two new evaluation tools will be shared with all learners who complete educational activities in TCEO, causing the annual burden estimate to increase significantly. The annual burden table has been updated to reflect the new TCEO Post-course Evaluation (66,667 burden hours) and the new TCEO Follow-up Evaluation (2,000 burden hours), for a total of 85,934 burden hours that include all four TCEO tools. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Educational Developers (Health Educators).	TCEO Proposal	120	1	5	600
Public Health and Health Care Professionals (Learners).	TCEO New Participant Registration	200,000	1	5/60	16,667
Public Health and Health Care Professionals (Learners).	TCEO Post-course Evaluation	200,000	2	10/60	66,667
Public Health and Health Care Professionals (Learners).	TCEO Follow-up Evaluation	20,000	2	3/60	2,000
Total		420,120			85,934

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–18PR]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled The World Trade Center Health Program (WTCHP): Impact Assessment and Strategic Planning for Translational Research (Part 1, Formative Research: Focus Groups) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 15, 2018 to obtain comments from the public and affected agencies. The WTCHP is administered by the CDC/National Institute for Occupational Safety and Health (NIOSH). CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

The World Trade Center Health Program: Impact Assessment and Strategic Planning for Translational Research (Part 1, Formative Research: Focus Groups)—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The World Trade Center Health Program (WTCHP) was established by the James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111–347 (hereafter referred to as ''the Zadroga Act''). Under subtitle C, the Zadroga Act requires the establishment of a research program on health conditions resulting from the 9/11 terrorist attacks. The Research to Care (RTC) model is the strategic framework employed by the WTCHP to prioritize, conduct, and assess research that informs excellence in clinical care for the population of responders and survivors affected by the 9/11 attacks in New York City. It is the focus of this assessment.

The RTC model assumes the collective involvement of different WTCHP stakeholders, including members, researchers, clinicians, and program administrators. It accounts for a variety of inputs that can affect the progress and impact of WTCHP research. These inputs include people and organizations (*e.g.,* program members, providers, clinical centers of excellence, extramural researchers, and program staff), resources (*e.g.,* technology, data centers, the NYC 9/11 Health Registry) and regulatory rules, principally the Zadroga Act. The program supports activities such as research prioritization, conduct of research, delivery of medical care, and iterative assessments of the translation of research to improvements in health care services and chronic disease

management. These activities aim to produce tangible outputs such as research findings on WTC-related conditions, healthcare protocols, peer-reviewed publications, quality assessment reports, and member and provider education products. Finally, the model anticipates short-, intermediate-, and long-term measurement of outcomes and serves as a communication tool for program planning and evaluation.

In 2016, NIOSH contracted with the RAND Corporation to conduct an independent evaluation of the WTCHP RTC model including the research investments to date and the effectiveness with which the Program translates its research to different stakeholder groups. RAND was selected given the project team's expertise with similar assessments and NIOSH's requirement for an objective analysis. This work will ultimately provide guidance for the WTCHP on strategic directions, as well as produce new knowledge about the translation of research into improved outcomes for individuals and populations exposed to disasters such as, but not limited to, the 9/11 attacks. In the formative stage of our assessment, we propose to hold a series of focus groups with different stakeholder groups to explore their perspectives on translational research in the context of the WTCHP. The focus groups will each consist of a well-defined stakeholder group, and will last approximately two hours. Focus group discussions will be held in-person or by telephone or webinar format. Depending on the timing of OMB approval, RAND anticipates conducting focus groups shortly after, most likely in the winter/early spring of 2019. If this occurs, results will be analyzed in the spring of 2019. If the timing of OMB approval coincides with one of the twice-yearly NIOSH-sponsored research meetings in NYC, RAND plans to hold in-person focus groups with the stakeholder groups in attendance (NIOSH and principal investigators, typically); the remainder of the focus groups will be held by webinar to minimize burden on the participants.

These focus groups are necessary to gather background information on the relationship between different stakeholders and the WTCHP that will complement data gathered during more detailed interviews with stakeholders in the interviews that will take place 6–12 months later. Specific topics to be addressed in the focus groups will include: Conceptualizations of research and ''translational research;'' relevance of WTCHP research topics, potential gaps, and stakeholder priorities, including responsiveness to regulatory issues; uses and usefulness of WTCHP research; barriers to conduct and use of WTCHP research; and understanding of and perspectives on the relevance and usefulness of the Research-to-Care model.

OMB approval is requested for one year. The total estimated burden in hours is 220. Participation is voluntary and there are no costs to the respondent other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Principal Investigators of WTCHP-Funded Research.	Focus Group Discussion Guide and Brief Demographic Survey.	30	1	2
Leadership from WTC Clinical Centers of Excellence and Other Stakeholders.	Focus Group Discussion Guide and Brief Demographic Survey.	20	1	2
WTC Health Registry staff	Focus Group Discussion Guide and Brief Demographic Survey.	10	1	2
Clinicians Caring for WTCHP Members	Focus Group Discussion Guide and Brief Demographic Survey.	20	1	2
WTCHP Responders and Survivors (State/local govt).	Focus Group Discussion Guide and Brief Demographic Survey.	15	1	2
WTCHP Responders and Survivors (private citizens).	Focus Group Discussion Guide and Brief Demographic Survey.	15	1	2

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4395]

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee (Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on February 12, 2019, from 8 a.m. to 6:30 p.m.

ADDRESSES: Hilton Washington, DC North/Gaithersburg; Salons A, B, C, and D; 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900; additional information available online at: *https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-north-gaithersburg-GAIGHHF/index.html.* Answers to