

GAO Highlights

Highlights of [GAO-23-105736](#), a report to congressional requesters

Why GAO Did This Study

The Department of Health and Human Services' NIH awards over 84 percent of its \$45 billion annual budget to support research projects conducted by external organizations. Such projects include laboratory research involving the use of live vertebrate animals in foreign facilities. NIH funds these projects through agreements with domestic and foreign award recipients.

GAO was asked to examine NIH's oversight of the foreign animal research projects it funds. This report (1) identifies the amount of funding NIH awarded to foreign institutions in fiscal years 2011 through 2021 for animal research projects overseas, (2) describes the requirements that foreign facilities must meet to be eligible to perform animal research for NIH-funded projects, and (3) examines NIH's procedures for overseeing the foreign animal research it funds.

GAO analyzed NIH documents and data, including policies and processes related to oversight of, and requirements for, foreign animal research. GAO also interviewed NIH officials and experts in animal research from several organizations.

What GAO Recommends

GAO recommends that NIH take steps—such as conducting site visits or requiring third-party verification—to provide reasonable assurance that award recipients' annual self-reported project information is reliable and adequate to ensure the humane care and use of laboratory animals. The Department of Health and Human Services concurred with this recommendation.

View [GAO-23-105736](#). For more information, contact Latesha Love-Grayer at (202) 512-4409 or lovegrayerl@gao.gov, or Steve Morris at (202) 512-3841 or morriss@gao.gov.

March 2023

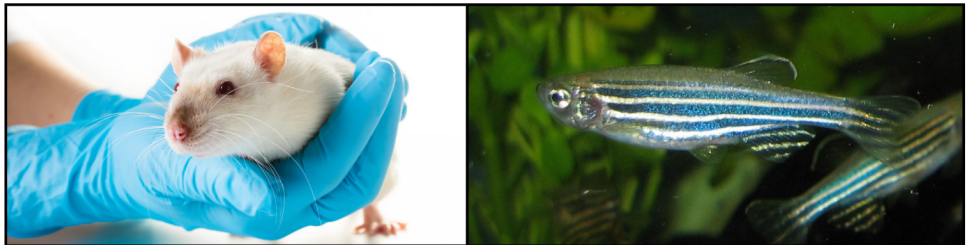
ANIMAL USE IN RESEARCH

NIH Should Strengthen Oversight of Projects It Funds at Foreign Facilities

What GAO Found

From fiscal year 2011 through fiscal year 2021, the National Institutes of Health (NIH) provided approximately \$2.2 billion in contracts or grants to foreign organizations for research projects involving animals. NIH contracts, totaling about \$1.9 billion, supported foreign animal research projects in 10 countries. About 90 percent of this contract funding supported research in the Netherlands, Denmark, and the United Kingdom. NIH grants, totaling about \$318 million, supported foreign animal research projects in 44 countries. About 66 percent of this grant funding supported research in Australia, Canada, and the United Kingdom.

Examples of Animals That May Be Used in NIH-Funded Foreign Animal Research



Sources: Left: Olexandr/stock.adobe.com. Right: Azul/goodfreephotos.com. | GAO-23-105736

Foreign facilities must meet several requirements to perform NIH-funded animal research. For example, the facilities are required to comply with U.S. policy governing animal care and use or provide evidence that acceptable standards for the humane care and use of animals will be met. Each facility must also commit to follow international principles for animal care and use and must certify compliance with relevant laws, regulations, and policies in the country where it operates. NIH has proposed two additional requirements for foreign facilities. These include a requirement that each facility submit an annual report affirming either that there was no reportable noncompliance with animal care and use standards during the year or that it notified NIH of any noncompliance.

NIH has established processes for oversight of foreign animal research, but it does not verify the reliability of annually reported information it uses to monitor compliance for ongoing projects. Before it awards funding, NIH takes some steps to identify, assess, and mitigate any animal welfare risks it identifies. After projects begin, NIH has processes to investigate and, if necessary, remediate any reported noncompliance with animal care and use standards. In addition, NIH uses annual reports submitted by award recipients to monitor foreign research facilities' ongoing compliance with these standards. However, because the award recipients self-generate the information in the annual reports, there are risks that any animal welfare issues may be misrepresented. Yet NIH does not take steps, such as conducting site visits or requiring third-party verification, to ascertain the reliability of this information. As a result, NIH may be missing opportunities to identify and respond to possible instances of noncompliance with animal care and use standards at foreign research facilities.