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Human Research Report™

PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

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IRBs Are Facing Their Most Significant Question in Decades: Are They Actually Doing Their Job? (#1)

Events of major importance to all IRBs in the United States (and elsewhere for some studies) are coming together with a growing impetus.

We believe that these events may lead to changes to IRB operations of such a magnitude that has not been seen in the human subjects protection field since its inception.

For several years, questions about the functions and very existence of IRBs have been raised in various quarters in different analyses.

For example, national studies conducted by the Office of Inspector General of the Department of Health and Human Services (HHS's OIG) and -- more recently -- the Government Accountability Office (GAO) have posed a crucial question.

That question is, what do IRBs really do and are they doing it right? Note that, as is typical, the GAO's IRB effectiveness study was conducted as a result of a Congressional inquiry.

How to Measure IRB "Effectiveness"

In its recent July 19-20 meeting, the SACHRP began a detailed examination of IRB effectiveness as SACHRP (based on the GAO report) raised sweeping questions and began making preliminary recommendations on how to measure IRB effectiveness.

"The GAO report, *INSTITUTIONAL REVIEW BOARDS: Actions Needed to Improve Federal Oversight and Examine Effectiveness*, released February 16, 2023, includes the following recommendation #4:

The Secretary of Health and Human Services should ensure that OHRP and FDA convene stakeholders to examine approaches for measuring IRB effectiveness in protecting human subjects and [to] *implement the approaches as appropriate.*

These could include effectiveness measures; peer audits of IRB meetings and decisions; mock protocols; surveys of IRB members, investigators, and human participants; or other approaches.

OHRP asks SACHRP to consider the following [three] points to support the convening of HHS "stakeholders" as recommended by GAO:

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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1. 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?" (SACHRP Minutes, lines 6-20; on the Web via regulations.gov; enter HHS-OASH-2023-0012; then scroll down to GAO SACHRP Recommendation 7.12.23).

Many Effectiveness Measures to Prioritize

"2. SACHRP is one HHS 'stakeholder'. What other stakeholder groups should HHS convene as part of examining approaches for measuring IRB effectiveness? What factors make an entity an appropriate stakeholder?

3. GAO provides several potential effectiveness measures. How do these approaches differ, and what are their benefits and limitations? What approaches should HHS and stakeholders prioritize?

Are there other approaches should HHS and these stakeholders consider for measuring IRB effectiveness in protecting human subjects? [sic]" (supra at lines 21-27).

In the HRR we often skip introductory text to focus on the highlights of selected materials. In this case, however, we have opted to present the SACHRP's " Introduction -- Scope of Recommendation" because it sets the stage for all of whatever is to come of this momentous development in what we think of as the world of " IRBdom."

More Federal Oversight Is Recommended

"The conduct of research involving human subjects operates in a complex environment involving many individual and organizational roles, all of which have a responsibility to protect the rights and welfare of human subjects in research.

In addition to Institutional Review Boards, included are human subjects, patient advocacy groups, investigators, research staff, institutional officials, government and private sponsors of research, Contract Research Organizations, bioethicists, accrediting entities, and interest groups such as PRIM&R.

A complete analysis of the protection of the rights and welfare of human research subjects would require an analysis of the roles and effectiveness of all these entities.

However, GAO Report 23-104721 focuses solely on Institutional Review Boards, and addresses actions needed to improve federal oversight and examine the effectiveness of IRBs.

Therefore, this SACHRP recommendation will likewise be restricted to IRBs and will not address, except in passing, the role of the many other parties involved in the protection of the rights and welfare of human research subjects" (supra, lines 29-39).

Which Definition of "Effectiveness" Matters?

The first specific "charge" given to SACHRP by OHRP recently deals with details on who the various "stakeholders" might be to discuss ways of assessing IRBs' effectiveness.

Since that was summarized in SACHRP's introduction, we now skip that portion of the Minutes and move on to their second "charge" regarding the " Definition of 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?" (supra at lines 67-72). © **{TBC}**