



**BILLING CODE: 4150-36-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Scholarly and Journalistic Activities Deemed Not to be Research: 2018**

**Requirements; Draft Guidance**

**When Continuing Review Is Not Required During the 6-Month Delay Period of**

**July 19, 2018 through January 20, 2019: 2018 Requirements; Draft Guidance**

**Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements; Draft Guidance**

**AGENCY:** The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

**ACTION:** Notice of Availability

**SUMMARY:** The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health is announcing the availability of three draft guidance documents titled, “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements,” and

“Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements,” respectively.

**DATES:** Submit written comments by [INSERT 30 DAYS FROM PUBLICATION OF FR NOTICE].

**ADDRESSES:** Submit written requests for single copies of the draft guidance documents titled "Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements," "When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements," and "Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements," respectively, 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 240-453-6909. See the **SUPPLEMENTAL INFORMATION** section for information on electronic access to the draft guidance documents.

You may submit comments identified by docket ID number HHS-OS-OPHS-2018-0012 (Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements), docket ID number HHS-OS-OPHS-2018-0013 (When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements), and docket ID number HHS-OS-OPHS-2018-0014 (Elimination of

Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements), respectively, by one of the following methods:

- *Federal eRulemaking Portal: <http://www.regulations.gov>.* Enter the docket ID number and click on “Search.” On the next page, click the “Comment Now” action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:* Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to <http://www.regulations.gov>

**FOR FURTHER INFORMATION CONTACT:** Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; email [Irene.Stith-Coleman@hhs.gov](mailto:Irene.Stith-Coleman@hhs.gov)

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

#### *A. Overview*

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of three draft guidance documents entitled “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements,” “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018

Requirements,” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements.” The draft guidance documents, when finalized, will represent OHRP’s current thinking on these topics. OHRP obtained input from HHS agencies and the Common Rule departments and agencies in developing the draft guidance documents.

The “Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements” draft guidance explains how certain scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected are deemed not to be research under the 2018 Requirements of the regulations for the protection of human subjects (45 CFR Part 46), and consequently do not have to satisfy the requirements of those regulations. It is intended for IRB administrators, IRB chairpersons, relevant institutional officials, and investigators who may be concerned about whether scholarly or journalistic activities need to satisfy the 2018 Requirements of the regulations.

The “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements” draft guidance provides information on the HHS regulations for the protection of human research subjects at 45 CFR part 46 related to the circumstances in which continuing review of research is not required. In particular, this guidance applies to research that transitions to comply with the 2018 Requirements during the 6-month delay period from July 19, 2018 through

January 20, 2019. This guidance only applies during the 6-month delay period. It is intended for Institutional Review Boards (IRBs), investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subjects research conducted or supported by HHS.

The “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements” draft guidance provides guidance on the elimination of the requirement in the pre-2018 Requirements (45 CFR 46.103(f)) that each application or proposal for research undergo IRB review and approval as part of the certification process. It is intended 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.

## **II. Electronic Access**

Persons with access may obtain the draft guidance documents on OHRP’s website at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html>.

Dated: July 19, 2018.

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Jerry Menikoff,

Director,

Office for Human Research Protections.

[FR Doc. 2018-15908 Filed: 7/24/2018 8:45 am; Publication Date: 7/25/2018]