Based on your responses to the online screening, you are eligible to participate in the study. **You do not have to sign this consent form, but if you do not, you will not be able to participate in this study.**

UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

Study Title: **H**ealth **A**nd **R**esponse: Digital **M**arkers for **O**utcomes in Peri**N**atal Depression Treatment Stud**Y** (HARMONY)

Principal Investigator:
Nelson Freimer, MD
University of California, Los Angeles
695 Charles E. Young Drive South
3506 Gonda, Box 951761
Los Angeles, CA 90095-1761

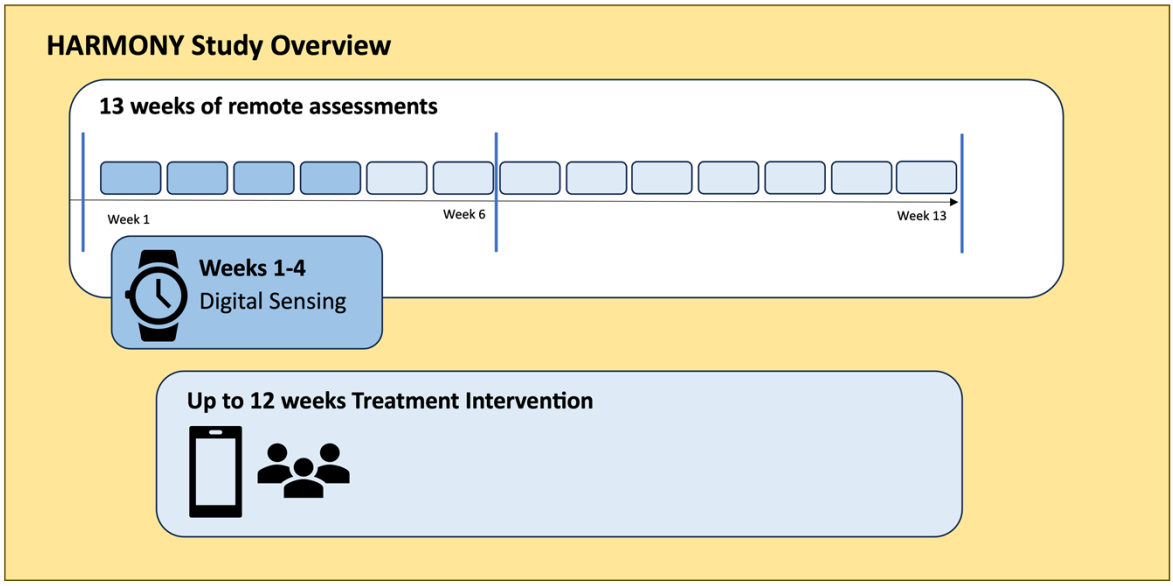
Study Contact: 310-339-9053 and harmonystudy@mednet.ucla.edu

KEY INFORMATION

- You are being asked to consider providing consent to participate in a voluntary research study conducted by Nelson Freimer, MD, from the Department of Psychiatry and Michelle Craske, PhD, from the Department of Psychology at UCLA. You are being asked to participate in this study because you are a UCLA Health System patient and have been determined to meet initial screening requirements.
- Research studies are voluntary. Whether or not you choose to participate is up to you. You can take your time to decide whether to participate. You can ask the study team any questions you have before deciding whether to participate.
- The goal of this study is to determine if the addition of digital sensing data collected from phones and smartwatches from expectant women and new moms can better predict the outcome of treatment for perinatal depression (PND) than monitoring of depression symptoms, alone.
- Your participation in this study is expected to last approximately 3 months. This study will be conducted entirely remotely.
- You will be asked to participate in an onboarding session at the start of the study with study staff, which will take place over secure video conference. This session must be completed before treatment initiation.
- You will be assigned to one of two treatment conditions, depending on your symptoms of depression at study entry: you will be offered coach-guided, digital cognitive behavioral therapy (CBT) tailored to PND if you are experiencing moderate symptoms of depression and no current suicidality, or you will be offered clinician delivered CBT if you are experiencing severe depression or suicidality. Treatment starts with an initial orientation session conducted over secure video conference, followed by weekly sessions as clinically determined, for up to 12 weeks.
- You will be asked to complete several online surveys throughout the 3-month study.
- During this study, you will be asked to download a study app onto your personal iPhone. You will be provided with a smartwatch (Apple Watch), if you do not own

an eligible model, and you will be asked to wear the smartwatch for at least 20 hours each day, including while sleeping, during the first four weeks of the study.

- Data will be collected from the sensors on your iPhone and Apple Watch. These data will be collected through the study app installed on your personal iPhone and shared with the UCLA research team.
- You will be asked to sign a HIPAA Authorization for research form, which allows the UCLA study team to access information from your UCLA Health medical record for research purposes
- Minor risks or discomforts that are associated with the research procedures are detailed below.
- The possible benefits you may experience from being in this study include improvement in depressive symptoms. However, a response to treatments offered cannot be guaranteed in any patient and neither the degree of response nor the duration of response to one of the treatments offered can be reliably predicted at this time.
- The alternative to participating in this study is to not participate.



WHO CAN TAKE PART IN THIS STUDY?

To be eligible to participate in this study, the following requirements must be met:

- Be at least 18 years of age
- Able to read and communicate in English
- Be between 28 weeks pregnant and 12 weeks postpartum at the time of enrollment
- Be experiencing moderate-to-severe depression as measured by a self-report measure of depression
- Not currently receiving mental health care from a provider
- Currently receiving care from an OB/GYN or Primary Care Provider (PCP)
- Own a functioning iOS smartphone (iPhone 11 or newer, iOS 18 or newer) with access to a reliable data plan and Wifi

- Be able to read and understand this written informed consent form
- Be willing to participate in treatment and complete study assessments, including providing HIPAA Authorization for research, installing a study app on personal iPhone, and wearing the provided Apple Watch for at least 20 hours every day in the first four weeks of the study (including while sleeping)

Participants are not eligible to participate in this study if any of the following conditions are met:

- Currently receiving treatment by a therapist or a psychiatrist
- Determined to be experiencing unstable suicidality (e.g., 1 or more suicide attempts or self-injurious behaviors resulting in hospitalization in the last 6 months)
- Determined to be experiencing current substance use disorder that interferes with treatment: specifically, patients meeting diagnostic criteria for substance use disorder (SUD) will be eligible for inclusion only if they are able to attend sessions while not under the influence of that substance, except individuals abusing opiates or freebase cocaine, who will be excluded
- Determined to have a diagnosis of psychosis unrelated to depression (unipolar or bipolar)
- Have neurological conditions
- Have severe uncontrolled medical conditions (e.g., anorexia nervosa, cardiac conditions requiring continuous monitoring)
- Have cognitive impairment (e.g., developmental disability, dementia)
- Previously participated in the UCLA Depression Grand Challenge “New Moms Mood Tracking & Wellbeing Study” (IRB #20-001924)

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We aim to enroll up to 250 participants to obtain complete data on at least 200 women. Women will be recruited from participating UCLA Health clinics in the Los Angeles area.

HOW LONG WILL I BE IN THE STUDY?

Your participation in the study is expected to last approximately 3 months and require approximately 4.5 hours over these 13 weeks to complete the research assessments. This study requires one onboarding session to be conducted remotely by secure video conference at the start of the study. You will be asked to complete study assessments, as often as every week, which can be completed online. You will also be asked to keep the study app installed on your iPhone and wear the Apple Watch during the day and while sleeping for the first four weeks of treatment, and to follow instructions for charging the study devices during this time.

This time estimate does not include the time you will participate in treatment sessions. The study will require multiple sessions with care providers, with the total number dependent on your personalized treatment plan. Treatment sessions will be conducted remotely by secure video conference.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

You have already completed an online screening and symptom assessment to determine eligibility. The following steps will happen if you decide to proceed with enrollment and participate in the study:

1) **Consent and Study Enrollment:**
   - You will be asked to read and sign this consent form if you agree to participate. By agreeing to participate, you are agreeing to receive study reminders and other communication regarding your participation in this study via secure video conference, phone, text, email and app notifications. You can read more about this in the Section "WHAT KINDS OF RISKS OR DISCOMFORTS CAN I EXPECT?"
   - At this time, you will be asked to read and sign the HIPAA Authorization for Research form that allows us to review your UCLA medical record to obtain information such as your diagnostic history and current medications. We will not extract identifying or financial information from your medical record, and these data will be stored in our secure database.
   - Consenting to participate in this study includes an agreement to establish care with an outside provider, if clinically indicated, by the end of the treatment offered. We will transfer your care to this outside provider when deemed clinically appropriate (either at the end of this study, or the end of your active treatment). By signing a Release of Information, you will agree that we may communicate with your outside provider before, during, and after the treatment session offered.
   - You will be directed to an online calendar where you can schedule your onboarding session with study staff, or you can request to schedule your onboarding session by phone or email with study staff.
   - You will be asked to provide your mailing address so that we can send you study materials, including an Apple Watch, if needed, prior to your onboarding session. If you own your own eligible Apple Watch (Watch S8 or newer with watchOS 11 or newer) you can use your personal watch during the study rather than receiving one from the study team.
   - If you do not sign this consent form within 7 days from completing screening and being notified of your eligibility, you may need to redo portions of the online screening in order to resume again.

2) **Baseline Assessment** (*approximately 2 hours*):
   - Prior to your onboarding session, you will be asked to complete online surveys (see Survey Data in Section "WHAT INFORMATION WILL BE COLLECTED FOR RESEARCH?" for details). These surveys will capture information about demographics, depression symptoms (including suicidality), medical and treatment history, history of pregnancy, sleep quality and daily routines, maternal social support, infant bonding, and breastfeeding difficulties (if applicable), stressful life experiences and experiences of discrimination. These surveys will take approximately 46 minutes to complete.

- Your onboarding session will be scheduled by secure video conference for 60 minutes with a member of our study team.
- During the onboarding session, you will be asked to ensure your iPhone and the Apple Watch are updated and meet the requirement of the study, install the study app on your personal iPhone, review data sharing requirements with study staff, and make sure that you have passcodes on both devices.
- With your consent, specific data that is collected from your iPhone and Apple Watch and/or data stored in the Apple Health app will be shared with the study. You will have the ability to review and authorize each data type request in the study app on your iPhone before data are shared. No data are collected from devices until you authorize sharing the data with the study.
- During the onboarding sessions, you will be asked about your previous and current prescribed medication use by study staff.
- During the onboarding session, study staff will provide an overview of the study schedule, tasks that you will be asked to complete, and information about compensation.
- Study staff will provide information about your assigned treatment and may schedule your treatment orientation session during the onboarding session, if it has not yet been scheduled.

3) **Remote Data Collection** *(approximately 2 hours total over the course of the study)*
   - After your onboarding session, you will be asked to complete the following assessments. You will receive compensation depending on the number of assessments completed (see “WILL I BE PAID FOR TAKING PART IN THIS STUDY?” below).
   - Daily (weeks 1-4): You will be asked to leave the study app installed on your personal phone and ensure that your iPhone is regularly connected to cellular data or Wifi during this period. You will be asked to wear and use the Apple Watch on your wrist after it has been unlocked for at least 20 hours each day (during the day and while sleeping) and follow charging requirements for the devices. You will be asked to charge the devices for two hours each day (this can be broken up into smaller chunks of time), while the devices are Bluetooth connected and on the same Wifi network.
   - Weekly: You will be asked to complete a weekly symptom assessment. This survey will take approximately 5 minutes to complete.
   - Midpoint assessment: Six weeks after you initiate treatment, you will be asked to complete self-report surveys. These surveys will be sent via secure link in your email or by text. They will capture information about depression symptoms (including suicidality), changes in medical or treatment history, pregnancy and delivery status, sleep quality and daily routines, infant bonding, social support and breastfeeding difficulties (if applicable), as well as recent stressful life experiences and experiences of discrimination.
   - Final assessment: Twelve weeks after you initiate treatment, you will be asked to complete self-report surveys. These surveys will be sent via secure link in your email or by text. They will capture information about depression symptoms (including suicidality), changes in medical or treatment history, pregnancy and delivery status, sleep quality and daily routines, infant bonding, social support

and breastfeeding difficulties (if applicable), recent stressful life experiences and experiences of discrimination, and feedback about your experience in the study.

- Clinical assessments (based on treatment schedule): During your participation in treatment, you will be additionally asked to complete two online surveys, approximately four weeks after initiating treatment and at the end of treatment. These surveys will be sent via secure link in your email or by text. They will capture information about your evaluation of the care that you have received and satisfaction with treatment.
- For any of these remote assessments, you may be contacted by study staff by email or phone if there is a gap in data received or other related issues.

4) **Treatment Intervention:** You will be notified of your treatment assignment during your onboarding session with study staff. You will not have the option to choose your treatment assignment.

   The schedule and nature of treatment sessions will vary depending on the assigned treatment tier; however, both will start with an Orientation session conducted via secure video conference. This Orientation session is required for study participation. The onboarding session with study staff and baseline assessments must be completed prior to the Orientation session with your care provider. As such, there will be at least one week delay between your onboarding session and starting treatment in the study.

   Participants who miss over four scheduled treatment or coaching sessions may be excluded from further participation.

   All treatment sessions will be recorded for supervision purposes. You will be asked at the bottom of this consent form whether you consent to share these recordings for research purposes, or whether you want them deleted once your study participation ends.

   - The following can be expected if you are assigned to Tier 2 - PND Digital Therapy with Coaching:
     - You will start Tier 2 treatment with an Orientation session conducted via secure video conference with your assigned Coach.
     - You will be given access to an online cognitive-behavioral therapy (CBT) course for individuals who are pregnant or recently gave birth and are experiencing symptoms of depression. This is called the ParentMood program.
     - The ParentMood course offers lessons that focus on symptoms of depression that can be experienced around childbirth and motherhood. Some of the lesson content is presented in the form of illustrated videos.
     - You will be able to access the ParentMood program through the study app that will be installed on your personal iPhone during the onboarding session, or through a web-browser.

- We recommend spending approximately one hour per week for reading the course lessons, which includes accessing lesson summaries and tools for practicing skills covered in the lessons.
- You can schedule up to 9 coaching sessions with your Coach. These sessions will be conducted via secure video conference. Your Coach can provide additional support and guidance based on the content in the lessons.

- The following can be expected if you are assigned to Tier 3 – Clinical Care:
  - You will start Tier 3 treatment with an Orientation session conducted via secure video conference with your assigned provider.
  - You will be asked to attend your regularly scheduled appointments with your assigned provider. The number and schedule of sessions will be determined by the provider, but will conclude at the end of the 13-week study. All treatment sessions will occur via secure video conference.
  - You may receive a referral to meet with a psychiatrist at a UCLA Health Clinic, if deemed appropriate by the clinical team. The consultation with psychiatry and potential pharmacotherapy will not be managed by the study team.

- Treatment Adjustments: You may receive information about additional treatment resources outside of those being provided in the study, depending on your symptom scores.

- Treatment Discontinuation during the Study: You may be referred out to other care resources during the study if the study team determines that this referral is clinically indicated.

- Treatment Continuation after Study End: If continued care is needed, you will receive referrals to other available resources in the community.

5) **Study End** *(approximately 5 minutes)*
   - At the end of your assessment schedule, after you have completed the assessments sent 12 weeks after treatment initiation and have completed your final treatment evaluation, you will receive information about compensation earned via email. Depending on your completion of study tasks (see “WILL I BE PAID FOR TAKING PART IN THIS STUDY?” below), you may be eligible to keep the Apple Watch. Otherwise, you will be sent a pre-labeled box to return the device.
   - Although watch wear is required for only the first four weeks of study participation, you will be asked to leave the study app installed on your phone until the end of the study. At this time, you will receive instructions for discontinuing study participation in the app installed on your iPhone and/or deleting the study app from your iPhone, if preferred. This step will take approximately 5 minutes.
   - You will be asked to confirm this step online before receiving any final compensation.

- If you do not confirm completion of this final step by the end of week 16, study staff will discontinue contact attempts and issue final compensation. Your data will continue to be used to support study goals.

Note: While your participation in the study is expected to last 3 months, if you start your participation in the study during your pregnancy period, we may need to adjust your treatment and assessment schedule by two weeks to account for your changed availability post-delivery. If this occurs, the total duration of your study participation may be closer to four months.

We will ask you questions about potentially sensitive topics. If your responses to study surveys at any point indicate that you are feeling suicidal and with a plan to harm yourself or you endorse thoughts of harming your infant or having harmed your infant, our clinical team will be notified and will review this information, confidentially. The clinical team will contact you to determine if there are safety concerns that require immediate help, may follow-up on potentially concerning responses to the symptom surveys, and may provide referrals to clinical services that may be available to you. If we are concerned that you are going to seriously harm or kill yourself or someone else imminently, we may need to share that information with someone outside of our research team to ensure your safety or the safety of others. We may additionally need to share information with your current provider.

If you are having thoughts of hurting yourself or someone else, call 988 Lifeline at 988 or call 911 for immediate assistance.

WHAT INFORMATION WILL BE COLLECTED FOR RESEARCH?

Your study data will only be retained for as long as needed for the purposes of the study, but in no case longer than 10 years after the study ends or when no longer required to comply with applicable law or regulatory requirements (whichever is later). The following data will be used to conduct the study and includes the following:

- **Contact Information**, such as name, email address, phone number, mailing address.
- **Demographic Data**, such as date of birth, zip code, biological sex, gender, race/ethnicity, marital status, height, weight, first/second language, place of birth, your level of education, occupation, personal/family income, and health insurance coverage status.
- **Audio/Video Data** include recordings of clinical sessions. These data are collected for the purposes of clinical supervision. You will have the option to provide consent to allow these recordings to be used by the study team for research purposes.
- **Health app Data** are collected from your iPhone and Apple Watch via the study app installed on your personal iPhone. These include data such as exercise time, stand minutes/hours, steps, flights climbed, walking and wheelchair related data, resting energy, active energy, VO_2 max, heart rate related data (including irregular rhythm notifications), sleep related data, awake time, respiration rate,

environmental sound levels, blood oxygen (including pulse strength), weather and time zone. Some data may only be collected if you make an entry or complete an applicable activity. Examples include respiratory rate, workouts, ECG results, daily mood, emotions, mindful minutes, height, weight, body mass index, blood pressure, sleep apnea event, body temperature, oxygen saturation, respiratory rate, symptoms (including those related to menstrual cycle), information related to menstruation, pregnancy, ovulation and related tests, lactation, contraceptives, sexual activity, the results of a test to detect the softest sounds you can hear, audio exposure, nutrition information such as macronutrients, minerals, hydration, caffeine, and vitamins, and information on whether the data was entered by you will be collected. This collection may include data from the past 24 months before you enrolled in this study if any such data were stored in the Health app.

- **Sensor Data from the iPhone and Watch** are captured via the study app installed on your personal iPhone. With your consent, specific data that is collected by iPhone and Apple Watch and/or data stored in the Apple Health app, will be shared with the study. You will have the ability to review and authorize each data type request in the study app on your iPhone before data is shared. Such data is not collected from devices until you authorize sharing the data with the study. Data types from Apple devices include the following:
    - Device usage, such as frequency and duration of device and app usage, notification data, and charging data. This does not include specific names of websites and apps, and content of notifications.
    - Keyboard usage, such as number of words typed, typing speed and accuracy, and number of emojis used. This does not include typed content, such as specific words.
    - Information about the watch's position on the wrist and times that the watch is worn, as well as wrist temperature during sleep.
    - Rotation rate, which includes rotation motion data.
    - Motion, including acceleration motion data.
    - Odometer data for workouts such as speed and slope.
    - Pedometer data, which includes step count and pace.
    - Heart rate data, including high fidelity optical sensor data that can be used to measure things like heart rate.
    - Electrocardiogram (ECG) sensor data, which describes the timing and rhythm of heart beats.
    - Visits information includes frequently visited locations that have been given an anonymized identifier, distance from home, approximate arrival and departure times, as well as location type. This does not include GPS data and specific location information
    - Facial expression data such as brow raise and gaze direction. This does not include images or video.
    - Speech metrics includes measurements of speech to Siri such as speaking rate, pitch, tenor, and volume. This also includes measurements of speech during phone calls and VOIP, such as speaking rate, pitch, tenor, and volume. This does not include raw audio data or content of conversations.

  - Message usage, which includes the use of the Messages app, such as number of messages and number of individuals messaged. This does not capture any message content and information about people messaged.
  - Phone usage, which includes the amount of time on phone calls per day, number of calls and number of individuals called. This does not capture any audio content and information about people you've talked to.
  - Media events, which includes the timestamp of video or images displayed during the use of messaging apps. This does not include the content of image or video.
  - Ambient light information.
  - Barometric pressure and elevation change.
  - Sleep sessions include time and duration of detected sleep sessions.
  - Audio preferences saved on the device, such as accessibility and music settings, including background sounds, environmental sound measurement, headphone safety, and audio levels.
- **Medication Use** will be collected by study staff at your onboarding session. You will be asked about previous and current prescribed medication use.
- **Survey Data** collected through self-report assessments will include questions about your current depression symptoms (including suicidality), medical and treatment history, history of pregnancy, sleep quality and daily routines, maternal social support, infant bonding, and breastfeeding difficulties (if applicable), stressful life experiences and experiences of discrimination. We will also collect feedback from you about your experience in the study.
- **Treatment Engagement:** information about the number of lessons completed or Coaching sessions attended, or the number of psychotherapy sessions, as well as notes regarding treatment engagement and response from the clinical team, will be recorded and considered study data. Information about whether medication management was provided will also be captured.
- **Electronic Medical Record Data**, including demographics, diagnoses, prescriptions, prescription fulfillments, visits, procedures, observations, labs and vaccinations. The HIPAA Authorization you sign at enrollment gives permission for us to access and use the information described above from your UCLA electronic medical record. Because these data can include certain prescription or treatment information, they may contain information about sensitive conditions such as HIV/AIDs, communicable diseases, substance use disorders, and mental health.
- **Emergency contact:** We ask you to provide us with your emergency contact. We will contact your emergency contact only if we have consistently failed to reach you using a variety of channels (phone, text, email) and if we are concerned about your safety. We will disclose to your emergency contact only that you are participating in a UCLA research study and that we have been trying to reach you but failed to do so. We will disclose that we are concerned about your safety if that is the case. We will not disclose the nature of the study or any other information you have provided to us.

By participating in this study, you are agreeing to provide and share the data listed above. If you do not wish to share any of the required study data with the UCLA research team, you should not participate in this Study.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The Principal Investigator and authorized members of the study staff will have access to study data in identifiable form as needed to conduct the study. This team may include subcontractors, vendors, or other individuals hired by the Study Organizer to support the study under appropriate contracts.

In addition, when required by law, legal process, or litigation, study data in identifiable form may also be made available to the IRB and to regulatory or government authorities, including law enforcement if they want to make sure that your health information has been collected appropriately, or for other reasons that are allowed under the law.

USE OF DATA FOR FUTURE RESEARCH

Before the Principal Investigator and UCLA study staff share your study data with others, your name and other contact information will be removed and a random, unique code, known as the Study ID Number, will be assigned to the data. This code will not be based on any information about you. Additional steps will be taken to have additional identifying information removed from your study data, so that they are considered "**De-Identified Data**". Video recordings are not included in the "De-Identified Data". These De-Identified Data may be used to support future research.

Video Recordings: Your treatment sessions will be recorded for the purposes of clinical supervision. These sessions will be conducted via secure video conference and stored in a secure file repository that only members of the study team can access. You will have the option when you sign this consent form to choose whether to allow these recordings to be used for research by the UCLA study team. Even if you provide consent for the UCLA study team to use these recordings for research purposes, these recordings will not be shared with outside investigators.

Sensor Data: Sharing of your Sensor Data will be more restricted and will only be shared by the UCLA study team for use in research with similar purposes as this study and only when such other research is also conducted by the UCLA study team. Before your De-Identified Data are shared, the planned research will be reviewed by the Principal Investigator to make sure the research meets these requirements. Other researchers will only be able to access your De-Identified Data in a controlled, secure electronic environment managed by the UCLA study team.

By agreeing to participate, you are agreeing to allow your study data to be kept for use in future research to learn about, prevent or treat depression or other health-related problems. By signing this consent form, you will also give us permission to share your information with people other than the researchers who are conducting this study. If you do not want your data to be used for future research, you should not participate in this study.

Your de-identified data may be available to other investigators through one or more 'controlled-access' databases managed by the UCLA team. The Principal Investigator must approve such access and will do so on a case-by-case basis. These other investigators may be at other research centers (academic or commercial). You will not be informed of the details of any specific research studies that might be conducted using your data, including the purposes of the research, and it is possible that you might not have chosen to consent to some of those specific research studies. Results from these studies may not be disclosed to you.

HOW WILL MY DATA BE USED?

By signing this Consent, you agree that the UCLA study team and any third parties identified in this Consent can collect, use, store, analyze, disclose and otherwise process your study data for the following purposes:

- To support and carry out the study.
- To analyze the study data and publish the study results.
- To verify that the study is done properly.
- To combine the results of this study with the results of other studies, for the purpose of the study goal.

Publication and Presentation: Your study data may be used by the UCLA study team for publication and presentation purposes. The results of this study may be published in academic, medical, or scientific journals and presented at academic, medical, or scientific meetings. If information about this study is published or presented in any settings, it will only include aggregated results and/or De-identified Data.

Mandated reporting: Identifying information may be released in some circumstances. Specifically, the study staff are legally required to report known or reasonable suspicion of abuse to a child, elder, or dependent adult and serious threats against a reasonable identifiable victim or victims. Information will be released only to responsible agencies and others that the study staff are mandated to report to by law or University policy, including relevant authorities such as law enforcement We also might need to release information about you if you are in danger and need emergency care (for example if we believe there is an imminent threat of suicide or serious self-harm or that you may harm others). Any relevant information obtained during the course of the study can be used in mandated reporting if indicated (e.g., emergency contact). This information obtained may be shared with your treating OBGYN provider and your clinical team. You have the right to privacy, and it is your choice whether or not you answer a question or provide information.

Data sharing with you*:* We are unable to share your individual results from the study with you or your health care provider. This includes, but is not limited to, digital sensing data obtained from your iPhone sensors. The exception is that, in the event of an incidental health finding made during the study, study staff may contact you. You can read more about this provision in the Section "WHAT IS AN INCIDENTAL FINDING, AND WHAT WILL HAPPEN IF ONE IS FOUND?"

HOW WILL MY STUDY DATA BE KEPT CONFIDENTIAL?

This section of the consent form describes how study data will be kept confidential.

Data Storage and Access: The study data described above that are collected from or about you as part of the study (including any information that can directly identify you, such as your name and address) will be held confidential by UCLA study team in a secure database. Access will be limited to those members of study staff who need access to administer and conduct the study, and they will be required to complete training about requirements to protect your privacy.

Employees of the University may have access to identifiable information as part of routine processing of your information, such clinical encounter scheduling and documentation. However, University employees are bound by strict rules of confidentiality.

Video Recordings: Although the video recordings captured for clinical supervision purposes will not be labeled with your identifying information, you may be recognized by a member of the UCLA study team that sees or hears the recordings because your face and voice will be unaltered.

iPhone and Watch Passwords: There are also steps you can take to protect your privacy. Because the information collected in this study can be sensitive, study staff will ask you to password protect your iPhone and Watch.

WHAT IS AN INCIDENTAL FINDING, AND WHAT WILL HAPPEN IF ONE IS FOUND?

The Principal Investigator may review the data collected from you during or after you have completed your participation in the study and may discover an “incidental finding” about you. An example of such incidental information could be an abnormality in your heart rate or rhythm.

It is not the responsibility of the Principal Investigator to recognize or identify any such findings, but by agreeing to participate in this study you also consent to have the study staff contact you and inform you of any information that they observe and believe could be an incidental health finding. The decision (and any costs) to proceed with further evaluation of the incidental findings will then lie solely with you. If you do not wish to be informed of such findings, or for study staff to take the above actions, you must decline to participate in this study.

WHAT KIND OF RISKS OR DISCOMFORTS COULD I EXPECT?

The possible risks and/or discomforts associated with the procedures described in this consent form include the following:

Risks associated with mood assessments: There is a minor risk of fatigue from filling out the surveys. To help with this you will be able to save survey responses and come back to them at any time. There is also a risk of emotional discomfort, for example, when

you are asked about your medical history, mood, and experiences. However, you can choose not to answer any questions or withdraw from the study at any time.

Overall risks of loss of confidentiality: Although all Study Data will be protected and treated as confidential, total confidentiality cannot be guaranteed. There is a risk of loss of confidentiality in research studies. It is possible that researchers who see or hear the video or audio recordings will recognize you. Additionally, the study staff may be able to see parts of your home during the remote video conference sessions. Every effort will be made to protect you and your health information to the extent possible (see Section titled "HOW WILL MY STUDY DATA BE KEPT CONFIDENTIAL?" above).

Risks associated with notifications, text and email messages: Notifications from the study app may include the study title, which could be seen by a bystander and reveal your participation in the study. Texting and email may not be secure communication methods as unencrypted messages could be intercepted. The study staff commits to sending the minimum necessary information when communicating with you using these methods.

Discomfort related to the Apple Watch: You may experience slight to moderate discomfort or fatigue associated with wearing the Apple Watch for prolonged periods of time (for example, skin rash or pressure artifacts). This is expected to be minimal as the band and study smartwatch are consumer grade and intended for long term wear.

Risks associated with the collection of Face Shape and Expression: The collection of face shape and expression data as described above may make you feel uncomfortable. As a reminder, no photos or videos are collected during these activities. The data that are collected for Face Shape and Expression consist of measurements of your face position and movements such as eyebrow raises and blinking.

If at any time you are no longer comfortable with these data being collected, you can stop sharing this metric and withdraw from the study.

Risks associated with the collection of Speech Metrics: The collection of Speech Metric data as described above may make you feel uncomfortable. As a reminder, no raw audio of, or words used in your conversations are collected during these activities. The data that are collected consists of data about your voice such as tenor pitch and cadence.

If at any time you are no longer comfortable with these data being collected, you can stop sharing this metric and withdraw from the study.

Risks associated with smartphone app installation: Your smartphone battery may drain more quickly than usual while the study apps are installed on your device. While the study apps have been designed to use a minimal amount of data, there is a small chance you could experience an increase in data plan usage during your participation.

Risks associated with prepaid Visa debit card: If you receive a US Bank Focus Blue Program Visa debit card to receive compensation for study participation, you may incur fees if 1) you use an out-of-network ATM, 2) require more than 2 card replacements within a 12-month period, or 3) if your card carries a balance and you do not use the card for over 365 days.

Unknown risks: As with all studies, there may be risks that we do not know about. Study staff will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me: The possible benefits you may experience from participating in the treatment intervention might include improvement in depressive symptoms. However, a response to treatments offered cannot be guaranteed in any patient and neither the degree of response nor the duration of response to one of the treatments offered can be reliably predicted at this time. You have the right to refuse to participate in this study.

Possible benefits to others in society: This study aims to further medical knowledge and may improve future treatment of depression in expectant and new moms. This research may improve the scalability and accessibility of historically inaccessible PND treatments.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

Participation in research is completely voluntary. You can decide to participate or not to participate. Instead of being in this research study, your choices may include:

- Psychotherapy
- Receiving pharmacotherapy to treat depression
- Taking part in another study

If you do not have or cannot afford a private psychologist or psychiatrist, we will recommend low-cost treatment options that may be available to you.

Disclosure Statement

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. You are not under any obligation to participate in any research project offered by your clinician. Your health care provider might be informed about study-related information relevant to your treatment.

Because this study involves the treatment of a medical condition and/or medical procedures, information about your participation in this study and care received may be placed in your medical record. This will allow the doctors that are caring for you to obtain information about what medications and/or procedures you are receiving in the study and treat you appropriately.

HOW DO I WITHDRAW FROM THIS STUDY?

Your decision to participate in this study is voluntary. You can choose not to participate or stop participating in the study at any time, for any reason, without penalty or loss of

benefits to which you are otherwise entitled and without any effect on your future medical care

You can withdraw from this study by contacting the study staff and by withdrawing from the study app on your iPhone. Withdrawing from a study doesn't delete any previously gathered data, but the app stops collecting any new data. Deleting the study app from your phone does not withdraw you from this study.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

You may be withdrawn from the study by the Principal Investigator or study staff at the discretion of the Principal Investigator or study staff if it is in your best medical interest or to guarantee the proper conduct of the study.

The Principal Investigator or study staff may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions, if you choose to receive treatment elsewhere (e.g., become a participant in another treatment study), or if you miss scheduled visits. For example, if you become ill during the research, you may have to withdraw, even if you would like to continue. The Principal Investigator or study sponsor might also decide to stop the study at any time. You will be provided information about available resources if this occurs.

Note that if you decide to stop participating in the study, or are removed from the study, or the study is stopped, no new information or data will be collected from or about you after the date of your withdrawal. However, the data collected about you up to that point will remain part of the study and may not be removed from the study database. The data collected may continue to be used by the UCLA study team in accordance with this consent form.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

You will not be charged to participate in this study. There will be no cost for treatment services. If you are referred to a UCLA Health Clinic for consultation with psychiatry, scheduling and billing will be managed by the clinic, in which case you or your insurance are required to pay for the psychiatry appointments and potential prescribed medication.

While the study apps have been designed to use a minimal amount of data, there is a small chance you could experience an increase in data plan usage during the study period. Standard phone usage and text messaging rates may apply when you communicate with study staff. If you receive a US Bank Focus Blue Program Visa card to receive compensation for study participation, you will only incur fees if 1) you use an out-of-network ATM, 2) require more than 2 card replacements within a 12-month period, or 3) if your card carries a balance and you do not use the card for over 365 days.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You can earn up to $200 for completing all of the study assessments, as illustrated in the figure below. Compensation includes:

- $50 for completing all baseline assessments, including the onboarding session
- $20 for completing all mid-point assessments
- $20 for completing all study end assessments
- You can receive compensation according to the amount of recorded watch wear in weeks 1-4:
    - For wearing the watch on 4/7 days each week, on average, across weeks 1-4, you will reach Base tier and earn $10 in compensation.
    - For wearing the watch on 5/7 days each week, on average, across weeks 1-4, you will reach Silver tier and earn $15 in compensation.
    - For wearing the watch on 6/7 days each week, on average, across weeks 1-4, you will reach Gold tier and earn $20 in compensation.
- You can receive compensation according to the amount of weekly mood surveys completed in each approximately four-week interval. At the end of blocks 1, 2, and 3:
    - If you complete at least 2 of the 4 weekly surveys in the previous block, you will reach Base tier and earn $10 in compensation.
    - If you who complete at least 3 of the 4 weekly surveys in the previous block, you will reach Silver tier and earn $15 in compensation.
    - If you who complete all 4 of the 4 weekly surveys in the previous block, you will reach Gold tier and earn $20 in compensation.
- In addition, if you reach Gold tier for watch wear and in each of the three blocks, you will earn a completion bonus of $30.

	Compensation Amount		
Baseline assessments & Onboarding session*	$50		
Mid-point assessments*	$20		
Study end assessments*	$20		
	Base Tier*	**Silver Tier**	**Gold Tier**
Watch Wear (block 1)	$10	$15	$20
Weekly Surveys (block 1)	$10	$15	$20
Weekly Surveys (block 2)	$10	$15	$20
Weekly Surveys (block 3)	$10	$15	$20
Gold Tier Bonus			$30

*Must be met in order to keep the Apple Watch at the end of the study

Earned compensation will be provided at four different points:

- (1) All parts of the baseline must be completed before the first payment is issued, including baseline surveys and the remote onboarding session. The onboarding session tasks include iPhone and Watch setup, training on the study protocol, enrollment into the study app on your iPhone, and confirming receipt of the issued US Bank Focus Blue Program Visa card.
- At the end of each block, so long as any open technical issues have been resolved and you completed the required assessments: (2) after week 4; (3) after week 8;

and (4) after week 13, once all final study assessments have been completed and you have confirmed ending study participation in the study app.
- If you discontinue study participation before the end of a given block, you will not receive compensation based on the amount of tasks completed in that block.

Note that compensation for the mid-point and study end assessments, watch wear, and weekly surveys (in each block) are independent from each other.

If you deliver after enrollment and your study schedule is delayed by up to two weeks, those two weeks will not be considered for compensation purposes. You will continue to receive weekly symptom surveys during this two-week delay, but your compensation will be tied to a four-week window that does not include this two-week interval following delivery.

If an Apple Watch is issued to you, and if you complete all assessments at baseline, mid-point, and study end, and reach Base tier for Watch Wear in the first block and Base tier for Weekly Surveys in each of the three blocks, you will be able to keep the Apple Watch at the end of the study. If you discontinue study participation before reaching the end of the study, you are not eligible to keep the Apple Watch. If you do not complete enough tasks to be eligible to keep Apple Watch, study staff will contact you until the devices are returned. A return kit will be mailed to you for the return of the Apple Watch. You will be contacted by study staff until you return the Apple Watch.

Compensation can be provided as a prepaid Visa debit card offered through the Focus Blue Program by US Bank, or as an electronic gift card. This US Bank Focus Blue Program Visa debit card will be registered to your name and loaded with the amount earned. It will be mailed directly to your home address or will be included in the study kit that is shipped to you prior to your onboarding session. Study staff will collect your date of birth in order to register the card to you. You will be provided with the schedule of fees associated with the card and will receive a printed copy when you receive the card in the mail or can ask to receive a copy from study staff. Once you notify study staff to confirm receipt of the card, study staff will load the amount earned from the baseline assessment onto your US Bank Focus Blue Program Visa card. The remaining compensation will be provided as described above.

If you have any questions regarding your compensation for participation, please contact study staff using the contact information on the first page of this form. Note: It is important to inform the study staff right away if you encounter technical issues with Study devices or the study app, encounter issues with device availability, or have extenuating personal circumstances. The study staff will work with you to address issues.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Principal Investigator: You may contact the Principal Investigator, Dr. Nelson Freimer at (310) 794-9571, or contact our study staff using the contact information provided on the first page of this form, with any questions or concerns about the research or your participation in this study.

UCLA Office of the Human Research Protection Program (OHRPP): If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you, and you will not lose any of your regular benefits. Furthermore, you will not lose any of your legal rights to which you are otherwise entitled by signing and dating this consent form.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at any time.
- If you decide to stop being in this study, you should notify study staff right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study, you should sign and date at the bottom of this form. You will have the option to save a copy of the signed consent form. Once this form is counter-signed by a member of the research team, you can request to receive a completed version by email.

You will be asked to sign a separate HIPAA Authorization form authorizing access, use, creation, or disclosure of health information about you.

(*The following additional, optional consents, will require you to opt-in below and are not required to participate in the study.)*

Optional Consent to use Video Recordings for Research Purposes: By agreeing to participate, you agree to allow the recording of treatment sessions for the purposes of clinical supervision. This includes clinical and coaching sessions.

You also have the option to allow your clinical interview recordings to be used for the purposes of research. Please indicate below if you allow use of these recordings for this purpose.

Optional Consent to be Re-Contacted for Future Research
We would like to be able to contact you in the future for other studies that you may be eligible for. Please indicate below if you would like to allow the use of your contact information to contact you about these opportunities to participate in future studies.