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# SACHRP: Assuring IRB Effectiveness Takes Funding, Standards Development

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More inspections, certification or accreditation, participant surveys, standards and training. These are key strategies the federal government could undertake to strengthen the oversight and operation of institutional review boards (IRBs) and their related human research protection programs (HRPPs), according to the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP).[1]

Finalized at SACHRP's recent meeting, the recommendations respond to a report by the Government Accountability Office (GAO)—ordered by members of Congress—that found gaps in IRB oversight by the HHS Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA).[2] Although mostly aimed at the government, some of SACHRP's recommendations could be implemented by institutions.

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," according to the report. "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."

*RRC* has documented OHRP's lack of inspections and formal enforcement actions against noncompliant IRBs and investigators for more than a decade. So far this year, OHRP has posted one determination letter, documents that describe findings arising from complaints or inspections initiated without cause.

In previous talks, OHRP officials said the agency had a 62% vacancy rate among its workforce but could not fill the positions due to lack of funding.[3]