

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a)	75	1	75	300	22,500
Product Quantity Change SE Report	125	1	125	87	10,875
Same Characteristics SE Report	100	1	100	47	4,700
Totals					38,075

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

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA's expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the SE requirements of sections 905(j) and 910(a) of the FDC Act (21 U.S.C. 387j(a)). Based on current information, FDA now estimates that it will receive 300 section 905(j) reports each year. Of these 300 reports, FDA estimates that 75 of these reports will be "full" SE reports that take a manufacturer approximately 300 hours to prepare. Under the newly issued guidance entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions," FDA is recommending that certain modifications might be addressed in either a "Same Characteristics SE Report" or "Product Quantity Change Report." FDA estimates that it will receive 100 Same Characteristics SE Reports and that it will take a manufacturer approximately 47 hours to prepare this report. FDA estimates that it will receive 125 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this report. Therefore, FDA estimates the burden for submission of SE information will be 38,075 hours.

Dated: July 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-16952 Filed 7-10-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Extension of Comment Period for the Office of the Assistant Secretary for Preparedness and Response Public Access Plan to Federally Funded Research: Publications and Data

AGENCY: Department of Health and Human Services.

ACTION: Notice of extension of public comment period until July 13.

SUMMARY: The Department of Health and Human Services (HHS) is extending the comment period on the Assistant Secretary for Preparedness and Response (ASPR) Public Access Plan for Federally Funded Research: Publications and Data. The document is available to the public via <http://www.phe.gov/Preparedness/planning/science/Pages/AccessPlan.aspx>. The comment period was previously scheduled to end June 25, 2015. The public comment period is extended until July 13, 2015.

FOR FURTHER INFORMATION CONTACT: Please submit comments via email to Harvey.ball@hhs.gov

SUPPLEMENTARY INFORMATION: Pursuant to Section 103 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358), the Executive Office of the President, Office of Science and Technology Policy (OSTP) issued a memorandum on February 22, 2013 to the heads of federal agencies directing them to develop plans to enhance access to the results of federally-funded scientific research. ASPR is voluntarily developing a public access plan in order to maximize availability of digitally-formatted scientific data resulting from research supported wholly or in part by federal funding that will improve the public's ability to locate and access this data.

Background: This plan considers the interests and needs of various stakeholders, including, but not limited to, federally funded researchers, universities, libraries, publishers, data users and civil society groups.

Availability of Materials: The draft copy of the ASPR Public Access Plan

will be posted on the [phe.gov](http://www.phe.gov) Web site: <http://www.phe.gov/Preparedness/planning/science/Documents/AccessPlan.pdf>.

Procedures for Providing Public Input: All comments must be received by July 13, 2015. Please submit comments to Harvey Ball via email harvey.ball@hhs.gov.

Dated: July 2, 2015.

Nicole Lurie,
Assistant Secretary for Preparedness and Response.

[FR Doc. 2015-16969 Filed 7-10-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education—Health Reform Cooperative Agreement; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on June 19, 2015, for the FY 2015 National Indian Health Outreach and Education, Health Reform Cooperative Agreement Program. The notice contained two incorrect dates.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Gettys, Grant Systems Coordinator, Division of Grants Management (DGM), Indian Health Service, 801 Thompson Avenue, Suite TMP 360, Rockville, MD 20852, Telephone direct (301) 443-2114, or the DGM main number (301) 443-5204. (This is not a toll-free number.)

Corrections

In the **Federal Register** of June 19, 2015, in FR Doc. 2015-15157, on page 35373, in the third column, under the heading Key Dates, the correct Application Deadline Date and Proof of Non-Profit Status Due Date should read as follows:

Application Deadline Date: August 19, 2015.

Proof of Non-Profit Status Due Date: August 19, 2015.

Dated: July 1, 2015.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 2015-16953 Filed 7-10-15; 8:45 am]

BILLING CODE 4160-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); 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 section 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 Advisory Child Health and Human Development Council.

Date: August 27, 2015.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Caroline Signore, M.D., MPH., Acting Director, Division of Extramural Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 4A05, Bethesda, MD 20892-9304, (301) 496-5577, signorec@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 7, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-16959 Filed 7-10-15; 8:45 am]

BILLING CODE 4140-01-P

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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurologic Disorders.

Date: July 29, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Samuel C Edwards, Ph.D., IRG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwards@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics in HIV/AIDS Behavioral Research.

Date: July 29, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, rubertm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: August 6-7, 2015.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuck@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 7, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-16960 Filed 7-10-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Hospital Data Abstraction, Formerly Entitled Evaluation of Emergency Department Crisis Center Follow-Up—(OMB No. 0930-0337)

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct an evaluation to assess the impact of crisis center follow-up with patients admitted to emergency departments following a suicide attempt.

The overarching purpose of the Hospital Data Abstraction, formerly