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The Ohio State University Combined Parental Permission and HIPAA Authorization for Child's Participation in Research

Study Title: Healthy Lifestyle Prenatal Care Study - OSU

Principal Investigator: Bernadette Melnyk, PhD, RN, CRNP, FAANP, FAAN

Sponsor: National Institutes of Health

- **You are being asked to be a participant in a research study**. You were chosen because you are a pregnant Hispanic or Black woman between 18 and 40 years old and are less than 19 weeks pregnant. This consent form contains important information about this study and what to expect if you decide to take part. You should ask the study staff all the questions you have before deciding whether or not to take part. Please read this information carefully and feel free to discuss it with your relatives.
- **This is a parental permission form for research participation.** It contains important information about this study and what to expect if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate.
- **Your child's participation is voluntary.** You or your child may refuse participation in this study. If you and your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect you and your child's future relationship with The Ohio State University. If you are an employee at Ohio State, your decision will not affect your grades or employment status.
- **Your child may or may not benefit as a result of participating in this study.** Also, as explained below, your child's participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.
- **You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider permitting your child to participate in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this study is to evaluate the effect of two different programs: COPE-P and PregnancyPlus. We want to learn how these two programs might change the healthy lifestyle behaviors, psychosocial/mental health, and birth and post-natal outcomes in pregnant minority women with anxiety, stress, or depressive symptoms.

It will:

- Look at changes in lifestyle behaviors, overall health and outcome of the delivery.
- Look for trends in order to help improve coping, depression and anxiety.
- Compare the results of the COPE-P with the PregnancyPlus program.

Dr. Bernadette Melnyk, the person responsible for the conduct of the study, has a personal financial interest in the Creating Opportunities for Personal Empowerment (COPE) program used in this research. As a result, Dr. Melynk could financially benefit from the testing and sale of the program. The Ohio State University Institutional Review Board and the University's Conflict of Interest Advisory Committee have reviewed the financial interest and determined that it poses no significant additional risk to the safety of participants in the study or to the integrity of the research. Any questions about this financial relationship can be answered by Dr. Kate Gawlik (440-821-2537) who has no personal financial interest in the COPE program.

2. How many people will take part in this study?

The study will have 2 groups, COPE-P and PregnancyPlus. Four groups will run in each 18 week segment. Each group will have at least 3 women. A total of 250 Black or Hispanic women will be enrolled through OSU Total Health and Wellness Clinic and The Ohio State University Wexner Medical Center OB/GYN Clinic and a total of 250 Black or Hispanic women will be enrolled through Jacobi Medical Center in New York.

3. What will happen if my child takes part in this study?

If you sign this consent form, you will then be asked to complete the following three surveys:

- The General Anxiety Scale (GAD-7)
- Perceived Stress Scale (PSS)
- Edinburgh Postnatal Depression Scale (EPDS)

Please answer them to the best of your ability. Once you are done, they will be scored to see if you are able to continue in this study. Depending on your scores, the study staff may have to let your doctor know your scores.

- If your GAD-7 score is less than 10, PSS score is less than 20, and the IIEPDS is less than or equal to 10, you will not be able to continue with the rest of the study procedures.

- If your score is 10 or higher on the GAD-7, 20 or higher on the PSS questionnaire, or higher than 10 on the EPDS, you will continue with the rest of the study procedures.

You will be told if you are not able to continue based on your scores and paid for your time. If you are able to continue, you will be asked to fill out more forms. You will also have your weight measured on a scale in the clinic. You will be given a Fitbit Flex 2 pedometer and directions on how to start using it right away. You should wear it every day to monitor your activity level. You will be assigned to the next available group based on how many weeks pregnant you are. Groups will be randomly chosen as either COPE-P or PregnancyPlus ahead of time. You will be given an appointment for your first group prenatal care session.

If you are eligible to continue with the study, you will complete the following forms today:

- A demographic and personal information form to provide basic information about you (such as where you live)
- A 24 hour diet recall (list of foods eaten in the last 24 hours).
- Healthy Lifestyle Beliefs Scale
- Healthy Lifestyle Behaviors Scale

Group prenatal care sessions will be conducted by advanced practice registered nurses. At each in person session, standard prenatal care will be provided (weight, BP, urine test, etc.). In addition to standard care, the intervention group will also receive the COPE-P intervention. The intervention will involve completing a study manual Goal Setting and Self-Monitoring Logs and these completed logs will be copied and their data analyzed at the conclusion of the group sessions. The PregnancyPlus group will not receive the COPE program, but will receive standard care prenatal care and discuss a topic related to pregnancy. At the end of the 6 group sessions, women in both groups will return to receiving one on one standard prenatal care.

In the interest of patient safety, some groups will be conducted virtually during the COVID-19 pandemic. Your prenatal care will be provided in-person or by telehealth through your prenatal clinic, per the recommendation of your provider. You will be scheduled for a separate virtual session, through Zoom or a similar platform, to complete the group sessions.

The COPE program is a cognitive behavioral therapy (CBT) based skills building program for pregnant Hispanic and Black women. It includes teaching women techniques to learn positive coping skills. Goals of the COPE program include setting goals, teaching problem solving, and dealing with emotions in healthy ways. This means it is made to help pregnant women understand how their thoughts and feelings might affect their behaviors. Hispanic and Black women have a higher chance for poor birth outcomes than women of other ethnic groups.

In the PregnancyPlus program, women will discuss a pamphlet (designed for patient education by The American College of Obstetricians and Gynecologists) each week for six weeks. These pamphlets will cover healthy choices during pregnancy.

You may be contacted by email, mail, or phone using the information you give the study staff. You may also be contacted in person in clinic. Study staff members, doctors, midwives, and nurses who are part of you and your child's care team may contact you.

Study staff members may also contact you and your child's medical team, like doctors, midwives, and nurses who are taking care of you and your child. Study staff members are required to report risky behaviors (thoughts of suicide, drugs, alcohol, or abuse) in pregnant women to their supervisors. Your doctor may talk to you about them and provide, or refer you to, help when needed. If a woman answers item 10 (self-harm) with a 1, 2, or 3 she will be referred to a mental health provider for immediate care. Women with high depressive scores will be referred to their primary care provider and we will monitor to assure follow up.

Throughout the study, you will receive text or email reminders about study visits. You will have the opportunity to select which of these you would prefer to receive. Reminders may be sent through an automated system called "Remind" or another platform.

4. How long will my child be in the study?

If you choose to consent and screen as eligible, your first study timepoint will be today. There are 4 timepoints in total. The group prenatal care sessions start around week 16 of your pregnancy and lasts 18 weeks ending around week 30 of your pregnancy. There are 6 group sessions, 3 weeks apart. They will last about 1.5 hours. At the last group session, you will be asked to complete the study surveys again. Your next timepoint will be at your postpartum visit and your last timepoint at you and your child's 6 month check-up. Study timepoints may also be conducted virtually.

Timepoint 0 (T0)	Enrollment
Timepoint 1 (T1)	Last group prenatal care session
Timepoint 2 (T2)	Postpartum check-up
Timepoint 3 (T3)	6-month well-baby check-up

5. Can my child stop being in the study?

Your child may leave the study at any time. If you and your child decide to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect you and your child's future relationship with The Ohio State University.

6. What risks, side effects or discomforts can my child expect from being in the study?

There are minimal risks for you or your child connected with the study, although some risks may be unknown at this time. There is a risk that you may become upset by the questions on the surveys. If this occurs the study staff will notify your doctor for follow up.

7. What benefits can my child expect from being in the study?

There is no guarantee that you and your child will benefit as a result of you and your child's participation in this study. If you have certain emotional problems during your pregnancy, these conditions may improve, stay the same or get worse. However, your feedback may provide knowledge and information about the COPE intervention that may help minority women in the future cope with pregnancy.

8. What other choices does my child have if he/she does not take part in the study?

You and your child may choose not to participate without penalty or loss of benefits to which you and your child are otherwise entitled.

9. What are the costs of taking part in this study?

You are not expected to have costs from being in this study. You and/or your medical insurance will be responsible, in the usual way, for the costs of your pregnancy and you and your child's standard care that you would have even if you were not in this study. If you choose to receive text reminders, you are responsible for any fees charged by your mobile provider.

10. Will I or my child be paid for taking part in this study?

If you and your child consent to participate but are not able to continue with the study because of your screening scores, you will receive a $10 gift card for your time. If you are able to continue with the study, you will receive a $30 gift card when you complete your baseline T0, including screening tools and surveys. At the end of your 6 group sessions, you will receive another $30 gift card for completing the study visit (T1), including another set of surveys, a weight measurement, and the collection of your Fitbit data. You will receive a $40 gift card after you have completed the study surveys at your postpartum visit (T2), and a $50 gift card after you have completed the study surveys (T3) 6 months after your baby is born for the final visit. Additionally, you will be able to keep the Fitbit as an incentive for participating in this study. You will need to sign a receipt to confirm the money you received. For study visits completed virtually, you may receive your gift card by mail or by email. If you and your child leave the study early, you will be reimbursed only for each visit you complete.

By law, payments to subjects are considered taxable income.

11. What happens if my child is injured because he/she took part in this study?

Because this study involves only collecting information and requires no specific procedures, tests, or treatments, no research-related injuries are expected.

If you or your child suffers an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if your child should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my child's rights if he/she takes part in this study?

If you and your child choose to participate in the study, you and your child may discontinue participation at any time without penalty or loss of benefits. By signing this form, you and your child do not give up any personal legal rights you and your child may have as a participant in this study.

You and your child will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You or your child may refuse to participate in this study without penalty or loss of benefits to which you and your child are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

13. Will my child's study-related information be kept confidential?

Efforts will be made to keep you and your child's study-related information confidential and you and your child's name will not be used in any written or verbal reports. You and your child's research records and medical records may be inspected by members of the research team, the sponsor, and other institutions that participate in this study. Support for

this study is provided by Boston College Connell School of Nursing. The researcher and research staff will review you and your child's medical records and will keep the information private. The research records will be kept in a secured manner and computer records will be password protected. The people who reviewed this research study as members of the Biomedical Research Alliance of New York Institutional Review Board, Jacobi Medical Center, and NYC Health and Hospitals Corporations (HHC) may also review you and your child's research study records. All of these groups have been requested to keep your name private.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Efforts will be made to keep you and your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding you and your child's participation in this study may be disclosed if required by state law.

To help us protect you and your child's privacy, the National Institutes of Health has issued a Certificate of Confidentiality for this study. This Certificate will be used to resist attempts to force us to disclose information that may identify you and your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The Certificate cannot be used to resist a demand for information that is used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your participation in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will release the information even though we have the Certificate of Confidentiality.

The Certificate of Confidentiality also does not prevent us from disclosing voluntarily, without your consent, information that would identify you and your child as a participant

in the research if required by state and/or federal law. In Ohio, if we have reasonable knowledge that a felony has been or is being committed we are required to notify state officials. If we learn of possible child abuse or elder abuse, we are required to report this to state officials. If we believe that you may harm yourself or others, we will obtain help to make sure you and/or others are safe.

We will work to make sure that no one sees your Fitbit data without approval. But, because we are using the Internet, there is a chance that someone could access your Fitbit data without permission. In some cases, this information could be used to identify you.

The Certificate does not protect study information that is placed into you and your child's medical records.
Also, you and your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you and your child. At most, the website will include a summary of the results. You can search the website at any time.

Study text messages may be sent through Remind, a service that was designed for use in schools. It has been certified by iKeepSafe, an organization that makes sure that companies meet federal regulations to protect student information. Text message platforms will not have access to any of your medical information. Research personnel will enter your participant identification number and either your cell phone number or your email address into the system. They will not be provided any additional information about you or your child.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information about my child may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about you and your child's study visits;
- Information that includes personal identifiers, such as you and your child's name, or a number associated with you and your child as an individual;
- Information obtained during this research about laboratory test results;
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history;
- Billing records

II. Who may use and give out information about your child?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you and your child are participating in a research study and have access to you and your child's information;
- If this study is related to you and your child's medical care, study-related information may be placed in you and your child's permanent hospital, clinic or physician's office record;
- Others: Jacobi Medical Center in New York, Boston College, data safety monitoring boards, accrediting agencies

IV. Your child's information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;

- To study the results; and
- To make sure that the research was done right.
- To meet the reporting requirements of governmental agencies

VI. When will my permission end?

There is no date at which your permission ends. You and your child's information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. The authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose you and your child's health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you and your child will not be able to stay in this study. When you withdraw your permission, no new health information identifying you and your child will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my child's health information?

Then you and your child will not be able to be in this research study and receive research-related treatment. However, if you and your child are being treated as a patient here, you and your child will still be able to receive care.

IX. Is my child's health information protected after it has been given to others?

There is a risk that you and your child's information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my child's information?

Signing this authorization also means that you may not be able to see or copy you and your child's study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you or your child has been harmed as a result of study participation, you may contact ***Bernadette Melnyk*** *at 614-292-4844.*

For questions related to you and your child's privacy rights under HIPAA or related to this research authorization, please contact *Mary Beth Happ* at 614-292-8336

For questions about you and your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you or your child is injured as a result of participating in this study or for questions about a study-related injury, you may contact **Bernadette Melnyk** at 614-292-4844.

Signing the parental permission form

I have read (or someone has read to me) this form, and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject

Printed name of person authorized to provide permission for subject

Signature of person authorized to provide permission for subject

Relationship to the subject

Date and time **AM/PM**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time **AM/PM**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness

Signature of witness

Date and time **AM/PM**

Printed name of witness

Signature of witness

Date and time **AM/PM**