#COGROct2023

GAO Oversight Work Involving Academic Research

October 26, 2023

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GAO Oversight Work Involving Academic Research Community

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U.S. Government Accountability Office (GAO)

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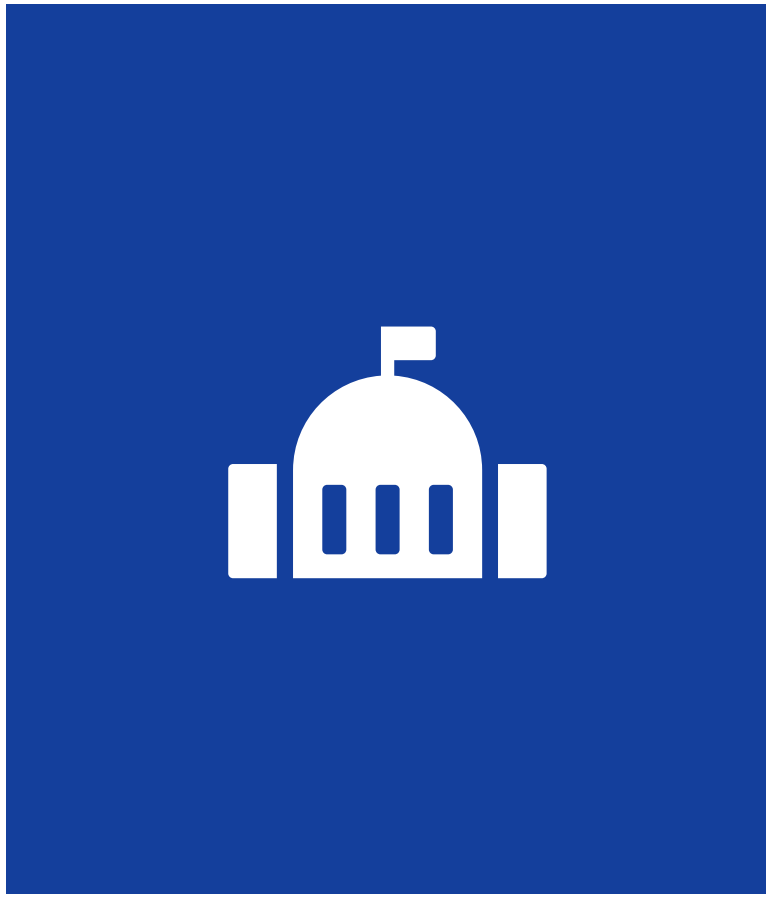
- Independent, nonpartisan, legislative branch agency.
- Supports Congress in its oversight responsibilities.
- Improves government performance and accountability.

Science, Technology Assessment, and Analytics (STAA)

GAO S&T support to Congress:



Technology assessments

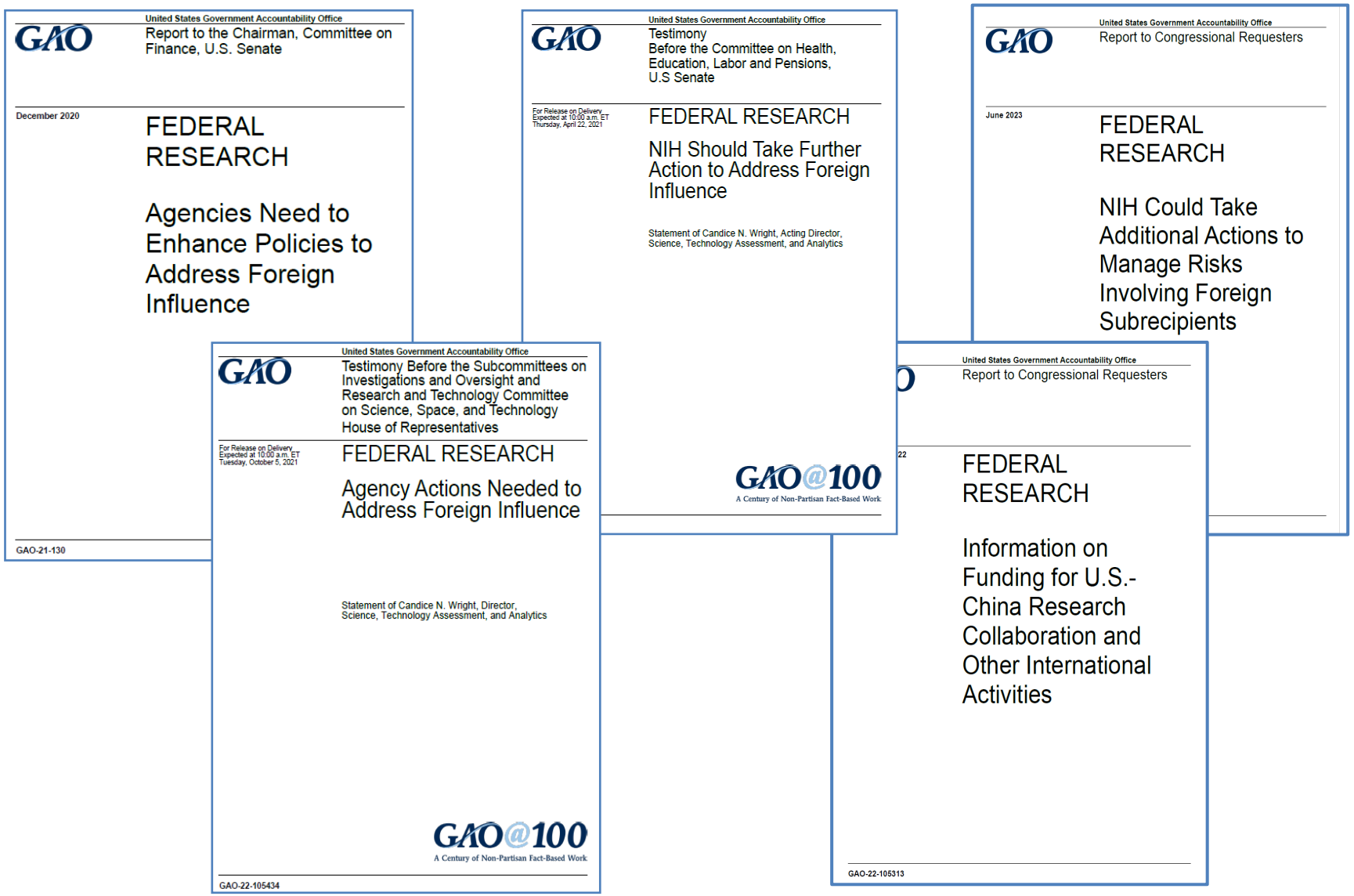
S&T performance audits

On-demand S&T assistance

Research Security: Challenges

- U.S. collaborations with foreign entities can lead to scientific advancements. As other countries seek to exploit federally funded research, need to balance free collaboration and exchange of ideas with security risks.
- Globalized collaboration puts pressure on research community to identify and mitigate threats, while also maintaining an open research environment.
- Researchers must now be crossover artists armed with skills beyond their field of expertise—policy, security

Research Security

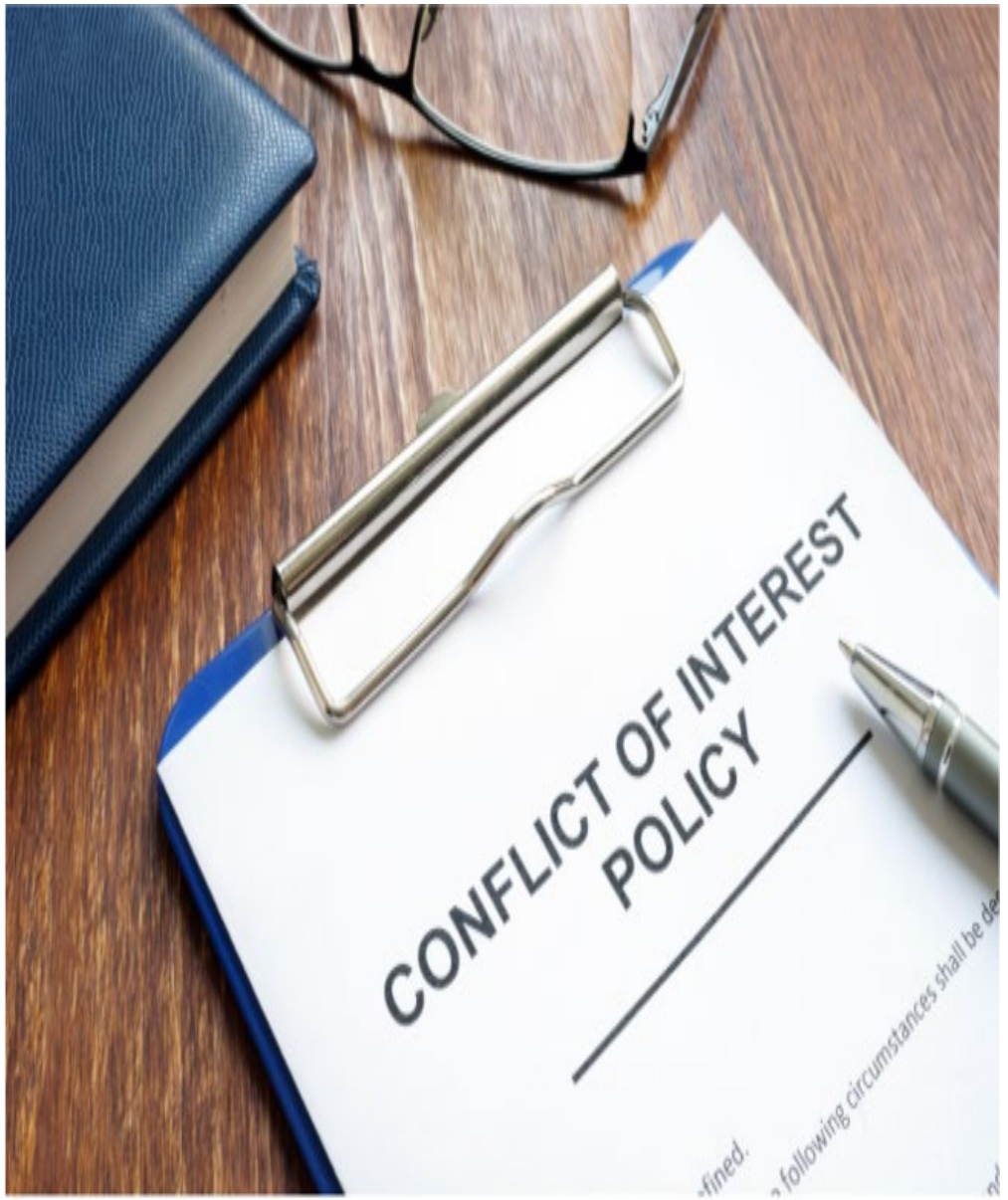


Ongoing Work

- NIST Research Security
- R&D Funding to Foreign Entities of Concern
- SBIR/STTR Foreign Risk Management
- DOE Technology Transfer

Research Security: Highlights from Recent Work

- Agencies' policies and disclosure requirements generally focused on financial conflicts
- Agencies rely on universities to monitor conflicts but lack clear enforcement procedures
- Stakeholders shared need to improve ability to identify and address foreign threats to federally funded research
    - harmonize grant proposals
    - better communicate identified risks
    - provide training on foreign risks
- Recommendations:
    - OSTP issue guidance
    - Agencies address financial and non-financial conflicts of interest in their policies and document enforcement procedures



Source: Vitalii Vodolazskyi/stock.adobe.com.

Research Security: Highlights from Recent Work

- Federal agencies can fund research through grants or other agreements that involves foreign entities such as universities and labs. Identifying the full extent of such funding can be challenging—particularly for subawards
- GAO and HHS OIG reviews found that NIH's oversight did not always ensure that foreign institutions complied with award terms and conditions—which can include biosafety requirements
- Recommended that NIH look for more immediate actions to improve oversight of foreign subrecipients—such as changes to its internal processes

health care

GAO's Healthcare Portfolio

Medicaid

This portfolio includes our evaluation of the Medicaid program, such as issues related to access, quality, financing, and program integrity.

Medicare

This portfolio includes our evaluation of Medicare reforms, financing, and expenditures, operations, and program integrity issues.

VA, DOD, and IHS

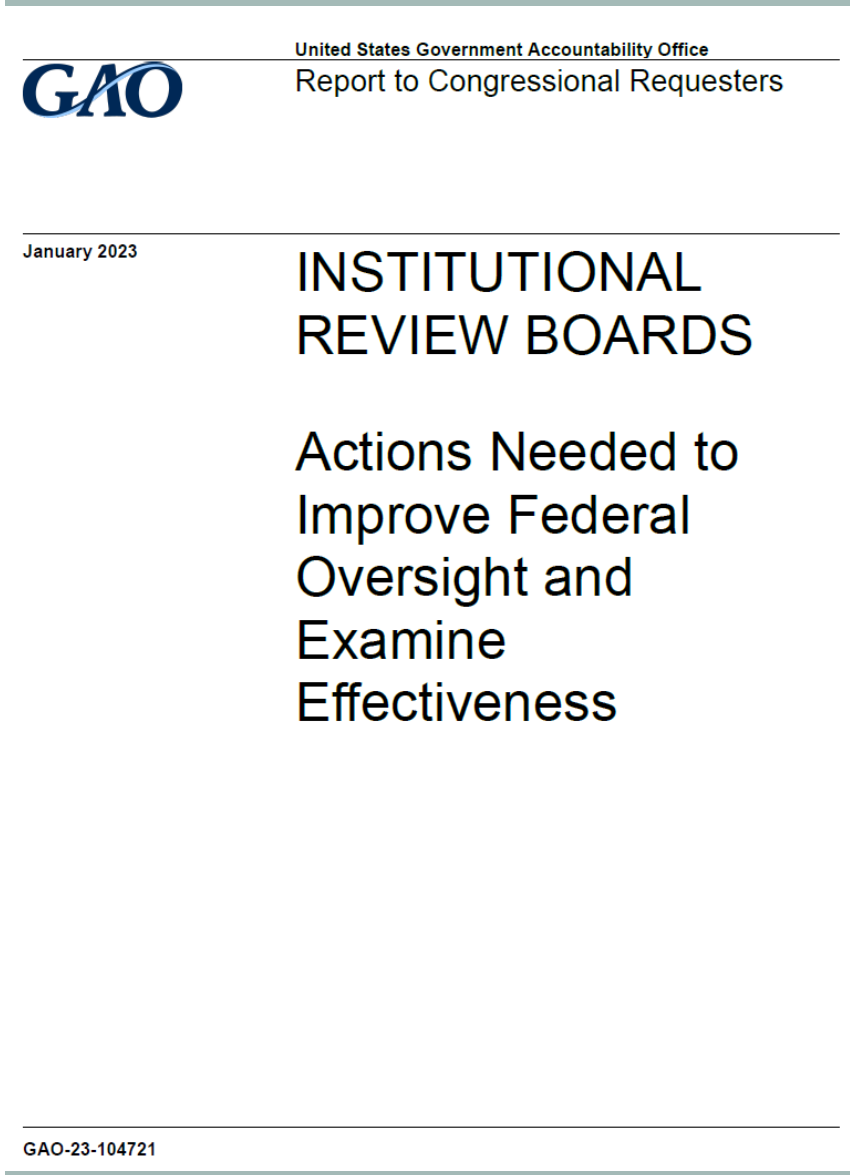
This portfolio includes our evaluation of actions and options for improving VA and DOD's health care services and the administration of health care programs through the Indian Health Service.

Public Health and Private Markets

This portfolio includes our evaluation of the effectiveness of federal programs to promote and ensure public health and prevent and respond to public health emergencies as well as assess trends, costs, and issues in private health insurance coverage and reform.

Cross-cutting Issues

We also coordinate work on several cross-cutting issues, including behavioral health, long term care, health equity, and quality and health care cost drivers, and prescription drugs.



Research objectives:

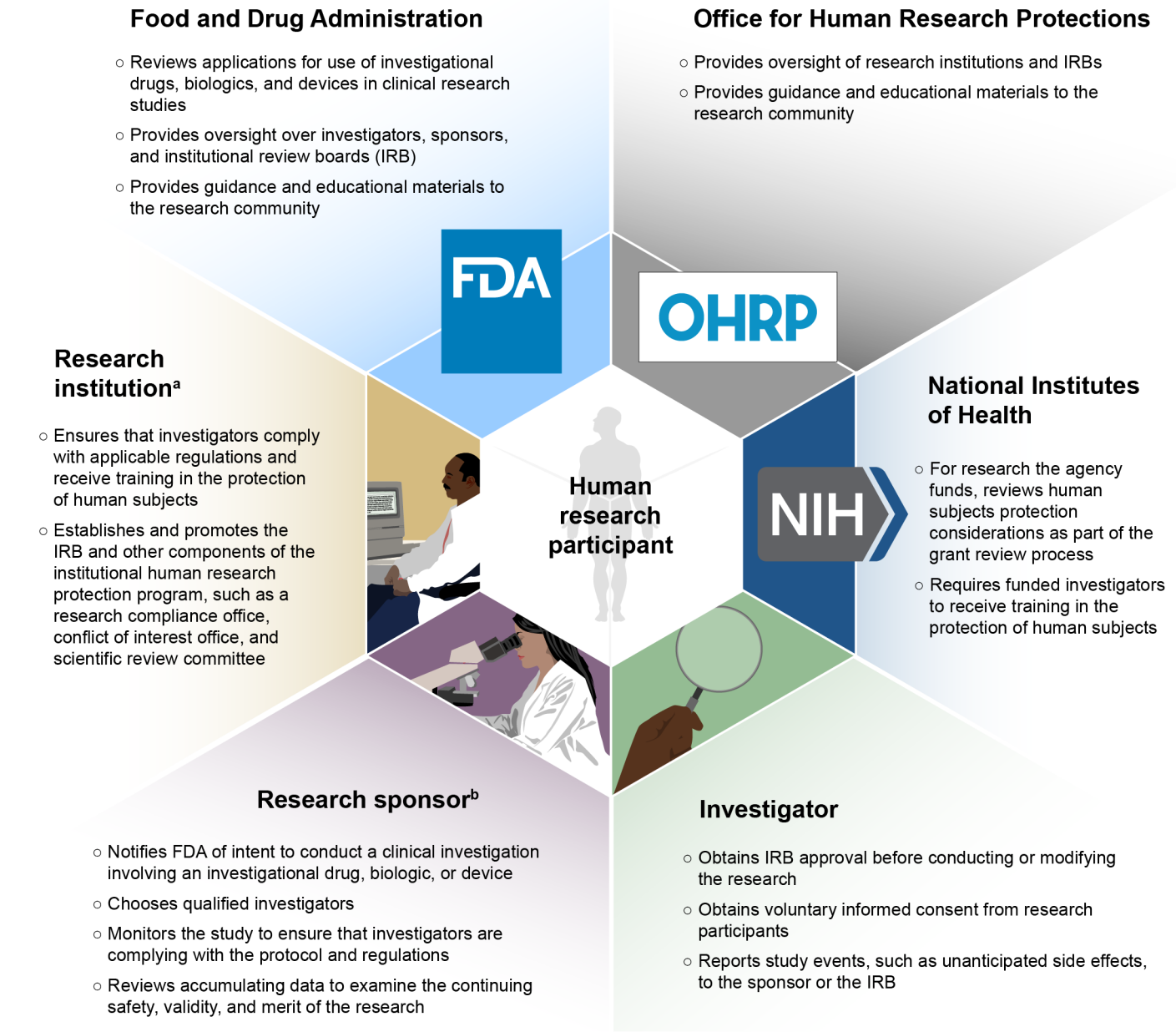
(1) Describe the composition of the institutional review board (IRB) market

(2) Describe the practices selected IRBs have implemented to help strengthen the quality of their reviews

(3) Examine oversight of IRBs by HHS's Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA)

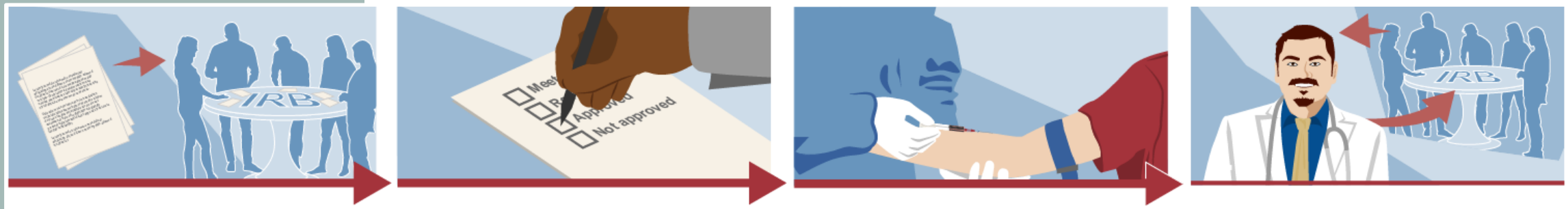
Protection

Examples of Other Entities Involved in the Protection of Human Subjects for HHS-supported or FDA-regulated Research



Source: Information from the Department of Health and Human Services (HHS); HHS Office of Inspector General; the National Academy of Medicine; and the World Health Organization. | GAO-23-104721

Process



Investigator submits research protocol and materials to the IRB for review.

The IRB may approve, require modifications, or disapprove the protocol.

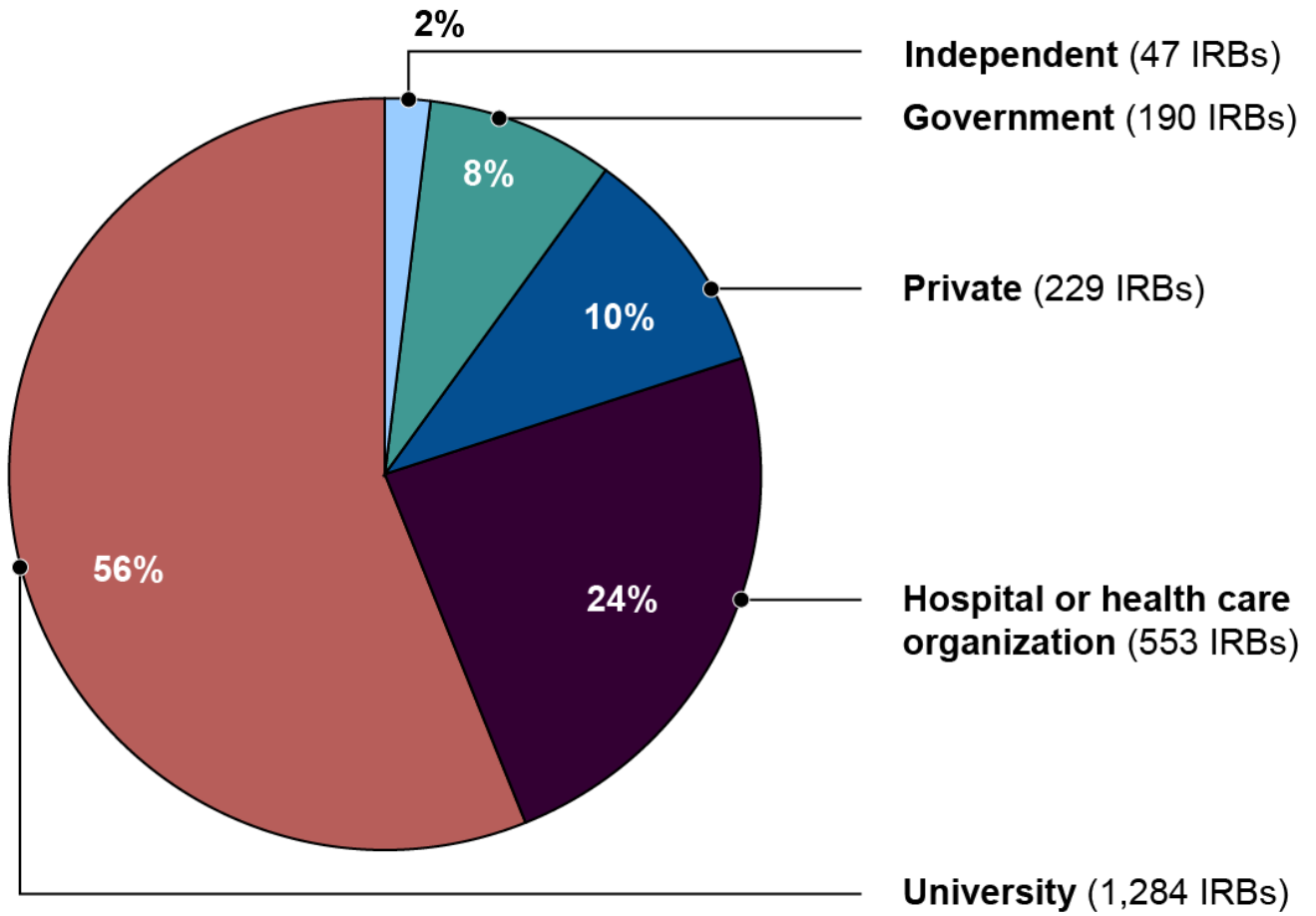
Once the IRB approves the protocol, the investigator may begin recruiting and enrolling subjects.

The investigator continues to communicate with the IRB for the duration of the study.

Source: GAO analysis of Department of Health and Human Services information. | GAO-23-104721

Types of IRBs

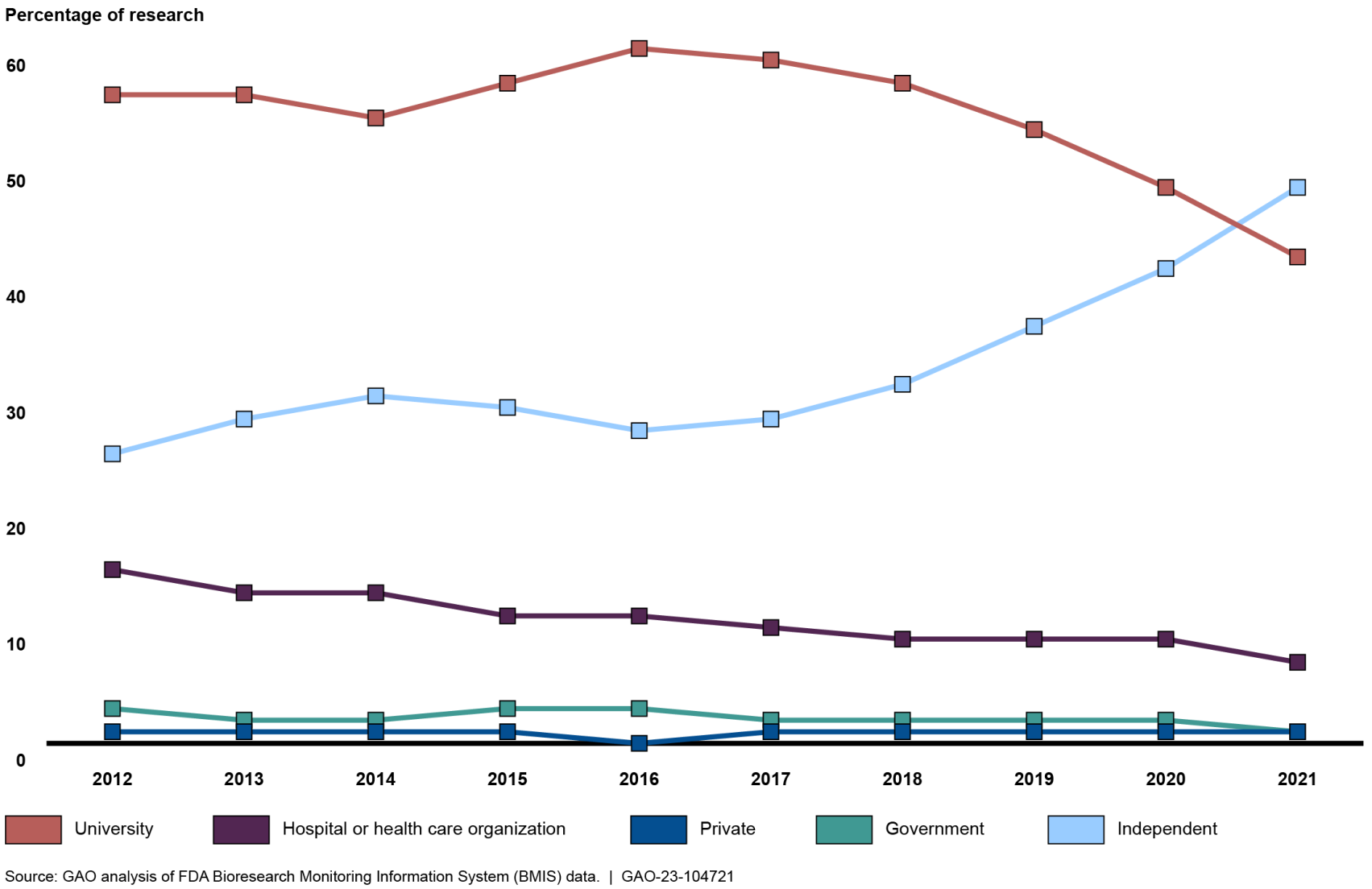
There are different types of IRBs that review research studies.



Source: GAO analysis of Office of Human Research Protections (OHRP) data. | GAO-23-104721

FDA-regulated drugs

IRB Review of Clinical Research Conducted under FDA Investigational New Drug Applications



Source: GAO analysis of FDA Bioresearch Monitoring Information System (BMIS) data. | GAO-23-104721

Inspections

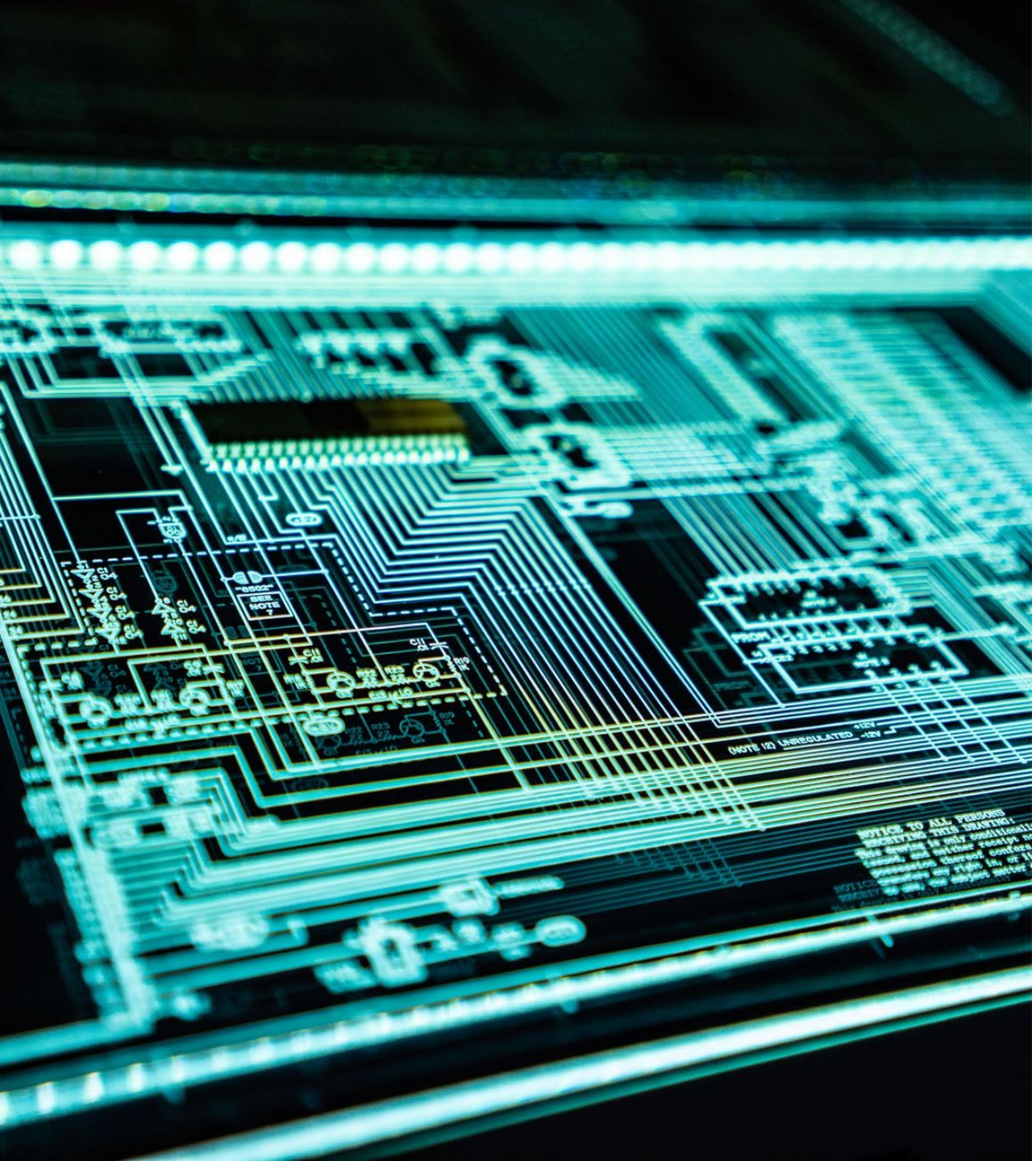
Number of Completed Inspections by Inspection Type and Fiscal Year

Inspection type	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Total
Food and Drug Administration (FDA)													
Routine	175	183	136	149	140	118	132	137	131	98	52	18	**1,469**
For-cause[a]	20	15	20	16	18	12	8	7	11	2	0	2	**130**
Total	**195**	**198**	**156**	**165**	**158**	**130**	**140**	**144**	**141**	**100**	**52**	**20**	**1,599**
Office for Human Research Protections (OHRP)													
Routine	3	4	4	3	4	2	4	3	1	1	0	0	**29**
For-cause[a]	12	12	9	5	2	3	8	3	0	2	3	0	**59**
Total	**15**	**16**	**13**	**8**	**6**	**5**	**12**	**6**	**1**	**3**	**3**	**0**	**88**

Source: GAO analysis of FDA Field Accomplishments and Compliance Tracking System and OHRP inspection data. | GAO-23-104721

Recommendations

1. Ensure that OHRP takes steps to ensure the accuracy of protocol data collected in OHRP's IRB registry (e.g., update instructions to IRBs and examining data accuracy for a sample of IRBs).
2. Ensure that OHRP & FDA conduct an annual risk assessment to determine whether the agency is conducting an adequate number of routine IRB inspections and to optimize the use of IRB inspections in the oversight of IRBs and protection of research participants.
3. Ensure that OHRP and FDA convene stakeholders to examine approaches for measuring IRB effectiveness in protecting human subjects, and implement the approaches as appropriate.



Questions or comments?

https://www.gao.gov/science-technology
https://www.gao.gov/health-care