There are no capital, operating, or maintenance costs.

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 Dr. Rachel Sturke, Evaluation Officer, Division of Science Policy, Planning, and Evaluation, FIC, NIH, 16 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 480–6025 or email your request, including your address to: rachel.sturke@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: September 14, 2012.

Dexter Collins,
Executive Officer, FIC, National Institutes of Health.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Evidence-Based Methodology Workshop on Polycystic Ovary; Syndrome

Notice

Notice is hereby given of the National Institutes of Health (NIH) Evidence-based Methodology Workshop on Polycystic Ovary Syndrome, to be held December 3–5, 2012. The workshop’s opening session will be on December 3, from 6:30 p.m. to 9:00 p.m. at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814. The workshop will continue December 4–5 at the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892; beginning at 8:00 a.m. on December 4 and at 8:30 a.m. on December 5. The workshop will be open to the public.

Polycystic ovary syndrome (PCOS) is a common hormone disorder that affects approximately 5 million reproductive-aged women in the United States. Women with PCOS have difficulty becoming pregnant (i.e., are infertile) due to hormone imbalances that cause or result from altered development of ovarian follicles. One such imbalance is high blood levels of androgens, which can come from both the ovaries and adrenal gland. Other organ systems that are affected by PCOS include the pancreas, liver, muscle, blood vasculature, and fat.

In addition to fertility impairment, other common symptoms of PCOS include:
- Irregular or no menstrual periods (for women of reproductive age)
- Acne
- Weight gain
- Excess hair growth on the face and body
- Thinning scalp hair
- Ovarian cysts.

Women with PCOS are often resistant to the biological effects of insulin and, as a consequence, may have high insulin levels. As such, women with PCOS are at risk for type 2 diabetes, high cholesterol, and high blood pressure. Obesity also appears to worsen the condition. Costs to the U.S. health care system to identify and manage PCOS are approximately $4 billion annually; however, this estimate does not include treatment of the serious conditions associated with PCOS.

For most of the 20th century, PCOS was a poorly understood condition. In 1990, the NIH held a conference on PCOS to create both a working definition of the disorder and diagnostic criteria. The outcome of this conference, the NIH Criteria, served as a standard for researchers and clinicians for more than a decade. In 2003, a consensus
workshop in Rotterdam developed new diagnostic criteria, the Rotterdam Criteria.

The 2012 NIH Evidence-based Methodology Workshop on PCOS will seek to clarify:
- Benefits and drawbacks of using the Rotterdam Criteria
- The condition’s causes, predictors, and long-term consequences
- Optimal prevention and treatment strategies.

The NIH workshop is sponsored by the Office of Disease Prevention and the Eunice Kennedy Shriver National Institute of Child Health and Human Development. A multidisciplinary steering committee developed the workshop agenda. The NIH Library created an extensive, descriptive bibliography on PCOS to facilitate workshop discussion. During the 2½-day workshop, invited experts will discuss the body of evidence and attendees will have opportunities to provide comments during open discussion periods. After weighing the evidence, an unbiased, independent panel will prepare a report that summarizes the workshop and identifies future research priorities.

Advance information about the workshop and workshop registration materials may be obtained by calling 888–644–2667, or by sending email to prevention@mail.nih.gov. Registration and workshop information are also available on the NIH Office of Disease Prevention Web site at http://prevention.nih.gov.

Please Note: As part of the measures to ensure the safety of NIH 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 the NIH campus. For more information about the security measures at NIH, please visit the Web site at http://www.nih.gov/about/visitorsecurity.htm.


Francis S. Collins,
Director, National Institutes of Health.
[FR Doc. 2012–23965 Filed 9–27–12; 8:45 am]

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request

The Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Site Visits With Grantee Integrating HIV Primary Care, Substance Abuse, and Behavioral Health Services—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting approval to conduct in-person Site Visit Interviews with Minority AIDS Initiative—Targeted Capacity Expansion (MAI–TCE) Grantees Integrating HIV Primary Care, Substance Abuse, and Behavioral Health Services. This is a new project request targeting the collection of programmatic level data (e.g., services provision, program administration, consumer involvement, evaluation planning, organizational capacity) through one-on-one and group interviews and site assessment surveys with grantee personnel.

The goals of the MAI–TCE project are to facilitate the development and expansion of culturally competent and effective integrated behavioral health and primary care, which include HIV services and medical treatment within 11 of the 12 Metropolitan Statistical Areas (MSAs) and Metropolitan Divisions (MDs) most heavily impacted by HIV/AIDS. The program also supports the integration of behavioral health services (i.e., prevention, treatment, and substance abuse) into the CDC’s Enhanced Comprehensive HIV Prevention Plans (ECHPP). Interviews conducted with MAI–TCE grantees during site visits are an integral part of efforts to evaluate: (1) The effectiveness of program implementation across the grantee sites; (2) grantee efforts to integrate behavioral health, substance abuse and HIV care; (3) the variety of program models in use across the grantee sites; and, (4) grantee efforts to engage and successfully reach their target populations.

SAMHSA will conduct a total of two in-person site visits with each of the 11 MAI–TCE program grantees, with surveys being administered prior to each site visit.

SAMHSA will conduct interviews with grantee staff who will provide information on their program’s integration of primary care and behavioral health services. While participating in the evaluation is a condition of the grantees’ funding, participating in the interview and survey process is voluntary. Both instruments are designed to collect information about: Specific program components; HIV testing integration challenges, successes, and lessons learned; HIV care and evidence-based behavioral health services for their specific populations of focus; and engaging consumers in the Behavioral Health and Primary Care Network Committee and other aspects of the project, including how cultural competence is operationalized.

Below is the table of the estimated total burden hours:

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<thead>
<tr>
<th>EXHIBIT 1—ESTIMATE OF REPORTING BURDEN: ONE SITE VISIT ROUND</th>
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<tbody>
<tr>
<td>Data collection tool</td>
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<tr>
<td>Interview Guide</td>
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<td>Assessment Form</td>
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<td>Total</td>
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* Note: The 55 respondents identified for the self-assessment are included in the 132 overall participants listed for the site visit protocol.