Information Sheet: Single Institutional Review Board Requirements

Background

The NIH published its single Institutional Review Board (sIRB) policy in 2016 which applies to the competitive renewal application submitted on or after January 25, 2018. The revised Common Rule went into effect January 21, 2019. This regulation applies to all research conducted or supported by any Common Rule Agency, including HHS. This regulation requires that as of January 20, 2020, for all multi-site clinical research that include more than one domestic site and obtain initial IRB approval on or after January 20, 2020, the domestic sites must be overseen by a single IRB (45 CFR 46.114).

The regulations at 45 CFR 46.114 regarding cooperative research state the following:

> (a) Cooperative research projects are those projects covered by this policy that involve more than one institution.
>
> (b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a sIRB for that portion of the research that is conducted in the United States. The reviewing 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.

The NIH policy was superseded by the revised Common Rule (Additional Guidance on NIH Policy). NIH-funded multi-site studies being conducted at more than one domestic site that obtain initial IRB approval on or after January 20, 2020 will be subject to the requirements of 45 CFR 46.114. Ex.U.S. sites do not fall under the sIRB requirement and would continue to function as usual.

Common sIRB Question

Who does the sIRB oversee and when is the sIRB required?

Answer: *The sIRB only oversees domestic institutions. A sIRB is only required when there are more than one domestic institution participating in a clinical research study. In cases where IRB approval would usually be required for a given institution to participate/engage in the research, then the institution would require sIRB approval under the revised Common Rule. There is no change for ex U.S. sites. Ex-U.S. sites will continue to be overseen by the IRB/ethics committee (EC) of record.*

Common sIRB Scenarios

Scenario 1

A grantee institution is receiving the federal funds; however, for some of the pilot projects, the grantee institution has sub-awards to another institution to conduct the pilot project research. How is the sIRB requirement applied to grants that are comprised of

multiple institutions and fund pilot projects at all of their institutions? Who should provide the sIRB?

Answer: *All institutions engaged in nonexempt human participant research, (i.e., the recipient of an NIH award and any sub-awardees at different institutions conducting all of the nonexempt human participant research activities) would have to be under the sIRB. The institutions are responsible for determining who should provide the sIRB. The legal requirement is for a sIRB to review the research.*

Scenario 2

The LOC and the SDMC are not individual US-based sites implementing a research protocol. Are these entities subject to the sIRB requirement?

Answer: *This would depend on whether or not the LOC and the SDMC are considered to be engaged in human participant research.*

Some considerations may include:

1. *Are the staff (e.g., statisticians) involved in the research?*
2. *Do the statisticians have access to fully identifiable participant information and/or have access to coded data but also have access to the key to the code?*
3. *Are the statisticians analyzing any fully identifiable and/or coded data?*
4. *Does the SDMC or any of its statisticians provide advice on the design and statistical analysis of any individual research studies?*
5. *Is the SDMC or any of its statisticians included as an author on any study-related publications?*

Scenario 3

An investigator from University A sends a request to a Network to use stored specimens. The Network statistician is from University B and facilitates the selection of specimens and associated clinical data. All the research activities are conducted at University A. However, the Network statistician from University B provides advice on the design and statistical analysis of the research study. Per the revised Common Rule, is University B considered engaged in the research, and thus the research is a multi-site research study requiring the use of a single IRB?

Answer: *Determination of engagement of institutions should be done in accordance with institutional policies and the Office for Human Research Protections (OHRP) guidance on Engagement of Institutions in Human Subjects Research. Please note that if IRB approval would usually be required for an institution to participate/engage in the research, then sIRB approval would also be required under the revised Common Rule.*

For this scenario, a consideration may include:

1. *Is the statistician at University B receiving de-identified information or have access to identifiable private information or identifiable biospecimens?*