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The Use of a Single IRB in Human Subjects Cooperative Research (#1)

The federal Office for Human Research Protections (OHRP) has issued a long-awaited draft guidance titled "Use of a Single Institutional Review Board for Cooperative Research."

We say "long-awaited" because such a requirement for studies that could involve multiple IRBs at different institutions is controversial.

> "The document is intended primarily to help entities implement the requirement for use of a single IRB for cooperative research (subpart A of Part 45 CFR part 46.114)" (87 Fed. Reg. 39534, July 1).

From the outset of this approach, tensions have arisen over allegations of loss of control by local IRBs if they are "forced" into such arrangements.

Combating those objections have been those who point to the undeniable increase in efficiency and reduced confusions when several institutions must follow the decisions of one IRB versus those of several IRBs.

One IRB Does the Work of Many IRBs

We shall begin our HRR coverage by presenting highlights from OHRP's draft guidance. Then, we will present selected questions about the guidance for which OHRP is most interested in receiving input from the IRB compliance community, researchers, and others.

Note that any such comments on the guidance are due by August 30. We present more information on how to submit comments on this draft guidance at the end of this HRR article.

We begin by addressing the most basic question of all; namely, what studies are affected by this IRB guidance?

> "This guidance applies to nonexempt human subjects research activities that are conducted or supported by HHS [federal Department of Health and Human Services]. It applies to cooperative research projects that involve more than one institution for which the 2018 Requirements, including the single IRB review requirement, apply.

It provides guidance on the 2018 Requirements set forth in 45 CFR 46.114(b)(1) that require any institution located in the United States engaged in cooperative research to rely on approval by a single institutional re-

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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view board (IRB) for that portion of the research that is conducted in the United States, with some exceptions as described at §46. 114(b)(2).

The single IRB is the IRB that would be held responsible for compliance with the relevant provisions of 45 CFR part 46 in a cooperative research project. This IRB would perform review on behalf of multiple institutions.

The single IRB may also be referred to as the 'reviewing IRB,' the 'IRB of record,' or the 'central IRB'" (guidance, in Section titled "*Scope*," July 1; see below for full citation).

IRB Federal Regulations Have Changed

"In this document, the term 'pre-2018 Requirements" refers to subpart A of 45 CFR part 46 as published in the 2016 edition of the CODE OF FEDERAL REGULATIONS.

The pre-2018 Requirements were originally promulgated in 1991 and subsequently amended in 2005.

For purposes of this document, the term '2018 Requirements' refers to subpart A of 45 CFR part 46 as published in the July 19, 2018[,] edition of THE CODE OF FEDERAL REGULATIONS.

The 2018 Requirements were originally published on January 19, 2017[,] and further amended on January 22, 2018[,] and June 19, 2018" (supra in section titled "*Regulatory Background*").

"Engaged" in Human Subjects Research

"The HHS protection of human subjects regulations at 45 CFR 46.114 refer to 'cooperative research projects' as non-exempt human subjects research to which the regulations apply that involves more than one institution engaged in cooperative research.

Note that each institution that is engaged in the human subjects research does not have to be conducting the same activities in a protocol to be subject to the mandate for review by a single IRB.

For example, an institution could be an awardee institution or responsible for seeking consent from participants, another could be performing research procedures, and another could be conducting laboratory analyses for a key study endpoint.

Note that only those institutions that are 'engaged' in the cooperative research need to comply with the regulations (see OHRP's guidance and correspondence on engagement)" (supra in a Q&A section titled "General - 1. *What is Cooperative Research?*").

However, There Are Exceptions

"The first exception is for cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) (45 CFR 46.114(b)(2)(i)).

The second exception is for research for which any federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context (45 CFR 46.114(b)(2)(ii)) ....

OHRP currently provides exception determinations for classes of research as opposed to single studies.

OHRP's exception determinations, thus far, can be found through the Single IRB Exception Determinations webpage" (above text from section titled, "2. *When Must an Institution Rely on a Single IRB for Approval of Cooperative Research?*").

Who Decides on Single IRB?

"Per the requirement at 45 CFR 46.114 (b)(1), the single IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research (supra in section titled 3. "*Who Decides Which IRB Will Be the Single IRB for the Purposes of Regulatory Compliance?*").

For HHS conducted or supported research this determination would come from an HHS division such as NIH or CDC. If the