

and Other Variations in Organ Distribution and the Alignment of the Centers for Medicare and Medicaid Services' Regulatory Requirements with the Organ Procurement and Transplantation Network and the Health Resources and Services Administration. ACOT presentations will include an update on the Kidney Allocation Policy; financial challenges of kidney paired donation; circulatory determination of death criteria; organ donation and transplantation alliance; vascularized composite allografts; and disease transmission and informed consent. Agenda items are subject to change as priorities indicate.

After the presentations and Committee discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting summary notes will be made available on the Department's donation Web site at <http://www.organdonor.gov/legislation.asp>. The draft meeting agenda will be available on the Department's donation Web site at <http://www.organdonor.gov/legislation.asp> and at <http://www.team-psa.com/dot/spring2011/ACOT>.

Registration can be completed by e-mailing or faxing a confirmation of participation to Brittany Carey, with the HRM/Professional and Scientific Associates (PSA), the logistical support contractor for the meeting. Ms. Carey's e-mail address is b_carey@team-psa.com and her fax number is (703) 234-1701. Individuals without access to the Internet who wish to register may call Brittany Carey with HRM/PSA at (703) 889-9033.

For Further Information Contact: Patricia Stroup, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857; telephone (301) 443-1127.

Dated: July 21, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Comments Under the Paperwork Reduction Act, Section 3506

SUMMARY: The National Institute of Health (NIH), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the

Paperwork Reduction Act of 1995, Section 3506.

Proposed Collection: Title: The Genetic Testing Registry; *Type of Information Collection Request:* New collection; *Need and Use of Information Collection:* Laboratory tests for more than 2,000 genetic conditions are available; however, there is no centralized public resource that provides information about the availability and scientific basis of these tests. Recognizing the importance of making this information easily accessible to health care providers, patients, consumers, and others, NIH is developing a voluntary registry of genetic tests. The Genetic Testing Registry (GTR) will provide a centralized, online location for test developers, manufacturers, and researchers to submit detailed information about genetic tests. The overarching goal of the GTR is to advance the public health and research in the genetic basis of health and disease.

As such, the Registry will have several key functions, including (1) encouraging providers of genetic tests to enhance transparency by publicly sharing information about the availability and utility of their tests; (2) providing an information resource for the public, including health care providers, patients, and researchers, to locate laboratories that offer particular tests; and (3) facilitating genetic and genomic data-sharing for research and new scientific discoveries.

Frequency of Response: The information will be submitted voluntarily on a non-repeating, continual basis, which means submitters will register a test once and can add new tests on a continual basis. Submitters will be requested to update their test information at least once every 12 months.

Description of Respondents: Submitters to the GTR are expected to include clinical laboratories, test manufacturers, researchers, and entities that report and interpret tests performed elsewhere. The GTR is not limited to U.S. respondents; it will also include submissions from outside the United States. Information will be collected and managed using an online submission system.

Estimate of Burden: Data from the GeneTests Laboratory Directory, which is currently the most comprehensive listing available for laboratories that provide genetic tests, was used to estimate both the number of participating laboratories as well as the number of genetic tests which might be submitted to the GTR. Analysis of the

database showed that there are 593 laboratories and approximately 7,800 genetic tests listed in GeneTests. Approximately half of the laboratories in GeneTests (291, or 49 percent) list 12 or fewer tests, while approximately 40 percent (239) list between 13 and 100 tests, and the remaining 10 percent (63) list 100 or more tests. To account for genetic test providers that are not listed in GeneTests, the number of laboratories was multiplied by 1.2, bringing the estimated number of potential participants in GTR to 770. A multiplier of 1.2 was used to account for tests that are not in GeneTests but that might be submitted to the GTR, including test categories not covered by GeneTests (e.g., pharmacogenomic tests), as well as tests that meet the criteria for GeneTests but that have not been submitted to the database. Applying the 1.2 multiplier yields an estimated 9,360 tests for which information could be submitted to GTR.

Although participation in the GTR is voluntary, in order to participate, the submitter must provide information for a certain subset of data fields, identified as the "minimal fields." GTR includes 31 minimal fields and 85 optional fields. Separate estimates of hour burden are provided for minimal, optional, and all fields (Table 1). The calculations include the time and effort necessary for the test provider to gather information for the data elements and to enter the information into the GTR online submission form.

Based on simulated trials of entering test information into GTR, it will take submitters an average of 0.5 hours per test to provide information for the minimal fields. With an average of 12.2 tests per respondent, the estimated annual hour burden for a respondent to complete the minimal fields is 6.1 hours. An estimated additional 2.5 hours per test was projected for the optional fields for an annual burden of 30.5 hours per respondent. The annual hour burden for a respondent to complete all fields is 36.6 hours.

The calculations for annual burden reflect the average time for submitters who are familiar with their tests and know where to find information about the tests. For those submitters who are not familiar with information about their tests, it may take longer than the estimated 2.5 hours to provide the optional fields information. However, submitters should become more efficient in data entry as they gain experience with GTR, and significant time savings can be achieved by laboratories with large numbers of tests who use the bulk upload feature. In addition, those test providers whose

tests are already listed in GeneTests will automatically transferred to GTR, saving have the data from GeneTests them data entry time.

TABLE 1—ESTIMATES OF HOUR BURDEN

Type of respondent	Number of respondents	Frequency of response	Estimated average time per response	Annual hour burden per respondent	Total annual hour burden
Laboratory Personnel	770	An average of 12.2 tests per respondent; submitted once.	Minimal Fields: 0.5 hr	6.1	4,697
			Optional Fields: 2.5 hr	30.5	23,485
			Total (All Fields): 3.0 hr	36.6	28,182

To estimate the annualized cost to respondents, NIH used the mean hourly wage of medical and clinical laboratory technicians from the U.S. Bureau of Labor and Statistics 2010 National Occupational Employment and Wage

Estimates.¹ Based on an average of 12.2 submissions per respondent, 3.0 hours to provide information for all data fields (i.e., minimal and optional fields) per submission, and a mean hourly wage of \$22.85, the estimated annualized cost to

respondents is \$836.30. Cost savings can be achieved by laboratories with large numbers of tests that use the bulk upload feature. Table 2 provides the estimated annualized cost per respondent and for all respondents.

TABLE 2—ESTIMATED ANNUALIZED COST TO RESPONDENTS

Type of respondent	Average number of submissions per respondent	Estimated average time (hours) per submission per respondent	Mean hourly wage	Estimated annual cost per respondent	Total annual cost (based on a total of 9,360 submissions for 770 respondents)
Laboratory Personnel	12.2	Minimal Fields: 0.5	\$22.85	\$139.38	\$106, 938
		Optional Fields: 2.5	22.85	696.92	534, 690
		All Fields: 3.0	22.85	836.30	641, 628

Request for comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this

publication. Comments should be directed to Amy Patterson, M.D. through the contact information below.

FOR FURTHER INFORMATION CONTACT: For additional information on the proposed project, please visit the GTR Web site (<http://oba.od.nih.gov/gtr/gtr.html>) or contact: Amy P. Patterson, M.D., Associate Director for Science Policy, NIH by mail to the Office of Biotechnology Activities, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892; telephone 301-496-9838; fax 301-496-9839; or e-mail gtr@od.nih.gov, Attention: Dr. Patterson.

Dated: July 21, 2011.

Amy P. Patterson,
Associate Director for Science Policy, NIH.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: National Cancer Center (NCI)

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, National Cancer Center (NCI) has submitted a Generic Information Collection Request (Generic ICR): "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" to OMB for approval under the Paperwork

¹ U.S. Bureau of Labor and Statistics. May 2010 National Occupational Employment and Wage

Estimates. See http://www.bls.gov/oes/current/oes_nat.htm#29-0000. Accessed June 8, 2011.