

Supplemental Form and agency-specific instructions is used in combination with the SF424 (R&R) forms/instructions for Fellowships and is used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The PHS 416-5 is used by individuals to indicate the start of their NRSA awards. The PHS 6031 Payback Agreement is used by individuals at the time of activation to certify agreement to fulfill the payback provisions. *Frequency of response:* Applicants may submit applications for published receipt dates. For NRSA awards, Fellowships are activated and trainees appointed. *Affected Public:* Universities and other research institutions; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* University administrators and principal investigators. The annual reporting burden is as follows: *Total Estimated Number of Respondents:* 94,326; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 21.75; *Estimated Total Annual Burden Hours Requested:* 2,051,794. The estimated annualized cost to respondents is \$71,812,769.

Request for Comments: 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.

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 sent via email to OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Seleda M.

Perryman, Chief, Project Clearance Officer, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3509, 6705 Rockledge Drive, Bethesda, MD 20892-7974; or call non-toll-free number 301-594-7949; or email your request, including your address, to perrymansm@od.nih.gov.

Comments 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.

Dated: June 25, 2012.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2012-15930 Filed 6-28-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Post-Award Reporting Requirements Including New Research Performance Progress Report Collection; Revision

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 5, 2012, page 13131 (corrected on March 26, 2012, page 17488), and allowed 60 days for public comment. One public comment was received, which asked for clarification about new reporting burdens. It was noted in follow-up that NIH has seen a 21-percent increase in competing applications since the last clearance, which has resulted in an increase in the burden hours. We are also transitioning to the Research Performance Progress Report as mandated by OMB. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection: Title: Public Health Service (PHS) Post-award Reporting Requirements. *Type of Information Collection Request:* Revision, OMB 0925-0002, Expiration Date 06/30/2012. This collection represents a consolidation of post-award reporting requirements under the Paperwork Reduction Act and includes the new Research Performance Progress Report (RPPR). It also includes continued use of the PHS Non-

competing Continuation Progress Report (PHS 2590, currently approved under 0925-0001, expiration 06/30/2012), and the NIH AHRQ Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Progress Report for Continuation Support (PHS 416-9). Only one interim progress report (RPPR or PHS2590/416-9) will be utilized for any given award until the RPPR is fully implemented for all awards. This collection also includes other PHS post-award reporting requirements: PHS 416-7 NRSA Termination Notice and PHS 6031-1 NRSA Annual Payback Activities Certification. Post-award reporting requirements previously cleared under OMB 0925-0001 now included under 0925-0002 are: PHS 2271 Statement of Appointment, HHS 568 Final Invention Statement and Certification, Final Progress Report instructions, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. Pre-award reporting requirements are simultaneously consolidated under 0925-0001.

Need and Use of Information Collection: The RPPR will replace existing interim performance reports used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR requires the maintenance of dual reporting processes for a period of time. Thus this information collection is for the new use of the RPPR, the continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), and the use of the NIH AHRQ Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Progress Report for Continuation Support (PHS 416-9). Only one interim progress report (RPPR or PHS2590/416-9) will be utilized for any given award. The PHS 416-7, 2271, and 6031-1 are used by NRSA recipients to activate, terminate, and provide for payback of an NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another.

Frequency of response: Grantees are required to report annually. *Affected Public:* Universities and other research

institutions; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* University administrators and principal investigators. The annual reporting burden is as follows: *Total Estimated Number of Respondents:* 112,986. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 5.6. *Estimated Total Annual Burden Hours Requested:* 640,677. The annualized cost to respondents is estimated to be \$22,423,709.

Request for Comments: 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.

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: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Seleda M. Perryman, Chief, Project Clearance Officer, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3509, 6705 Rockledge Drive, Bethesda, MD 20892-7974; or call non-toll-free number 301-594-7949; or email your request, including your address to: *perrymansm@od.nih.gov*.

Comments 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.

Date: June 25, 2012.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of NIH Consensus Development Conference: Diagnosing Gestational Diabetes Mellitus

SUMMARY: The National Institutes of Health (NIH) is holding a conference titled "Consensus Development Conference: Diagnosing Gestational Diabetes Mellitus." The conference will be open to the public.

DATES: The conference will be held October 29-31, 2012, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892.

FOR FURTHER INFORMATION CONTACT: Advance information about the conference and conference registration materials may be obtained from the NIH Consensus Development Program Information Center by calling 888-644-2667 or by sending an email to *Prevention@mail.nih.gov*. The Information Center's mailing address is P.O. Box 2577, Kensington, Maryland, 20891. Registration and conference information are also available on the NIH Consensus Development Program Web site at <http://prevention.nih.gov/cdp>.

SUPPLEMENTARY INFORMATION: Gestational diabetes mellitus (GDM) is a condition in which women without previously diagnosed diabetes exhibit high blood glucose levels during pregnancy (especially during the third trimester of pregnancy). It is defined as carbohydrate intolerance, which is the inability of the body to adequately process carbohydrates (sugars and starches) into energy for the body that develops or is first recognized during pregnancy. GDM is estimated to occur in 1-14 percent of U.S. pregnancies, affecting more than 200,000 women annually. It is one of the most common disorders in pregnancy and is associated with an increased risk of complications for the mother and child. Potential complications during pregnancy and delivery include preeclampsia (high blood pressure and excess protein in the urine), caesarean delivery, macrosomia (large birth weight), shoulder dystocia (when a baby's shoulders become lodged during delivery), and birth injuries. For the neonate, complications include difficulty breathing at birth,

hypoglycemia (low blood sugar), and jaundice. Up to one-half of women who have GDM during pregnancy will develop type 2 diabetes later in life.

Although the U.S. Preventive Services Task Force found in 2008 that the evidence was insufficient to assess the balance between the benefits and harms of screening women for GDM, the American College of Obstetricians and Gynecologists recommends universal screening for gestational diabetes using patient history, risk factors, or laboratory testing, such as with a glucose challenge test (GCT). Different approaches are used internationally for screening and diagnosis of GDM. The standard method in the United States begins with a GCT, which involves drinking a sweetened liquid containing 50 grams of sugar (glucose). A blood sample is taken after 1 hour, which measures the glucose level. If high, a diagnostic test is administered using a larger dose of glucose, and several blood tests are performed over 3 hours. Depending on the test used, and the chosen blood glucose levels that are used to diagnose GDM, the number of women who will receive the diagnosis will vary. Debate continues regarding the choice of tests and the effectiveness of treatment, especially in women with mild to moderate glucose intolerance. Potential harms of screening for GDM include anxiety for patients and the potentially adverse effects of a "high-risk" label in pregnancy. In addition, women diagnosed with GDM face stressors including dietary constraints, a need to add or increase exercise, frequent self-monitoring of blood glucose levels, and for some, self-administration of insulin which will require adjustments of insulin doses.

To better understand the benefits and risks of various GDM screening and diagnostic approaches, the NIH has engaged in a rigorous assessment of the available scientific evidence. This process is sponsored by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the Office of Disease Prevention. A multidisciplinary planning committee developed the following key questions:

1. What are the current screening and diagnostic approaches for gestational diabetes mellitus, what are the glycemic thresholds for each approach, and how were these thresholds chosen?
2. What are the effects of various gestational diabetes mellitus screening/diagnostic approaches for patients, providers, and U.S. health care systems?
3. In the absence of treatment, how do health outcomes of mothers who meet various criteria for gestational diabetes