

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### NIH Consensus Development Conference on Inhaled Nitric Oxide Therapy for Premature Infants

##### Notice

Notice is hereby given of the National Institutes of Health (NIH) "NIH Consensus Development Conference on Inhaled Nitric Oxide Therapy for Premature Infants" to be held October 27–29, 2010, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on October 27 and 28, and at 9 a.m. on October 29, and will be open to the public.

Infants born before the 37th week of pregnancy are said to be "premature" or "preterm" and face increased risk for a variety of complications. Babies born before the 28th week of pregnancy—more than 30,000 per year in the United States—are particularly vulnerable to breathing problems such as respiratory distress syndrome and respiratory failure due to their underdeveloped lungs. These infants often need respiratory support in the first days and weeks after birth. Those premature infants who still require supplemental oxygen 36 weeks after conception are diagnosed with bronchopulmonary dysplasia, which places them at greater risk for death or problems with long-term lung health, brain development, and brain function.

Nitric oxide is a chemical compound in gas form that is sometimes used to treat infants with severe breathing problems. Inhaled nitric oxide therapy was approved by the U.S. Food and Drug Administration in 2000 to treat term and near-term infants (born after the 33rd week of pregnancy) with respiratory failure. Inhaled nitric oxide therapy is typically administered in the neonatal intensive care unit using a device that delivers the drug in constant concentrations. It acts as a pulmonary vasodilator, widening the opening of blood vessels in the lungs. In term and near-term infants, use of this therapy may shorten the length of time respiratory support is required, thereby reducing progression to bronchopulmonary dysplasia and improving long-term lung health and brain development and function.

Since its approval, researchers have examined expanding the use of inhaled nitric oxide therapy to treat premature babies born at less than 34 weeks' gestation. Studies to evaluate its safety

and efficacy for these infants have had mixed results in terms of key outcomes. Thus, the potential benefits and harms of its use for premature infants with varying degrees of respiratory illness are not completely understood.

To advance understanding of these important issues, the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Office of Medical Applications of Research of the NIH will convene a Consensus Development Conference from October 27–29, 2010. The conference will address the following key questions:

- Does inhaled nitric oxide therapy increase survival and/or reduce the occurrence or severity of bronchopulmonary dysplasia among premature infants who receive respiratory support?
- Are there short-term risks of inhaled nitric oxide therapy among premature infants who receive respiratory support?
- Are there effects of inhaled nitric oxide therapy on long-term pulmonary and/or neurodevelopmental outcomes among premature infants who receive respiratory support?
- Does the effect of inhaled nitric oxide therapy on bronchopulmonary dysplasia and/or death or neurodevelopmental impairment vary across subpopulations of premature infants?
- Does the effect of inhaled nitric oxide therapy on bronchopulmonary dysplasia and/or death or neurodevelopmental impairment vary by timing of initiation, mode of delivery, dose and duration, or concurrent therapies?
- What are the future research directions needed to better understand the risks, benefits, and alternatives to nitric oxide therapy for premature infants who receive respiratory support?

An impartial, independent panel will be charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality. The first day and a half of the conference will consist of presentations by expert researchers and practitioners and open public discussions. On Friday, October 29, the panel will present a statement of its collective assessment of the evidence to answer each of the questions above. The panel will also hold a press telebriefing to address questions from the media. The draft statement will be published online later that day, and the final version will be released approximately six weeks later. The primary sponsors of this meeting

are the NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH Office of Medical Applications of Research.

Advance information about the conference and conference registration materials may be obtained from the NIH Consensus Development Program Information Center by calling 888–644–2667 or by sending e-mail to [consensus@mail.nih.gov](mailto:consensus@mail.nih.gov). The Information Center's mailing address is P.O. Box 2577, Kensington, Maryland 20891. Registration information is also available on the NIH Consensus Development Program Web site at <http://consensus.nih.gov>.

**Please Note:** The NIH has instituted security 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 NIH buildings. For more information about the security measures at NIH, please visit the Web site at <http://www.nih.gov/about/visitorsecurity.htm>.

Dated: July 19, 2010.

**Francis S. Collins,**

*Director, National Institutes of Health.*

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form N–644, Revision of a Currently Approved Information Collection; Comment Request

**ACTION:** 30-Day notice of information collection under review: Form N–644, Application for Posthumous Citizenship; OMB Control No. 1615–0059.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. This information collection was previously published in the **Federal Register** on April 22, 2010, at 75 FR 21013, allowing for a 60-day public comment period. The 60-day notice mentioned that during the 60-day comment period USCIS would be evaluating whether to revise the Form