services, who had control over a distributed product when the deviation occurred, to report to CBER as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Similarly, § 1271.350(b), in brief, requires HCT/P establishments that manufacture non-reproductive HCT/Ps described in § 1271.10 to investigate and report to CBER all HCT/P deviations relating to a distributed HCT/P that relates to the core CGTP requirements, if the deviation occurred in the establishment's facility or in a facility that performed a manufacturing step for the establishment under contract, agreement or other arrangement. Form FDA 3486 is used to submit BPD reports and HCT/P deviation reports.

Respondents to this collection of information are: (1) Licensed manufacturers of biological products other than human blood and blood components, (2) licensed manufacturers of blood and blood components including Source Plasma, (3) unlicensed registered blood establishments, (4) transfusion services, and (5) establishments that manufacture non-reproductive HCT/Ps regulated solely under section 361 of the PHS Act as described in § 1271.10. The number of respondents and total annual responses are based on the BPD reports and HCT/P deviation reports FDA received in fiscal year 2018. The number of licensed manufacturers and total annual responses under § 600.14 include the estimates for BPD reports submitted to both CBER and CDER. Based on the information from industry, the estimated average time to complete a deviation report is 2 hours, which includes a minimal one-time burden to create a user account for those reports submitted electronically. The availability of the standardized report form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER has developed a Web-based addendum to Form FDA 3486 (Form FDA 3486A) to provide additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested includes information not contained in the Form FDA 3486 such as: (1) Distribution pattern; (2) method of consignee notification; (3) consignee(s) of products for further manufacture; (4) additional product information; (5) updated product disposition; and (6) industry recall contacts. This information is requested by CBER through email notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. CBER estimates that 5 percent of the total BPD reports submitted to CBER would need additional information submitted in the addendum. CBER further estimates that it would take between 10 to 20 minutes to complete the addendum. For calculation purposes, CBER is using 15 minutes.

Activities such as investigating, changing standard operating procedures or processes, and followup are currently required under 21 CFR parts 211 (approved under OMB control number 0910–0139), 606 (approved under OMB control number 0910–0116), 820 (approved under OMB control number 0910–0073). and 1271 (approved under OMB control number 0910–0543) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14; Reporting of product deviations by licensed manufacturers.	3486	93	6.14	571	2.0	1,142
606.171; Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services.	3486	1,937	23.847	46,192	2.0	92,384
1271.350(b); Reporting requirements (human cells, tissues, and cellular and tissue-based products).	3486	93	2.61	243	2.0	486
1271.350(b) (CBER addendum report)	3486A [2]	102	22.76	2,322	0.25	580.5
Total				49,328		94,592.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of the number of respondents ((1,937 + 93) × 0.05 = 102) and total annual responses to CBER ((46,192 + 243) × 0.05 = 2,322).

Our estimated burden for the information collection reflects an overall increase of 739 hours and a corresponding increase of 398 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: July 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16243 Filed 7–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) has scheduled a public meeting. Information about ACBSCT and the agenda for this meeting will be available on the ACBSCT website at *https://bloodcell.transplant.hrsa.gov/about/advisory_council/meetings/index.html.*

DATES: September 10, 2019, 10:00 a.m.–4:00 p.m. Eastern Time (ET).

ADDRESSES: This meeting will be held by webinar. Members of the public can access the webinar link and conference call-in number at *https://bloodcell.transplant.hrsa.gov/about/advisory_council/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Designated Federal Official, (DFO), at Division of Transplantation, Healthcare Systems

Bureau, HRSA, 5600 Fishers Lane, 8W60, Rockville, Maryland 20857; 301–443–6839; or *RWalsh@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACBSCT provides advice and recommendations to the Secretary of HHS (Secretary) and the HRSA Administrator on the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program. The principal purpose of these programs is to make blood stem cells from adult donors and cord blood units available for patients who need a transplant to treat life-threatening conditions such as leukemia, and who lack a suitably matched relative who can be the donor.

During the September 10, 2019, meeting, ACBSCT will discuss issues related to utilization of cord blood for transplant and utilization of blood stem cells in cellular therapies. Agenda items are subject to change as priorities dictate. Refer to the ACBSCT website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACBSCT must be sent to Robert Walsh, DFO, using the contact information above at least three business days before the meeting.

Individuals who plan to participate in the webinar and need special assistance or other reasonable accommodations should notify Robert Walsh at the address and phone number listed above at least 10 business days before the meeting.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–16306 Filed 7–30–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

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

The meetings 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Resource-Related Research Projects (R24).

Date: August 20, 2019.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: David C. Chang, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852 *david.chang3@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required).

Date: August 22, 2019.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Roberta Binder, Ph.D. Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G21A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5050, *rbinder@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 25, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–16245 Filed 7–30–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Proposed Collection; 60-Day Comment Request; NIH Information Collection Forms To Support Genomic Data Sharing for Research Purposes (Office of Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Lyric A. Jorgenson, Acting Director, Division of Scientific Data Sharing Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call non-tollfree number (301) 496–9838 or email your request including your address to: *SciencePolicy@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on May 1, 2019, page 18555 (84 FR 18555) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of the Director (OD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes—0925–0670—Expiration Date 07/31/2019—Revision—Office of the Director (OD), National Institutes of Health (NIH).