



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

PART 3: INSTRUCTIONS FOR PREPARING THE FINAL REPORT

Organization and Length of the Report

HEI asks investigators to present all the results of HEI-funded research. To organize the material most effectively and best serve our audiences, HEI is looking for the following organization in the investigators' reports:

- The **Core Report** should be relatively short (no more than 20,000 words) and well organized. The Core Report should summarize all major findings and key conclusions, placed in the context of all results (both positive and negative), and present a *combined total* of only 10 to 15 essential summary tables and figures. The Core Report will be published both in print and online.
- Further figures, tables, and text presenting all the study's results should be placed in **web-only Appendices** (which will receive a minimum of editing but no formatting at HEI) or as web-only **Additional Materials** (which will not be edited or formatted by HEI: e.g., computer code for statistical analyses or raw data tables). The investigators should contact the assigned Staff Scientist if there are questions about where to place certain results.
- HEI's editorial policy is to publish all Appendices online only rather than to leave them in the Core (printed) Report. The Staff Scientist and Review Committee will provide guidance about the Appendices during the review process. If investigators feel that an Appendix should be part of the Core Report, they should indicate that when they send in the Revised Final Report.
- Specific report sections to include are listed in the next section.
- All raw data collected during the study must be available to the Review Committee on request in a form suitable for review (e.g., raw data tables, computer code, or output of statistical programs). It is at HEI's discretion whether such materials will be made available to the public in consultation with the investigators and with appropriate protection of privacy. Please consult HEI's data access policy for more information (see "Policy on the Provision of Access to Data Underlying HEI-Funded Studies" at www.healtheffects.org/research/investigators/final-report.)
- HEI recommends that authors whose first language is not English have a native English speaker review their report before submission.
- Reports that are incomplete or incomprehensible (e.g., do not meet basic language requirements) will be returned to the author.

Components of the Report

Authors should include the following sections, presented in this order:

Title Page Include the report title and the names and affiliations of all authors. Provide a contact address for the Principal Investigator (PI). By HEI convention, the PI should be the first author. If there are compelling reasons to list one of the co-investigators as the first author, the PI can request it with an explanation, and HEI will review the request. Please confirm the spelling of co-authors' names; this is crucial for the indexing services.

Table of Contents Include all subsections and clearly indicate heading levels and page numbers. In the report text, make sure that every heading stands out and that the heading level is clear. Do not number subsections.

Abstract Summarize the study, key findings, and implications of the work. Please use the following structure: Introduction / Methods / Results / Conclusions. Limit the abstract to approximately 1000 words.

Introduction Summarize the issues and related work by your group and others that led to the research questions addressed in your study.

Specific Aims State specifically what the project was intended to accomplish and what hypotheses were tested. Briefly note any modifications (and their justification) of the original aims that occurred during conduct of the study.

METHODS AND STUDY DESIGN

- The Methods section should consist of general descriptions with enough detail so that readers can understand the study design and approach. More detailed information about methods and procedures (such as sample collection, biological assays, exposure modeling) should go in a web-only Appendix.
- If the study is based on specific assumptions, note them.
- Define the study sample (such as cell type, animal strain, or human population) and size, and the rationale for choosing it (with power calculation, if available).
- For each pollutant or pollutant mixture in toxicological or human clinical studies, explain the choices of exposure concentrations and route of administration. In epidemiological studies, describe the approach used to estimate exposure for human populations.
- If the study involved human data, include a statement that the study was approved by the Institutional Review Board or that the study was exempted. Describe how the participants were selected, the inclusion and exclusion criteria, and the informed-consent procedure. If the study involved human tissue, describe when and how it was acquired. Indicate whether participants were paid or otherwise remunerated for their participation.
- In an Appendix, describe the quality control procedures implemented in compliance with the procedures for “Studies Using Human Participants” and “Quality Assurance and Quality Control” described in the HEI Request for Applications.

- If the study involved animals, include a statement that animal care procedures met government guidelines.
- For equipment and special chemicals, list the manufacturer or source and the model number and name. Include the city and state or country of the manufacturer or source, if possible.

Statistical Methods and Data Analysis The Core Report should include a description of statistical design and analytical methods in sufficient detail to enable readers to understand the general approach of the analyses. Additional detail that would allow a knowledgeable reader with access to the original data to verify the reported results should be described in a web-only Appendix. The investigator should do the following:

- Clearly state the hypotheses that were tested and the specific comparison groups.
- Describe the randomization procedures (or other methods of treatment allocation); methods used for any blinding of assessments; treatment complications; number of observations; and any losses to observation (such as missing animals or participants who did not complete the study).
- Identify computer programs used, and document that you have evaluated the program's performance.
- Include sensitivity analyses to evaluate whether important epidemiological findings are stable over a reasonable range of modeling strategies.
- Throughout the report, reserve statistical terms such as *random*, *significant*, *normal*, and *correlation* for use in their technical sense.

RESULTS

- State the main findings of the study and support them with data summaries (in no more than a combined total of 10 to 15 tables and figures). Be sure to include both negative as well as positive findings and put the results in a broader context.
- Make sure that the results reported match the methods described.
- When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid sole reliance on statistical results that fail to convey important quantitative information, such as *P* values.
- In tables and figures, call attention to statistically significant findings by using bold font, asterisks, etc. In figure captions and table footnotes, state the statistical tests and/or methods used and define any symbols. Check that any terms and abbreviations are included in the List of Abbreviations and Other Terms (described at the end of this section).
- Present detailed data (individual or subgroup studies) in additional tables and figures that are placed in Appendices to the report, which will be published only online.
- When preparing figures with comparable content, it is helpful to match the scales and units on the axes, so readers can more easily compare curves or data patterns among figures.

Discussion and Conclusions Interpret the results and state the conclusions. Discuss the uncertainties that remain and relate the findings to those of previously published research by your group and other investigators.

Implications of Findings If appropriate, explore the link between this study and unresolved scientific questions related to public health and environmental issues.

Acknowledgments (optional) Use this paragraph if funds other than the HEI Research Contract need to be acknowledged or if contributors other than the authors need to be mentioned.

References Cited All references cited in the text must be included in the reference list. Delete any references in the list that do not appear in text. References should be formatted in accordance with HEI's style (see *Part 4: Text and Reference Style*).

Appendices We strongly encourage using Appendices to present details that are not essential for the Core Report, including details of experimental methods, statistical methods, and further results with tables and figures.

- Appendices will be prepared for posting on the HEI website only. They will be reviewed for spelling, basic grammar, and cross-reference accuracy but will not be edited or formatted by HEI staff.
- If an Appendix is deemed *essential* for understanding the main report (as decided by HEI and the investigator), it will undergo the same editorial process applied to the main text and will be incorporated into the Core Report. Very few (if any) Appendices will qualify for inclusion in the Core Report.

Additional Materials Additional background information (such as questionnaires for human studies, raw data, consent forms, and computer code for statistical analyses) will be published as Additional Materials, also available only online. Additional Materials will not undergo any editing or formatting and will be posted “as is.”

About the Authors Provide a brief biography (one paragraph) about each author. Include education and background, current title, role on this project, and research interests. If an investigator has moved since working on the project, please provide both titles and both institutions. (However, on the title page, list the affiliation in effect at the time the contract was signed.)

Other Publications Resulting from This Research List full citations of all publications based on research from this contract. Be sure to send HEI all published articles as well as copies of abstracts and manuscripts submitted.

Abbreviations and Other Terms Provide a list of all abbreviations, acronyms, chemical formulas, and shortened terms used, along with brief definitions.

Please refer to *Part 5: Requirements for Electronic File Submission* for the submission requirements, and contact your assigned Staff Scientist if you have any questions.