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PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

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IRBs and New Recommendations on Protecting Human Research Subjects (#1)

The influential Secretary's Advisory Committee on Human Research Protections (SACHRP) has once again issued detailed recommendations for IRBs and others on better ways to protect human research subjects.

This particular set, along with its background explanations, was submitted to the Secretary of Health and Human Services (HHS's Xavier Becerra, J.D.) on July 25.

As is our continuing HRR policy, we will briefly summarize each of the SACHRP's areas in this introductory article.

One quick note on this latest set of SACHRP recommendations. "Attachment A" of this communication to HHS is titled "Recommendations on the Draft Guidance for Use of Single Institutional Review Board[s] for Cooperative Research."

This document is related to, but not the same as, the document on this same issue that we discuss in the third article of this current HRR issue.

The document we discuss in this HRR's third article was issued separately by the federal Office for Human Research Protections (OHRP).

Hopefully, the recommendations for IRBs in this area will be reconciled and clarified in the future.

Current OHRP Recommendations For IRBs Offer "Inadequate Guidance"

Of the total of five "Attachments" to SACHRP's July 25 letter to HHS, the remaining four are: "Draft Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data (Attachment B)," "The Interpretation of 'HHS Support' in the Application of 45 CFR Part 46 (Attachment C)," "A Re-interpretation of 'Engagement' in Human Subjects Research in the Application of 45 CFR Part 46 (Attachment D)," and "Considerations for IRB Review of Research Involving Artificial Intelligence (Attachment E)."

SACHRP notes in Attachment A that OHRP is publishing a guidance on the use of a single IRB in cooperative research (as previously noted, please see the third article of this HRR issue). However, SACHRP states that:

"… the proposed guidance offered by OHRP in its current form lacks specificity

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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and offers inadequate assistance to single IRBs seeking to achieve the twin goals of (1) being informed by local conditions and attitudes and (2) being equipped readily to find facts regarding serious problems in study conduct.

The draft guidance, in its present form, also lacks any indication of appropriate processes that could be followed by single IRBs and their relying institutions regarding how to resolve differences in judgment about essential features of a proposed study" (p. 2; on the Web at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-july-25-2022-letter/index.html).

Current NIH Guidance for IRBs "Lacks Consistency"

In Appendix B, SACHRP proposes changes to the NIH Policy on Date Sharing that NIH issued on May 12 of this year.

"In this document [i.e., in the July 25th SACHRP Appendix B] SACHRP offers its commentary and recommendations for NIH's consideration ….

SACHRP observes that there is inconsistency within the document as to how items are classified as principles, best practices, or points to consider[,] or just statements.

There is also confusion in the document between what is considered 'required' or an 'obligation' versus 'best practice' or a [mere] 'think about'" (page 2; on the Web at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-july-25-2022-letter/index.html).

Relieving the Ongoing "Administrative Burden" for IRBs

The HHS definition of "support" as discussed in Appendix C is another factor used in determining when the federal human subject protection regulations must be followed in human research.

Regarding that particular qualifier, SACHRP states:

"The primary purpose of this SACHRP recommendation is to provide a clear definition of 'support' that will provide the regulated community, including HHS [itself], with consistency in determining when research is supported by HHS, which in turn should ease administrative burden.

The easing of administrative burden must be appropriately balanced with providing appropriate protection to research subjects through application of the Common Rule.

This recommendation does not address agencies other than HHS" (p.1; on the Web at https://www.hhs.gov/sachrp-committee/recommendations/attachment-c-july-25-2022-letter/index.html).

What Does "Engaged in Research" Mean?

In SACHRP's Appendix D, the committee acknowledges that there has been:

"… recurrent frustration and confusion among the regulated community (including IRBs) regarding the current OHRP standards for determining which entities are 'engaged in research' for the purpose of specific studies ....

[Due to said confusion, which affects whether or not federal regulations apply,] OHRP in 2021 therefore asked SACHRP to undertake an examination of these standards, without any assumption that these existing standards should be continued, and to analyze whether other standards, more easily applied by the regulated community, and yet still protective of human subjects, could be identified" (page 2; on the Web at https://www.hhs.gov/sachrp-committee/recommendations/attachment-d-july-25-2022-letter/index.html).

Appendix D is devoted to discussing and presenting such new standards for IRBs.

Finally, the concluding Appendix E is self-explanatory ("Considerations for IRB Review of Research Involving Artificial Intelligence").

Although that title does seem straightforward enough, the ten pages of new recommendations for IRBs in this document contain numerous details and tips for IRBs.

As is true for all five of the new SACHRP recommendation documents, we shall present more key highlight areas in future issues of our HRR. **© {TBC}**