October 8, 2020: Exception to the Single IRB Review Requirements for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018

Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Please note: After May 11, 2023, the Public Health Emergency for COVID-19 is no longer in effect. Consequently, the exception to the single Institutional Review Board (IRB) requirement for certain categories of cooperative research supported or conducted by HHS and subject to the 2018 Requirements created in response to the circumstances of the COVID-19 pandemic cannot be applied to additional studies as of May 12, 2023. Research studies for which the HHS division supporting or conducting the research previously approved the use of the exception will continue to be excepted from the single IRB requirement, since the exception applies for the duration of the research study. For more information see the announcement here: https://www.hhs.gov/ohrp/news/announcements-and-news-releases/2023/important-updates-about-the-covid-19-single-irb-exception.html <https://www.hhs.gov/ohrp/news/announcements-and-news-releases/2023/important-updates-about-the-covid-19-single-irb-exception.html>

On October 8, 2020, the Office for Human Research Protections (OHRP), on behalf of the Department of Health and Human Services, issued an exception determination (as permitted by 45 CFR 46.114(b)(2)(ii)) stating that certain categories of cooperative research supported or conducted by HHS and subject to the 2018 Requirements are not required to comply with the 2018 Requirements' single IRB mandate. The full text of the determination appears below.

I. Background

Section 46.114 of the 2018 Requirements[1] requires that any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States (45 CFR § 46.114(b)(1)). Cooperative research projects are those projects covered by the 2018 Requirements that involve more than one institution (45 CFR § 46.114(a)). The compliance date for this requirement was January 20, 2020.

The 2018 Requirements provide that the Federal department or agency conducting or supporting cooperative research may except the research from the single IRB mandate. To do so, the Federal department or agency must both determine and document that using a single IRB is not appropriate for the particular context (45 CFR 46.114(b)(2)(ii)).

Due to the public health emergency posed by COVID-19, the Office for Human Research Protections (OHRP) is exercising its discretion, as specifically permitted by 45 CFR § 46.114(b)(2), to issue this exception to apply in the conditions outlined herein, on the basis that using a single IRB is not appropriate for this research context. We believe that this determination of exception is a statement of agency policy that is not subject to the notice and comment requirements of the Administrative Procedure Act (APA) (5 U.S.C. § 553(b)(A)). For the same reasons explained above, OHRP additionally finds that, even if this determination of exception were subject to the public participation provisions of the APA, prior notice and comment is impracticable and contrary to the public interest, and there is good cause to issue this determination of exception without prior public comment and without a delayed effective date (5 U.S.C. §53(b)(B) & (d)(3)).

This exception is applicable as of October 8, 2020

II. Determination of Exception

To ensure that institutions conducting cooperative research are able to take advantage of the most appropriate IRB review structure, OHRP has determined that, for studies that are conducted or supported by HHS and subject to the 2018 Requirements, and for purposes of 45 CFR 46.114(b) (2)(ii), an exception to the requirement to use a single IRB is appropriate for the following category:

Cooperative research:

1. that is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency, as declared by the Secretary of Health and Human Services at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx <https://www.phe.gov/emergency/news/healthactions/phe/pages/2019-ncov.aspx> ;
2. where reliance on a single IRB would not be practical; and
3. for which the HHS division supporting or conducting the research approves of the use of this exception.

This exception applies for the duration of the research.

OHRP has made this exception determination due to concerns regarding the application of the single IRB requirement to cooperative research subject to the 2018 Requirements when this research is initially reviewed or ongoing during the COVID-19 public health emergency. The COVID-19 public health emergency has created unprecedented burdens and disruption to the research enterprise, while at the same time requiring urgent research responses that necessitate flexible approaches to oversight in order to provide vital information and to allow other research to continue where possible. This exception represents an effort to prioritize the health and safety of both research subjects and investigators, and provides flexibility to institutions in seeking IRB review due to the unique challenges created by the COVID-19 outbreak.

Scenarios for which OHRP anticipates it may not be practical to rely on use of a single IRB for multi-site, cooperative research trials during the ongoing COVID-19 pandemic include (but are not limited to):

- Trials for which timely administration of an intervention for the rapidly emerging COVID-19 outbreak is paramount, but:
  - research sites cannot be identified in advance due to the unpredictable nature of the exact location of the outbreak and patients cannot be moved to an existing trial site or to a newly established site without further increasing public health exposure risks; or
  - institutions lacking existing reliance agreements, especially those in underserved or under-resourced areas, may face delays in starting the trial and in administration of the intervention while reliance agreements are negotiated.
- Trials leveraging existing federally-supported trial networks to maximize access to appropriate patients, but where each network is operating under a different single IRB of record and negotiating reliance agreements between the networks and single IRBs could reduce the ability of qualified sites to access appropriate patients at the correct stage of disease.
- Trials in which a federal research agency wishes to participate as a research site with non-federal (but federally-supported) sites but is legally prohibited from agreeing to certain terms in reliance agreements required by the non-federal sites.
- A cooperative research study supporting the response to the COVID-19 outbreak in which the lead site is engaged in administration of an intervention and in addition is receiving study-wide identifiable samples and/or data for the purposes of determining risk factors linked to COVID-19 disease susceptibility, severity, outcome, or for developing potential diagnostics or therapeutics. The sites that would be engaged in the research may include institutions that do not have standing reliance agreements within a research network and establishing new reliance agreements would cause unacceptable delays as well as result in a lost opportunity to collect critical COVID-19 samples and data.
- Trials in which the lead site or IRB is unable to provide oversight due to disruption in operations caused by the COVID-19 public health emergency, but other sites can continue, and selecting another site as the IRB of record would require renegotiation of reliance agreements with a new IRB of record, and the study would otherwise be required to halt until such agreements were in place.

Note that this exception determination is only made for purposes of section 46.114(b)(2)(ii) - namely, for determining whether certain cooperative research may be excepted from the single IRB mandate. This exception determination does not prevent, nor should it be viewed as discouraging, the voluntary use of a single IRB in cooperative research subject to the 2018 Requirements that would fall into the above category. HHS fully expects use of single IRB where possible even during the COVID-19 public health emergency. Approved use of the flexibilities provided under this exception do not change any other obligations under the 2018 Requirements.

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[1] The term “2018 Requirements” refers to subpart A of 45 CFR part 46 as published in the July 19, 2018 edition of the e-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.

Content created by Office for Human Research Protections (OHRP)
Content last reviewed February 17, 2023