

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:

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Dated: October 1, 2010.

**Michael Curtis,**

*Director, Office of Information Services.*

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## 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.