availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(2) State of West Virginia, Secretary of State, Code of State Regulations.

(i) 45 CSR 23: West Virginia legislative rule; Title 45, Department of Environmental Protection, Air Quality; Series 23, Control of Air Pollution from Municipal Solid Waste Landfills, effective June 1, 2018.

(ii) [Reserved]

■ 3. Section 62.12126 is revised to read as follows:

§ 62.12126 Identification of sources.

(a) The plan in § 62.12125(a) applies to all existing West Virginia municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991 and that accepted waste at any time since November 8, 1987, or that have additional capacity available for future waste deposition, as described in 40 CFR part 60, subpart Cc.

(b) The plan in § 62.12125(b) applies to all existing municipal solid waste landfills under the jurisdiction of the West Virginia Department of Environmental Protection for which construction, reconstruction, or modification was commenced on or before July 17, 2014.

■ 4. Section 62.12127 is revised to read as follows:

§ 62.12127 Effective date.

(a) The effective date of the plan submitted on May 29, 1998, and as amended on May 15, 2000 by the West Virginia Department of Environmental Protection for municipal solid waste landfills is July 23, 2001.

(b) The effective date of the plan submitted on September 13, 2018 by the West Virginia Department of Environmental Protection for municipal solid waste landfills is December 23, 2019.

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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.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Director, Division of Policy and Assurances, Office for Human Research Protections (OHRP), Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone: 240–453–6900 or 1–866–447–4777; facsimile: 240–453–8409; email: *Irene.stith-coleman@hhs.gov.*

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 departments and agencies, either as Common Rule signatories, or as required by Executive Order or statute. The revised Common Rule, including amendments made by a January 22, 2018 interim final rule (83 FR 2885) and June 19, 2018 final rule (83 FR 28497) (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 policy [1] 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

[1] See ''Guidance on Exceptions to the NIH Single IRB Policy'' released October 11, 2017. Available at: *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html.*

Rule and initiated before January 20, 2020.

OHRP has considered this request. One of the objectives of the revised Common Rule's single IRB requirement is to reduce administrative costs of cooperative research. For cooperative research that already has been initially approved by multiple IRBs, the cost savings associated with reduced IRB reviews would not be achieved by making the single IRB requirement applicable to such cooperative research. Members of the regulated community report that transitioning cooperative research from multiple IRBs to a single IRB would, conversely, be costly for most institutions. Further, excepting such research from the single IRB mandate would not adversely affect the rights and welfare of the research subjects. For these reasons, OHRP has decided to except cooperative research approved before January 20, 2020, from the single IRB mandate. This general exception does not apply to NIH research; an NIH-specific exception is discussed *infra.*

OHRP has determined that a relatively small number of HHS protocols (other than NIH research) will be eligible for exception. OHRP surveyed the HHS agency, other than NIH, that OHRP expects conducts or supports the majority of such human subjects research. Based on the information provided by that agency, OHRP understands that this agency is supporting five ongoing cooperative research studies that are subject to the revised Common Rule. Approximately three to five additional cooperative research studies supported by this agency that would be subject to the revised Common Rule are expected to be initiated before January 20, 2020.

Cooperative Research Conducted or Supported by NIH

The NIH policy on the use of a single IRB for multi-site research has been in effect since January 25, 2018. It requires all U.S. sites participating in NIH-funded multi-site (*i.e.,* two or more sites) studies involving non-exempt human subjects research where the sites are following the same protocol to use 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 decided to except NIH 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. For more information on the NIH single IRB policy, see: *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html.*

This exception is an exercise of OHRP's enforcement discretion, as specifically permitted by 45 CFR 46.114(b)(2), that affects relatively few research protocols for a limited time. As required by 45 CFR 46.114(b)(2), OHRP determines and documents that using a single IRB is not appropriate for the described categories of research, and, for the reasons stated above, OHRP excepts this research from the single IRB mandate. The full text of the exception is listed below, and may also be found in the ''Single IRB Requirement'' tab in the ''Regulations, Policy, & Posting'' section of the OHRP website (see *https://www.hhs.gov/ohrp/regulations-and-policy/index.html*).

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)(ii), 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)(ii)—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

50 CFR Part 679

[Docket No. 180713633–9174–02]

RTID 0648–XY016

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.