The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for categorical exclusions listed under § 25.32(i) and (g) that the Agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission. The burden for submitting a categorical exclusion is captured under § 25.15(a) and (d).

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter’s company and prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 8 hours per submission. For the information requested for the categorical exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 8 hours per submission.

For the information requested for the environmental assessments in § 25.40(a) and (c), we believe that submitters will submit an average of 57 environmental assessments annually. We estimate that each submitter will prepare an EA within 3 weeks (120 hours) and revise the EA based on Agency comments (between 40 to 60 hours), for a total preparation time of 180 hours. The burden relating to this collection has been previously approved under OMB control number 0910–0322, “Environmental Impact Consideration—21 CFR part 25”. Upon approval of this collection of information by OMB, FDA will revise OMB control number 0910–0322 to remove the annual reporting burden for categorical exclusions and environmental assessment requests related to food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, and submission of a food contact notification for a food contact substance. The future burden for categorical exclusion or environmental assessments for these requests will be captured under OMB control number 0910–0541, this collection of information.

Dated: November 15, 2016.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

Privacy Act of 1974; System of Records Notice

AGENCY: Department of Health and Human Services (HHS), Office of the Secretary (OS)

ACTION: Notice to establish a new system of records, and to delete related systems.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, HHS is establishing a new, department-wide system of records, System No. 09–90–1601 “Outside Experts Recruited for Non-FACA Activities,” and deleting four related systems of records that are obsolete or that will be rendered duplicative by the new system. The new system will cover recruitment and other administrative records about individuals outside the HHS workforce who serve or are considered for service on HHS mission-related committees and other assignments requiring specific outside expertise or experience (excluding those that are subject to the Federal Advisory Committee Act (FACA), which are covered under System No. 09–90–0059). The new department-wide System No. 09–90–1601 and the related system deletions are more fully explained in the SUPPLEMENTARY INFORMATION section of this Notice.

DATES: The new system of records established in this Notice is effective upon publication, with the exception of the routine uses. The routine uses will be effective 30 days after publication of this Notice, unless comments are received that warrant a revision to this Notice. Written comments on the Notice should be submitted within 30 days. The deletion of System Numbers 09–20–0168, 09–30–0049, 09–37–0022, and 09–90–0080 will be effective 30 days after publication of this Notice.

ADDRESSES: The public should address written comments to: Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Building—Suite 729H, 200 Independence Avenue SW., Washington, DC 20201, beth.kramer@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Building—Suite 729H, 200 Independence Avenue SW.,
SUPPLEMENTARY INFORMATION:

I. Explanation of New System No. 09–90–1601

The records to be covered in the new system of records are similar in type and function to the records covered in System No. 09–90–0059, which pertain to individuals who serve or are considered for service on committees that are subject to the Federal Advisory Committee Act (FACA). 5 U.S.C. App., et seq.; the key difference is that they will be about outside individuals serving or considered for service on mission-related committees and other activities that are not subject to FACA. Following are the non-FACA-related programs at HHS that recruit and utilize individuals with outside expertise or experience and maintain records about the outside individuals in systems that retrieve the records by personal identifier:

- Curricula Vitae of Consultants to the National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention (CDC) (formerly covered under SORN 09–20–0168). This program maintains records about individuals with special expertise, training, and professional experience who may be enlisted to assist CDC/NCHS as consultants. The records are used by CDC/NCHS to select individuals to participate in assignments such as: planning and conducting surveys, studies, statistical reporting programs, and statistical analyses of data; providing training and technical assistance; and planning and conducting conferences. These records currently are covered under SORN No. 09–20–0166, which is being deleted and subsumed under the new department-wide SORN No. 09–90–1601.

- The Food and Drug Administration (FDA) Patient Representative Program. This program enlists individuals with patient advocacy experience to serve as patient representatives on both FACA committees and non-FACA assignments. For example, patient representatives may provide input that is used in making decisions to approve devices or drugs, or may contribute to discussions at presentations and conferences. Records about patient representatives are retrieved by the representatives’ names, and will be covered under either SORN No. 09–90–0059 or the new department-wide SORN No. 09–90–1601, depending on whether the records pertain to service on a FACA committee or service on a non-FACA assignment.

- Peer Review Programs at the Administration for Children and Families (ACF), Health Resources and Services Administration (HRSA), and Substance Abuse and Mental Health Services Administration (SAMHSA) that recruit and use outside individuals to serve on peer review committees formed to review applications for grants and cooperative agreements. These programs exist in several HHS components, but only ACF, HRSA, and SAMHSA sometimes use a personal identifier (i.e., name) to retrieve administrative records about the outside individuals they recruit and use. Other components (including the Office of the Assistant Secretary for Health (OASH), Centers for Medicare & Medicaid Services (CMS), and National Institutes of Health (NIH)) use only non-personal identifiers (e.g., expertise type, or funding opportunity announcement number) for retrieval.

- Consultants on Other SAMHSA Projects (formerly covered under SORN 09–30–0049). SAMHSA contractors arrange for outside consultants to be used in other SAMHSA programs (besides peer review programs) when technical assistance is needed in conferences, meetings, and evaluation projects that involve a specialized area of research, review, or advice. A report on the new system of records has been sent to Congress and OMB in accordance with 5 U.S.C. 552a(r).

II. Deletion of Four Related Systems of Records

The following systems of records are being deleted as duplicative of new department-wide System No. 09–90–1601:

- 09–20–0168 Curricula Vitae of Consultants to the National Center for Health Statistics
- 09–30–0049 Consultant Records Maintained by SAMHSA Contractors

The following system of records is being deleted as duplicative of System No. 09–90–0059 Federal Advisory Committee Membership Files as to files that pertain to candidates for FACA committees, and as duplicative of new department-wide System No. 09–90–1601 as to files that pertain to candidates for non-FACA committees and other activities:

- 09–90–0080 The Secretary’s Advisory Committee Candidate Files

The following system of records is being deleted because it is obsolete and the records no longer exist:

- 9–37–0022 Records of Health Experts Maintained by the Office of International Health

III. The Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the U.S. Government collects, maintains, and uses information about individuals in a system of records. A “system of records” is a group of any records under the control of a federal agency from which information about an individual is retrieved by the individual’s name or other personal identifier. The Privacy Act requires each agency to publish in the Federal Register a system of records notice (SORN) identifying and describing each system of records the agency maintains, including the purposes for which the agency uses information about individuals in the system, the routine uses for which the agency discloses such information outside the agency, and how individual record subjects can exercise their rights under the Privacy Act.

Dated: November 1, 2016.

Beth Kramer,

Privacy Act Officer, FOIA/Privacy Act Division, Assistant Secretary for Public Affairs, Department of Health and Human Services.

Notice of Deletion of Related Systems

The following systems of record are deleted, effective 30 days after publication of this Notice:

1. 09–20–0168 Curricula Vitae of Consultants to the National Center for Health Statistics
2. 09–30–0049 Consultant Records Maintained by SAMHSA Contractors
3. 09–90–0080 The Secretary’s Advisory Committee Candidate Files
4. 9–37–0022 Records of Health Experts Maintained by the Office of International Health

SYSTEM NUMBER:

09–90–1601

SYSTEM NAME:

Outside Experts Recruited for Non-FACA Activities

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Physical locations include:
- CDC program offices that recruit consultants to assist in statistical projects and reporting programs conducted or sponsored by NCHS, in Atlanta, GA and Hyattsville, MD;
- FDA’s committee management office in Silver Spring, MD;
- Program offices at ACF in Washington, DC, at HRSA in Rockville, MD, and at SAMHSA in Rockville, MD.
that recruit individuals to serve as peer reviewers; and

• Locations of SAMHSA contractors that arrange use of consultants on SAMHSA projects.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records in this system pertain to individuals outside the HHS workforce who serve or are considered for service on HHS mission-related committees or other assignments that require specific outside expertise or experience (for example, medical, scientific, or manufacturing expertise, or patient advocacy experience), but that are not subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App., et seq.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records consist of recruitment and other administrative records, including:

• An application and resume or curricula vitae, describing the individual’s qualifications;

• Nomination/recommendation records, or other records used in evaluating an individual’s qualifications and any potential conflicts of interest and selecting an individual for a specific assignment; and

• Records used to plan and arrange the individual’s participation in the assigned activities, including scheduling records and records used to coordinate parking, badging, and payment of any stipend or honorarium.

The records may contain these data elements:

• The individual’s name and other identifying information (e.g., sex, place and date of birth);

• Contact information (e.g., home and business addresses, telephone numbers, email addresses);

• Occupation, job titles, employers, employment status and history, and whether currently employed by the federal government;

• Work and organizational affiliations, memberships, credentials, and licenses;

• Degrees held, and general educational and/or experience background;

• Racial classification or ethnic background;

• Areas of specialization, expertise, or experience, and special qualifications (e.g., language or technical skills, ability to drive to an assignment);

• Dates and descriptions of past assignments or past experience;

• Sources and references, and any information provided by sources/references; and

• Information about availability and any special needs.


AUTHORITY FOR MAINTENANCE OF THE SYSTEM:


For ACF Peer Reviewer Records: 42 U.S.C. 790(f), 806(e).

For HHS Peer Reviewer Records: 42 U.S.C. 790(f), 806(e).


See also: 5 U.S.C. 3109.

PURPOSE(S):

The records will be used within the agency on a need-to-know basis for the purpose of staffing committees and other assignments and managing administrative matters pertaining to individuals serving on committees and other assignments, including to:

• Prepare reports and lists of past, present, and recommended members, vacancies, acceptances, and separations;

• Send recruitment notices to individual prospective candidates, and send informational notices to selectees;

• Identify qualified candidates and document the selections; and

• Manage and coordinate the selected individuals’ participation in assignment activities (including sharing information within the agency to coordinate aspects such as badging, parking, travel, training, and payment of any stipend or honorarium).

ROUTE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the statutory disclosures of information permitted in the Privacy Act at 5 U.S.C. 552a(b)(2) and (b)(4)–(11), HHS may make the following disclosures of information about an individual from this system of records to parties outside the agency without the individual’s prior, written consent:

1. Disclosures may be made to federal agencies and Department contractors that have been engaged by HHS to assist in accomplishment of an HHS function relating to the purposes of this system of records and that have a need to have access to the records in order to assist HHS in performing the activity. Any contractor will be required to comply with the requirements of the Privacy Act.

2. Records may be disclosed to parties such as educational institutions, current and former employers, and qualified experts, when necessary to check or obtain an opinion about a candidate’s qualifications.

3. Records about consultants and patient advocates may be disclosed to parties organizing or hosting assignment activities, such as grantee institutions and federal, foreign, state, tribal, local, and other government agencies and public authorities (e.g., U.S. Embassies and Ministries of Health), when necessary to apprise them of an individual’s qualifications for the assignment or coordinate the individual’s participation in the activities.

4. Records may be disclosed to supervisors and administrative assistants at the individual’s place of employment, for administrative purposes such as coordinating the individual’s participation in the activities.

5. Records may be disclosed to external parties that audit committee or assignment activities.

6. Relevant information will be included in any required reports to the President, the Office of Management and Budget (OMB), and the General Services Administration (GSA) about committees and other assignments that are mission-related.

7. Information may be disclosed to the U.S. Department of Justice (DOJ) or to a court or other tribunal, when: a. The agency or any component thereof, or b. Any employee of the agency in his or her official capacity, or c. Any employee of the agency in his or her individual capacity where DOJ has agreed to represent the employee, or d. The United States Government, is a party to litigation or has an interest in such litigation and, by careful review, HHS determines that the records are both relevant and necessary to the litigation and that, therefore, the use of such records by the DOJ, court or other tribunal is deemed by HHS to be compatible with the purpose for which the agency collected the records.

8. Records may be disclosed to student volunteers and other individuals performing functions for the
and technical safeguards. These safeguards include protecting the facilities where records are stored or accessed with security guards, badges and cameras, securing hard-copy records in locked file cabinets, file rooms or offices during off-duty hours, limiting access to electronic databases to authorized users based on roles and two-factor authentication (user ID and password), using a secured operating system protected by encryption, firewalls, and intrusion detection systems, requiring encryption for records stored on removable media, and training personnel in Privacy Act and information security requirements. Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800–88.

RETENTION AND DISPOSAL:
Records pertaining to recruitment and use of outside peer reviewers are destroyed three years after final action; they are retained longer if required for business use (see General Records Schedule (GRS) 1.2, Item 010, Grant and Cooperative Agreement Program Management Records). Records pertaining to recruitment and use of other outside individuals (e.g., experts, patient advocates, and members of mission-related non-FACA committees) are currently unscheduled. Unscheduled records must be retained indefinitely pending the agency’s submission, and NARA’s approval, of a disposition schedule. HHS anticipates proposing to NARA, as an appropriate retention period for these records, “three years after final action, or longer if required for business use” (similar to the period provided in GRS 1.2, Item 010) or “when no longer needed for administrative purposes” (similar to the periods applicable to similar records not retrieved by personal identifier which are not covered under this SORN; i.e.: N1–442–93–1, Item 37 for the Agency for Toxic Substances and Disease Registry’s Curriculum Vitae Files, and NC1–235–82–1, Item 100–3 for the Office of the Secretary’s Advisory Committee Candidate Resume Files).

RECORD ACCESS PROCEDURE:
An individual seeking to access records about him or her should submit a written request to the relevant System Manager indicated above. The individual must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act, subject to a five thousand dollar fine.

RECORD SOURCE CATEGORIES:
Most information is obtained directly from the individual record subject.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Human Virome in Heart, Lung, and Blood Health and Resilience.

Date: December 9, 2016.
Time: 8:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301-496-2434, kristen.page@nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; T32—Training Programs for Institutions that Promote Diversity.

Date: December 9, 2016.
Time: 11:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301-443-9784, constantsl@nhlbi.nih.gov.

(Department of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 15, 2016.
Michelle Trout,
Program Analyst, Office of Federal Advisory Committee 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 (5 U.S.C. App.), 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: Heart, Lung, and Blood Initial Review Group, NHLBI Institutional Training Mechanism Review Committee.

Date: December 9, 2016.
Time: 10:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Room 7194, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7194, Bethesda, MD 20892–7924, 301–435–0289, cjoyce@mail.nih.gov.

(Department of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 15, 2016.
Michelle Trout,
Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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