

## MEMORANDUM

**Date:** October 26, 2020  
**From:** Jui Shah, PhD, Chief, Protection of Participants, Evaluation and Policy Branch, OPCRO, DAIDS, NIAID, NIH  
**To:** Network Leadership and Operations Centers, DMID, DCR  
**CC:** DAIDS, HANC  
**Subject:** OHRP's Exception to the Single IRB Review Requirements for Certain HHS-Conducted or-Supported Cooperative Research Activities During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

OHRP has issued an exception, effective immediately, to the single Institutional Review Board (sIRB) requirement for certain cooperative (multi-site) research during the coronavirus disease 2019 (COVID-19) public health emergency. For complete information, please review the entire exception [here](#).

### Background:

Section 114 of the revised Common Rule<sup>1</sup> requires that, as of January 20, 2020, any institution located in the United States that is engaged in cooperative research (domestic sites participating in multisite clinical research studies) must rely upon approval by a sIRB for that portion of the research that is conducted in the United States.

In an effort to prioritize the health and safety of both research subjects and investigators, ensure that institutions conducting cooperative research can use the most appropriate IRB review structure and provide flexibility to institutions in seeking IRB review due to the unique challenges created by this public health emergency, OHRP, as specifically permitted by 45 CFR 46.114(b)(2), has issued this exception from the sIRB requirement applies to certain studies that are conducted or supported by HHS and subject to the 2018 Requirements<sup>2</sup>.

### OHRP Determination of sIRB Exception:

The exception applies to 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<sup>3</sup>;
2. where reliance on a sIRB would not be practical; and
3. for which the HHS division supporting or conducting the research approves of the use of this exception.

### DAIDS' Guidance:

1. OHRP's determination of exception is effective immediately (as of October 08, 2020).
2. The exception applies to COVID-19 and non-COVID-19 related cooperative research that was ongoing or initially approved during the public health emergency.
3. NIH expects the use of this exception to be rare but will consider exception requests. A request must be submitted to NIH including justification as to why the study meets the OHRP defined exception criteria<sup>4</sup>.
4. Approved exceptions apply for the entire duration of the clinical research.
5. OHRP continues to encourage the use of a sIRB when feasible for COVID-19 and non-COVID-19 clinical research.

## References:

1. The revised Common Rule [[45 CFR 46 Subpart A](#)]
2. OHRP Determination of Exception of October 08, 2020: <https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/october-2020-exception-determination/index.html>
3. Coronavirus Disease 2019 (COVID-19) public health emergency, as declared by the Secretary of Health and Human Services: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>
4. NIH-OD-21-006: Exceptions to Use of a Single IRB During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-006.html>