

# U.S. Department of Health and Human Services

## Task Force on Research Specific to Pregnant and Lactating Women

### Agency Activities: National Institutes of Health (NIH)

#### Research

NIH is the largest biomedical research agency in the world. Through its institutes and centers (ICs), as well as the NIH Office of the Director, the NIH supports extramural, intramural, and interagency research related to pregnant and lactating women. These studies range from investigations into the fundamental processes that drive biological changes during pregnancy to the development and testing of new interventions in pregnant and lactating women. NIH's studies specifically related to pregnant and lactating women cover a range of conditions, both those associated with pregnancy itself and chronic conditions that many pregnant women experience before and during pregnancy and lactation.

NIH reports on its research to the public by scientific category, using a standardized process that combines scientific expertise with sophisticated automated systems. In 2017, NIH developed and implemented two new scientific categories – (1) Pregnancy and (2) Breastfeeding, Lactation, and Breast Milk – to enable the agency to analyze and track research in these areas. As of August 2017, although FY 2017 is not yet complete, preliminary analysis were generated to inform the initial Task Force discussions.

#### ***Pregnancy***

For pregnancy, the preliminary review of NIH grants indicates that:

- A total of 21 of NIH's 27 ICs support at least one grant or project related to pregnancy. (A list of NIH ICs is included in Appendix I.)
- The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports the largest share of NIH grants on pregnancy. Other ICs with significant research investments include the National Heart, Lung, and Blood Institute (NHLBI), National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), the National Institute of Environmental Health Sciences (NIEHS), and the National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK).
- The largest share of these grants are funded using the R01 type of research grant mechanism.
- The majority of NIH's pregnancy research grants – 87 percent – are directly applicable to the Task Force mission. The remaining grants are related to pregnancy but are not applicable to therapies for pregnant and lactating women. For example, NIH supports some research on the impact of short pregnancy intervals on maternal and child health.

Examples of NIH research grants related to pregnancy include:

- The [Obstetric-Fetal Pharmacology Research Unit Network](#) is designed specifically to improve the safety and effective use of therapeutic drugs in women during pregnancy and lactation. The network provides the expert infrastructure needed to test therapeutic drugs during pregnancy, and conducts and promotes cooperative multidisciplinary research to enhance the understanding of obstetric pharmacokinetics and pharmacodynamics. This program allows

researchers to conduct safe, technically sophisticated, and complex studies that will help clinicians protect women's health, improve birth outcomes, and reduce infant mortality.

- The [Maternal Fetal Medicine Unit Network](#) responds to the need for well-designed clinical trials in maternal- fetal medicine and obstetrics, particularly with respect to the continuing problem of preterm birth. The aims of the network are to reduce maternal, fetal, and infant morbidity related to preterm birth, fetal growth abnormalities, and maternal complications, and to provide the rationale for evidence-based, cost-effective obstetric practice.
- The Chronic Hypertension and Pregnancy (CHAP) project is a large pragmatic multi-center randomized clinical trial designed to evaluate the comparative effectiveness and safety of pharmacologic treatment of mild chronic hypertension in pregnancy.
- Researchers are assessing how pregnancy-related hormones and/or growth factors affect specific enzymes and placental drug transporters during pregnancy.
- An early career scientist is evaluating how in utero malaria exposure affects immune tolerance in the offspring.
- Researchers are exploring how maternal arsenic exposure and micronutrient deficiencies alter maternal and newborn influenza antibody function, respiratory morbidity, and systemic immune function following maternal influenza vaccination.
- An early career scientist is currently assessing the impact of pharmacogenomics on the pharmacokinetics and pharmacodynamics of risperidone in pregnant women. Risperidone is a second generation antipsychotic drug used to treat bipolar disorder and schizophrenia.

### ***Breastfeeding, Lactation, and Breast Milk***

For breastfeeding, the preliminary review of NIH grants indicates that:

- A total of 19 of NIH's 27 ICs support at least one grant related to breastfeeding.
- The NICHD, NIAID, and NIDDK support the greatest shares of NIH grants on breastfeeding and lactation.
- The largest share of these grants are funded using the R01 type of research grant mechanism.
- The majority of NIH's breastfeeding research grants – 56 percent – are directly applicable to the Task Force mission. The remaining grants are related to breastfeeding but are not applicable to therapies for pregnant and lactating women. For example, NIH supports some research on the most effective ways to promote breastfeeding in general, particularly in disadvantaged communities.

Examples of NIH research grants related to breastfeeding include:

- Because infants less than six months of age rely on maternal antibodies for protection against influenza, it is important to know the types of maternal influenza vaccines that best protect infants. Scientists aim to compare maternal response to the intranasal live-attenuated influenza vaccine and the systemic inactivated influenza vaccine, and to evaluate levels of influenza specific antibodies and cellular immunity in breast milk and blood.
- To avert a decrease in long-term bone mineral density in breastfeeding women who suffer from perinatal depression, researchers are studying the effect of serotonin reuptake inhibitors (SSRIs) on maternal bone health.
- Since little information is known about the specific molecular mechanisms responsible for the development of necrotizing enterocolitis (NEC), a neonatologist is examining the relationship between breast milk and NEC pathogenesis, including characterizing the effects of breast milk on intestinal epithelial cell proliferation and mucosal healing.

- To help prevent new pediatric HIV-1 infections, researchers are testing a passive-active immunization strategy to protect newborns through maternal immunization. The scientists hope that passive antibody transfer in breast milk and in utero will help protect infants once maternal antibodies decline.

## Clinical Practice Information and Recommendations

NIH does not directly support clinical care, but the agency works with professional societies, federal agencies, and other stakeholders to help ensure that the scientific evidence produced by NIH research is effectively translated into clinical practice. For example, many of the clinical practice guidelines of the American Congress of Obstetricians and Gynecologists are rooted in NIH-funded studies ( <https://www.acog.org/About-ACOG/ACOG-Departments/Deliveries-Before-39-Weeks/ACOG-Clinical-Guidelines> ).

NIH works with the Agency for Healthcare Research and Quality to inform the U.S. Preventive Services Task Force (USPSTF), an independent, volunteer panel of national experts in prevention and evidence-based medicine ( <https://www.uspreventiveservicestaskforce.org/Page/Name/home> ). The Task Force works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. A total of 18 USPSTF recommendations are directly related to pregnancy and/or lactation, and 26 recommendations include a component related to pregnancy and/or lactation.

## Communications

NIH supports several public health campaigns related to pregnant and lactating women. The Mom's Mental Health Matters campaign, spearheaded by the National Child and Maternal Health Education Program (NCMHEP), focuses on depression and anxiety around pregnancy. Other NCMHEP efforts have focused on preventing preterm birth, especially elective deliveries before 39 weeks of gestation. The long-standing Safe to Sleep campaign was designed to educate parents and caregivers about ways to reduce the risk of Sudden Infant Death Syndrome and other sleep-related causes of infant death, such as suffocation. The Safe to Sleep campaign recognizes the importance of breastfeeding and has worked with breastfeeding advocacy groups.

Many NIH ICs provide resources to the public on pregnancy and treatment of pre-existing conditions. For example, NIDDK include information on its web site about pregnancy for women who have diabetes, thyroid disease, or kidney disease. The National Cancer Institute provides detailed information for women undergoing breast cancer treatment during pregnancy. The National Heart, Lung, and Blood Institute provides information on high blood pressure in pregnancy. The NIH's National Library of Medicine (NLM), through its Medline Plus resource, provides both general information on pregnancy and more detailed information on specific conditions in pregnancy.

NLM also supports the LactMed® database, an important resource for lactating women and their health care providers. The LactMed® database contains information on drugs and other chemicals to which breastfeeding mothers may be exposed. It includes information on the levels of such substances in breast milk and infant blood, and the possible adverse effects in the nursing infant. Suggested therapeutic alternatives to those drugs are provided, where appropriate. All data are derived from the scientific literature and fully referenced ( <https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm> ).

## Other Collaborative Efforts

In addition to efforts noted above, NIH participates in the Federal Interagency Forum on Child and Family Statistics, an interagency group designed to improve both the quality and use of data on children and families by investigating questions of data quality, data measurement, and data integration and by coordinating the development and use of statistical databases among federal agencies (<http://childstats.gov> }. NIH participates in the Center for Disease Control and Prevention (CDC)'s Treating For Two initiative, which is working to expand and accelerate research to fill knowledge gaps; evaluate available evidence; and deliver up to date information to support decision making among prescribers, pharmacists and consumers (<https://www.cdc.gov/pregnancy/meds/treatingfortwo/index.html>). NIH also partners on Text4baby, a text messaging application free to pregnant women and women with infants to inform them of a variety of pregnancy- and lactation-related health issues ([www.text4baby.org](http://www.text4baby.org)).

NIH has supported a variety of inter-agency scientific collaborations, and has received support from other agencies interested in using NIH-funded infrastructure for pregnancy-related research. Several NIH ICs recently worked with the US Food and Drug Administration (FDA) and other agencies to bring experts together and develop a research agenda on Opioid Use in Pregnancy, Neonatal Abstinence Syndrome, and Childhood Outcomes. Other examples include the Antiretroviral Pregnancy Registry, a collaborative effort of NIH, CDC, FDA, and Health Resources and Services Administration (HRSA), and the Zika Experimental Science Team (ZEST) data portal, an electronic collaboration tool for Zika researchers supported by NIH, FDA, and HRSA.

**Appendix: NIH Institutes and Centers Supporting Pregnancy- and Lactation-Related Research Grants and Projects**

<b>Acronym</b>	<b>Organization</b>	<b>Pregnancy</b>	<b>Lactation</b>
FIC	Fogarty International Center	X	X
NCATS	National Center for Advancing Translational Sciences	X	
NCCIH	National Center for Complementary and Integrative Health	X	X
NCI	National Cancer Institute	X	X
NEI	National Eye Institute	X	X
NHLBI	National Heart, Lung, and Blood Institute	X	X
NHGRI	National Human Genome Research Institute	X	X
NIA	National Institute on Aging		X
NIAAA	National Institute on Alcohol Abuse and Alcoholism	X	X
NIAID	National Institute of Allergy and Infectious Diseases	X	X
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	X	X
NIBIB	National Institute of Biomedical Imaging and Bioengineering	X	
NICHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development	X	X
NIDA	National Institute on Drug Abuse	X	X
NIDCD	National Institute on Deafness and Other Communication Disorders		
NIDCR	National Institute of Dental and Craniofacial Research	X	X
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	X	X
NIEHS	National Institute of Environmental Health Sciences	X	X
NIGMS	National Institute of General Medical Sciences	X	X
NIMH	National Institute of Mental Health	X	X
NIMHD	National Institute on Minority Health and Health Disparities	X	X
NINDS	National Institute of Neurological Disorders and Stroke	X	
NINR	National Institute of Nursing Research	X	X
NLM	National Library of Medicine		
OD	Office of the Director, National Institutes of Health	X	X