

# Independent Peer Review

Meeting the Standards of the Scientific and Technical Community

Scientific/Technical Advisory Committee  
World Trade Center Health Program  
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John Piacentino, MD, MPH  
Associate Director for Science  
National Institute for Occupational Safety and Health

# Outline

- Independent peer review and Zadroga Act reauthorization
- Purpose and methods of peer review
- Identification of peer reviewers
- Questions

# Addition of health condition to List of WTC-Related Health Conditions

(F) Independent peer reviews

“Prior to issuing a final rule to add a health condition to the list in paragraph (3), the WTC Program Administrator shall provide for an independent peer review of the scientific and technical evidence that would be the basis for issuing such final rule.”

Public Health Service Act, Section 3312(a)(6)(F) (to be codified in 42 U.S.C. § 300mm-22(a)(6)(F))

# Identification of Peer Reviewers

(G) Additional advisory committee recommendations

(i) Program policies

(ii) Identification of individuals conducting independent peer reviews

“Not later than 1 year after December 18, 2015, and not less than every 2 years thereafter, the WTC Program Administrator shall seek recommendations from the Advisory Committee regarding the identification of individuals to conduct the independent peer reviews under subparagraph (F).”

Public Health Service Act, Section 3312(a)(6)(G)(ii) (to be codified in 42 U.S.C. § 300mm-22(a)(6)(G)(ii))

# What is peer review?

- Used to ensure that the quality of published information meets the standards of the scientific and technical community.
- A form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.
- Involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft.

Office of Management and Budget, "Final Information Quality Bulletin for Peer Review" December 2004: Available at: <https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 75.

# What do peer reviewers evaluate?

- Are you aware of any other studies which should be considered?
  - If so, please identify them.
- Have the requirements of this Policy and Procedures been fulfilled?
  - If not, please explain which elements are missing or deficient.
- Is the interpretation of the available evidence appropriate, and does it support the conclusion to add the health condition, as described in the regulatory text, to the List?
  - If not, please explain why.

The questions given to the peer reviewers may be modified by the Administrator, as necessary, for the specific health condition being considered.

Policy and Procedures for Adding Types of Cancer To the List of WTC-Related Health Conditions, Revised May 11, 2016

Policy and Procedures for Adding Non-Cancer Conditions To the List of WTC-Related Health Conditions, Revised May 11, 2016

# Selection of Peer Reviewers

Based on:

- Expertise necessary to evaluate the science relied on
- Any potential conflicts of interest
- Independence from the sponsoring agency
- Balance a diverse representation of respected scientific perspectives
- Rotation

Office of Management and Budget, “Final Information Quality Bulletin for Peer Review” December 2004: Available at: <https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

# *Expertise* – Qualifications, Knowledge and Experience<sup>1</sup>

Some examples

- Cardiology
- Gastroenterology
- Nephrology
- Neurology
- Obstetrics and Gynecology
- Occupational Medicine
- Pathology
- Pediatrics
- Psychiatry
- Pulmonology
- Rheumatology
- Urology

1. National Academy of Sciences, “Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports,” May 2003: Available at: <http://www.nationalacademies.org/coi/index.html>.



# *Conflict of Interest*

“Conflict of Interest” means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.

National Academy of Sciences, “Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports,” May 2003: Available at: <http://www.nationalacademies.org/coi/index.html>.

# Stakeholder Review and Public Comment

- Peer review is not the same as stakeholder review or public comment
- Stakeholders and members of the public may have conflict of interest or may not provide an “impartial” review
- Stakeholder and members of the public may have valuable input for rulemaking

# *Independence, Balance and Rotation*

Specialists in the field who were not involved in producing the Notice of Proposed Rulemaking (NPRM)

Independence from the sponsoring agency

Breadth and diversity within the scientific and technical community

Rotation of peer reviewers

Office of Management and Budget, “Final Information Quality Bulletin for Peer Review” December 2004: Available at: <https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

National Academy of Sciences, “Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports,” May 2003: Available at: <http://www.nationalacademies.org/coi/index.html>.

# Tips for the Identification of Peer Reviewers

- Match peer reviewer expertise to the health condition being proposed for addition
  - Review of the scientific and technical evidence for adding a health condition to the list of covered conditions
- Identify individuals with sufficient expertise, independence and freedom from conflict of interest
- Identify a balance of individuals representing a diverse set of scientific perspectives
- Describe a process for identifying peer reviewers