



Highlights of [GAO-05-191](#), a report to congressional requesters

## Why GAO Did This Study

An institute at the National Institutes of Health (NIH) and an office in the Environmental Protection Agency (EPA) entered into collaborative arrangements with the American Chemistry Council (ACC) to support research on the health effects of chemical exposures. NIH accepted a gift from ACC to help fund the research. EPA and ACC funded their proposals separately. The arrangements raised concerns about the potential for ACC to influence research that could affect the chemical industry. GAO determined the agencies' legal authorities to enter into the arrangements; the extent to which the agencies evaluated and managed potential conflicts of interest resulting from these arrangements; the extent to which the NIH institute complied with NIH's gift acceptance policy; and the extent to which NIH, EPA, and other agencies have similar arrangements.

## What GAO Recommends

GAO recommends, among other things, that NIH and EPA develop formal policies for evaluating and managing conflicts of interest when entering into research arrangements with nongovernmental partners, particularly those representing a regulated industry, and that NIH revise its gift policy to require conflict of interest evaluations and documentation of decisions.

[www.gao.gov/cgi-bin/getrpt?GAO-05-191](http://www.gao.gov/cgi-bin/getrpt?GAO-05-191).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Anu Mittal at (202) 5123841 or [Mittala@gao.gov](mailto:Mittala@gao.gov).

## FEDERAL RESEARCH

# NIH and EPA Need to Improve Conflict of Interest Reviews for Research Arrangements with Private Sector Entities

## What GAO Found

NIH's National Institute of Environmental Health Sciences (NIEHS) used the authorities granted to NIH's institutes and centers under sections of the Public Health Service Act to enter into its arrangement with ACC. Similarly, EPA's Office of Research and Development (ORD) relied on authorities granted to EPA under sections of the Clean Air Act, the Clean Water Act, and the Solid Waste Disposal Act to enter into its research arrangement. Nothing in these statutes appears to prohibit either agency from entering into research arrangements with nonprofit organizations such as ACC.

NIEHS and ORD did not formally evaluate the potential for conflicts of interest with ACC before they entered into the arrangements, but both agencies took steps to manage the potential as the arrangements were implemented. NIH and EPA had no specific policies requiring officials to evaluate or manage potential conflicts of interest when they entered into the ACC arrangements, nor do they currently have such policies. Although no formal evaluation occurred, agency officials managed the arrangements through their existing research management processes. Both agencies believe these actions helped mitigate the potential for undue influence by ACC and adequately protected the integrity of the scientific research conducted under the arrangements. Because the agencies' research management processes were not designed to address conflict of interest issues they are not a substitute for a formal evaluation of such conflicts. Without policies requiring a formal evaluation and management of conflicts, there is no assurance that similar arrangements will be appropriately evaluated and managed for such conflicts in the future.

NIEHS officials complied with portions of NIH's gift acceptance policy that guide the acknowledgement and administration of gifts. However, the policy's guidance on evaluating and managing potential conflicts is extremely broad, and it lacks clarity and consistency. As a result, the policy gives officials wide discretion in this area. In addition, the policy does not require the agency to document the basis for its decisions. Consequently, the policy does not provide sufficient assurance that potential conflicts of interest between NIH and donor organizations will be appropriately considered.

While some institutes and centers at NIH had arrangements somewhat similar to the ACC arrangements, GAO did not find any similar arrangements at other program offices at EPA or at the Food and Drug Administration and the Federal Aviation Administration—two other agencies with significant research budgets. None of the nine research arrangements GAO found at NIH institutes and centers involve organizations that represent industry in the same direct manner that ACC represents the chemical industry.