulting from work funded by HEI. Please refer to Article 16 of your Research Contract for the disclaimer text.

Conflict of Interest

HEI requires investigators to disclose any actual or potential conflicts of interest. Investigators should report financial relationships with entities in the exposure science or environmental health arenas that could be perceived to influence, or that give the appearance of potentially influencing the research described in the final report.

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 (e.g., monies paid for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, or expert testimony) and nonfinancial support (e.g., reagents or equipment, travel costs). They should also report any patents — whether planned, pending, or issued — broadly relevant to the work and any other relationships or activities, such as investment interests (e.g., stocks, bonds, and other financial instruments and investments, including partnerships).

Sample disclaimer to be added to the final report submitted to HEI:

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 or modify as appropriate*) _____ company that may be affected by, or has a financial interest in, the research reported in this final report. I have disclosed those interests fully to Health Effects Institute.

or

This research is co-sponsored by [company A] (and may lead to the development of products that may be licensed to [company B] (*optional*),) in which I have a business and/or financial interest. I have disclosed those interests fully to Health Effects Institute.

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