

Council members are appointed by the Secretary.

Dated: January 31, 2022.

B. Kaye Hayes,

Acting Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2022-03353 Filed 2-15-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

60-Day Report to Congress on Domestic Content Procurement Preferences Applicable to Federal Financial Assistance

AGENCY: Assistant Secretary for Financial Resources (ASFR), Health and Human Services (HHS or the Department).

ACTION: Notice.

SUMMARY: The Infrastructure Investment and Jobs Act (IIJA) requires Federal awarding agencies to identify and report to Congress each Federal financial assistance program for infrastructure administered by the Federal awarding agency.

FOR FURTHER INFORMATION CONTACT: Johanna Nestor at *Johanna.Nestor@hhs.gov* or (202) 631-0420.

SUPPLEMENTARY INFORMATION: Section 70913(b) of the IIJA requires that the report:

- Identify all domestic content procurement preferences applicable to the Federal financial assistance;
- Assess the applicability of the domestic content procurement preference requirements, including—(A) section 313 of title 23, United States Code; (B) section 5323(j) of title 49, United States Code; (C) section 22905(a) of title 49, United States Code; (D) section 50101 of title 49, United States Code; (E) section 603 of the Federal Water Pollution Control Act (33 U.S.C. 1388); (F) section 1452(a)(4) of the Safe Drinking Water Act (42 U.S.C. 300j-12(a)(4)); (G) section 5035 of the Water Infrastructure Finance and Innovation Act of 2014 (33 U.S.C. 3914); (H) any domestic content procurement preference included in an appropriations Act; and (I) any other domestic content procurement preference in Federal law (including regulations);
- Provide details on any applicable domestic content procurement preference requirement, including the purpose, scope, applicability, and any

exceptions and waivers issued under the requirement; and,

- Include a description of the type of infrastructure projects that receive funding under the program, including information relating to—
 - the number of entities that are participating in the program;
 - the amount of Federal funds that are made available for the program for each fiscal year; and,
 - any other information the head of the Federal agency determines to be relevant.

In accordance with the Office of Management and Budget (OMB) Memorandum M-22-08—“Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act,” Federal awarding agencies must also include a separate notice to each appropriate congressional committee, including the Committee on Homeland Security and Governmental Affairs, the Committee on Commerce, Science, and Transportation, the Committee on Environment and Public Works, the Committee on Banking, Housing, and Urban Affairs, and the Committee on Armed Services of the Senate; and the Committee on Oversight and Reform, the Committee on Armed Services, and the Committee on Transportation and Infrastructure of the House of Representatives.

The following report provides the Department of Health and Human Services (HHS) initial analysis of its programs and the Build America, Buy America requirements.

Background: Title IX of the IIJA, entitled “Build America, Buy America” (BABA), requires that no later than May 14, 2022, each Federal awarding agency must ensure that none of the funds made available for a Federal financial assistance program for infrastructure may be obligated for a project, unless all of the iron, steel, manufactured products, and construction materials used in the project, are produced in the United States (absent a waiver authorized by statute). Section 70912(5) of the IIJA, defines “infrastructure” to include at a minimum, the structures, facilities, and equipment for, in the United States—roads, highways, and bridges; public transportation; dams, ports, harbors, and other maritime facilities; intercity passenger and freight railroads; freight and intermodal facilities; airports; water systems, including drinking water and wastewater systems; electrical transmission facilities and systems; utilities; broadband infrastructure; and buildings and real property.

Analysis: The financial assistance programs funded by HHS focus on medical research, health services, and essential human services. As part of this focus, HHS occasionally provides construction support for health centers, medical centers, and research facilities. The IIJA, through the BABA imposes requirements on Federal financial assistance for infrastructure projects, and focuses on sectors of domestic infrastructure beyond the scope of HHS’s programs. HHS has determined that such construction support is not subject to BABA requirements. If it is determined on a case-by-case basis that the BABA requirements apply to any particular Federal financial assistance provided by HHS, HHS will evaluate whether pursuing a waiver authorized by statute is appropriate.

Historically, most recently in May 2019, OMB has concurred with HHS’s characterization of HHS financial assistance programs. On December 20, 2021, OMB issued to Federal awarding agencies, Memorandum M-22-08—“Identification of Federal Financial Assistance Infrastructure Programs Subject to the Build America, Buy America Provisions of the Infrastructure Investment and Jobs Act.” The Memorandum provides additional implementation instructions, however, the Memorandum did not alter HHS’s current assessment. Should OMB issue additional guidance, HHS will re-evaluate the applicability of the BABA requirements to our financial assistance programs.

Alice Bettencourt,

Deputy Assistant Secretary for Grants.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary’s Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act notice is hereby given that the Secretary’s Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website

at <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Thursday, March 10, 2022 from 11:00 a.m. until 4:30 p.m., and Friday, March 11, 2022, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website when this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Thursday, March 10, 2022, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with discussion of new draft recommendations on ethical and regulatory considerations for the use of artificial intelligence in human subjects

research, followed by a presentation of draft recommendations on the risks for third parties involved in research, and finally draft recommendations for the Request for Information currently open for the National Institutes of Health's Genomic Data Sharing Policy. The second day, March 11, will include consideration of the current HHS policy of engagement and the interpretation of HHS support in 45 CFR 46, and continue discussion of topics from the first day's agenda. Other topics may be added; for the full and updated meeting agenda, see <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>. The meeting will adjourn by 4:30 p.m. March 11th, 2022.

The public will have an opportunity to send comment to the SACHRP during the meeting's public comment session or to submit written public comment in advance. Individuals submitting written statements as public comment should submit their comments to SACHRP at SACHRP@hhs.gov by midnight March 4th, 2022, ET. Comments are limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by the SACHRP.

Dated: January 31, 2022.

Julia G. Gorey,

Executive Director, SACHRP, Office for Human Research Protections.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Document Identifier: OS-0990-0279J

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before April 18, 2022.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0990-0279-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 795-7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Department of Health and Human Services (HHS) Registration of an Institutional Review Board (IRB) Form.

Type of Collection: Extension.

OMB No.: 0990-0279.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Department of Health and Human Services (HHS) Registration of an Institutional Review Board (IRB) Form, OMB No. 0990-0279. The purpose of the IRB Registration Form is to provide a simplified procedure for institutions engaged in research conducted or supported by HHS to satisfy the (1) HHS regulations for the protection of human subjects at 45 CFR 46.103(b), 45 CFR 46.107, and 45 CFR 46, subpart E, Registration of Institutional Review Boards; and, the Food and Drug Administration (FDA) regulations for institutional review boards at 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.