GAO Highlights

Highlights of GAO-23-104721, a report to congressional requesters

January 2023

INSTITUTIONAL REVIEW BOARDS

Actions Needed to Improve Federal Oversight and Examine Effectiveness

Why GAO Did This Study

IRBs review research studies involving human subjects to ensure that risks to subjects are minimized and participants have sufficient information to consent to participate. In the past, IRBs were based at research institutions, such as academic centers. Over time, independent IRBs have played a more prominent role in reviewing research on human subjects. Some policymakers and others have raised questions about the increased use of independent IRBs and the effects on protecting human subjects.

GAO was asked to examine independent IRBs, processes used to protect human subjects, and standards of IRB quality, among other things. This report describes the composition of the IRB market and examines OHRP and FDA oversight of IRBs, among other objectives.

GAO reviewed federal laws and regulations and articles published between 2010 and June 2021; analyzed IRB registration, drug application, and inspection data; and interviewed FDA and OHRP officials, experts and stakeholders, and 11 IRBs selected for variation in type, size, and other factors.

What GAO Recommends

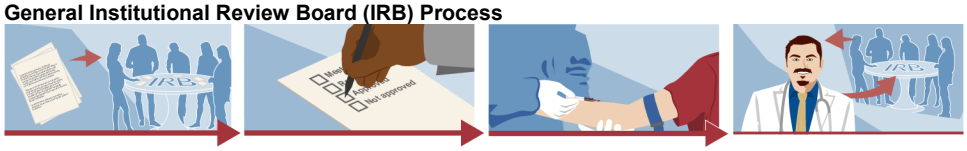
GAO is making four recommendations, including that HHS and FDA conduct annual risk assessments to determine if the agencies are routinely inspecting an adequate number of IRBs and to optimize the use of inspections in the oversight of IRBs and protection of research participants, and examine and implement approaches for measuring IRB effectiveness. HHS concurred with the recommendations.

View GAO-23-104721. For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

Institutional review boards (IRB) are groups that review ethical and safety considerations for research involving human subjects, such as clinical trials.

General Institutional Review Board (IRB) 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

Most IRBs are based at universities, according to Department of Health and Human Services (HHS) data. University-based IRBs were also responsible for reviewing most research involving certain investigational drugs from calendar years 2012 through 2020, according to Food and Drug Administration (FDA) data. Some IRBs are independent, meaning they are not part of institutions that conduct or sponsor research. FDA data show these independent IRBs have reviewed an increasing share of investigational drug research: 25 percent of this research in 2012, and 48 percent in 2021. At the same time, the number of independent IRBs has decreased largely due to consolidation; this is, in part, related to private equity investment in IRBs.

FDA and HHS's Office for Human Research Protections (OHRP) oversee about 2,300 U.S.-based IRBs (operated by about 1,800 separate organizations, which may register and operate one or more IRB) through routine or for-cause inspections. These inspections assess whether IRBs follow federal regulations when reviewing research. FDA and OHRP consider several factors when selecting organizations for inspections, such as the volume of research reviewed. However, GAO found the agencies inspect relatively few IRBs. OHRP officials said they aim to conduct three to four routine inspections annually, while FDA conducted an average of 133 inspections annually between fiscal years 2010 and 2021. Neither agency has conducted a risk-based assessment of their IRB inspection program to help ensure they inspect enough IRBs annually and to optimize their responsibilities in protecting human subjects. Such an approach would be consistent with federal risk management principles.

While the agencies oversee IRBs to determine their adherence to regulations, OHRP and FDA have not assessed to what extent IRB reviews are effective in protecting human subjects. This is because the agencies have not determined the best approaches for doing so. Evaluating effectiveness is challenging in part due to an absence of validated measures and because IRBs are only one part of the framework of stakeholders responsible for protecting human subjects. Convening stakeholders to identify approaches for evaluating IRB effectiveness would be consistent with OHRP and FDA responsibilities and change management practices, and would help provide assurance that IRBs are successful in protecting human subjects.