America's Oldest National Monthly IRB Newsletter

Human Research Report

PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

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IRBs To Be Evaluated On Effectiveness (#4)

We continue this month with more details of a development that will affect all IRBs in the United States; i.e., evaluation of their performance and increased federal oversight of their activities.

We resume where we left off in our presentation of the document titled "SACHRP Recommendation on GAO-23-104721, INSTITUTIONAL REVIEW BOARDS: Actions Needed to Improve Federal Oversight and Examine Effectiveness."

The SACHRP's proposals represent the committee's reaction to a related document issued by OHRP in which OHRP seeks SACHRP's response to various IRB evaluation questions.

We resume by examining SACHRP's assessment of some of the standards that IRBs already must follow, with a discussion of how they might be changed.

Federal Audits Are Current Mechanisms to Evaluate IRBs

"SACHRP Provisional Analyses of the Standards that are Partially Impacted by IRB Operations and Review

- ***Human Research Participant Experiences with Research and Research Oversight***
- ***Compliance of Other HRPP Constituencies with IRB requirements***

SACHRP has analyzed each of these proposed standards of measuring IRB effectiveness according to the following considerations:

1. Feasibility for government to enact
2. Measurability, and
3. Procedural versus substantive nature of the proposed standard. This is an assessment of whether the standard is more administrative/procedural or [addresses] more substantive ethics.

For instance, turnaround time is an administrative measure, whereas ensuring participant autonomy can be viewed as substantive.

SACHRP Provisional Analyses of Standards that are Directly Tied to IRB Effectiveness with Regulatory Requirements

Based on the ethical principles identified in the BELMONT REPORT, the Common Rule seeks to protect research subjects' and groups' rights and welfare, while also promoting research.

The failure of an IRB to comply with the regulations can be assessed through audits, and this is the standard currently used by OHRP and FDA to

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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assess IRBs" (October 19, 2023; on the Web at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-october-19-2023-letter/index.html).

Increased Funding Could Support More Audits of IRBs

"There are processes and documents in place for conducting these audits. This process has government authority, with provisions in place for corrective actions and penalties as appropriate ....

Feasibility for Government to enact

This standard is feasible for government to enact as it is in place now at FDA, OHRP, and other Common Rule agencies. That said, it is clear that these programs could benefit from increased funding so that more inspections are performed.

In addition, education and training resources which have been gradually cut over the years from OHRP and FDA budgets could be restored and expanded. SACHRP views these educational and training opportunities as critical components to ensure regulatory compliance and improved research community understanding of what is expected of them" (ibid).

Four Ways to Evaluate IRB Performance

"*Measurability*

There is a process for conducting and documenting inspections already in place. FDA has a publicly available in-depth inspection manual.[2]

[FN #2: FDA has a fifty-nine page inspection tool for its IRB inspectors, 'Food and Drug Administration Compliance Program Manual No 7348.809, Subject: Institutional Review Boards,' online at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/chapter-48-7348809-bioresearch-monitoring.

Dr. Min-Fu Tsan has proposed four examples of regulatory criteria that could be used to assess IRBs, including: appropriately determining the status of protocols as exempt, expedited[,] or needing full IRB review; whether IRBs consider and document all Common Rule criteria and conflicts of interest prior to approving or disapproving protocols; whether IRBs appropriately consider and approve waivers of consent or waivers of documentation of consent; and whether IRBs conduct timely continuing review when required.

While the regulatory criteria for approval are intended to embody the BELMONT principles, government inspections at the present time often do not address the sections of the regulations based on the BELMONT principles.

Tsan, Min-Fu, 'Assessing the quality and performance of institutional review boards,' 2022, JOURNAL OF EMPIRICAL RESEARCH ON HUMAN RESEARCH ETHICS, pg. 50.]" (ibid).

What IRB Inspections Typically Do Not Cover

"[For instance, FDA findings are unlikely to include findings such as an inappropriate risk benefit ratio under 21 CFR 56.111(a)(2). Instead, the findings tend to focus on more easily quantifiable regulatory elements such as necessary elements of minutes, convened meeting quorum, and missing elements of consent.

However, that is not to say that OHRP and FDA do not at times address difficult ethical issues in research. OHRP spent a considerable amount of resources looking into allegations regarding the SUPPORT study. (https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-disclosing-risk-in-standards-of-care/index.html)

Similarly, FDA has considered difficult issues of pediatric trial design, such as the FDA review of a pediatric muscular dystrophy study. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6002149/)

A final issue with the government process of conducting inspections to assess compliance with regulatory requirements is that it does not capture issues that are self-reported by institutions, sponsors, and investigators.

For instance, if there is a Corrective Action Plan that resolves an issue without a resulting government inspection, that will not be captured in the publicly available documentation.]

OHRP has similar processes, outlined in the OHRP guidance document, 'Compliance Oversight Procedures for Evaluating Institutions (2009)'" (ibid). © **{TBC}**

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