ESTIMATES OF ANNUAL BURDEN

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average time per response (in Hours)	Total annual burden hour
Investigators and Designee for Investigator Registration and DARF.	Statement of Investigator	20,220	1	15/60	5,050
	Supplemental Investigator	20,112	1	10/60	3,352
	Financial Disclosure	20,800	1	5/60	1,733
	Electronic Curriculum Vitae	100	1	15/60	25
	Drug Accountability Record Form (DARF and DARF-Oral).	3,907	16	4/60	4,168
Totals					14,328

Dated: February 11, 2013.

Vivian Horovitch-Kelley,

National Cancer Institute Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2013–03571 Filed 2–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of NIH Consensus Development Conference: Diagnosing Gestational Diabetes Mellitus

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

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 on March 4–6, 2013, 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, and 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), cesarean 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 the 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 NIH 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 mellitus and their offspring compare with those who do not?

4. Does treatment modify the health outcomes of mothers who meet various criteria for gestational diabetes mellitus and their offspring?

5. What are the harms of treating gestational diabetes mellitus, and do they vary by diagnostic approach?

6. Given all of the above, what diagnostic approach(es) for gestational diabetes mellitus should be recommended, if any?

7. What are the key research gaps in the diagnostic approach for gestational diabetes mellitus?

An evidence report on GDM was prepared through the Agency for Healthcare Research and Quality's Evidence-based Practice Centers program and this Consensus Development Conference will be held on March 4–6, 2013.

During the conference, invited experts, including the authors of the evidence report, will present scientific data. Attendees will have opportunities to ask questions and provide comments during open discussion periods. After weighing the evidence, an unbiased, independent panel will prepare and present a consensus statement addressing the key questions. The statement will be widely disseminated to practitioners, policymakers, patients, researchers, the general public, and the media.

Please Note: As part of the NIH's measures to ensure the safety of employees and property, all visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the security measures at NIH, please visit the Web site at *http://www.nih.gov/about/visitorsecurity.htm*.

Dated: February 8, 2013.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2013–03574 Filed 2–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Program Project on Intestinal Transport.

Date: April 5, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 11, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–03525 Filed 2–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Service Awards for Individual Predoctoral Fellows.

Date: March 7, 2013.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Michael Micklin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Genomics, Molecular Evolution and Biochemical Genetics.

Date: March 7, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: David J. Remondini, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892, 301–435–1038, *remondid@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Grant Applications: Immunology.

Date: March 8, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Stephen M. Nigida, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4212, MSC 7812, Bethesda, MD 20892, 301–435–1222, *nigidas@csr.nih.gov*.

Name of Committee: AIDS and Related Research Integrated Review Group; HIV/AIDS Vaccines Study Section.

Date: March 8, 2013

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 033 M Street NW., Washington, DC 20036.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biological Chemistry, Biophysics and Drug Discovery.

Date: March 8, 2013.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street, NW, Washington, DC 20037.

Contact Person: Vonda K Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7892, Bethesda, MD 20892, 301–435–1789, *smithvo@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular and Surgical Devices

Date: March 8, 2013.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.