



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

September 7, 2016

MEMORANDUM

SUBJECT: Project Notification:
Follow-Up Review on EPA's Human Subjects Research Policy and Guidance
Project No. OPE-FY16-0030

FROM: James L. Hatfield, Director, Air Evaluations *James L. Hatfield*
Office of Program Evaluation

TO: Lek Kadeli, Principal Deputy Assistant Administrator for Management
Office of Research and Development

The purpose of this memorandum is to notify you that the Office of Inspector General (OIG) for the U.S. Environmental Protection Agency (EPA) plans to begin a follow-up review of the EPA's Human Subjects Research (HSR) policy and guidance. This follow-up evaluation is in response to a congressional request. Our objective is to determine whether the EPA has implemented the recommendations in a prior OIG report, *Improvements to EPA Policies and Guidance Could Enhance Protection of Human Study Subjects*, Report No. 14-P-0154, issued March 31, 2014; and how the EPA recruits and compensates human study subjects.

During fieldwork, we plan to review the HSR study, *The Interaction of Social Factors with Air Pollution (SOZIAL)*, to determine whether the EPA is implementing the recommendations in the OIG's 2014 report. We may look at other human subject studies conducted since the issuance of the report to determine whether the recommendations were implemented. We will also conduct fieldwork on the EPA's recruitment of human study subjects and how they are compensated, as well as whether the EPA considered the practices and policies of other federal agencies engaged in human subject studies.

We will contact your audit liaison to arrange a mutually agreeable time for an entrance conference to discuss the assignment's objective and our planned work. We will also answer any questions about the evaluation process and reporting procedures. Prior to or during our entrance conference, we request that you provide us with copies of (or links to) the following materials:

- Protocol applications, consent forms, adverse events documentation, approval documents, and recruiting materials for the SOZIAL study.
- List of all other HSR studies conducted by the EPA since the issuance of the report.
- Any HSR-related policy and guidance documents not currently on the EPA's intranet site.
- Contacts for the SOZIAL and other HSR studies conducted since the issuance of the report.

To ensure the success and timely completion of this project, we respectfully note that the OIG is authorized by the Inspector General Act of 1978 to have timely access to personnel and all material necessary to complete its objectives. For this evaluation, we may request access to EPA databases, meetings and interviews with EPA personnel and contractors, and documentation related to the HSR Program. We will request your resolution if an agency employee or contractor refuses to provide requested records to the OIG, or otherwise fails to cooperate with the OIG. We may report unresolved access matters to the Administrator and include the incident in the Semiannual Report to Congress.

If you or your staff have any questions, please do not hesitate to contact me at (919) 541-1030 or hatfield.jim@epa.gov; or Renee McGhee-Lenart, Project Manager, at (913) 551-7534 or mcghee-lenart.renee@epa.gov.

cc: Thomas Burke, Deputy Assistant Administrator and EPA Science Advisor, Office of Research and Development
Robert Kavlock, Deputy Assistant Administrator for Science, Office of Research and Development
Susan Pearce, Audit Liaison, Office of Research and Development
Nic Grzegozewski, Agency Follow-Up Coordinator
Frank Benenati, Associate Administrator for Public Affairs
Melissa Harrison, Press Secretary, Office of Public Affairs
Regional Audit Follow-Up Coordinators, Regions 1–10
Arthur A. Elkins Jr., Inspector General
Charles Sheehan, Deputy Inspector General
Alan Larsen, Counsel to the Inspector General
Carolyn Copper, Assistant Inspector General for Program Evaluation
Kevin Christensen, Assistant Inspector General for Audit
Patrick Sullivan, Assistant Inspector General for Investigations
Edward Shields, Acting Assistant Inspector General for Management
Christine El-Zoghbi, Deputy Assistant Inspector General for Program Evaluation
Jennifer Kaplan, Deputy Assistant Inspector General for Congressional and Public Affairs
Jeffrey Lagda, Congressional and Media Liaison, OIG
Patrick Gilbride, Director, Science, Research, and Management Integrity Evaluations, OIG
Erin Barnes-Weaver, Project Manager, Science, Research, and Management Integrity Evaluations, OIG
Renee McGhee-Lenart, Project Manager, Air Evaluations, OIG