TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN 1—Continued

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Number of non-respondents</th>
<th>Number of responses per non-respondent</th>
<th>Total annual non-responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021–2022 Data Collection—Completion of Section 2—All Facility Types ............................ 800 1 800 — — 0.5 (30 minutes) 400</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>2021–2022 Data Collection—Entry Refusals—All Facility Types ..................................... — — — 16 1 16 0.08 (5 minutes) 1.28</td>
<td></td>
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<td></td>
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<tr>
<td>Total Hours .................................................. — — — — — — 1,637.28</td>
<td></td>
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<td></td>
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<td></td>
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</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

II. References

The following references are on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the Federal Register, but websites are subject to change over time.


Dated: July 26, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16199 Filed 7-28-21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

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 September 27, 2021.

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–New–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.


Type of Collection: New. OMB No.: OS–0990–New.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a new approval from the Office of Management and Budget of the Office for Human Research Protections (OHRP) requirement that Institutional Review Board records be submitted when an IRB or its institution request an HHS consultation process, for proposed research involving, respectively: (1) Pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children, as subjects that are not otherwise approved by an IRB. The Office of the Assistant Secretary for Health, on behalf of the Secretary of HHS, may determine that such research can be conducted or supported by HHS after consulting with experts and allowing for public review of, and comment on, the proposed research.

Likely Respondents: Institutional Review Boards (IRBs).
ANNUALIZED BURDEN HOUR TABLE

<table>
<thead>
<tr>
<th>45 CFR part 46—HHS consultation process provision</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpart B, § 46.207</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Subpart C, § 46.306 (iii) and (iv)</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Subpart D, § 46.407</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>10</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sherrette A. Funn, Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

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

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a virtual meeting. The meeting will be open to the public. The committee will discuss recommendations to improve the supply chain and data infrastructure that supports the blood industry, especially during public health emergencies. To facilitate this discussion, key stakeholders from across the nation and around the world will present on hemovigilance, preparedness, inventory management systems and other relevant issues.

DATES: The meeting will take place virtually on Tuesday, August 17, 2021 from approximately 10:00 a.m.–6:00 p.m. and Wednesday, August 18, 2021 from approximately 10:00 a.m.–6:00 p.m. Eastern Time (ET). Meeting times are tentative and subject to change. The confirmed times and agenda items for the meeting will be posted on the ACBTSA web page at https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2021-08-17/index.html when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the ACBTSA; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC 20024. Email: ACBTSA@hhs.gov.

SUPPLEMENTARY INFORMATION: ACBTSA is a discretionary Federal advisory committee. ACBTSA The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees. On the day of the meeting, please go to https://www.hhs.gov/live/index.html to view the meeting. The public will have an opportunity to present their views to the ACBTSA orally during the meeting’s public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meetings/2021-08-17/index.html and respond by midnight August 9, 2021, ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible. Written public comments will be accessible to the public on the ACBTSA web page prior to the meeting.

ACBTSA functions to provide advice to the Secretary through the Assistant Secretary for Health on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national survey and data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997.


James J. Berger, Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability, Office of Infectious Disease and HIV/AIDS Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Implementation Research to Improve Case Finding, Cascade Screening, and Treatment for Familial Hypercholesterolemia (FH).

Date: September 2, 2021.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–Z, Bethesda, MD 20892, (301) 827–7987, susan.sunnarborg@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung