

MEMORANDUM

Date: February 10, 2020

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

To: Network Leadership and Operations Centers, Rohan Hazra, Jack Moye, Eric Lorenzo, Jennifer Bryant

CC: Network Leadership Grant Program Officers, Carol Worrell, Dara Potter, DAIDS ProPEP, DAIDS RAB, Diana Finzi, Peter Kim, Mary Marovich, Sheryl Zwierski, OCSO Program Officers, OCSO MOB, HANC

Subject: Update on the single IRB requirement

Background:

NIH published its single IRB policy in [NOT-OD-16-094](#) and [NOT-OD-17-076](#). The NIH sIRB policy applies to the competitive renewal application submitted on or after January 25, 2018, but the compliance date with the NIH sIRB policy is at the time of award since the policy requirement will be incorporated as a term and condition in the Notice of Award.

The revised Common Rule [[45 CFR 46 Subpart A](#)], became effective on January 21, 2019. This regulation applies to all research conducted or supported by any Common Rule Agency, including HHS, and requires that, as of Jan 20, 2020, domestic sites participating in multisite studies must be under a single IRB (sIRB). This is in addition to the NIH single IRB policy described above that went into effect on Jan 25, 2018.

On November 22, 2019 OHRP announced its “Determination of Exception to the Required Use of a Single IRB for Certain HHS Cooperative Research that is Subject to the 2018 Requirements” which can be found at: [OHRP Determination of Exception](#). Per this Determination, all NIH-supported studies in non-competing awards with receipt dates prior to January 25, 2018 and with initial IRB approval prior to January 20, 2020 would be covered under the OHRP Determination of Exception as if they were an NIH “time limited exception”. Therefore, they would not be required to comply with the OHRP federal sIRB mandate until the new competitive award begins.

DAIDS’ Guidance:

Based on our current understanding, we have the following overarching guidance:

1. The compliance date for the NIH sIRB policy for all NIH awardees, including the NIAID HIV/AIDS networks is at the start of the next competitive grant renewal i.e. December 1, 2020. NOTE: All ongoing, multisite, domestic studies must be using a single IRB per the NIH sIRB policy at the time of award i.e. December 01, 2020; and,
2. Only studies with initial IRB approval on or after January 20, 2020 are required to use a sIRB from their inception, since they do not meet criteria for the OHRP’s Determination of Exception.

We will share additional information as appropriate.