

January 4, 2023

SUMMARY EXPLANATION OF RESEARCH

Penn State College of Medicine and Penn State Health

Title of Project: Pennsylvania - Maternal and Infant Health Outcomes in a Pandemic

Principal Investigator: Kristin K. Sznajder, MPH, PhD, Assistant Professor, Department of Public Health Sciences, College of Medicine, Penn State University

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Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. 717-531-4482.

You are being invited to volunteer to participate in a research study. Research studies include only people who voluntarily choose to take part. This summary explains key information about this research. You are urged to ask questions about anything that is unclear to you. The purpose of this research is to examine the direct and indirect effects of the pandemic on pregnant women and their infants.

We will ask you to complete a baseline survey during pregnancy and monthly check-ins (one to three questions) during pregnancy. You will also receive a survey at one month postpartum, a survey at six months postpartum, and a final survey at 12 months postpartum. In the survey, we will ask you questions about your pregnancy, access to health care, other illnesses you may have, your mental health, your experience with the COVID-19 pandemic, symptoms you may experience during pregnancy, and about your child's health and behavior.

Surveys will take approximately 30-60 minutes of your time. You will receive a \$25 gift card after the completion of the baseline survey, a \$30 gift card after the completion of the one-month postpartum survey, a \$40 gift card after the completion of the six-month postpartum survey, and a \$55 gift card after the completion of the 12-month survey.

In the event that your current pregnancy ends in miscarriage, stillbirth, or early death of your child, we will kindly refrain from contacting you further about this study. In the event we lose contact with you or you have missing information in your survey, we will attempt to connect with you via phone, text message, portal message, mail, or email.

We will link your survey with the medical records of you and your child (or children if having a multiple birth) for research purposes including data up to 10 years before your pregnancy, during your pregnancy, and until 5 years postpartum. The medical record data includes information such as you and your child(ren)'s health problems and the times you and your child(ren) visited the doctor. The information being collected may include: HIV/AIDS, drug/alcohol treatment and mental health data. These data will not be shared outside the research team and will help us include important clinical information which will improve the research findings and enable a greater understanding of maternal and child health.

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Your permission for the use of your identifiable health information will continue indefinitely. You have the right to withdraw your permission for us to use your health information for this research. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the top of this form.

There is a possible risk for loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

While you may not directly benefit from taking part in this research study, results of the study may benefit other people in the future by helping us learn more about the impact of the pandemic on maternal and child outcomes.

We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information we will remove any information that shows your identity.

Some of the questions on the survey will be about your feelings, such as depression, sadness and anxiety. If you are in a crisis, please call the National Suicide Prevention Lifeline at 1 800 273 8255 or go to the Emergency Room. If you would like to be contacted by a social worker from your prenatal care office, you will have the opportunity to request this during the survey.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be included.

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have been harmed from participating in this research, you should contact Dr. Kristin Sznajder at (717) 531-4482. If you have questions regarding your rights as a research subject or concerns regarding your privacy, you may contact the research protection advocate in the HMC Human Subjects Protection Office at (717) 531-5687. You may call this number to discuss any problems, concerns or questions; get information or offer input.

You do not have to participate in this research. Taking part in the research study is voluntary. Your decision to participate or to decline participation in this research study will not result in any penalty or loss of benefits to which you are entitled.

This study has been funded by the research study sponsor, the Commonwealth of Pennsylvania, Department of Health. The Penn State University Institutional Review Board, the Human Subjects Protection Office and the Research Quality Assurance Office at Penn State University, the sponsor, and Office for Human Research Protections in the Pennsylvania Department of Health may need to read your medical and research records if they need to review this study as part of their reporting requirements.

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Your completion of the questionnaire implies your voluntary consent to participate in the research and to allow your information to be used and shared as described above.