

NIH-led task force to address research needs of pregnant women and nursing mothers

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Experts seek to identify ethical issues, improve research studies

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Stock image of pregnant women.

The [Task Force on Research Specific to Pregnant Women and Lactating Women \(PRGLAC\)](#), established by the 21st Century Cures Act, will advise the Secretary of Health and Human Services on research aimed at optimizing therapies for pregnant women and nursing mothers. Led by NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the task force will conduct its first meeting on [August 21-22, 2017](#), at NIH in Bethesda, MD.



“When clinical studies omit pregnant women and nursing mothers, health care providers are left without evidence-based research to inform care decisions,” said Catherine Y. Spong, M.D., NICHD Deputy Director. “Without this research, treatment of pregnant or nursing moms who experience common medical conditions may be not be effective or even potentially cause harm. Therapies for pregnant and lactating women ideally should have the best available evidence, given the implications for the developing fetus and newborn. The task force will address these issues and propose solutions.”

PRGLAC will review current research on pregnancy and lactation, identify ethical issues surrounding the inclusion of pregnant women and nursing mothers in clinical research, and chronicle the federal activities that focus on therapies for pregnant women and nursing mothers. The effort will include a focus on specific drugs, formulations, and other pharmacological factors that may affect health outcomes for pregnant women and nursing mothers and their children.

Currently, insufficient information exists to guide the care and treatment of pregnant women in many areas. For instance, the safety, efficacy, and dosing of medications approved for the general population may not apply to pregnant or nursing women. There are safety considerations for the developing fetus or newborn, and pregnancy can change how drugs are metabolized and cleared, altering the dose needed to treat a condition. Pregnancy-related conditions also can affect the health of a mother or newborn long after delivery. Furthermore, research is needed to develop new drugs to treat pregnancy-related conditions, including basic science research to identify new drug targets.

Ultimately, the task force will provide recommendations to the HHS Secretary on how to improve the development of safe and effective therapies for pregnant women and nursing mothers, as well as guidance on how to best collaborate and coordinate these activities at the federal level. PRGLAC will also plan ways to effectively communicate research findings and other pertinent information to health care providers and the public.

Federal members of PRGLAC include the Directors (or their designees) of NIH, NICHD, the Centers for Disease Control and Prevention, the Office on Women's Health, the National Vaccine Program Office, the Agency for Healthcare Research and Quality, and the Health Resources and Services Administration, as well as the Commissioner of the Food and Drug Administration and the Secretaries of the Department of Veteran Affairs and the Department of Defense.

Non-federal members will include representatives from medical societies, non-profit organizations, and companies that focus on the health of pregnant women, nursing mothers, or children.

Meeting Information:

Task Force meetings are open to the public and are announced in the *Federal Register*. The first meeting will be held on August 21-22, 2017.

Information is available at the PRGLAC website, <https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx>.

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About the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD): NICHD conducts and supports research in the United States and throughout the world on fetal, infant and child development; maternal, child and family health; reproductive biology and population issues; and medical rehabilitation. For more information, visit [NICHD's website](#).

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