DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

HHS Policy for the Protection of Human Research Subjects

AGENCY: Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS)

ACTION: Determination of Exception: required use of single institutional review board for cooperative research.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS), excepts two categories of research from the required use of a single institutional review board (IRB) to review cooperative research under the HHS regulations for the protection of human subjects. This determination is specific to research conducted or supported by HHS.

DATES: This exception is applicable as of November 22, 2019.


SUPPLEMENTARY INFORMATION:

I. Background

Regulatory History

In a final rule published on January 19, 2017, HHS and other Federal departments and agencies revised the Federal Policy for the Protection of Human Subjects (the “Common Rule”), codified with respect to HHS at subpart A of 45 CFR part 46. The Common Rule is followed by 19 other Federal agencies. The revised Common Rule, including amendments made by a January 22, 2018 interim final rule (83 FR 28585) and June 19, 2018 final rule (83 FR 26497) (also referred to as the “2018 Requirements”), became effective on July 19, 2018.

The revised Common Rule requires that U.S. institutions engaged in cooperative research must rely on a single institutional review board (IRB) to review and approve the portion of the research conducted at domestic sites. See 45 CFR 46.114(b). The compliance date for the single IRB requirement is January 20, 2020.

The revised Common Rule applies to all research initially approved by an IRB on or after January 21, 2019. See 45 CFR 46.101(l)(5). As of January 20, 2020, the compliance date for the single IRB requirement, all cooperative research subject to the revised Common Rule will be required to use a single IRB, whether the research was initially approved by a single IRB or multiple IRBs.

Regulatory Allowance of Exceptions to Single IRB Review Requirement

The revised Common Rule provides that the agency conducting or supporting cooperative research may except the research from the single IRB mandate. To do so, the agency must both determine and document that using a single IRB is not appropriate in the particular context. See 45 CFR 46.114(b)(2).

Research Contexts Qualifying for Exception

With respect to HHS-conducted or supported research, OHRP has determined that the following research is excepted from the single IRB mandate: (1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB approved the research before January 20, 2020, or (2) cooperative research conducted or supported by NIH if either (a) the NIH single IRB policy1 does not apply, and the research was initially approved by an IRB before January 20, 2020, or (b) NIH excepted the research from its single IRB policy before January 20, 2020.

Cooperative Research Approved Before January 20, 2020

In May 2019, the Association of American Medical Colleges (AAMC), the Council on Governmental Relations (COGR), the Association of American Universities (AAU), and the Association of Public Land-Grant Universities (APLGU) wrote to the director of OHRP expressing concern regarding the application of the single IRB requirement to cooperative research subject to the revised Common Rule when the research was approved before January 20, 2020 (available at https://www.aamc.org/download/497410/data/finaljointassociationlettertoohrponsingleirb.pdf). The organizations asserted that much of the research community did not fully understand the way this requirement would operate, and informed OHRP that shifting a multisite study in midstream to a single IRB review system would be difficult and expensive. On this basis, the organizations requested that OHRP issue an exception to the single IRB requirement for cooperative research conducted under the revised Common Rule.

designed its policy to exclude certain single IRB requirement, although NIH coextensive with the Common Rule need. NIH’s single IRB policy is largely exception after an assessment of the determines whether to grant an justification for the exception. NIH or policy, or if there is a compelling federal, tribal, or state law, regulation, the proposed IRB is prohibited by a single IRB for the review. Exceptions to this policy are made where review by the proposed IRB is prohibited by a federal, tribal, or state law, regulation, or policy, or if there is a compelling justification for the exception. NIH determines whether to grant an exception after an assessment of the need. NIH’s single IRB policy is largely coextensive with the Common Rule single IRB requirement, although NIH designed its policy to exclude certain categories of cooperative research (e.g., training protocols for activities that do not involve human subjects research at initiation). NIH also has issued case-specific exceptions to its single IRB policy for particular research studies. However, on January 20, 2020, the revised Common Rule single IRB requirement will take effect for certain studies, regardless of whether they are subject to NIH’s policy, which would require this NIH-conducted or supported research to use a single IRB review structure.

As stated above, if more than one IRB initially reviewed and approved cooperative research, imposition of the single IRB mandate in mid-stream could result in increased costs and burdens to regulated entities, rather than cost savings. Excepting such NIH-conducted or supported research from mandated single IRB review will not adversely affect the rights and welfare of the research subjects. Further, NIH has given thoughtful consideration to these research contexts, and already determined that single IRB review should not be required. NIH deliberately structured its single IRB policy such that certain research would fall outside the scope of coverage. Likewise, in issuing case-by-case exceptions to its single IRB policy, NIH concluded that single IRB review is not appropriate for those particular research contexts. Thus, OHRP has determined that single IRB cooperative research from the Common Rule single IRB mandate if either (a) the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or (b) NIH excepted the research from its single IRB policy before January 20, 2020.

II. Determination of Exception: Required Use of Single Institutional Review Board for Cooperative Research

The Office for Human Research Protections (OHRP) has determined that for HHS cooperative research subject to the 2018 Requirements, and for purposes of 45 CFR 46.114(b)(2)(i), an institution may continue to use multiple IRBs, in lieu of a single IRB, for the following research:

(1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020.

(2) Cooperative research conducted or supported by NIH if either:
   a. The NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or
   b. NIH excepted the research from its single IRB policy before January 20, 2020.

Note that this determination is only made for purposes of section 46.114(b)(2)(i)—namely, for determining whether certain cooperative research may be excepted from the single IRB mandate. This 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 within the above two categories. Further, note that category (2)(b), above, applies for the duration of NIH’s exception from its policy for the particular research study; categories (1) and (2)(a) apply for the duration of the research.

Dated: November 12, 2019.

Jerry Menikoff,
Director, Office for Human Research Protections.

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DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

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Fisheries of the Exclusive Economic Zone Off Alaska; Atka Mackerel in the Bering Sea and Aleutian Islands Management Area
AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.