U.S. Environmental Protection Agency
Office of Inspector General

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At a Glance

Why We Did This Review

In response to a congressional request, we determined whether the U.S. Environmental Protection Agency (EPA) implemented the recommendations in Office of Inspector General (OIG) Report No. 14-P-0154, *Improvements to EPA Policies and Guidance Could Enhance Protection of Human Study Subjects*, issued March 31, 2014. We also determined how the EPA recruits and compensates human study subjects and whether the EPA considered the practices and policies of other federal agencies that conduct human subjects research (HSR) studies.

The EPA's HSR studies are governed by 40 CFR Part 26, including Subpart A, which is known as the Common Rule. This regulation sets the standards for conducting research involving human subjects. The EPA conducts controlled exposure HSR studies to better understand the health effects of pollution on humans.

This report addresses the following EPA goal or cross-agency strategy:

- *Addressing climate change and improving air quality.*

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EPA Implemented Prior OIG Recommendations, but Additional Guidance Could Strengthen the Human Subjects Research Program

What We Found

The EPA can take additional measures to track its HSR guidance and provide greater public transparency of the agency's HSR studies.

The EPA implemented the recommendations from the OIG's 2014 report, including issuing and revising HSR guidance and improving management controls for the HSR study approval process. The EPA also used this guidance and these controls, as applicable, in two HSR studies conducted after we issued our 2014 report. During this current review, however, we found that the EPA did not track revisions to its intranet guidance. The EPA could reduce risk to the program by maintaining prior versions of its guidance. In addition, we found that public transparency could be improved. While the EPA posted information about its controlled exposure HSR studies on a National Institutes of Health website and on the public website of its contractor that recruits study subjects, the agency did not post basic information about these studies on its own public website.

We also found that the EPA's practices for recruiting and compensating human study subjects are similar to those of other federal agencies. For example, the EPA and other agencies that conduct HSR may use contractors to recruit study subjects, and an Institutional Review Board approves the compensation received by study subjects. In addition, we found that interagency collaboration informs the EPA's HSR program. For instance, the EPA consults with other agencies about record retention, grant reviews and informed consent.

We found areas where the EPA could improve its procedures. For example, during our review, the EPA discussed three procedures related to its HSR program: (1) subjects participating in multiple studies must undergo waiting periods between each study to ensure that biological changes return to a baseline level, (2) the number of bronchoscopies that can be performed on a study subject in 1 year are limited, and (3) nurses and physicians who conduct the initial health exams on study subjects evaluate whether participation is in a subject's best interest. However, the EPA did not have any guidance documenting these procedures. Based on our current findings, the EPA developed guidance regarding screening and tracking HSR participation.

Recommendations and Planned Agency Corrective Actions

We recommend that the EPA track and document revisions to HSR guidance and post basic information about the agency's open and closed HSR studies since 2016. The EPA concurred with all recommendations and provided planned corrective actions and completion dates that meet the intent of the recommendations. All recommendations are resolved.