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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-18PR; Docket No. CDC-2018-0021]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *The World Trade Center Health Program (WTCHP): Impact Assessment and Strategic Planning for Translational Research—Focus Group Protocol*. This project includes a series of focus groups with different stakeholder groups to explore their perspectives on the decisions that each of them makes in the context of the WTCHP.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0021 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate 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. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

The World Trade Center Health Program: Impact Assessment and Strategic Planning for Translational Research (Focus Group Protocol) – New – National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111-347 (hereafter referred to as "the Zadroga Act"), established the World Trade Center Health Program (WTCHP). Under subtitle C, the Zadroga Act requires the establishment of a research program on health conditions resulting from the 9/11 terrorist attacks. Thus, the CDC seeks a one-year OMB approval to collect information using focus groups.

The WTCHP employs the Research-to-Care (RTC) model strategic framework employed to prioritize, conduct, and assess research that informs excellence in clinical care for the population of responders and survivors affected by the 9/11 attack in New York City. The RTC model assumes the collective involvement of 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 Research and Development (RAND) Corporation to evaluate the WTCHP RTC model including the research investments to date and the effectiveness with which the Program translates its research to different stakeholder groups. This work will ultimately provide guidance for the WTCHP on strategic directions, as well as produce generalizable knowledge about the translation of research into improved

outcomes for individuals and populations exposed to disasters such as 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.

These focus groups are necessary to gather background information on the relationship between different stakeholders and the WTCHP that will inform the development of more detailed interview protocols to be used with stakeholders in the next phase of this evaluation. 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.
- Uses and usefulness of WTCHP research.
- Barriers to conduct and use of WTCHP research.
- Understanding of and perspectives on the relevance and usefulness of the Research-to-Care model.

The total estimated burden hours is 360. There are no costs to the respondent other than their time and local travel to the location of the focus group.

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)
WTCH Researchers	Focus Group Protocol	40	1	3	120
WTCH Research Users	Focus Group Protocol	70	1	3	210
WTCH Funders (NIOSH)	Focus Group Protocol	10	1	3	30
Total					360

Leroy A. Richardson,

Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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