



July 21, 2020

Ms. Adrienne Griffen
Executive Director
Maternal Mental Health Leadership Alliance
3068 North Quincy Street
Arlington, Virginia 22207

Dear Ms. Griffen:

Thank you for your letter on behalf of the Maternal Mental Health Leadership Alliance regarding the National Institutes of Health (NIH) research program on coronavirus disease 2019 (COVID-19) and the inclusion of pregnant and lactating women, women of color, and women who live in poverty in clinical research related to COVID-19 therapeutics and vaccines. I appreciate your attention to these important populations and am pleased to respond to your letter.

The COVID-19 pandemic has brought into sharper focus the continuing challenges associated with health disparities in the United States and has reinforced the guiding principle that the knowledge gained from NIH research must benefit all people at risk for infection by SARS-CoV-2, the novel coronavirus that causes COVID-19. NIH agrees it is important to include pregnant and lactating women in clinical trials, and has a longstanding commitment to eliminating health disparities and ensuring that women and individuals from racial and ethnic minority groups are included in clinical research studies.

NIH is engaging in several efforts to ensure inclusion of women and minorities in COVID-19 research. One of the most notable is the [RADx Underserved Populations \(RADx-UP\)](#)¹ initiative, which leverages existing community partnerships to build community-engaged implementation projects focused on understanding the factors associated with testing for COVID-19 so that disparities in morbidity and mortality are better understood. This initiative aims to lay the foundation to reduce disparities for those underserved and vulnerable populations who are disproportionately affected by, have the highest infection rates of, and/or are most at risk for complications or poor outcomes associated with the COVID-19 pandemic. These populations include pregnant women, people in rural areas, underserved urban areas, nursing homes, jails and prisons, and the homeless.

As you know, we currently lack sufficient information about the effects of infection by SARS-CoV-2 on maternal and neonatal outcomes, including information relating to perinatal transmission of the virus *in utero*, disease diagnosis and management in newborns, and the long-term impact of infection. To help address these gaps in knowledge, the *Eunice Kennedy Shriver* National Institute on Child Health and Human Development (NICHD) has launched a multipronged study using existing networks and partnerships to understand the effects of the COVID-19 pandemic during and after pregnancy. Researchers in the Maternal-Fetal Medicine

¹ <https://www.nih.gov/research-training/medical-research-initiatives/radx>

Units (MFMU) Network, a group of 12 U.S. clinical centers, will analyze the medical records of up to 21,000 women to evaluate whether changes to healthcare delivery that were implemented as a result of the pandemic have led to higher rates of pregnancy-related complications and cesarean delivery. MFMU Network sites cover more than 160,000 deliveries a year, and their racial, ethnic, and geographic diversity allows researchers to generalize their study findings to the U.S. population. They will also seek to establish the risk of pregnant women with SARS-CoV-2 infection transmitting the virus to their fetus. Newborns will be monitored and assessed until they are discharged from the hospital. In addition, the study will track more than 1,500 pregnant women confirmed with SARS-CoV-2 infection, monitoring their health for six weeks after childbirth. MFMU Network investigators plan to contribute data collected from the current study to a larger registry to help inform future studies of how SARS-CoV-2 affects maternal health and pregnancy.

The National Heart, Lung, and Blood Institute (NHLBI) is starting a large observational study, for which pregnant women are eligible, that will be one of the most diverse and in-depth clinical characterizations of hospitalized COVID-19 patients across several dimensions, including age, sex/gender, race/ethnicity, and geography. In addition, the National Institute on Drug Abuse (NIDA) at NIH is supplementing HEALthy Brain and Child Development awards to explore the impact of the COVID-19 pandemic on pregnant and post-partum women and outcomes for their children, including infection as well as psychosocial and environmental contexts that may shape the trajectory of neurodevelopment. NIDA and NICHD also co-chair a subgroup of the NIH Pediatric Research Consortium focused on the impact of the COVID-19 pandemic on pregnant/lactating women and children. This subgroup is coordinating activities to ensure that these populations are included in COVID-19 research activities across NIH and to identify gaps and synergies in ongoing research to inform efforts to improve the short- and long-term outcomes for pregnant women and children.

The National Institute of Allergy and Infectious Diseases (NIAID), the lead Institute within NIH responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID-19, is conducting a serosurvey to test those without known exposure or illness for the presence of antibodies against the SARS-CoV-2 virus in the blood that indicate a prior infection. Consistent with its aims regarding all COVID-19 clinical research, NIH is undertaking efforts to ensure demographic and geographic diversity among participants in this study. The study allows pregnant and lactating women to participate, and it seeks to identify individuals with antibodies to the virus, as well as to explore cross-reactive immunity and other markers of immunity. NIAID is supporting longitudinal studies of pregnant and lactating women infected by SARS-CoV-2 and their infants to assess the contribution of the different clinical, immunologic, and virologic factors to disease severity, and to determine factors associated with transmission, clinical recovery, development of protective antibody responses, and their impact on the infants' immune system. NIH also is planning to track pregnant and lactating women through natural history studies. One example includes an NIAID-supported study examining the epidemiology of COVID-19 and severity in pregnant women, new mothers, infants, and children that will collect key specimens for investigating COVID-19 immunity and immune-mediated pathogenesis in these populations.

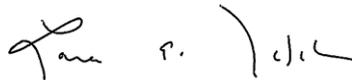
NIAID has also been working closely with the developers of SARS-CoV-2 candidate vaccines and therapeutics to explore opportunities for the inclusion of pregnant and lactating women in clinical trials. For example, NIAID and NICHD, through their co-funded clinical research

network, are planning a clinical trial to test the safety and pharmacokinetics of remdesivir in pregnant women with COVID-19 given that the effects of remdesivir on the fetus, breastfeeding infants, and pregnant women are not fully known. In addition, NIH is actively investigating the feasibility of including pregnant and lactating women when studying the repurposing of FDA-approved drugs for COVID-19.

Led by NICHD, the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), which also includes NIAID, NHLBI, the Office of Research on Women's Health ORWH, and other NIH Institutes and Centers, are actively discussing how best to include pregnant and lactating women in clinical research. These NIH Institutes will continue to engage with the PRGLAC Task Force as NIH accelerates its research response to COVID-19.

Increasing diversity in clinical trials is essential to improving the likelihood that research discoveries related to preventive measures and therapeutics in response to the COVID-19 emergency will be applicable to all relevant populations, including pregnant and lactating women, and women of color. We are grateful for your coalition's efforts to expand knowledge and create avenues that will help us ensure that all populations are included in our research to develop therapeutics and preventive measures to combat COVID-19.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence A. Tabak". The signature is fluid and cursive, with the first name being the most prominent.

Lawrence A. Tabak, D.D.S, Ph.D.
Principal Deputy Director