

Columbia University Study of Endotoxin, Obesity, and Asthma in NYC Head Start: Study Data Use and Publication Policies

The following guidelines have been prepared at the suggestion of the Data Management team for use by investigators and research staff associated with the above study in the preparation of manuscripts and presentations using study data. We hope that these guidelines will help the study team and collaborators to make explicit their understandings and intentions concerning the use of study data, to keep track of the use of study data, to share data appropriately, to obtain assistance as needed from the Data Management team in statistical analysis and interpretation of findings, and to ensure that researchers who have made original scientific contributions to the field receive credit for their work. The DSM team has the responsibility of entering, cleaning, integrating, monitoring, analyzing, and eventually archiving study data. This last function is particularly important because some biological samples will be stored for future use, and it is important that the entire database be available for use by the investigators at that future time.

1. Members of the investigative team and other faculty members may initiate data requests. Students, staff, and others who wish to analyze study data require a faculty sponsor.
2. We encourage individuals who wish to use study data to meet with the Data Management team prior to submitting a data request form. Howard Andrews, director of the Data Management team, can be reached at 212-543-6022, Mailman room 328, or by email hfa1@columbia.edu. All requests for data must be submitted on a study data request form to Howard with a copy to Judith Jacobson, study PI (212-305-2502, Mailman room R736, or email jsj4@columbia.edu).
3. Howard and Judith will determine the appropriateness and feasibility of the data requests. Howard and Judith will determine if the data are ready to be released (i.e., complete with respect to entry, cleaning, editing, standardization if relevant, and validation/quality assurance if relevant).
4. The investigative team comprises individuals with a variety of expertise relevant to the study. We encourage individuals requesting data to collaborate with and to acknowledge as collaborators and co-authors all those on the team who have relevant expertise.
5. All co-authors and Judith must have the opportunity to review all manuscripts based on study data before they are submitted to a journal. The co-authors and Judith must provide feedback or approval in written form to the authors of the paper within two weeks. If serious differences of opinion occur, the investigative team should review the manuscript and resolve them. If revisions are required, the co-authors and Judith must have the opportunity to review the revised manuscript.
6. Whenever a manuscript based on study data is submitted to a journal, Howard must receive a copy accompanied by the data file(s) used in the analysis, and the programming/methods used to manipulate the data, create new variables, and perform the statistical tests. This procedure will help us to achieve consistency in the use of derived, composite, or scaled variables in subsequent publications by the same or different authors, and to respond to requests from the funding agency for information about publications and results.
7. We hope that these guidelines facilitate the analysis and publication of study results.