



At a Glance

Why We Did This Review

In response to a congressional request, we conducted this review to determine whether the U.S. Environmental Protection Agency (EPA) followed applicable laws, regulations, policies, procedures and guidance when it exposed human subjects to diesel exhaust emissions or concentrated airborne particles. In particular, we reviewed five studies that the EPA conducted during 2010 and 2011 to determine whether the agency (1) obtained sufficient approval to conduct these studies; (2) obtained adequate informed consent from the human study subjects; and (3) adequately addressed adverse events that occurred during the studies. The EPA's human studies are governed by 40 Code of Federal Regulations (CFR) Part 26, also known as the Common Rule, which establishes minimum standards. The EPA conducts human research studies to better understand the health effects of pollution on humans.

This report addresses the following EPA theme:

- *Addressing climate change and improving air quality.*

For further information, contact our public affairs office at (202) 566-2391.

The full report is at:
www.epa.gov/oig/reports/2014/20140331-14-P-0154.pdf

Improvements to EPA Policies and Guidance Could Enhance Protection of Human Study Subjects

What We Found

The EPA followed applicable regulations when it exposed 81 human study subjects to concentrated airborne particles or diesel exhaust emissions in five EPA studies conducted during 2010 and 2011. However, we identified improvements that could be made to the EPA's policies and guidance to enhance protection of study subjects.

The EPA can enhance its human studies by improving how it obtains approval for studies; how it communicates risk to people who participate in EPA studies; and how it addresses adverse events in its guidance.

The EPA obtained approval to conduct the five human research studies, including approval from a biomedical Institutional Review Board (IRB) and the EPA Human Studies Research Review Official (HSRRO). However, the EPA's policies and guidance do not address when HSRRO approval is needed for significant study modifications. Developing guidance for when HSRRO must approve significant modifications would ensure their independent review.

The EPA obtained informed consent from the 81 human study subjects before exposing them to pollutants. While the consent forms met the requirements of 40 CFR Part 26, we found that exposure risks were not always consistently represented. Further, the EPA did not include information on long-term cancer risks in its diesel exhaust studies' consent forms. An EPA manager considered these long-term risks minimal for short-term study exposures. We believe presenting consistent information about risks further ensures that study subjects can make the most informed choice about participating in a study.

The EPA addressed six adverse events during its studies, reported them to the IRB, and provided clinical follow-up after the events. While the clinical follow-up appeared to be reasonable, the EPA's policies, guidance and consent forms do not establish the EPA's clinical follow-up responsibilities. According to EPA managers, the agency uses the latest University of North Carolina at Chapel Hill (UNC) IRB's adverse event definitions and reporting timeframes to respond to adverse events. However, the agency's guidance provides different definitions and reporting timeframes and does not state that the EPA has adopted the UNC-IRB definitions and timeframes. Using EPA's guidance, the EPA reported two of the six adverse events later than required and did not report two other events to IRB.

Recommendations and Planned Corrective Actions

We recommend that the EPA establish procedures for obtaining HSRRO approval of significant study modifications, ensure consent forms consistently address pollutant risks, update its guidance to include the EPA's clinical follow-up responsibilities, and address a number of other recommendations. The EPA concurred with all recommendations and provided planned corrective actions and completion dates that meet the intent of the recommendations. All recommendations have been resolved.