The provision of access to data underlying studies of the health effects of air pollution is an important element of ensuring credibility, especially when the studies are used in controversial public policy debates. The open and free exchange of data is also an essential part of the scientific process. Therefore, it is the policy of the Health Effects Institute to provide access expeditiously to data that it has funded and to provide that data in a manner that facilitates review and verification of the work but also protects the confidentiality of any volunteers who may have participated in the study and respects the intellectual interests of the original investigator of the work.

This policy applies to all research funded by HEI; it is consistent with amendments to Office of Management and Budget (OMB) Circular A-110 which requires access under the federal Freedom of Information Act (FOIA) to data from federally-supported research that was used in developing a federal agency action that has the force and effect of law.

In responding to FOIA requests through the U.S. EPA or other federal agency for HEI data that are subject to the Circular A-110 amendments, HEI will follow the principles established in the amendments.

In responding to non-FOIA, direct requests to HEI for data, HEI will in general follow the principles described below, which are designed to be consistent with the principles contained in the recent A-110 Amendments, although specific cases may require other arrangements for providing access.

1. **Research Data** The research data that will be made available in response to requests will vary from study to study, but in general will consist of the recorded factual material commonly accepted in the scientific community as necessary to replicate and verify the original research findings. It will include digital records including analytical summary and computer codes, where appropriate, but will not include any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. The “recorded” material excludes physical objects (e.g. laboratory samples). Research data also excludes (a) trade secrets, commercial information, materials necessary to be held confidential by a researcher until published, or similar information which is protected under law; and (b) personal and medical information and similar information that is personally identifiable, and the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

2. **Data Plan and Provision of Access to Research Data** HEI will expect each Principal Investigator (PI) it funds to provide, at the outset of the study: (1) a plan for organizing, protecting, archiving and making all data, data descriptions, analytical summary and computer codes described above available to HEI upon completion of the study, and (2) a plan for making research data available to other investigators following publication of the results as set forth under this policy. In cases where all of the data used is from publicly available data sets and the analytic data set can readily and expeditiously be recreated, HEI and/or the PI might as an alternative provide detailed descriptions of how to access and use these public data sets to recreate the analytic data set in lieu of providing the full analytic data set.

3. **Third Party Data** In cases where the PI uses data for HEI sponsored research collected by a third party – whether public or private – and the PI is contractually bound with the third party to keep the data confidential, HEI and/or the PI will provide information on the process the third party has in place for access to the data and will direct the requestor to the third party to seek access to the data; wherever possible, HEI will facilitate this process. HEI will provide access to third party data when such access is consistent with the confidentiality or other obligations HEI or its PIs have with respect to such data.

4. **Timing** HEI will seek to provide access to data as expeditiously as possible after the completion and publication of the HEI Research Report (or Reports) resulting from the study. In doing so, HEI will, to the maximum practical extent, take into consideration the legitimate intellectual interests of the PI to have the opportunity to benefit from his or her intellectual endeavors and to publish subsequent analyses.
from the data set (including additional analyses funded by HEI). In some cases, e.g. for studies of particularly high regulatory importance being used to inform decisions over a short time frame, HEI may need to work to balance the PI interests against the need for interested parties to obtain access in a timely manner.

5. **Length of Data Retention:** HEI funded PI are required to retain all data generated in the course of HEI-funded research for at least ten (10) years from the date of publication of the research by HEI, or a longer period if required by a funding agency or third-party data provider or as directed by HEI. HEI retains the right to access the data at any time during this period. If the PI has kept the data beyond this time, HEI will continue to have the rights to access to the data. At any point, and at least ninety (90) days prior to any alteration or destruction or other disposal of the data, the PI will notify HEI so as to enable the Institute to request such data under this provision.

6. **Responsibility and Reimbursement for Costs** To the maximum extent possible, HEI will encourage the PI to be the primary sharer of the data. To the extent that providing the data would place an undue burden on the PI (e.g. in a situation where the sheer number of requests would not allow the PI to continue to conduct her or his research or academic activities), HEI will be prepared to establish an alternative procedure for it to share the data. In either case, HEI will expect to receive from data requesters reasonable reimbursement for both the direct costs of providing the data, and for the time of the PI and/or HEI staff to gather, transmit, and explicate the data. In order to facilitate data access for all future and current studies in which HEI and the PI expect that the results have a high likelihood of being used in supporting a regulatory decision, HEI will consider requests from the PI for a reasonable budget of data archiving funds, to be provided as part of the project budget.

7. **Confidentiality** Any requester of research data will be expected to obtain any approvals and enter into any required data use agreements necessary to permit the requester access to such data. The requester will be fully responsible for adhering to all such approvals from the appropriate agencies (e.g. the National Center for Health Statistics) or other third-party data providers. HEI will not knowingly itself provide, or require a PI to provide, information that can be used to identify a specific individual without the requester having already obtained all such necessary approvals.

8. **Responsibility of the Data Requester** In addition to the payment of reasonable costs and the obtaining of any necessary confidentiality approvals, HEI will ask the data requester, as would be normal courtesy in the scientific community, to inform both the PI and HEI promptly of any findings emerging from their analysis, to provide the PI an opportunity to respond to those findings prior to publication, to provide copies to both the PI and HEI of any papers submitted for publication from the data, and to cite both HEI and the PI in any publication, noting explicitly that the views expressed are those of the new analyst and not those of the PI, HEI, or HEI’s sponsors.

9. **HEI Decision Making** All requests for research data will be reviewed and decided upon by a Committee of the HEI Science Director, and the Chairs of the HEI Research and Review Committees, in consultation with both the research and review staff scientists responsible for the study in question. Any significant policy questions arising from a particular request will be considered, upon recommendation of the Committee and the President, by the Board of Directors.

The provision of data will not be simple to accomplish and will at times raise concerns and controversy from one or more parties. HEI will attempt to provide data in a manner that to the maximum extent practical fosters an atmosphere of collegiality and mutual respect among all parties, with the aim of obtaining from the sharing of data the maximum benefit for science and for the quality of the public policy decision-making process.