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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Guidance on Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements

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

ACTION: Notice

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a guidance document titled, "Guidance on Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements." The guidance document provides OHRP's first formal guidance on this topic. The document, which is available on OHRP's Website at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html, is intended primarily for institutions, IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of nonexempt research involving human subjects conducted or supported by HHS. The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the *Federal Register* on July 25, 2018 (83 FR 35278). OHRP received 2 comments from individuals or organizations on the draft document and those comments were considered as the guidance was finalized.

DATES: Comments on OHRP guidance documents are welcome at any time.

ADDRESSES: Submit written requests for a single copy of the guidance document titled "Guidance on Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements" to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-453-8420. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance document.

Submit written comments to Comments on Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements Guidance, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to ohrp@hhs.gov or via facsimile at 240-453-8420.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, PhD, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6700; email Irene.Stith-Coleman@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP is announcing the availability of a guidance document titled "Guidance on Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements." The guidance document provides OHRP's first formal guidance on this topic. The document is intended primarily for institutions, IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of nonexempt research involving human subjects conducted or supported by HHS.

The guidance document applies to nonexempt research involving human subjects that is conducted or supported by HHS. It provides guidance on the elimination of the requirement in section 45 CFR 46.103(f) of the pre-2018 Requirements that each application or proposal for research undergo IRB review and approval as part of the certification process. This guidance also addresses the requirement in the 2018 Requirements for certification of each proposed research study prior to initiation. In particular, the guidance addresses the following two topics: (1) Pre-2018 Requirements; and, (2) 2018 Requirements.

The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the *Federal Register* on July 25, 2018 (83 FR 35278).

II. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP's website at OHRP's Website at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html.

Dated: July 16, 2020.

Jerry Menikoff,

Director,

Office for Human Research Protections.

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