

MEMORANDUM

Date: November 19, 2020

From: Protection of Participants, Evaluation and Policy Branch, OPCRO, DAIDS, NIAID, NIH

To: Network Leadership and Operations Centers, DMID, DCR

CC: DAIDS, HANC, NIH OD/OER/DHSR

Subject: Requesting Exceptions from NIH OD for the sIRB requirement

Background:

For NIH awardees, there are two different sets of requirements that require the use of a single Institutional Review Board (sIRB):

(A) the revised Common Rule (rCR)¹ [45 CFR 46, specifically part 114], and

(B) the NIH policy on sIRB [<https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm>].

On October 08, 2020, OHRP issued an exception to the single Institutional Review Board (sIRB) requirement for certain cooperative (multi-site) research during the coronavirus disease 2019 (COVID-19) public health emergency². This exception requires that the HHS division supporting or conducting the research approves of the use of this exception.

Following the publication of the OHRP determination of exception, NIH issued a notice, NIH-OD-21-006: Exceptions to Use of a Single IRB During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, regarding the OHRP sIRB exception³.

Subsequently, DAIDS issued a memo with our guidance regarding the OHRP exception and the NIH notice⁴. Since then, the NIH Office of the Director (OD) has received requests for exceptions from the use of a sIRB and have requested that DAIDS provide the following guidance to our staff and stakeholders. Please see the OD guidance below and share the information, as appropriate, with your staff and stakeholders.

Please direct queries to SingleIRBPolicy@mail.nih.gov.

NIH OD Guidance:

1. Submit exception requests (policy and rCR) at least 30 days before the exception is needed to ensure the NIH OD has sufficient time to obtain any missing information and process the request before the decision is needed.
2. Multisite studies funded through an ongoing non-competing award that will be subject to the NIH sIRB policy when the competing renewal is funded are required to have the sIRB in place by the time of the new award.
3. The sIRB exception request needs to state under which mechanism the exception is being requested (i.e., rCR COVID or NIH sIRB policy). A NIH sIRB policy exception request should *not* reference COVID since the COVID exception request is *not* applicable to NIH sIRB policy exception requests.
4. For those studies subject to the rCR cooperative research provision and requesting exception under the NOT-OD-21-006 during the COVID public health emergency, “the

HHS division supporting or conducting the research” is NIH. Institutes or Centers do not have the authority to approve sIRB exception requests.

5. The exception request should clearly state the justification supporting this request.

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. 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>
4. DAIDS Memo (dated October 26, 2020) regarding the 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: <https://www.niaid.nih.gov/sites/default/files/MEMOsIRBCOVID-19.pdf>