

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2016-0029]

Final Revised Vaccine Information Materials for Varicella Vaccine

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

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA), CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. On March 15, 2016, CDC published a notice in the **Federal Register** (81 FR 13794) seeking public comments on proposed updated vaccine information materials for polio vaccine and varicella vaccine. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials for varicella vaccine. Copies of the final vaccine information materials for varicella vaccine are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC-2016-0029).

DATES: Beginning no later than June 1, 2018, each health care provider who administers varicella vaccine to any child or adult in the United States shall provide copies of the relevant vaccine information materials referenced in this notice, dated February 12, 2018, in conformance with the February 23, 2018 CDC Instructions for the Use of Vaccine Information Statements prior to providing such vaccinations.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon (msj1@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road NE, Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health

Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC website at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

Revised Vaccine Information Materials

The varicella vaccine information materials referenced in this notice were

developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials covering varicella vaccine have been finalized and are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC–2016–0029). The Vaccine Information Statement (VIS) is “Varicella (Chickenpox) Vaccine: What You Need to Know,” publication date February 12, 2018.

With publication of this notice, by June 1, 2018, all health care providers must discontinue use of the previous edition and provide copies of these updated varicella vaccine information materials prior to immunization in conformance with CDC’s February 23, 2018 Instructions for the Use of Vaccine Information Statements.

Dated: March 12, 2018.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2018–0024, NIOSH–302]

Draft—National Occupational Research Agenda for Respiratory Health

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of a draft NORA Agenda entitled *National Occupational Research Agenda for Respiratory Health* for public comment. To view the notice and related materials, visit <https://www.regulations.gov> and enter CDC–2018–0024 in the search field and click “Search.”

Table of Contents

- DATES:

- ADDRESSES:
- FOR FURTHER INFORMATION CONTACT:
- SUPPLEMENTARY INFORMATION:
- BACKGROUND:

DATES: Electronic or written comments must be received by May 14, 2018.

ADDRESSES: You may submit comments, identified by CDC–2018–0024 and docket number NIOSH–302, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov> Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All submissions received in response to this notice must include the agency name and docket number [CDC–2018–0024; NIOSH–302]. All relevant comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226–1998.

FOR FURTHER INFORMATION CONTACT:

Emily Novicki *NORACoordinator@cdc.gov*, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: The National Occupational Research Agenda (NORA) is a partnership program created to stimulate innovative research and improved workplace practices. The national agenda is developed and implemented through the NORA sector and cross-sector councils. Each council develops and maintains an agenda for its sector or cross-sector.

Background: The National Occupational Research Agenda for Respiratory Health is intended to identify the research, information, and actions most urgently needed to prevent occupational injuries. The National Occupational Research Agenda for Respiratory Health provides a vehicle for stakeholders to describe the most relevant issues, gaps, and safety and health needs for the sector. Each NORA research agenda is meant to guide or promote high priority research efforts on a national level, conducted by various entities, including: Government, higher education, and the private sector.