Official Study Title: **Resources, Inspiration, Support and Empowerment (R.I.S.E.) for Black Pregnant Women**

NCT05552053

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CONSENT FORM FOR RESEARCH

Study title: Resources, Inspiration, Support and Empowerment (RISE) for Black Maternal Mental Health

Sponsor: National Institutes of Health

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Cedars-Sinai study contact information: (323) 866-8107, risestudy@cshs.org

After-hours emergency contact (24 hours): Maternal Fetal Medicine on Call (310) 423-9999

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you chose not to take part or stop taking part.

- **Purpose:** The purpose of this study is to improve clinical care of Black women during the perinatal period. The overall goal is to improve mental health and physical health outcomes.

- **Procedures:** You will be asked to complete a mental health questionnaire at 3 different times, engage with a mobile-health (m-Health) application (app) during your pregnancy, interview with study staff about your experience with the app, and provide an optional blood-spot collection. Additionally, we will review your medical chart after your delivery.

- **Duration:** Taking part in this study will last for the duration of your pregnancy and 3 months postpartum.

- **Risks:** All research studies involve some risk. Risks or discomforts from this study may be potential psychological uneasiness when describing depressive or PTSD symptoms, potential breach in confidentiality, and loss of privacy.

- **Benefits:** There is no guarantee of benefits from this study; however, there could be an improvement in mental and physical health outcomes.

- **Alternatives:** You can choose not to take part in this research. There may be other choices for you. Some other choices may be to join a prenatal therapy group in our Reproductive Psychology Clinic or join a support group for Black pregnant women through Postpartum Support International. Please talk about these choices with the study team.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

Given the burden of both adverse pregnancy outcomes (APOs) like preeclampsia and perinatal mood and anxiety disorders (PMADs) among Black mothers and the numerous consequences on maternal and child outcomes, it is important that we develop and implement targeted and effective interventions to reduce stress. This study is designed to test a new mobile health intervention. This intervention is informed by real world experiences that will allow you to engage with educational modules about PMADs, stress management techniques, and help you tailor a self-help plan.

Testing the interventions will provide valuable patient-centered data that can then be used in future clinical care services planning specifically for Black pregnant women.

You are being asked to take part in this research study because you are a Black pregnant woman that has taken an interest in the study or was referred to the study by a clinician.

The study will include up to 150 people in total.

Optional Sub-study
There is also an optional sub-study described later in this consent form. You are not required to take part in the sub-study. You can say no to the sub-study and still be in the main study.

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the flowchart of procedures on page 17.

The flowchart of procedures shows a timeline of the study. It shows which study procedures are research-related. **Research-related procedures** are procedures done only for the research study. They would not be performed for your routine care outside of the study.

Section 5 in this form describes the common medical procedures that will be done or repeated only for this research study.

Description of main research procedures:

All surveys will be sent to you via email, which will include a link allowing you to enter information on your own personal device (e.g., an iPad or smart phone). The survey questions will be electronically entered on a secure online database called REDCap. All surveys will be labeled with a unique study number that will link your identity so that only the research team will recognize you.

- You will complete 1 survey online entitled "Medical History" at your first visit. It will take about 15-30 minutes to complete the survey and will include questions about the following:
    - Medical History
    - Surgical History
    - Obstetric History

- You will complete 1 survey entitled "Maternal Survey" online at three separate timepoints: at your first visit, 1 month postpartum, and 3 months postpartum. It should take about 30-45 minutes to complete the entire survey and will inquire about:
    - Demographic Information (Education, Marital Status, Employment)
    - Social Support and Social Media
    - Physical Activity and Diet/Nutrition
    - Smoking and Alcohol Habits

- The survey will include the following brief questionnaires:
    - **Edinburgh Postnatal Depression Scale (EPDS):** This is a 10-item section that asks questions about depression and anxiety symptoms. This will take about 3 minutes to complete.
    - **Impact of Events Scale (IES):** This is a 15-item section about post-traumatic stress symptoms. This will take about 5 minutes to complete.
    - **Overall Anxiety Severity and Impairment Scale (OASIS):** This is a 5-item section about different types of anxiety symptoms and focuses on impairment and severity takes 3 minutes to complete.
    - **Perceived Stress Scale (PSS):** This is a 10-item questionnaire that measures subjective stress. This will take about 3 minutes to complete.
    - **Childhood Trauma Questionnaire (CTQ-**SF): This is a 28-item questionnaire that assesses history of abuse. This will take about 5 minutes to complete.
    - **Medical Discrimination Scale (MDS):** This is a 9-item section that asks about racial discrimination in medical settings and takes 2 minutes to complete.
    - **Pittsburgh Sleep Quality Index (PSQI):** This is a self-report questionnaire that assesses sleep quality over a 1-month time interval. The measure consists of 19 individual items. This will take about 3 minutes to complete.

  - **Adverse Childhood Experiences (ACE):** This is a 10-item questionnaire that asks about negative experiences in childhood. This will take about 3 minutes to complete.
  - **The posttraumatic growth inventory (PTGI):** This is a 12-item questionnaire that asks about ways one has grown through difficult experiences and with social support. This will take about 3 minutes to complete.
  - **Communication Assessment Tool (CAT):** This is a 14-item assessment that measures patient perceptions of physician interpersonal and communication skills This will take about 5 minutes to complete.
  - **Patient Self-Advocacy Scale (PSAS):** This is a 12-item questionnaire that asks about patient activism. It assesses the dimensions of (a) increased illness and treatment education, (b) increased assertiveness in health care interactions, and (c) increased potential for nonadherence. This will take about 3 minutes to complete.
  - **Brief COPE Survey:** A 28-item questionnaire that measures how you have been coping with stress in your life. This will take about 5 minutes to complete.

- Application Engagement:
  - You will be asked to engage with the mobile health app throughout your pregnancy for about an hour. Your time spent on the app will be monitored. There will also be occasional answering checkpoints as you spend time on the app. Care navigators will check in at least once at the prenatal time point to ask if you need help and will guide you as needed.

- Collection of your data from your medical chart or a delivery survey:
  - If you deliver at Cedars-Sinai, your medical records will be reviewed once at the time of your delivery. It will be necessary to review your records to record any delivery outcomes, like the weight of your baby.
  - If you do not deliver at Cedars-Sinai, you will be asked to fill out a delivery survey with your delivery and postpartum outcomes. This survey will ask for current medication, BMI, birth weight, mode of delivery, gestational age at birth, neonatal outcomes, length of stay, and whether you had an adverse pregnancy outcome.

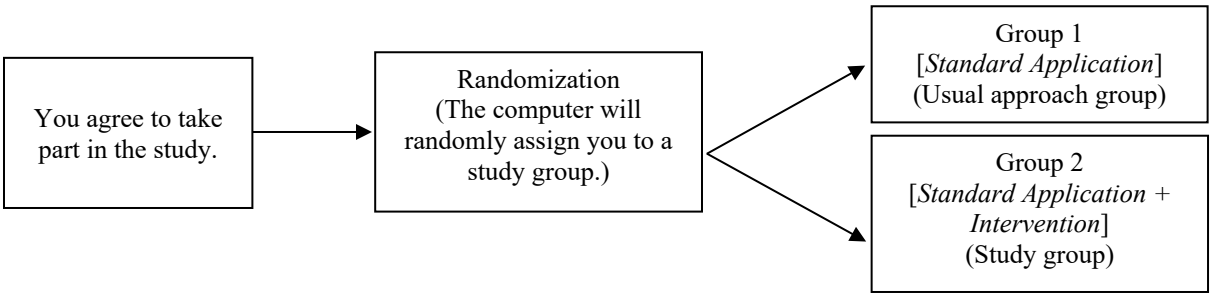
This study has 2 study groups:
- The control group: Group 1 will use a standard app meant to educate you about mental health during pregnancy.
- The intervention group: Group 2 will use a standard app plus our stress reduction intervention app.

This is a randomized, double-blind research study.
- **Randomized**: This means that you will be put in a study group by chance (like flipping a coin). You will be randomly put in one of the above study groups. You will have an equal chance of being placed in any one of the groups described above. A computer will randomly put you in a study group. We do this because no one knows if the results in one study group are different than the others. The results could be better, the same or worse than the results

in other groups. Once you are put in one group, you cannot switch to another group. You and your doctor cannot choose the group you are in.

- **Double-blind:** This means you and the researchers will not know what group you are in. The only person who will know which group you are in is your assigned Master's level care navigator.

The chart below outlines what will happen during the study.



People in the control group will engage with a standard app that provides education on PMADs, stress management techniques and other coping strategies. The control group is the group that will engage with the standard app without an intervention. The information gathered from this group will be used to compare to the group that had an intervention to draw conclusions on whether the intervention was effective or not.

How long will you be in the study?

We think you will be in this study for the duration of your pregnancy and until 3 months postpartum. You will be enrolled in this study in the prenatal period (12-32 weeks gestation) and complete a total of 3 study visits.

- The first study visit (12-32 weeks gestation):
  - App Engagement – Throughout your pregnancy
  - Optional blood spot collection (Tasso) – for biomarker testing
  - Surveys – Medical history and Maternal questionnaire (2 surveys)
    - If symptoms are severe, a diagnostic interview

- The second study visit (1 month postpartum):
  - Survey – Maternal questionnaire (1 survey)
    - If symptoms are severe, a diagnostic interview

- The third study visit (3 month postpartum):
  - Optional blood spot collection (Tasso) – for biomarker testing
  - Survey – Maternal questionnaire (1 survey)
    - If symptoms are severe, a diagnostic interview

4. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and/or discomforts of the study procedures.

Risks of common medical procedures performed for research purposes are described below in Section 5. Side effects and risks of standard of care procedures are not described in this consent form.

Unknown Risks
There may be other risks that we cannot predict. Many complications are minor and do not last long. However, in some cases, they can be serious.

Mental Health Questionnaires:

- **Likely (***Out of 100 people, 20 to 100 people may have this happen.)*
  - You may experience minimal psychological uneasiness when asked to describe depressive or PTSD symptoms.

- **Less Likely (***Out of 100 people, 4 to 20 people may have this happen.)*
  - If responses to the questionnaires indicate risk, you would be referred to our Masters' level clinician who will conduct a brief diagnostic interview and provide referrals for psychotherapy and/or medical management.

- **Rare but Serious (***Out of 100 people, occurs in 3 or fewer people* ***and*** *may require staying at the hospital; or may be irreversible, long-term, life-threatening or fatal.***)**
  - The clinician also performs a full suicide assessment if suicidal ideation is endorsed. Those who have active suicidal ideation will be evaluated by a licensed Clinical Psychologist (PI) or a Psychiatrist (co-I). Medical or psychological concerns that are raised by women during assessments will be attended to immediately.

Collection of Pregnancy Outcomes
We will collect information on the pregnancy. Data collected about you, and your child may include:
- Outcomes of the pregnancy
- Details of the birth
- Birth defects, abnormalities or complications
- Health status of your child

5. Common Medical Procedures Performed for Research Purposes and Risks

The procedures listed below are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research-related. This means they are being *repeated* or performed *more frequently* for this study. These common procedures and their risks should be the same as when performed outside this study.

Study Procedure	Related Risks
Demographic Information: We will ask you about demographics, which may include your age, education, gender identity, sexual orientation, and marital status	This does not have any physical risks.
Medical History Review: We will ask you about your medical and surgical history.	This does not have any physical risks.
Drug and Alcohol Screen: This is an assessment of your past and/or present drug use. You will take a survey that asks about your drug or alcohol use.	We will record your history of drug or alcohol use in the study records. We will follow all steps to protect the confidentiality of this information as outlined in this consent form.
Screening of Depression/Suicidality: You will be asked questions about your overall quality of life. This includes coping mechanisms, times of depression or circumstances where you feel a wish to harm yourself or others. The study team may ask you questions or ask you to answer questionnaires.	Tell the study team right away if you have feelings or thoughts of harming yourself or others. This is so that the study team can help you. The study team will closely monitor your symptoms of depression. A diagnostic interview may be conducted if your symptoms are high.
Questionnaires: You will be asked to complete questionnaires. We will ask questions to find out about your mental health, your childhood, history of abuse, sleep quality, rates of self-advocacy, level of discrimination in medical settings, and interpersonal and communication skills. We think it should take about 45-60 minutes to complete the questionnaires. Questionnaires will ask you to respond to sensitive questions about depression, anxiety, post-traumatic stress disorder, insomnia, history of abuse, and your history of discrimination. You will also be asked about diet/nutrition, sleep, your physical activity as well as social support and social media use.	Some questions may make you feel uncomfortable or embarrassed. The questionnaires will be labeled with a unique study number. This will link your identity so that only the research team can recognize you.
Diagnostic Interview: Based on your responses to surveys/questionnaires, we may possibly schedule you for a 60-90 minute interview with a clinician or trained mental health professional. They will evaluate your mental health and, if needed, provide referrals for therapy or medical management. Not every participant will be eligible for a diagnostic interview.	Some questions may make you feel uncomfortable or embarrassed.

6. Benefits From Taking Part in the Study

Taking part in this research study may or may not have a direct benefit to you. The possible benefits of taking part in the research study are improvement in mental and physical health outcomes. Additionally, prenatal or postpartum depression or anxiety may be identified. Education about mental health during this time is valuable and early referral to outside mental health providers may be provided.

However, no benefit is guaranteed. It is possible that your mental health condition may remain unchanged or even get worse.

We hope the information learned from this research study will benefit other pregnant Black women in the future by helping us learn whether Black women-centered interventions in pregnancy can help with mental and physical health outcomes. Also, if these interventions can help with early identification of stress, anxiety, or depression they may reduce risk for future mental health problems.

After your delivery, and completion of your final research visit, you will be provided with FREE access to the full mobile Health application designed specifically for Black women, regardless of which group you were randomized into.

7. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

8. Choosing to Take Part and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

The study team will discuss these options and their risks and benefits with you. You may also choose to discuss these with your treating physician.

9. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will **not** use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitors the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

We might share your unidentified data and/or research samples collected in this study. It might be shared with other researchers at Cedars-Sinai, other academic institutions or third-party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will **not** be shared with other researchers or anyone outside of Cedars-Sinai.

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

You may be contacted in the future about the possibility of participating in other related studies with separate consent documents. The study team will contact you about future research studies that are approved by the Cedars-Sinai Institutional Review Board (IRB). At that time, you are free to decide whether you are interested in participating in that study.

Protections From Forced Disclosures (Subpoenas) – Certificates of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence, unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research, if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

10. Research-Related Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

11. Financial Considerations

Costs of Participation
You and your insurance company will not be charged for your participation in this research study. The Study Sponsor will cover the cost of all items and services required by this study. This includes any procedures required by the study that may be standard of care.

Payment
You will be paid $20 for each time you fill out a survey. The total amount for completing all 3 surveys is $60. If you do not take part in the optional Tasso blood collections, this is the total amount you will receive for taking part in the study.

You will also receive an additional $20 for each blood spot if you chose to provide the optional Tasso blood spots. The total amount for completing the 2 optional Tasso blood collections is $40.

If you complete all surveys and Tasso blood collections, you will receive a total of $100.

There may also be an additional $20 compensation for completing a 60-90 minute diagnostic interview. Not every participant will be eligible for a diagnostic interview.

You will be paid after each visit. You will only be paid for those visits and procedures you complete.

The payment breakdown for this study is below:

- $20 for completion of the Visit 1 "Maternal Survey"
- $20 for Visit 1 Tasso blood spot collection
- $20 for completion of the Visit 2 "Maternal Survey"
- $20 for completion of the Visit 3 "Maternal Survey"
- $20 for a diagnostic interview
- $20 for Visit 3 Tasso blood spot collection

You will be paid $20 in the form of a Gift Card for completion of each task listed above after each study visit. Cedars-Sinai must collect your name, phone number, address, and the last 4 digits of your Social Security number for tax purposes. This information will be collected by the study team, but the study team will not keep this information. They will provide it to the Cedars-Sinai financial office for their tax records.

Financial Interest in the Research
A co-investigator, Dr. Sinmi Bamgbose, has stock options in Candlelit Care that represent ownership of less than 5% of the company. A financial interest is a situation in which financial considerations could influence a person's professional judgement. This study has been designed to minimize the impact of the co-investigator's financial interest. You can ask the principal investigator to explain how the financial interest disclosed will be managed.

12. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Resources, Inspiration, Support, and Empowerment (RISE) for Black Maternal Mental Health" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

- ☐ Laboratory tests
- ☐ Pathology reports
- ☐ Imaging reports (e.g., x-rays or scans)
- ☐ Photographs or videos of your image
- ☒ Doctor/clinic records
- ☒ Hospital/medical records
- ☒ Mental health records
- ☐ Billing records
- ☒ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation
- ☒ Other tests or other types of medical information: Blood draw, response to questionnaires, diagnosis

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

6. OPTIONAL SUB-STUDY

In addition to the main research study, you have the option to agree to participate in the optional sub-study as explained to you during the informed consent process. Your decision to take part in the optional sub-study does not impact your ability to participate in the main research study.

If you agree that your identifiable health information may be used and/or disclosed for the optional sub-study described in the informed consent process and above, you will be required to sign a second time in the signature section.

Optional Blood Spot Collection Sub-Study

Introduction

You are being provided with this information to consider taking part in an optional sub-study. **You can decline to take part in this optional sub-study. You can still be in the main study whether you are in the sub-study or not. Your medical care at Cedars-Sinai will not be changed in any way because of your decision.**

Before you decide, you should read the rest of this optional sub-study section. You can also ask the study team any questions to help you understand the sub-study. If you agree to take part in the sub-study, you will be asked to sign the sub-study signature lines on the Signature Page.

A. Purpose of Optional Sub-Study

This optional sub-study will be a test for biomarkers of depression and stress in blood using a Dried Blood Spot (DBS) collected from a Tasso M-20 device. A biomarker is a biological molecule found in blood, other body fluids or tissues. Biomarkers may be a sign of a condition or disease and can be used to predict someone's response to a specific treatment. The U.S. Food and Drug Administration (FDA) has approved the Tasso M-20 device as it is being used in this study.

Blood does contain genetic information. Being asked to be part of a genetic study does not necessarily mean that you or other family members have a specific disorder or an inherited risk for a disorder.

B. Optional Sub-Study Procedures

Blood specimens will be self-collected at your home using the Tasso M-20 device. The Tasso M-20 is approved for at-home sample collection, requiring no trained professional.

You will receive a Tasso-M20 kit which includes written, visual, and video instructions for use; the Tasso-M20 device; materials for application; and return shipping instructions and materials. The return shipping materials follow standard guidelines using standard post (e.g., USPS) and are approved as an exempt human specimen (UN3373 exempt). Return labeling of the package will not include any identifying information but simply a barcode matching your participant ID.

You would collect using a Tasso M-20 device twice: once at your first visit and again at your third visit (3 months postpartum). In total, about 2 tablespoons of blood will be collected.

Your sample will be taken only for research purposes.

C. Length of This Optional Sub-Study

You will be in the optional sub-study for the duration of the main study. Samples will be collected for this optional sub-study during the first and third visit. The timing of optional sample collections is outlined in the flowchart of procedures.

In this optional sub-study, testing of your specimens may go on for a long period of time. Your direct participation in this optional sub-study will be done once you have completed the procedures/visits described above. Your specimen(s) may be studied for many years.

D. Possible Risks or Discomforts of This Optional Sub-Study

Blood Spot Collection Risks:

- **Likely (***Out of 100 people, 20 to 100 people may have this happen.)*
  - Soreness

- **Less Likely (***Out of 100 people, 4 to 20 people may have this happen.)*
  - Bruising on needle puncture site
  - Pain from needle puncture site

- **Rare but Serious (***Out of 100 people, occurs in 3 or fewer people* ***and*** *may require staying at the hospital; or may be irreversible, long-term, life-threatening or fatal.***)**
  - Infection
  - Swelling
  - Bleeding
  - Fainting from needle stick
  - Formation of a blood clot

Genetic studies may place research subjects at risk for discrimination based on genetics. The federal Genetic Information Nondiscrimination Act (GINA) was passed to address this concern. GINA makes it illegal for medical insurance companies and most employers to discriminate based on genetic information. The protections of GINA do not apply to life, disability or long-term care insurance. We follow federal and state privacy laws to protect against unauthorized disclosure of your protected health information that could lead to discrimination or the misuse of your genetic information.

Data collected about you will be submitted to the Genome Wide Association Studies (GWAS) database. This database allows researchers around the world to access and study the data. Data submitted will have your identifying information, such as your name and medical record, removed. Once submitted, this data will be controlled by the National Institutes of Health (NIH). The NIH is committed to protecting the confidentiality of all the information it receives. The NIH will also comply with relevant laws which might include Freedom of Information Act (FOIA) requests for non-identifiable information.

E. Benefits of This Optional Sub-Study

You should not expect to benefit from taking part in this sub-study.

While no benefit is ever guaranteed, we hope the information learned from this optional sub-study will benefit other Black women who are pregnant in the future.

F. Whether Research Results Will Be Shared

The research tests done in this sub-study are performed in a research-only lab (not a certified clinical lab). The results are for research use only. Therefore, we will not give you the test results from this sub-study. We will not put the results in your Cedars-Sinai medical record.

Unanticipated Incidental Findings
We will contact you using the last contact information you gave if, unexpectedly, we find results that suggest potentially clinically relevant medical information. We may suggest you talk with your treating physician about possible additional clinical testing to further evaluate the research finding. You and/or your insurance would pay for any additional testing and any related treatment.

G. Payment

You will be paid for $20 for each Tasso blood spot collection. The total amount for completing the sub-study is $40. You will be paid after each visit. You will only be paid for the collections you complete.

You will be paid by Gift Card. Cedars-Sinai must collect your name, phone number, address, and the last 4 digits of your Social Security number for tax purposes. This information will be collected by the study team, but the study team will not keep this information. They will provide it to the Cedars-Sinai financial office for their tax records.

You will not be paid for giving biological samples (e.g., blood, fluid, tissue) for this sub-study. Once you give the samples for the research, you no longer have access to them. Cedars-Sinai or the Sponsor will own your donated samples. Researchers might use your samples to develop new products, tests or discoveries. These inventions may result in commercial profit for the researchers, Cedars-Sinai and other organizations. If this happens, you will not receive any financial benefits.

Flowchart of Visits, Tests and Procedures

Legend
R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.

Procedures	Enrollment /Visit 1 (12-32w gestation)	Delivery	Visit 2 (1 month postpartum)	Visit 3 (3 months postpartum)
Medical History Survey	R			
Medical Chart Review and/or Delivery Survey		R		
Randomization	R			
Sign-up for App (with assistance from study team)	R			
Maternal Survey - Psychological Questionnaires	R		R	R
Biologic (Tasso blood spot collection) – optional	R			R
App Engagement (using the app)	R			

Signature Page

Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Optional Blood Spot Collection Sub-study: *I agree to take part in the optional sub-study described to me during the informed consent process and in this document.*

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Optional Blood Spot Collection Sub-study Authorization: *I hereby agree that my identifiable health information may be used and/or disclosed for the optional sub-study in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Witness
(Signature of a witness is required when an English-speaking subject who has been determined to have capacity to consent is unable to read or physically sign the consent form, but choses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

Witness name (please print)	Signature	Date