

in the voluntary paternity establishment program.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
None .....	1,167,097	1	.166	193,738

*Estimated Total Annual Burden Hours:* 193,738.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 29, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

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**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Plan To Develop a Genetic Testing Registry at the National Institutes of Health; Public Meeting; Request for Comments

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The National Institutes of Health is announcing a public meeting to gather stakeholder perspectives on its plan to develop the Genetic Testing Registry. The meeting will provide a forum for interested stakeholders to provide comments on specific aspects of the plan.

**Date and Time:** The public meeting will be held November 2, 2010, from 9 a.m. to 12 p.m.

**Location:** The public meeting will be held at the Walter E. Johnson Convention Center, Room 147, 801 Mount Vernon Place, NW., Washington, DC 20001. For directions, please contact the Convention Center at 202-249-3000 or refer to the following Web site: <http://www.dccconvention.com/>.

**Special accommodations:** Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, is asked to contact Cathy Fomous (see Contacts section) by October 26, 2010.

**Registration:** If you wish to attend the public meeting, please register by October 27, 2010. Registration is free and on a first-come, first-served basis. Pre-registration can be completed online at [http://oba.od.nih.gov/gtr/gtr\\_meetings.html](http://oba.od.nih.gov/gtr/gtr_meetings.html). Persons without Internet access may call Ms. Nicole Numbers at 301-650-8660. Onsite registration will be based on space availability.

**Requests for Oral Presentations:** Interested persons who would like to make oral comments during the meeting will be given 5 minutes to do so if they submit their request by October 27, 2010, to Cathy Fomous. Send requests

by e-mail to [cfomous@od.nih.gov](mailto:cfomous@od.nih.gov); by fax to 301-496-9839; or via postal service to Cathy Fomous, Ph.D., Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892. The request should include the commenter's name, title, affiliation, address, e-mail address, and telephone number. All requests should indicate which questions outlined below in the section on Public Meeting Focus will be addressed. Depending on the number of individuals and organizations that submit requests to make oral remarks, the allotted time may be expanded or shortened to provide all interested parties an opportunity to present.

**Written Comments:** Interested persons who cannot attend the meeting may submit written comments on the questions outlined below. Comments should be submitted to Cathy Fomous via e-mail, fax, or postal service using the above contact information. The comment period for written comments closes on November 12, 2010.

**Contacts:** For questions about the meeting logistics, please contact Ms. Nicole Numbers at [numbers@palladianpartners.com](mailto:numbers@palladianpartners.com) or 301-650-8660. For special accommodations or questions about the meeting agenda and public comments, please contact Cathy Fomous, Ph.D., NIH Office of Biotechnology Activities at [cfomous@od.nih.gov](mailto:cfomous@od.nih.gov) or 301-496-9838.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Advances in the knowledge of genetic factors involved in health and disease have been accompanied by a rapid rise in the availability of genetic tests, including those tests that diagnose or assess the risk for disease, provide prognostic information, and guide the selection of drug therapies and dosing. Although more than 2,000 genetic tests are available, there is no public resource that provides centralized information about the availability and scientific basis of these tests.

On March 18, 2010, the National Institutes of Health (NIH) announced its intent to develop the Genetic Testing

Registry (GTR) to provide access to information that enables informed decision making by patients, caregivers, health care professionals, clinical laboratory professionals, payers, and policy makers. The goals of the GTR are to promote transparency by encouraging test providers to share information about the purpose and validity of their tests; provide a resource for the public—including health care providers, patients, and researchers—to locate laboratories that offer particular tests; and facilitate genomic data sharing for research and new scientific discoveries.

The GTR project is overseen by the NIH Office of the Director. The National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH, is responsible for developing the registry, which is expected to be available in 2011.

As part of the development process, the NIH issued a Request for Information (RFI) on July 12, 2010, to seek input from the public on its plan for this project. The RFI comment period ended August 2, 2010. NIH received 68 comments in response to the RFI, and these comments are available at [http://oba.od.nih.gov/gtr/gtr\\_comments.html](http://oba.od.nih.gov/gtr/gtr_comments.html).

## II. Public Meeting Focus

NIH will begin the November 2 public meeting with an overview of the public comments that were received in response to the RFI and a presentation of prototype data elements for the GTR. The remainder of the meeting will be dedicated to a moderated discussion of responses to specific questions about the GTR. The meeting agenda will be available on the Internet at [http://oba.od.nih.gov/gtr/gtr\\_meetings.html](http://oba.od.nih.gov/gtr/gtr_meetings.html).

The RFI comments have been helpful in the development of a prototype of registry data elements. However, NIH seeks further public input on specific aspects of the GTR and requests that comments address the questions below. If time permits, discussion of additional issues will be accommodated.

1. Based on an analysis of RFI comments and other operational issues, NIH is considering a phased approach to developing the GTR in which some types of tests would be eligible for early entry in the GTR and other types of tests would be added later. If NIH adopts this approach, what criteria should be used to determine which genetic tests should be included in the first phase of the GTR, and what types of tests would meet these criteria?

2. Several RFI responders, who are potential data submitters, noted that it makes more sense for clinicians and genetics professionals to be the source

of clinical utility evidence rather than test developers and/or test providers. Given that data submitters are unlikely to have clinical utility information, how is this data element best addressed in the GTR?

3. Among responders to the RFI question about including a data element for test cost, half were in favor of including cost information and half were opposed. What are the benefits, risks, and challenges of including cost information in the GTR?

4. What safeguards can be put in place to prevent GTR users from misunderstanding, misinterpreting, or misusing the information in the Registry?

5. What mechanisms can be used to provide materials that explain the GTR's data elements to audiences with varying technical expertise?

Dated: October 5, 2010.

**Amy P. Patterson,**

*Acting Associate Director for Science Policy, NIH.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of Administration; Single-Source Cooperative Agreement Award; Announcing the Award a Single-Source Cooperative Agreement to the Johns Hopkins University, Applied Physics Lab (APL) and School of Public Health, To Support the Development of a Human Services National Interoperable Architecture

**AGENCY:** Office of Information Services, OA, ACF, HHS.

**ACTION:** Notice.

*CFDA Number:* 93.647.

*Legislative Authority:* This award will be made pursuant to the Patient Protection and Affordable Care Act (ACA) [Pub. L. 111-148] and the Improper Payments Elimination and Recovery Act of 2010 [Pub. L. 111-204].

*Amount of Award:* \$1,500,000.

*Project Period:* September 17, 2010 through September 16, 2011.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Administration (OA), Office of Information Services (OIS) announces the award of a single-source cooperative agreement to the Johns Hopkins University (JHU), Applied Physics Lab (APL) and School of Public Health, in Baltimore, MD, to support the

development of a Human Services National Interoperable Architecture. Under the award, APL will develop an architectural framework that will be used as a model to facilitate State and local agencies in information exchanges among eligibility and verification services that are developed by the HHS/Centers for Medicare and Medicaid Services (CMS) under the requirements of the Patient Protection and Affordable Care Act (ACA).

To address issues related to implementation of the ACA and the Improper Payments and Recovery Act of 2010, the Administration has directed Agencies to begin to design and execute plans related to the legislation. Under ACA, CMS has been directed to create a technical solution that enables health-related eligibility and enrollment functions and to ensure that the human services agencies can use the solutions for human services eligibility and verification determination. Under the Improper Payments and Recovery Act of 2010, Agencies must design and begin the execution of plans to eliminate improper payments and fraud.

JHU will create the development of a conceptual information technology architecture with ACF/Office of Information Services. The project will produce a solution that supports information exchanges and interoperability that will lead to reductions in improper payments as a preventative step in the program integrity process.

#### FOR FURTHER INFORMATION CONTACT:

David Jenkins, Federal Project Officer, Office of Administration, Office of Information Services, Administration for Children and Families, 901 D Street, SW., 3rd Floor West, Washington, DC 20047; E-mail: [David.Jenkins@acf.hhs.gov](mailto:David.Jenkins@acf.hhs.gov); Telephone: (202) 690-5802.

Dated: October 1, 2010.

**Michael Curtis,**

*Director, Office of Information Services.*

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**BILLING CODE P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2009-0560]

#### Collection of Information Under Review by Office of Management and Budget: OMB Control Number: 1625-New

**AGENCY:** Coast Guard, DHS.