preclude the expected benefit from correction of the mitral regurgitation.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 13, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 20, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 1, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 4, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Conference Management Staff, at *James.Clark@fda.hhs.gov* or 301–796–5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03488 Filed 2–14–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; Comment Request (30-Day FRN):

Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI)

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collected below. This proposed information collection was previously published in the **Federal Register** on September 20, 2012 (77 FR 58401) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after March 1, 2011, unless it displays a valid OMB control number.

Written comments or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response times, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301–496–5725 or Email your request, including your address to: *Hallch@mail.nih.gov.*

Comments regarding this information collection are best assured of having their full effect if received within 30 days following the date of this publication.

Proposed Collection: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI), OMB No.0925–0613, Expiration Date: 2/28/2013, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI) responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials and to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug and the response of the patient to that drug. Investigators are physicians who specialize in the treatment of patients with cancer. Data obtained from the Drug Accountability Record is used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. NCI and/or its auditors use this information for compliance purposes.

OMB approval is requested for 3 years. There are no costs to the respondents other than their time. The total estimated annualized burden hours are 14,328.

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?