Thursday, August 25, 2022


The Draft Guidance lists a set of nine frequently asked questions (FAQs) and answers related to cooperative research projects that involve more than one
In the Draft Guidance, OHRP reiterates that:

- only institutions that are “engaged” (per OHRP’s guidance and correspondence on engagement) in cooperative research must comply with the 45 C.F.R. § 46.114(b) single IRB requirement. However, each institution does not have to be conducting the same activities in the protocol to be subject to the mandate for review by a single IRB;

- multiple federal departments or agencies may have jurisdiction to issue a single IRB exception under 45 C.F.R. § 46.114(b)(2)(ii), but in these cases, it is important to understand whether an agency’s exception applies to a single institution or to all institutions involved in the cooperative research;

- the federal department or agency supporting or conducting the research, either individually or collaboratively with another, will determine which IRB will be the single IRB; and

- an institution participating in cooperative research that is not required to comply with the single IRB requirement (e.g., research that is not federally funded) may voluntarily elect to use a single IRB as provided under 45 C.F.R. § 46.114(c).

OHRP also explains the following:

- Institutions may choose to perform an internal IRB review of research in addition to the single IRB’s review required under 45 C.F.R. § 46.114(b). Although this review would not have any regulatory status in terms of compliance with the single IRB requirement, OHRP recommends that the decision to perform such an internal review and any related determinations be communicated to the single IRB.

  - However, OHRP does not elaborate on why or when an institution may choose to perform such review, what purpose this secondary and potentially duplicative review may serve, or what happens when such internal IRB review is inconsistent with the single IRB’s review.

- The relying institution and the organization operating the single IRB must
document the institution’s reliance on the single IRB and the responsibilities of each entity with respect to ensuring compliance with the Common Rule. This documentation could take the form of a reliance agreement, an institution-wide policy directive, or a description in the IRB-approved research protocol.

- Although OHRP lists examples of regulatory requirements and other considerations that such documentation may address, it stops short of recommending how responsibilities should be delegated in such documentation.

- In order to serve as a single IRB, the IRB should have the capacity to manage, review, and provide oversight of multiple research institutions and site investigators. The Draft Guidance lists examples of activities that may be performed by a single IRB, such as (i) tracking the status of research at multiple institutions, (ii) managing multiple consent forms and versions of consent forms from different institutions, (iii) communicating notifications of IRB actions to an individual institution or across all institutions as needed, (iv) storing institution-specific information (e.g., approval documentation, informed consent documents approved by the IRB, and other study-specific materials), (v) accessing and applying relevant state and local law, (vi) maintaining written IRB procedures that are available to relying institutions, and (vii) monitoring or auditing research at the relying institutions.

- OHRP does not provide additional guidance on when a single IRB should look to the relying institution for assistance with these activities and does not opine on how best to divide these responsibilities.

- If a single IRB needs specific information on “local context” (e.g., local circumstances, preferences, variability, culture and language, geography, socioeconomic factors, the professionals conducting the research, the institutions where the research will be conducted, or local standards of care), to make the required determination for approval of the research, the single IRB must have access to such information to meet its regulatory requirements. OHRP noted that local context information may be provided by the single IRB itself, by drawing upon its diverse membership. However, in general, the relying institution should provide information on local context as appropriate, consistent with the responsibilities that the relying institution and the single IRB have agreed upon and documented.

- Single IRBs must have access to information about applicable state and local laws that may affect the IRB’s ability to make the required determinations. However, the IRB should have the flexibility to obtain this information in the most efficient manner (e.g., provided as part of an application to the single IRB, or requested from other parties).

At the Secretary’s Advisory Committee on Human Research Protections’ (SACHRP’s) most recent meeting on July 20, 2022,[1] members identified areas of the Draft Guidance they wanted explained further. For example, SACHRP members suggested that OHRP provide additional guidance on when local context should prevail as a determinant in the approval decision for a proposed study and cautioned against relying too much on the IRB’s own membership diversity to access the local context.
In addition, SACHRP members suggested that OHRP should clarify the role and authority single IRBs should have when issues in study conduct require fact-finding and investigation and which responsibilities should remain with the relying institution. SACHRP members also noted that the Draft Guidance stopped short of delegating to any entity the responsibility for assessing and reviewing state and local laws. The committee is expected to submit its set of recommendations to OHRP.

We encourage the research community and members of the public with experience working with single IRBs in cooperative research to use this opportunity to provide feedback to OHRP on the issues discussed in the Draft Guidance and to request additional clarity and guidance by responding to the request for public comment by August 30, 2022.

ENDNOTE


©2022 Epstein Becker & Green, P.C. All rights reserved.

National Law Review, Volume XII, Number 237

Source URL: https://www.natlawreview.com/article/ohrp-draft-guidance-use-single-irbs-reminder-to-comment-august-30