CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Mothers' Support and Health in Pregnancy and Parenting (MotherSHIPP)
Principal Investigator(s): Katy Kaplan, M.S. Ed, PhD
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This study is funded by: The United States Department of Health and Human Services' Office on Women's Health

KEY INFORMATION
Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to create stronger supports for pregnant and postpartum birthing people with substance use disorders (SUD) and mental health conditions.
- **Procedures**: If you choose to participate, you will be asked to complete three surveys: when you first enroll in the study, at 6 weeks postpartum and 12 weeks postpartum. You will also be asked to use an app on your phone called MotherSHIPP and to attend virtual peer support zoom sessions with a recovery advocate and other study participants.
- **Duration:** The length of time you are in the study will vary depending on gestational age at enrollment- so it could be as long as 10 months, or as short as 3 months if enrolled within 2 weeks postpartum.
- **Risks**: The main risk or discomfort from this research study is the loss of confidentiality but the researchers have procedures in place to protect your identifying and health information.
- **Benefits:** There may be no direct benefit to you from participating in the study. Your participation will help us better understand how we can improve supports for pregnant and parenting people with substance use and mental health conditions.
- **Alternatives:** The alternative is to not participate in this study.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you and you will be compensated up to $120 in gift cards over 3 surveys, $40 per survey.
- **Participation:** Deciding to participate or not participate in this research study is your decision. You can decide to participate and then change your mind at any point and drop out of the study.

The Research Coordinator will review this the entire document with you. You can ask any questions you may have before deciding If you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether you want to participate.

PURPOSE OF THE STUDY

The purpose of this study is to create stronger supports for pregnant and postpartum birthing people with substance use disorders (SUD) and mental health conditions. The goals of Mothers' Support and Health in Pregnancy and Parenting (MotherSHIPP) Study are to:

1) Test the effectiveness of the MotherSHIPP app designed for iOS (Apple) and Android devices that provides mobile education on pregnancy, postpartum, parenting, and substance use and mental health recovery. Use of the MotherSHIPP app will be paired with access to a Recovery Advocate who is a mother with lived experience with SUD who will provide virtual peer support through individual and group sessions.

2) Examine if the use of the MotherSHIPP app with peer support improves health outcomes for pregnant and parenting people with SUD and mental health conditions.

WHO IS BEING ASKED TO PARTICIPATE?

You will be one of approximately 120 pregnant/postpartum participants in this study. You are being asked to participate because you meet the following criteria:

1. 18 or older, between 13 weeks' gestation (dated by last menstrual period or ultrasound) through 2 weeks postpartum
2. Reside in Philadelphia County
3. Fluent in English
4. Medicaid eligible (has Community Behavioral Health insurance)
5. Current or past struggles with drinking or drug use
6. Access to an iOS (Apple) or Android device
7. Access to the Internet

Participants are to be excluded if they have:

1. An untreated psychotic disorder
2. A known fetal abnormality (this refers to unusual or unexpected condition in baby's development such as a birth defect)

PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

As part of this study, you will be asked to:

- If you decide to enroll in this study, you will complete a baseline survey, and surveys at 6 weeks postpartum and 12 weeks postpartum. After you complete the baseline survey, you will be given access to the MotherSHIPP app. MotherSHIPP is an app for iOS (apple) and android devices where information is provided on biological, emotional, and psychosocial milestones and strategies for managing SUD during pregnancy and 12 months postpartum. The information on the app includes: a course introduction on how to use the app; 2) information about pregnancy from weeks 13 – 40 that cover what to expect in your pregnancy as well as strategies to reduce or abstain from substance use; relapse prevention; how to cope with cravings, etc.; 3) information on postpartum for months 1 to 12 that focus on what to expect for mom and baby, and strategies for staying well; 4) a parenting section that provides information on child development, reducing parental stress, understanding parenting with a

behavioral health condition and promoting resiliency in your child; and 5) a resources section. You can participate as much or as little as you'd like. We will encourage you to review information based on your stage of pregnancy/postpartum. You can read this information or use the speaker icon on the app to have it read the page to you. Search feature will also let you to ask specific questions and be directed to content that answers your question if that information is included in the app.

- In addition to getting access to the MotherSHIPP app you will be connected to a recovery advocate (RA). The recovery advocate will be a person with lived experience with substance use issues and have professional training in behavioral health services. The RA will be familiar with the MotherSHIPP content and invite participants to a zoom support group with other study participants, following an initial one-on-one virtual meeting. Participants will be encouraged to use the app and peer support group as much as they'd like.
- Surveys can be completed in person with the Research Coordinator or virtually. Surveys will take about 15-20 minutes to complete. While researchers will encourage you to participate in the MotherSHIPP app and peer support group, the amount of time you participate is your decision.
- The MotherSHIPP app with peer support is a new intervention. This has not been tested before but we expect risks to you to be minimal, as noted in the section below.
- In addition to collecting data through the surveys we are also asking permission to access data from Community Behavioral Health about your use of the healthcare services and health outcomes in the 12 months prior to the birth of your baby and 12 months after the birth of your baby. This is so we can understand how this intervention impacted your participation in treatment services.

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research study are loss of confidentiality, however all possible steps will be taken to protect private identifiable information and restrict access to only authorized study team members. This can also include loss of confidentiality in the peer support group. Group members will be asked to keep all discussion confidential but participants will choose what they feel comfortable sharing with the group. Any information about child abuse or neglect, or intent to harm self or others will be reported to authorities as required by law.There may be survey questions that make you feel uncomfortable or make you upset. You do not have to answer a question you don't want to answer. If you find any aspect of the intervention problematic (e.g. - negative interactions on the virtual support group) you are not required to participate and can leave the group at any time. You can also drop out of the study at any time.

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

There are no direct benefits to you from participation. Knowledge gained from your participation in this study will help us better understand how to create resources to better support pregnant and parenting people with substance use and mental health issues.

NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION

During this study, we may learn new important information. This may include information that could affect your decision about participating in the study. If any new important information becomes available while you are a participant, we will let you know.

CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Your study data will be handled as confidentially as possible. If you share that you are a danger to yourself or others, or you report child abuse or neglect, the research team is legally required to break confidentiality. If required, your records may be inspected by authorized personnel in the following groups and agencies: the University of Delaware Institutional Review Board, the City of Philadelphia Institutional Review Board, the United States Department of Health and Human Services' Office of Women's Health (OWH).

- **Maintaining Confidentiality of Records**: To minimize the risks to confidentiality, all data collected as part of this study will be entered directly into REDCap. Data will be stored and managed on REDCap, a secure, web-based application, which is supported by the Center for Human Research Coordination at the University of Delaware. To access the REDCap website, all users of the REDCap system must have a valid username and password which is generated and maintained by the RedCap administrators on the REDCap server. Data will be stored, managed, and analyzed on a secure, encrypted server behind the University of Delaware firewall. Any paper documents that contain identifying or sensitive information will be stored separate from any data in a locked cabinet in the PIs locked office. Whenever feasible, identifiers will be removed from study-related information. Data will be stored for 7 years following the end of the grant. Data will be destroyed under the direction of the University of Delaware IT administrators in the Biden School. The data will not be shared with anyone outside the research team.
- **How Research Results will be Reported:** All published reports and presentations will contain data reported either in aggregate form (where no individual responses can be identified), or where examples that are created so that identification is not possible. 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. At most, it will include a summary of the results. You can search this site at any time.

COSTS AND COMPENSATION

There are no costs associated with participating in this study. Participants can earn a $40 gift card for each survey you complete. Therefore, participants can earn up to $120 in gift cards for their time spent completing surveys at baseline, 6 weeks postpartum, and 12 weeks postpartum. If you miss the 6 week survey, you can still complete the 12 week survey.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or drop out of the study, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision about participation will not influence current or future relationships with the University of Delaware, The University of Pennsylvania, Community Behavioral Health, or any of your healthcare providers. To drop out of the study you can call or email the Principal Investigator, Dr. Katy Kaplan (302-831-0362, katykap@udel.edu), or the Research Coordinator, Michelle Obasi (302-831-0928, mobasi@udel.edu).

HIPAA AUTHORIZATION

The federal Health Insurance Portability and Accountability Act ("HIPAA") and other state and federal privacy laws protect your individually identifiable health information your health care providers create and maintain about you (called "Protected Health Information" or "PHI"). HIPAA says that, in most cases, your health care provider can release your PHI for the purpose of conducting research only if you give permission by signing an Authorization.

If you agree to participate in the research study, the research team will need to collect and use your PHI. To allow your health care provider to share your PHI with the research team, your approval is required. Signing this Authorization is completely voluntary. However, if you do not sign this Authorization, then you may not participate in the research study. The HIPAA Authorization form is attached to this Consent to Participate in a Research Study and requires a separate signature from you.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

If you have questions and concerns about your rights as a participant you may also contact the Phialdelphia Internal Review Booard at (215) 685-0869 or email irb_submissions@phila.gov.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, Dr. Katy Kaplan (302-831-0362, katykap@udel.edu).

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:

I have read and understood the information in this form, and I agree to participate in the study. I am 18 years of age or older. I have been given the opportunity to ask any questions I had, and those questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

_____	_____	_____
Printed Name of Participant (PRINTED NAME)	Signature of Participant (SIGNATURE)	Date
_____	_____	_____
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION

MEMBER NAME: _____ DATE OF BIRTH: ___/___/_____

I, _____ , request and authorize Community Behavioral Health ("CBH") to disclose My Medicaid Claims Data, defined below, to Katy Kaplan, PhD, the Principal Investigator of the research study titled "Mothers' Support and Health in Pregnancy and Parenting (MotherSHIPP)" (the "Research Study"), or such other members of her research team as she may designate from time to time (the "Research Team") because I am participating in the MotherSHIPP Research Study.

For purposes of this authorization, "My Medicaid Claims Data" means any individually identifiable health information CBH has created or maintains about me, specifically including information directly related to mental and physical health treatment, and substance use treatment such as, but not limited to, treatment in community and inpatient settings, including substance use facilities, medication access, (collectively, "My Medicaid Claims Data").

This authorization shall expire upon the conclusion of the Research Study. However, I understand I may revoke the authorization at any time by contacting CBH. I understand my revocation would not apply to any information CBH may have already disclosed to the Research Team in reliance on this authorization.

I understand CBH cannot condition my treatment on the execution of this authorization.

I understand that information from My Medicaid Claims Data may be subject to re-disclosure by the Research Team and with certain exceptions, including those set forth in at 42 USC 290dd *et seq*. and its implementing regulations at *42 CFR Part 2,* no longer protected by federal or state law.

I understand I have the right to receive a copy of this Authorization if I so request.

I acknowledge that I have fully read this form and that a copy of this form shall be as valid as the original.

_____ _____
Signature of the Member or Personal Representative Authorized by Law Date

Printed Name of Person Signing: _____

Relationship to Patient: _____

CONTACT INFORMATION

Having contact information for family members, friends or a treatment provider can help us connect with you if we're not able to reach you after several attempts have been made. Please identify two good contacts for this purpose. We will keep their contact information confidential. We will also maintain your confidentiality when reaching out to the contacts you've provided.

This study involves two follow-up surveys, at 6 weeks postpartum and 12 weeks postpartum. We would like to contact you to remind you about these follow-up surveys. As part of the study, we will ask you to fill out a **contact form**. This form will include your phone number, address, and email address. We will also ask you to give us the names and phone numbers of several people or agencies that you regularly see. We will contact these people or agencies only if we cannot directly reach you. When we contact you and the people or agencies listed on your contact form, we will say that we are part of a research study titled "MotherSHIPP." We will never share any details about the study.

I hereby authorize the study team to ***contact myself and the persons or agencies listed on my contact form***.
Name of research subject if not the person signing

_____ _____
Signature of Participant or Authorized Representative Date

Printed Name of Person Signing: _____

Relationship to Participant: _____

CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? If you agree to being contacted in the future, we will keep your contact information. Please write your initials next to your preferred choice.

_____ YES _____ NO