Human Research Report
PROTECTING RESEARCH SUBJECTS AND RESEARCHERS
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All U.S.-Based IRBs to Be Evaluated On Effectiveness Like Never Before (#2)

We continue here with more of the actions being proposed to assess the operations and effectiveness of IRBs around the country.

The original impetus for this revolutionary effort came from a report by the federal General Accounting Office titled, *"INSTITUTIONAL REVIEW BOARDS: Actions Needed to Improve Federal Oversight and Examine Effectiveness* (GAO Report 23-104721)," released on February 16, 2023 (see SACHRP's reaction at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-october-19-2023-letter/index.html).

In turn, the highly influential Secretary's Advisory Committee on Human Research Protections (SACHRP) issued its responsive report on how to begin implementing the GAO's recommendations.

The approach of the SACHRP was based on "charges" given to it by the Office for Human Research Protections (OHRP) after release of the GAO report.

We resume now with the SACHRP's recommendations on how to operationalize the GAO's "fourth recommendation" from its evaluation report regarding the assessment of whether IRBs are actually doing what they are supposed to be doing.

More Funding and More Oversight for IRBs Is In the Future ... One Way or Another

"To that end, SACHRP recommends both short term and aspirational goals. In the short term, SACHRP believes that the current regulatory oversight system should be enhanced by increased funding for inspection purposes to OHRP, FDA, and all of the agencies that have adopted the Common Rule.

Furthermore, non-governmental mechanisms that have been developed, including certification, accreditation[,] and other peer review or equivalent evaluation processes for evaluating IRB effectiveness, as well as training programs for IRB members and staff, should be reviewed and considered for improving IRB effectiveness.

In the longer term, there should be focused government inquiries and grants devoted to determining how best to measure the effectiveness of IRBs, of Human Research Protection Programs (HRPP), and public knowledge, trust, and attitudes toward these systems, including the best approach to making these assessments.

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, or missing words. However, we will on occasion insert words or edit text and/or formating in brackets [ ] to make the material easier to read.

NOTE #2: Emphases are added to articles by HRR by underlining or adding ***bold/italics*** to selected text, unless stated otherwise.

NOTE #3: Articles **T**o **B**e **C**ontinued in subsequent issues are marked at the end of the article with **{TBC}**.

Also In This Issue

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Scope of Recommendation

The conduct of research involving human subjects operates in a complex environment involving many individual and organizational roles, all of which have a shared responsibility to protect the rights and welfare of human subjects in research" (SACHRP report, October 19, 2023; see above for Web source).

More Government Oversight of IRBs Is Described Throughout Federal Report

"Consequently, there is universal agreement that we as a community seek to promote effectiveness in how IRBs operate and function.

The GAO Report focuses solely on IRBs and raises questions on what is needed to improve federal oversight and examine the effectiveness of IRBs.

Consistent with [OHRP] charges, SACHRP will restrict our discussion to IRBs and will not address, except in passing, the roles of the many other parties involved in the protection of the rights, interests, safety, and welfare of human research subjects.

These other stakeholder groups include but are not limited to the human research participants themselves, patient advocacy groups, research investigators, research staff, institutional officials, government, industry and sponsors of research, contract research organizations (CROs), bioethicists, certification/accrediting entities, and professional interest groups such as PRIM&R" (ibid).

There Are Several Different Ways To Define IRB Effectiveness

"We will highlight some of these organizations and entities with additional specificity when responding to Charge 2 [i.e., one of the charges from OHRP] later in this document.

In responding to the three charges [from OHRP], SACHRP has combined Charge 1 on 'effectiveness definition/standard' with Charge 3 on 'potential approaches to measures.'

Defining Effectiveness in Protecting Research Participants

Charge: *What constitutes effectiveness in protecting research participants? This could be defined in terms of avoiding harms, ensuring* [that] *subjects exercise informed consent, protecting subjects' rights and welfare, treating subjects equitably or fairly, or achieving greater consistency in applying the regulation, or something else.*

Depending on what is being protected, the IRB's actions could differ and measures of effectiveness would vary accordingly.

What definition of IRB effectiveness is the most important to focus on and measure?

[Thus,] The charge to SACHRP is to define effectiveness in protecting research participants" (ibid).

Committee Decides on Preliminary Definition of "Effective" IRB

"SACHRP suggests that an effective IRB could be defined as follows:

'A high-quality IRB could be described as one in which well-trained, well-supported IRB members with appropriate expertise carefully deliberate on the ethics and regulatory compliance of proposed and ongoing research in ways that promote participant protection and understanding, while also supporting and partnering with researchers to facilitate ethical, compliant research without imposing overly burdensome or inefficient requirements and reviews.'

(See the article 'We Measure What We Can Measure': Struggles in defining and evaluating institutional review board quality, Lynch et al., *Social Science and Medicine*, Nov 27, 2021.)"

Committee Suggests Additional Features to Help Decide on Best "Effectiveness" Measure

"SACHRP would add that an additional component of an effective IRB may include appropriate representation of the communities that it serves, and outreach as necessary to review protocols.

SACHRP suggests that the best way to move forward at this point is to focus on standards to protect human research participants.

SACHRP has identified a list of standards that could be used as a framework for assessing IRB effectiveness. SACHRP has analyzed each one of the standards based on three factors: (1) feasibility; (2) measurability; and (3) whether the standard measures effectiveness on a procedural or substantive basis" (ibid). © {TBC}