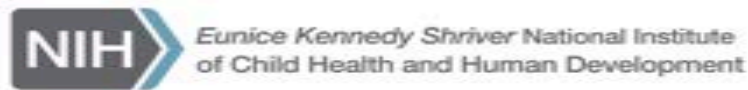


Task Force on Research Specific to Pregnant and Lactating Women

Background, Timeline, Goals and Report

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Background



21st Century Cures Act

- Passed the House on November 30, 2016, by vote of 392-26
- Passed the Senate on December 5 by a vote of 94-5
- President signed the bill on December 13



President Obama Delivers Remarks and Signs the 21st Century Cures Act



An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

Public Law 114-255

Purpose:

- Provide additional funding for the NIH and FDA, relieves administrative burdens, and increases access





SEC. 2041. TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall establish a task force, in accordance with the Federal Advisory Committee Act...

(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.



Task Force Membership

- Includes the following Federal members or the designees:
 - The Director of the Centers for Disease Control and Prevention;
 - The Director of the National Institutes of Health;
 - The Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development;
 - The Commissioner of Food and Drugs;
 - The Director of the Office on Women's Health;
 - The Director of the National Vaccine Program Office;
 - Head of any other research-related agency or department not listed:
 - The directors of such other appropriate national research institutes of the National Institutes of Health
 - The Director of the Agency for Healthcare Research and Quality
 - The Director of the Health Resources and Services Administration;
 - The Secretary, Department of Veterans Affairs;
 - The Secretary, Department of Defense;



Non-federal Organizations

- Representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;
- Nonprofit organizations with expertise related to the health of women and children;
- Relevant industry representatives; and
- Other representatives, as appropriate.



Non-federal Members

- Non-federal members will compose not more than one-half, and not less than one-third, of the total membership of the Task Force
- The Secretary will appoint all non-federal members
- All non-federal members serve as Special Government Employees



Timeline



Task Force Implementation

- January 19, 2017
 - Authority delegated from HHS Secretary to NIH Director
 - NIH Director asks NICHD to lead
 - Dr. Catherine Spong spearheading the effort
- February 2017
 - Task Force Plan submitted by NICHD
- March 13, 2017
 - Charter establishing Task Force filed (FACA Committee)
- May 2017
 - Slate of nominees prepared for Secretary's approval
 - Federal members designated



Collect the Data

- New reporting categories being developed for NIH-funded research:
 - Pregnancy
 - Breastfeeding, Lactation, and Breastmilk
- https://report.nih.gov/categorical_spending.aspx
- Federal representatives asked to submit information about their agency's activities



Upcoming Meetings

- Announced in Federal Register
- Open to the public
 - August 21-22, 2017
 - November 6-7, 2017
 - February 26-27, 2018 (tentative)
 - May 14-15, 2018 (tentative)
- Videocast and archived on the NIH videocast website
 - <https://videocast.nih.gov/default.asp>



Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC)

The screenshot shows the NIH website page for the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The page header includes the NIH logo, the name of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the tagline "Health research throughout the lifespan". There is a search bar and social media links for Facebook, Twitter, Pinterest, YouTube, and RSS. The navigation menu includes "Health & Research", "Grants & Funding", "Training & Career Development", "News & Media", and "About NICHD". The breadcrumb trail is "Home > About NICHD > Advisory Groups". The left sidebar menu includes "About NICHD", "Institute Overview", "Organization", "Budget & Appropriations", "Advisory Groups" (highlighted), "FOIA", "Jobs at NICHD", "Meetings, Conferences & Events", "Partnering & Donating to the NICHD", "Staff Directory", and "Interviews & Selected Staff Profiles". The main content area has the title "Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)" and a "Share this:" link with social media icons. The text describes the 21st Century Cures Act's establishment of PRGLAC and lists federal and non-federal members. It also lists meetings from August 2017 to May 2018 and provides more information links such as "Federal Register Notice - July 13, 2017" and "PRGLAC Charter (PDF - 73 KB)". A contact section lists Lisa Kaeser, JD, Executive Secretary, with the email address kaeserl@mail.nih.gov.

Web page created to inform the public:

<https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx>



Important Deadlines

- September 2018 – Send report to HHS Secretary and Congress
- December 2018 – Secretary required to act on Task Force recommendations
- March 2019 – Task Force will sunset after two years unless extended





Goals



Medications Used in Pregnancy and Postpartum

Purpose: “to identify and make recommendations to address gaps in knowledge and research about safe and effective therapies used during pregnancy and for lactating women”





Specific Topics Required

- Existing Federal efforts and programs to understand the health effects on pregnant and lactating women, and related birth and pediatric outcomes
- Research collaboration potential
- Ethical issues surrounding inclusion of pregnant and lactating women in clinical research
- Effective communication strategies with health care providers and the public



Report



Report to Include

- (1) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies;
- (2) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research;
- (3) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women;



Report to Include (continued)

- (4) Identification of Federal activities, including:
 - (a) The state of research on pregnancy and lactation;
 - (b) Recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;
 - (c) Dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and
 - (d) Existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities; and
- (5) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.



Strategy



Strategy for Report

TF 3	(1) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies;
TF 2	(2) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research;
TF 3	(3) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women;
TF 1	(4) Identification of Federal activities, including: <ul style="list-style-type: none">(a) The state of research on pregnancy and lactation;(b) Recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;(c) Dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and(d) Existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities; and
TF 4	(5) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.



Strategy for Task Force Meetings

- Presentations to cover specified topic
- Time for public comment at each meeting
- Recap discussions at end to outline report for that topic
- At beginning of each subsequent meeting, discuss report covering prior topic(s) – goal to have report drafted in real time to allow ample discussion and input
- Consider RFI prior to final meeting for additional input



Questions