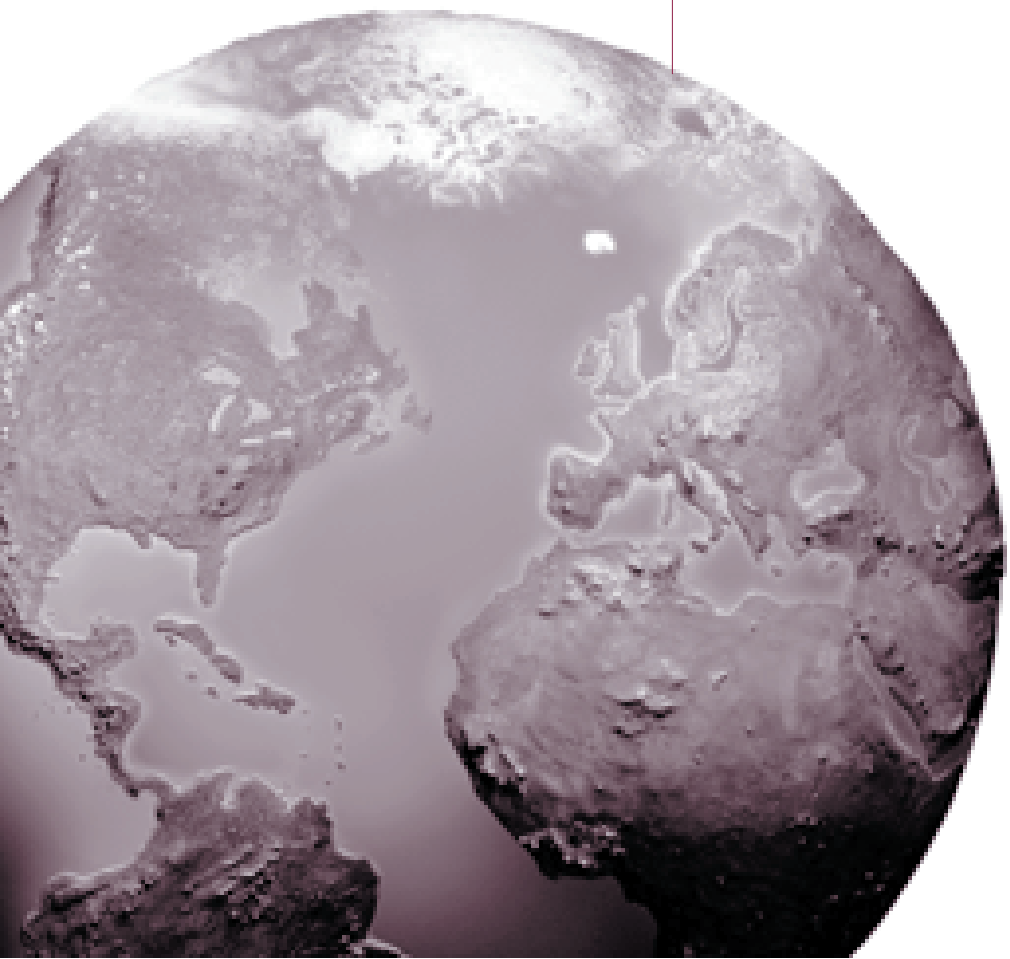
The Investigators' Complete Guide

HEALTH EFFECTS INSTITUTE

The HEI Review and Publication Process: Preparing the Final Report

September 2021



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

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

PREPARING THE FINAL REPORT

One of HEI's goals is to publish Research Reports of the highest scientific quality that will be of value to regulators, government officials, industry representatives, scientists, and the public. After investigators submit their Final Reports (as the Research Contract requires), the HEI Review Committee evaluates (a) the scientific quality and significance of the research and (b) the strengths and limitations of the study in order to meet this goal.

The Review Committee and HEI staff then compose a Commentary (or shorter Critique) that describes and evaluates the research, places it in scientific and regulatory context, and identifies future research opportunities. The Investigators' Final Report and the Review Committee's Commentary or Critique are published together to communicate all HEI research findings (both positive and negative) to the Institute's sponsors and the public.

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 bibliographic services such as the National Library of Medicine's Medline/PubMed database.

We have prepared this Guide to (1) familiarize you with the HEI review and publication processes, (2) ensure that your research is presented in the most informative way possible, and (3) let you know how to prepare and submit your Final Report. We ask that you help us meet these goals by reading the Guide and following our suggestions as best you can. For an abbreviated list of report submission requirements, please see the *Investigators' Quick Guide to Preparing the Final HEI Report* on our website at *www.healtheffects.org/publication/hei-investigators-guide-preparing-final-report*.

We continually seek feedback from all investigators about how we can make this part of your Research Contract move more smoothly and efficiently.

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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, in order 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; or
- the report be reorganized, including the possibility that some information be put into Appendices that will be available on the web only but not as 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. Thus, the reports may 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 certain animal studies of regulatory significance. 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; and
- 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 (monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony) and nonfinancial 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; and any other relationships or activities, including investment interests (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, 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 which 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."

HEI

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

PART 2: THE PUBLISHING PROCESS

When investigators submit the Revised Final Report, HEI checks the files to ensure that they have been provided in accessible electronic formats (see *Part 5: Requirements for Electronic File Submission*). Notice will be sent at this time to investigators if their files do not meet these requirements.

After the Revised Final Report has been approved for publication by the Review Committee and HEI has received all files as requested, an Editor reads the Investigators' Core Report carefully with the perspective of being the reader's advocate (see *Part 3: Instructions for Preparing the Final Report* for a description of report components and definition of Core Report). The Editor's underlying focus is to ensure that the methods and results are stated as simply and clearly as possible so that they are accessible to the reader.

For the Core Report, the Editor assures that

- information is presented in a logical sequence;
- the general approach and methods (experiments and variables) are described adequately so the reader can understand the subsequent results and discussion sections (with more details provided in Appendices; see next paragraph);
- illustrations are well designed, with informative captions;
- tables present data efficiently, clearly, and with little repetition;
- tables and figures make sense independent of the text, and data are consistent with the presentation in the text; and
- abbreviations and other terms are used consistently and in accordance with worldwide scientific nomenclature.

HEI's policy is to publish Appendices only online. The Editors review any web-only Appendix text for spelling, basic grammar, and accuracy of cross-references to the tables, figures, and text in the Core Report, but otherwise do not edit these materials. Appendix text, tables, and figures are not formatted by HEI. Some materials (such as data sets and computer code) are best presented as Additional Materials and are not reviewed by the Editor at all (see *Part 3: Instructions for Preparing the Final Report* for a description of web-only Appendices and Additional Materials).

After the report has been edited, it is sent to the investigator. HEI asks that the investigator read through the edited galleys and answer any queries **within two weeks** of receipt. No editorial recommendations are implemented without approval from the investigator.

The Editor then incorporates the investigators' responses to queries and proceeds with publishing the report and Appendices along with its Commentary or Critique on the HEI website. Subsequently, the Core Report is printed, while Appendices remain available only online.

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.

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PART 4: TEXT AND REFERENCE STYLE

Text Style

Investigators are encouraged to contact the Senior Editorial Manager to discuss the publishing conventions specific to the topic or nomenclature of the report.

- **Do not number sections, but rather use appropriate subheads.** Use the section subhead as the identifier for any cross-references in text (e.g., "see the section 'Statistical Analyses' for a full discussion"). Clearly indicate heading level through use of uppercase and lowercase letters, italics, or boldface, or a combination of these.
- **Avoid overuse of abbreviations and acronyms.** For those abbreviations and acronyms deemed necessary, spell out a term at its first mention, followed by the abbreviation in parentheses, and then use the abbreviation consistently throughout the remainder of the text. All such terms should be listed in the section Abbreviations and Other Terms. For plural abbreviations, add a lower case "s" (as in PAH and PAHs).
- **Spell out chemical compounds at the first text reference.** The formula should immediately follow in parentheses (for example, "nitrogen dioxide (NO_2)").
- **Number tables sequentially in the order mentioned in the text.** Use cardinal numbers, not decimal numbers (1, 2, 3, 4; not 1.1, 1.2, 1.3, etc.). Please add a descriptive title and include descriptive headings for all columns and rows. The information in the table should be complete enough to allow it to be understood separately from the main text.
- **Number figures sequentially in the order mentioned in the text.** Use cardinal numbers, not decimal numbers (1, 2, 3, 4; not 1.1, 1.2, 1.3, etc.). Ensure that figure captions are complete enough to allow illustrations to be understood separately from the main text.
- **Do not use engineering notations** (e.g., 7.3E-05 should be changed to 7.3×10^{-5}; 2.6E+03 to 2.6×10^{3}).
- **Make sure the number of significant digits is consistent for all values in a table.** Note that Excel cuts off the last Ø to the right of the decimal unless you set the program up not to do that.

Reference Style

References should be formatted according to HEI's style (see below). (HEI's style is very similar to that used by the journal *Environmental Health Perspectives*. Many reference manager programs, such as EndNote, include *EHP* style as an option.)

Only references that are cited in the report should appear in the reference list. Please check that (1) all cited references are listed and (2) those not cited have been deleted. ***Authors are responsible for the accuracy of their references, including spelling, diacritical marks, symbols, subscripts and superscripts, italics, and date accessed for URLs (e.g., databases and PDFs).***

IN-TEXT REFERENCE CITATIONS

For in-text citations, use the name and date format in parentheses with no comma.

- Single author: (Brook 2008).
- Two authors: (Mauderly and Garshik 2009).
- Three or more authors: (McDonald et al. 2004).
- Multiple reference citations in text at one spot: List alphabetically. Separate publications by the same author(s) with commas and those by different authors with semicolons: (Dockery et al. 2001; Pope et al. 2004, 2008; van Eeden et al. 2001a, 2001b).
- Multiple sources with different first authors but the same last name and date: Use the first author's last name plus initial(s): (Wong CM 2002; Wong TW 2002).
- Place URL addresses in the reference list (not in text) with full reference information. Cite author and date in text.

Any items that must be cited but are not accessible to the public (e.g., manuscripts submitted but not yet accepted, unpublished data, and personal communications) should appear in the text in parentheses but should not be listed in the references: for example, (Geiser N, personal communication, January 2011) or (Smith M, unpublished data).

REFERENCE LIST

All references must include the following:

- Author/editor last name plus initial(s) or authoring agency (if there are more than six authors, use "et al." after the sixth).
- Year of publication.
- Full title of article or chapter (sentence case).

- Title of journal (abbreviated according to Index Medicus or PubMed) or book/ proceedings in title case.
- For books and meeting reports, city/state/country of publication and name of publisher.
- Volume and inclusive page numbers separated by an en dash (–). These are not required if a URL or a DOI number is provided.
- Either a DOI number or a URL address is required for articles published online only (without volume and page numbers).
- Date accessed for any URLs (e.g., databases or PDFs of documents).

The list should be arranged alphabetically by the authors' surnames. If the author has more than one publication, list references in alphabetical order (letter by letter) of subsequent authors. If the first author shares the last name with another first author (Wong CW vs. Wong TW), alphabetize by initials. If you list more than one publication by the same author/group of authors, arrange by date (early to late). Assign suffixes (a, b, etc.) after the date to distinguish two or more works by the same author or authors in the same year.

In all reference citations, notice that no commas are used between the author's last name and initials and that no periods are used after initials or journal abbreviations.

REFERENCE CITATION EXAMPLES

Journal article — conventional reference

Davi G, Patrono C. 2007. Platelet activation and atherothrombosis. N Engl J Med 357:2482–2494.

Journal article with DOI reference

Anderson HR, Butland BK, van Donkelaar A, Brauer M, Strachan DP, Clayton T, et al. 2012. Satellite-based estimates of ambient air pollution and global variations in childhood asthma prevalence. Environ Health Perspect; 10.1289/ehp.1104724.

Journal article "in press"

Burn HJ, Dinsdale D, Smith T, Grigg J. In press. Ultrafine particles in alveolar macrophages from normal children. Thorax.

Book

Covello VT, Merkhofer MW. 1993. Risk Assessment Methods: Approaches for Assessing Health and Environmental Risks. New York:Plenum Press.

Book, edited

Wilson SH, Suk WA, eds. 2002. Biomarkers of Environmentally Associated Disease: Technologies, Concepts, and Perspectives. Washington, DC:Lewis Publishers.

Chapter in book, edited

Hill A, Whitley M. 2003. Quality control of expression profiling data. In: An Introduction to Toxicogenomics (Burczynski ME, ed). Washington, DC:CRC Press, 29–43.

HEI report

Brunekreef B, Janssen NAH, de Hartog JJ, Oldenwening M, Meliefste K, Hoek G, et al. 2005. Personal, Indoor, and Outdoor Exposures to $PM_{2.5}$ and Its Components for Groups of Cardiovascular Patients in Amsterdam and Helsinki. Research Report 127. Boston, MA:Health Effects Institute.

Government document

U.S. EPA (U.S. Environmental Protection Agency). 2004. Air Quality Criteria for Particulate Matter (Final Report). EPA/600/P-99/002aF-bF. Washington, DC:U.S. EPA.

Proceedings

When citing proceedings or a presentation, include the name, city, and state of the sponsoring organization or publisher so a reader can obtain a copy of the material cited.

> Vo-Dinh T, Miller GH. 1983. A new passive monitor for direct detection of PAH vapors. In: Proceedings of the International Symposium on Polyaromatic Hydrocarbons, 26–28 October 1983, Columbus, OH (Smith J, Jones E, eds). Columbus, OH:Batelle Laboratories, 66–72.

Web pages, PDFs of documents, and interactive databases or reports

Italicize all URLs. Include the date accessed.

> CDC (U.S. Centers for Disease Control and Prevention). 2003. Environmental Public Health Indicators Project. Available: *www.cdc.gov/nceh/indicators/default.htm* [accessed 18 August 2003].

PART 5: REQUIREMENTS FOR ELECTRONIC FILE SUBMISSION

Submission of the Draft and the Revised Final Reports for Review

For the Draft Final Report, please provide **one PDF file of the Core Report that includes all text, tables, and figures**. Also submit **separate PDFs for the Appendices and Additional Materials**. These documents will be distributed to reviewers.

Be prepared to send **clearly labeled files of computer code and any output of statistical programs** if requested by the Review Committee for their review. (Such files may be sent in their original formats instead of PDFs.) Also be prepared to send complete analytic data sets if requested by HEI. 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 "HEI Policy on the Provision of Access to Data Underlying HEI-Funded Studies" at *www.healtheffects.org/research/investigators/final-report*).

In the case of a Revised Final Report, in addition to the PDF file just described, send **a second PDF file that shows all changes** made since the Draft Final Report submission. Changes made to Appendices and Additional Materials should also be clearly marked. For the Revised Final Report, please also send **high-quality original files** (see a description of high-quality files in the next section) **of the text and, separately, any tables and figures appearing in the Core Report**. These high-quality files will be used to prepare the Revised Final Report for publication. For **Appendices**, send the text in Word and tables in Word or Excel. Original figure files are not needed for Appendices at this point.

At both the Draft and Revised Final Report stages, all co-authors are required to sign the **Investigators' Report Submission Form** indicating that each has reviewed the report and approves of its content, including interpretation of the results.

Files sent by e-mail to HEI cannot be larger than 20 MB. (If you have problems transmitting files, please contact the Science Administrative Assistant, Lissa McBurney, at *lmcburney@healtheffects.org*, or +1-617-488-2345.)

File and Formatting Requirements for the Revised Final Report

Note that we cannot begin to prepare your Revised Final Report for publication until these requirements are met.

TEXT REQUIREMENTS

All files must be submitted in PC-compatible electronic format. Please contact the Senior Editorial Manager, Kristin C. Eckles (*keckles@healtheffects.org*), with questions or concerns about preparing files.

Requirements for text files are as follows:

- Files must be in Microsoft Word.
- Text must be single-spaced.
- PDF files are NOT acceptable for editing and publication. (HEI requests PDF files only for the purpose of review.)
- We are unable to process LaTeX code; therefore text files that include LaTeX need to be converted to Microsoft Word (.doc, .docx, or .txt extension) before submission to HEI.
- Insert the file name in the header or footer to show on each page.
- Put a page number on every page of the whole document, including tables, figures, and captions. Appendices and Additional Materials should each start again with page 1.
- Add line numbers to the text.

TABLE AND ILLUSTRATION REQUIREMENTS

Permissions For each table and figure from another source, authors must determine if permission is required, acquire permission if needed, and send HEI a copy of the permission granted. Include an attribution line with wording approved by the original source, where necessary.

If a figure or table is modified from data from another source, permission from the author and publisher is not required, but you may want to notify the author as a courtesy. The phrase "Based on data from Doe et al. 2005" should be included in the table footnote or figure caption.

Tables

The Core Report should contain a combined total of only 10 to 15 essential summary tables and figures.

- Number tables sequentially in the order mentioned in the text. Use cardinal numbers, not decimal numbers (1, 2, 3, 4; not 1.1, 1.2, 1.3, etc.).

- Please add a descriptive title and include descriptive headings for all columns and rows. The information in the table should be complete enough to allow it to be understood separately from the main text.
- Use footnotes for definitions or comments necessary to interpret a table.
- Do not use engineering notation (e.g., 7.3E-05 should be changed to 7.3×10^{-5}; 2.6E+03 to 2.6×10^{3}).
- Tables must be in Microsoft Word or Excel for all components of the report (Core Report and Appendices).
- Tables embedded as graphics in Microsoft Word or PowerPoint are NOT acceptable.
- Tables in PDF files are NOT acceptable for editing and publication.
- Insert the file name in the header or footer so that it shows on each page.

Figures

The Core Report should contain a combined total of only 10 to 15 essential summary tables and figures.

- Number figures sequentially in the order mentioned in the text. Use cardinal numbers, not decimal numbers (1, 2, 3, 4; not 1.1, 1.2, 1.3, etc.).
- The caption should be complete enough to allow the illustration to be understood separately from the main text.
- Make symbols, letters, and numbers consistent in size and capitalization. Make sure labels are clearly readable.
- If possible, place all panels of a multipart figure on the same page.
- If the program allows, insert the file name in the header or footer so that it shows on each page.
- Maps need to be prepared with the same high quality as other art. Screen prints of online maps are not of high enough quality for print publications. If the map was not generated by the authors, obtain written permission to reproduce those protected by copyright.

Submitted figure files for the Core Report must be in the **original program** in which they were created, or saved from that program into a format given below. (Figures in web-only Appendices do not have to be submitted in their original files. If we find typos in these, we will ask for new, corrected figure files on a per-case basis.)

- **Acceptable figure file formats for the Core Report:** TIFF (.tif), JPEG (.jpg), EPS (.eps), Microsoft Excel (.xls or .xlsx), Sigma Plot (.png and similar formats), or high-resolution PDF (.pdf). For images ***drawn*** in Microsoft Word or PowerPoint, please submit original Word or PowerPoint file whenever possible.
- **Unacceptable figure file formats for the Core Report: *embedded*** images in Word or PowerPoint; JPEG files made from Word files; images saved as bitmaps; and images created with GraphPad Prism.

- **Resolution specifications**
    - *Black line art with no shades of gray:* 900–1200 dpi
    - *Grayscale or color,* ***with*** *line art and/or text:* 600–900 dpi (e.g., a photograph or photomicrograph with labels, arrows, scale bars, or text added to it, or a bar chart that uses colors or shades of gray to distinguish elements)
    - *Grayscale or color,* ***without*** *line art or text:* 300 dpi (for example, a photograph or photomicrograph)

Color Art

Please note that many readers print in black and white; as a result color variations in figures are lost. Often black/white shading and patterns are preferable. However, color may be essential for some types of graphics such as photomicrographs of cells and tissues when black/white contrast is not adequate and maps in which color is essential (e.g., spatial distributions).

Note that we cannot begin to prepare your report for publication until these requirements are met.

For an abbreviated checklist of these requirements, see *Part 6: Checklists for Submitting the Draft and Revised Final Reports.*

PART 6: CHECKLISTS FOR SUBMITTING THE DRAFT AND REVISED FINAL REPORTS

Use the checklists below, which summarize information in Parts 3, 4, and 5 of this Investigators' Guide, to ensure you have included everything. Please send your files to

Lissa McBurney, Science Administrative Assistant
lmcburney@healtheffects.org
Phone: +1-617-488-2345
Fax: +1-617-488-2335

Checklist for the *Draft* Final Report Submission

___ One PDF of the Draft Core Report, including all text, tables, and figures

___ A separate PDF (or PDFs, if file sizes are large) for Appendices and Additional Materials

___ A completed Investigators' Report Submission Form (provided by HEI) signed by all authors

___ Disclosure of actual or potential conflict of interest and disclaimer statement.

___ All required sections of the text in this order:

- ___ Title Page
- ___ Table of Contents (which includes all heading levels)
- ___ Abstract
- ___ Introduction
- ___ Specific Aims
- ___ Methods and Study Design (including a statement from the Institutional Review Board or Institutional Animal Care and Use Committee if applicable)
- ___ Statistical Methods and Data Analysis
- ___ Results
- ___ Discussion and Conclusions
- ___ Implications of Findings
- ___ Acknowledgments (optional)

___ References Cited

___ About the Authors

___ Other Publications Resulting from This Research

___ Abbreviations and Other Terms (with their definitions)

___ Appendices and Additional Materials

___ All abbreviations defined in the text at first mention and included in the Abbreviations and Other Terms section

___ References cited by author and year in the text, included in the list of references, and formatted in HEI's style.

___ A page number on every page of the whole document — text, tables, figures, and Appendices

___ A completed copy of this checklist

Checklist for the *Revised* Final Report Submission

___ Two PDFs of the Revised Core Report, including all text, tables, and figures — all reflecting any changes made since submission of the Draft Final Report. One file must show "tracked changes"; the other file must show changes as "accepted." Separate Appendices and Additional Materials should also have any changes clearly marked.

___ Original, high-quality electronic files of all components for editing and publishing (main text, tables, figures, and Appendices). Text must be in MS Word; tables must be in Word or Excel; and figures for the Core Report must be in TIFF, JPEG, EPS, Excel, Sigma Plot, or high-resolution PDF (**not acceptable:** embedded images in Word or PowerPoint; JPEG files made from Word files; images saved as bitmaps; and images created with GraphPad Prism).

(Figures in web-only Appendices do not need to be in original format.)

___ The name of the file in the header or footer on each page

___ Cover letter explaining the changes that were made in response to the Committee's comments and any other responses to the Committee's comments

___ All items on the checklist for the Draft Final Report have been included or addressed

___ Proof of any permissions required for reprinted tables or figures

___ A completed Investigators' Report Submission Form (provided by HEI) signed by all authors

___ Disclosure of actual or potential conflict of interest and disclaimer statement.

___ A completed copy of this checklist

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