

12,037; *Total Annual Responses*: 300,148; *Total Annual Hours*: 75,037. (For policy questions regarding this collection contact Fred Rooke at 404-562-7205. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request*: New Collection; *Title of Information Collection*: Evaluation of the Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration Focus Group Protocols; *Use*: On September 16, 2009, the Department of Health and Human Services announced the establishment of the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration, under which Medicare joined Medicaid and private insurers as a payer participant in state-sponsored patient-centered medical home (PCMH) initiatives. CMS selected eight states to participate in this demonstration: Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan, and Minnesota. CMS is proposing to conduct in-person focus groups with Medicare and Medicaid beneficiaries and their caregivers to more thoroughly understand patients' experiences with their PCMHs and how well their PCMHs are serving their needs.

The focus groups will provide CMS with answers to fundamental "what, how, and why" questions about beneficiaries' experiences with care and access to and coordination of care. The information obtained via in-person, focus groups will be utilized by CMS for the evaluation of the MAPCP

Demonstration. The focus group data will be collected to supplement other qualitative and quantitative analyses from primary and secondary data sources by providing data on context, structure, and process, as well as select aspects of the key outcomes. The data gathered from the interviews will allow for more complete interpretation of the quantitative claims and other data analysis by taking into account the unique perspectives of beneficiaries.

Form Number: CMS-10479 (OCN: 0938-NEW); *Frequency*: Annually; *Affected Public*: Individuals and households; *Number of Respondents*: 768; *Total Annual Responses*: 384; *Total Annual Hours*: 1,152. (For policy questions regarding this collection contact Suzanne Goodwin at 410-786-0226. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your

address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 28, 2013*:

1. *Electronically*. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail*. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection, 60-day Comment Request: Certificate of Confidentiality Electronic Application System

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, to provide the opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER) of the National Institutes of Health (NIH) is developing an electronic application form for the submission of requests to NIH for Certificates of Confidentiality (CoCs).

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the

methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: 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. Ann M. Hardy, NIH Extramural Human Research Protections Officer and Coordinator, Certificates of Confidentiality, Office of Extramural Programs, OER, NIH, 3701 Rockledge Drive, Room 3002, Bethesda, MD 20892; or call the non-toll-free number (301) 435-2690; or email your request, including your address, to hardyan@od.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Certificate of Confidentiality Electronic Application System 0925-NEW, Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This application system will provide one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of the Department of Health and Human Services (HHS), including NIH, to authorize researchers conducting sensitive research to protect the privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At the NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). The NIH ICs collectively issue approximately 1,000 new CoCs each year for eligible research projects. However, the process for submitting a CoC request is not consistent across the ICs, which creates confusion for applicants. To make the application process consistent across the entire agency, the OER is proposing to use an electronic application system that will be accessed by research organizations that wish to request a CoC from any NIH

IC. Having one system for all CoC applications to NIH will be efficient for both applicants and NIH staff who process these requests. As is currently done, the NIH will use the information

in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization.

Office of Management and Budget approval is requested for 3 years. There

are no costs to respondents other than their time. The total estimated annualized burden hours is 1,500.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (in hours)	Total annual burden hours
CoC Applicants- Private	400	1	1.5	600
CoC Applicants- State/local	450	1	1.5	675
CoC Applicants- Small business	50	1	1.5	75
CoC Applicants- Federal	100	1	1.5	150

Dated: April 22, 2013.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Request for Human Embryonic Stem Cell Line To Be Approved for Use in NIH-Funded Research

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection instrument listed below. This proposed information collection was previously published in the **Federal Register** on February 28, 2013, pages 13688-13689, 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 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.

Direct Comments to OMB: 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: NIH Desk Officer.

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

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. Ellen Gadbois, Office of Science Policy, Office of the Director, NIH, Building 1, Room 218, MSC 0166, 1 Center Drive, Bethesda, MD 20892; or call the non-toll-free number 301-496-1454; or email your request, including your address, to *gadboisel@od.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH-Funded Research, 0925-0601, Expiration Date 04/30/2013—EXTENSION, Office of Extramural Research, National Institutes of Health (NIH).

Need and Use of Information Collection: The form is used by applicants to request that human embryonic stem cell lines be approved for use in NIH-funded research. Applicants may submit applications at any time.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours is 2,550.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
NIH grantees and others in possession of hESC lines	50	3	17	2,550