

Drug Administration, 10903 New Hampshire Avenue, Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, *ACPS-CP@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Pharmaceutical Science and Clinical Pharmacology Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases; the quality characteristics which such drugs purport or are represented to have, and as required, any other product for which the Food and Drug Administration has regulatory responsibility; and makes appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

The Committee shall consist of a core of 14 voting members including two Chairpersons. Members and Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, microbiology); clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations and innovative methods in drug development); biostatistics, related biomedical and pharmacological specialties, current good manufacturing

practices, and quality systems implementation. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include up to three non-voting members who are identified with industry interests.

Further information regarding the most recent charter and other information can be found at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeForPharmaceuticalScienceandClinicalPharmacology/ucm107524.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). Due to a change in the committee name, FDA will publish a final rule will in the **Federal Register** amending 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: January 15, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Information Collection: Indian Health Service Forms To Implement the Privacy Rule

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, "IHS Forms to Implement the Privacy Rule (45 CFR parts 160 and 164)," Office of Management and Budget (OMB) Control Number 0917-0030.

DATES: *Comment Due Date:* March 22, 2016. Your comments regarding this

information collection are best assured of having full effect if received within 60 days of the date of this publication.

ADDRESSES: Send your written comments, requests for more information on the collection, or requests to obtain a copy of the data collection instrument and instructions to Tamara Clay by one of the following methods:

- *Mail:* Tamara Clay, Information Collection Clearance Officer, Indian Health Service, Office of Management Services, Division of Regulatory Affairs, 5600 Fishers Lane, Mail Stop 09E70, Rockville, MD 20857.

- *Phone:* 301-443-4750.

- *Email:* tamara.clay@ihs.gov.

- *Fax:* 301-443-2316.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** (78 FR 2412) on January 11, 2013, and allowed 30 days for public comment. No public comment was received in response to the notice. This notice announces our intent to submit the collection, which expires April 30, 2016, to OMB for approval of an extension, and to solicit comments on specific aspects of the information collection. A copy of the supporting statement is available at www.regulations.gov (see Docket ID IHS-2016-1).

Title of Collection: 0917-0030, IHS Forms to Implement the Privacy Rule (45 CFR parts 160 and 164). *Type of Information Collection Request:* Extension of the currently approved information collection, 0917-0030, IHS Forms to Implement the Privacy Rule (45 CFR parts 160 and 164). *Form(s):* IHS-810, IHS-912-1, IHS-912-2, IHS-913, and IHS-917. *Need and Use of Information Collection:* This collection of information is made necessary by the Department of Health and Human Services Rule entitled "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule) (45 CFR parts 160 and 164). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996, creates national standards to protect individual's personal health information, and gives patients increased access to their medical records. 45 CFR 164.508, 164.522, 164.526 and 164.528 of the Rule require the collection of information to implement these protection standards and access requirements. The IHS will continue to use the following data collection instruments to meet the

information collection requirements contained in the Rule.

45 CFR 164.508: This provision requires covered entities to obtain or receive a valid authorization for its use or disclosure of protected health information for other than for treatment, payment and healthcare operations. Under the provision individuals may initiate a written authorization permitting covered entities to release their protected health information to entities of their choosing. The form IHS-810 "Authorization for Use or Disclosure of Protected Health Information" is used to document an individual's authorization to use or disclose their protected health information.

45 CFR 164.522: Section 164.522(a)(1) requires a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information. The covered entity may or may not agree to the restriction. The form IHS-912-1 "Request for Restrictions(s)" is used to document an individual's request for restriction of their protected health

information, and whether IHS agreed or disagreed with the restriction. Section 164.522(a)(2) permits a covered entity to terminate its agreement to a restriction if the individual agrees to or requests the termination in writing. The form IHS-912-2 "Request for Revocation of Restriction(s)" is used to document the agency or individual request to terminate a formerly agreed to restriction regarding the use and disclosure of protected health information.

45 CFR 164.528 and 45 CFR 5b.9(c): This provision requires covered entities to permit individuals to request that the covered entity provide an accounting of disclosures of protected health information made by the covered entity. The form IHS-913 "Request for an Accounting of Disclosures" is used to document an individual's request for an accounting of disclosures of their protected health information and the agency's handling of the request.

45 CFR 164.526: This provision requires covered entities to permit an individual to request that the covered entity amend protected health

information. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must inform the individual that the amendment is accepted. If the covered entity denies the requested amendment, in whole or in part, the covered entity must provide the individual with a written denial. The form IHS-917 "Request for Correction/Amendment of Protected Health Information" will be used to document an individual's request to amend their protected health information and the agency's decision to accept or deny the request. Completed forms used in this collection of information are filed in the IHS medical, health and billing record, a Privacy Act System of Records Notice. *Affected Public:* Individuals and households. *Type of Respondents:* Individuals. *Burden Hours:* The table below provides for this information collection: Types of data collection instruments, estimated number of respondents, number of responses per respondent, average burden hour per response, and total annual burden hour(s).

Data collection instrument	Number of respondents	Number of responses per respondent	Average burden hour per response *	Total annual burden hours
Authorization for Use or Disclosure of Protected Health Information (OMB Form No. 0917-0030, IHS-810)	210,954	1	10/60	35,159
Request for Restriction(s) (OMB Form No. 0917-0030, IHS-912-1)	214	1	10/60	36
Request for Revocation of Restriction(s) (OMB Form No. 0917-0030, IHS-912-2)	3	1	10/60	.5
Request for Accounting of Disclosures (OMB Form No. 0917-0030, IHS-913)	39	1	10/60	6.5
Request for Correction/Amendment of Protected Health Information (OMB Form No. 0917-0030, IHS-917)	54	1	10/60	9
Total Annual Burden	211,264			35,211

* For ease of understanding, burden hours are provided in actual minutes.

The total estimated burden for this collection of information is 35,211 hours. There are no capital costs, operating costs and/or maintenance costs to respondents.

Requests for Comments: Your written comments and/or suggestions are invited on one or more of the following points:

(a) Whether the information collection activity is necessary to carry out an agency function;

(b) whether the agency processes the information collected in a useful and timely fashion;

(c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information);

(d) whether the methodology and assumptions used to determine the estimates are logical;

(e) ways to enhance the quality, utility, and clarity of the information being collected; and

(f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: January 13, 2016.

Robert G. McSwain,

Principal Deputy Director, Indian Health Service.

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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