RESEARCH PARTICIPANT CONSENT FORM

Everyday Mother-Baby Relations and Cellphone Engagement (EMBRACE)

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1. Key Study Information:

The focus of this study is to assess early mother behavior and feelings, infant development, and how mothers may choose to use their smartphone.

We seek women in the 3rd trimester of pregnancy or who are the mother of a young infant (0 to 12 weeks of age). (see more information in Section 2).

Starting when your baby is around 2 months old, you will be asked to complete monthly online surveys, as well as brief EMA survey bursts, sent to your smartphone (5 per day for 5 days) at 2, 3, 4, and 5 months of age to assess your well-being and feelings about your baby. Your phone use will also be passively measured through a study app which you install on your phone, and finally in the first study assessment and final study assessment (when your baby is about 2 months old and then 5 months old) you will take part in a feeding observation with your baby via a secure video call.

Participants will be compensated for their participation in the study (see Section 6).

Potential risks and what we will do to keep your data safe and secure are described in Section 8 and Section 9.

2. Who May Participate in this Study?

In order to participate in this research, you must meet all the following criteria:

- Be a woman 18 years of age or older
- Be the legal and custodial guardian of a 0-week to 12-week-old infant –OR—in the 3rd trimester of pregnancy and will soon fit this criteria.

- Be a frequent caregiver of the baby (or will be, once baby is born)
    - i.e., engages in daily child tasks such as feeding, bathing, play, caring for child, etc. Also includes those who work outside the home. Typically, should be with their infant at least 2 hours per day, not including while parent or infant is sleeping or infant night waking.
- Live with the child (or will do so once baby is born)
- Live in the U.S.
- Read and understand English
- Own a smartphone (this is necessary for the passive sensing of phone use)

You may <u>not</u> participate if:

- Infant has a developmental delay (diagnosed by the infant's pediatrician or physician).
- Infant has been or will be born pre-term (before 37 weeks of pregnancy).
- Infant has a medical condition that interferes with feeding by mouth.
- Your spouse/co-parent is already in the study. In other words, we will enroll only one mother from each family.

3. Study Procedures: What Will Happen in this Study?

This study will ask you about your technology use, parenting, your relationships, your infant, and your well-being. There are multiple parts (called "Waves") to this research study.

First, after consenting to the study, the study team will (1) set up a time to meet with you via a video call to go over the study methods, schedule, tasks, and an online survey, and (2) email you instructions on how and when to install the study app(s) (Chronicle, Avicenna, and/or RealizD) on your phone, which will passively measure your phone and app use throughout the study. You will also be asked to download another study app (MyCap) that allows for easy, protected, and secure communication between you and the study team.

Data collection begins at approximately 2 months of infant age (defined as any time between 4 weeks and 12 weeks of age), and at months 2, 3, 4, and 5 we will send you a larger monthly survey with demographic questions (e.g., age, race, income, gender, etc.) as well as measures of media use, depressive symptoms, parent responsiveness, parenting stress, sleep, infant behavior, and other well-being measures. Each of these months, you will also have a period where you are sent 5 brief surveys per day for 5 days. On the surveys you will report on your well-being and feelings about your baby.

Additionally, at about month 2 and month 5 (of infant age) you will take part in a video-recorded observation (via video conference software, e.g., Zoom) of you engaging with your baby in a feeding session.

Your participation in this research is completely voluntary and you can withdraw from the study at any time. We may call, text, or email you during the study to make sure that everything is ok, to answer any questions you might have, to communicate about the study, and to remind you of your research participation. You will receive text messages, messages via the MyCap app, and/or emails to remind you to complete your surveys and other parts of the study.

You will not need to go anywhere or travel to our lab to complete the phone use measurement, your online surveys, or the observations of your infant feedings. All the surveys are online, the measuring of your phone use happens in the background on your phone via an app that you install, and the observations will occur remotely via video conference software (e.g., Zoom).

We will now explain the steps involved in this research in more detail.

Pre-WAVE 1 (Consent and Getting Started):

You will be given an ID number and assigned a study schedule based on your availability. The schedule notes the dates of your surveys, observations, and phone measurement. This ID number and schedule will be emailed to you. You will use your ID number every time you complete one of the online surveys. We will also ask you for your name, phone number, phone model and carrier (e.g., iPhone, AT&T), and email address. This information will be used to send you the surveys, reminders, and compensation for your study participation.

We will then send you to the online consent form. Typically, you will have about 2 weeks from the time you receive our email to decide if you want to participate and to also complete your online consent form—although this time frame may be extended if needed; it is also possible that the time frame may be adjusted if your baby could become too old to participate in the study. If after reading the consent form you decide to take part in the study, you will enter your ID number and select "Yes" that you would like to participate in the study. You will also select "Yes" that you agree to your baby participating in the study.

After you complete the online consent form, the study team will email you about next steps and how to install the phone use measurement app(s) on your phone, your login information for the app(s), and instructions on how to uninstall the app(s). You will NOT use your personal email address or any personal information to install the app(s). The study team will be available via email or phone to answer any questions. Your study schedule and how to access the surveys will also be emailed to you.

The app(s) will measure your phone and/or app use from the moment you install and set up the app to the moment you uninstall the app. You will be able to uninstall the app(s) at any time if you no longer want to participate and have your phone usage logged. We simply ask that you email us to let us know you are uninstalling the app(s) and/or that you no longer wish to participate. During the study, the app(s) will track your phone use continuously and may give us the time of day, duration, which app is running (such as Facebook, Firefox, Pinterest, Instagram, etc.), whether screen is on or off, and battery status (e.g., 45%). The app does not track anything you do within an app, on the internet, or in a message you send. For example, it may report when and how long you used Facebook but it does not know anything that you did inside the app like posting an update, liking a post, or words typed.

You will also be asked to download another application to your smartphone called MyCap that will allow for easy, protected, and secure communication between you and the study team. If you are unable to receive your survey links via text messaging, we may also use MyCap to send your survey links or messages about your surveys.

The study team will also message you to set up a time to meet about the study. In this meeting, which will occur over a video call, we will discuss the study procedures and any questions you might have. We will also have you complete a dummy survey (so you get the feel for how the surveys will function), and we will assist you with installing the study apps on your smartphone (if you need assistance with this).

Finally, we will ask you to complete an online intake survey at the end of this video call. *This video call is important to get you oriented to the study and must be completed.*

WAVE 1 (About 2 Months of Infant Age):

At about 2 months of infant age, you will complete an online survey that assesses demographic questions (e.g., age, race, income, gender, etc.) as well as measures of media use, depressive symptoms, parent responsiveness, parenting stress, sleep, infant behavior, and other well-being measures. You will have about 7 days to complete your survey; however, this period may be adjusted if needed. You may receive email, text, or MyCap reminders to complete your survey.

You will also be scheduled to complete a period of 5 brief surveys per day for a total of 5 days sometime that month. These surveys will typically be fast, often taking only about 2 to 4 minutes to complete each time. On the surveys you will report on your well-being and feelings about your baby. You will receive your survey links via text message (unless this is not possible, then you may receive your survey links via the MyCap app). You may receive email, text, or MyCap reminders to complete your surveys.

You will also be scheduled for a remote video call observation of a feeding with your baby. The observation will take about 45 minutes. At the start of this remote feeding observation, a study team member will instruct you regarding how to set up your tablet, computer, or other device so that they have a clear view of the feeding interaction. They will ask you to respond to a brief Pre-Feeding Observation Survey, which will assess when your infant last ate and slept and whether your infant has experienced any disruptive events (e.g., shots, illness) that may impact the feeding interaction. They will read the questions and enter your responses directly into a secure survey database during the call. When your baby is ready to eat, you will be instructed to feed your infant as you normally would at home and to offer your infant's typical milk (breast milk or formula) from your typical mode (breast or bottle). We will video-record the feeding via Zoom video recording settings so we can study the behaviors later. We will only utilize the video recording in the ways you selected earlier in your Video Release Form during the consent process. During this video visit, there will also be a very short online survey for you to complete.

Your smartphone use will be passively measured via the Chronicle, Avicenna, and/or RealizD app that you installed earlier on your smartphone.

WAVE 2 (About 3 Months of Infant Age):

At about 3 months of infant age, you will complete an online monthly survey that assesses measures of media use, depressive symptoms, parent responsiveness, parenting stress, sleep, infant behavior, and other well-being measures. You will have about 7 days to complete your survey; however, this period may be adjusted if needed. You may receive email, text, or MyCap reminders to complete your survey.

You will also be scheduled to complete a period of 5 brief surveys per day for a total of 5 days sometime this month. On the surveys you will report on your well-being and feelings about your baby. You will receive your survey links via text message (unless this is not possible, then you may receive your survey links via the MyCap app). You may receive email, text, or MyCap reminders to complete your surveys.

Your smartphone use will continue to be passively measured via the Chronicle, Avicenna, and/or RealizD app that you installed earlier on your smartphone.

WAVE 3 (About 4 Months of Infant Age):

The same things that happened in Wave 2 will happen during Wave 3. In other words, you will receive a monthly survey to complete, you will complete a period of 5 days of surveys, and your smartphone use will continue to be passively measured via the Chronicle, Avicenna, and/or RealizD app that you installed earlier on your smartphone. You may also receive email, text, or MyCap reminders.

Wave 4 (About 5 Months of Infant Age):

The same things that happened in Wave 3 will happen during Wave 4. In other words, you will receive a monthly survey to complete, you will complete a period of 5 days of surveys, and your smartphone use will continue to be passively measured via the Chronicle, Avicenna, and/or RealizD app that you installed earlier on your smartphone. You may also receive email, text, or MyCap reminders.

You will also be scheduled for your final remote video call observation of a feeding with your infant. The feeding observation methods will be the same as those during the Wave 1 (Month 2) assessment.

End of Study

At the end of the study, we will send you an email stating that you have finished the study and requesting that you fill out a very brief informational survey (End of Study Survey) that will not be connected to any of your prior survey responses or any other data. In this separate survey, you will indicate your optional permission for us to contact you about future studies or study news and if you wish you can provide your name, email address, and other optional information.

4. How much of my time will be needed to take part in this study?

The phone measurement will not take any of your time, as it works in the background on your phone. However, it may take you about 10 to 30 minutes to install and set up the study app on your phone and then about 10 to 30 minutes to uninstall the app once your participation in the study is complete. There may be times we need to troubleshoot with you as well.

The EMA surveys (5 surveys per day for 5 days each month) will take about 2 to 5 minutes to complete each survey.

The online monthly surveys will take about 25 to 45 minutes to complete each month.

Each video recorded feeding will last about 45 minutes.

After consenting into the study, most participants will participate in the study for around 4 to 6 months (including allowing time for study and app set up, completing your surveys each month for 4 months, and your video call feeding observations).

5. How could I benefit if I take part in this study?

There are no direct benefits, although you may learn about and reflect on your experience and interactions in parenting.

6. Will I be paid or given anything for taking part in this study?

You will be compensated via Amazon gift card codes at the completion of each wave (month) of the study. The code will be emailed to you typically within 3 weeks of your completion of each wave.

This compensation includes $10 per monthly survey, $1 per EMA survey completed plus a $10 bonus if you complete at least 20 EMA surveys and phone use measurement, and $35 per remote video call mother-infant feeding observation. If you completed all monthly surveys, EMA surveys, and remote feeding observations, you would be compensated a total of $250 across the entire study.

The compensation is summarized below:

Research Activity	**Compensation**
Monthly Survey	$10
EMA surveys (5 brief surveys per day across 5 days) and phone use measurement via app	Up to $35*** ***$1 per completed EMA survey, plus a $10 bonus if complete at least 20 or more EMA surveys.
Remote observation	$35

7. Ending Your Participation in the Study:

If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell the research team by emailing them at EMBRACE@parkview.com.

Could the researchers take me out of the study even if I want to continue to participate?

Please note that we will withdraw you from the study if you are unresponsive to our attempts to contact you. We will make at least three contact attempts before withdrawing you from the study. We will also withdraw you from the study if you do not follow study procedures for installing the phone app for the passive sensing of your phone use or completing your EMA surveys. We may also withdraw you from the study if you do not participate in the feeding observations, become ineligible to participate, if the researchers believe it is not in your best interest to stay in the study, or if the study is suspended or canceled.

We will withdraw you if you choose “No” (on the Video Release Form) that you do not allow the video recordings of the mother-infant feeding interaction(s) to be studied by the research team, as then you will not be able to participate in the study.

If we find that a participant is the spouse/partner of a participant who is already enrolled in the study, we will withdraw this participant from the study and compensate this participant for the parts of the study they had already completed. Their data will also be deleted from the study, but their name/contact/enrollment information will be maintained in our tracking sheets so that they can be compensated and so that we have a record of what occurred. Their spouse/partner who was already in the study will be allowed to continue in the study.

Will I still receive compensation if I stop participating or am withdrawn from the study?

If you have completed part of the study and then withdraw or are withdrawn, you will still receive compensation for the part of the study you completed. For example, if you completed your monthly survey and were then unresponsive to us and were therefore withdrawn from the study, you will be compensated for the completion of your monthly survey.

8. What risks will I face taking part in this study?

The risks to you are not greater than those ordinarily encountered in daily life. Your participation in this study might make you feel emotional as you remember specific parenting interactions or daily activities. If you become emotionally distressed and feel you need help, you can speak to your physician to ask for local resources or a local counselor. You can also call 211 or go to http://www.211.org/ to find the resources you need. If you need immediate help, you should call 211. The following are also available to you 24/7 to contact: National Parent Helpline 1-855-427-PARENT (2736); SAMHSA's National Helpline 1-800-662-HELP (4357); and National Suicide Prevention Lifeline 1-800-273-8255.

As with any research study in which there are data points collected, there is the potential risk of breach of confidentiality and loss of privacy. In the next section (Section 9), we review the steps we take to minimize this risk and to protect your identity.

9. Confidentiality: How will the researchers protect my information?

Strict confidentiality of the data will be upheld. Your responses will not be associated with any identifying information; only your ID number will be connected to your data, and your name will not be attached to your responses at any point. We will require that you use your ID number on all surveys. Your email and other contact information may be collected but will only be used to contact you in regard to this research study, compensation, or in other ways for which you gave us permission. Your name, email address, and other identifying information will be destroyed after Parkview's record retention period has elapsed, unless you have given us permission to use your information to contact you about future research studies or newsletters/results. The de-identified data may be used for future research. The project's research records may be reviewed by the Parkview Health Institutional Review Board and/or the NIH and/or other government officials or auditors who may need the information to make sure the study is done in a safe and proper manner. Your confidential electronic data will be kept on secure servers, in password-protected files or folders, and/or on a password-locked computer. All physical records or data (e.g., backups of audio and video recordings on hard drives) will be stored in a locked office or cabinet or in a location only accessible to the study team. Only the principal investigator (the lead researcher in charge of the study) and approved study personnel will have access to any identifiable data. The information you give to us in this study will only be used in ways that will not reveal who you are. You will not be identified in any publication, presentation, online article, or newsletter resulting from this study or in any data files shared with other researchers. Any personal

information that could identify you will be removed or changed before files or results are shared with other researchers or the public.

All phone use data stored on Chronicle app or Avicenna app servers will be deleted from those servers within approximately one month of the completion of all data analysis for this study.

The passive sensing app (Chronicle, Avicenna, and/or RealizD) will measure your phone use continuously. This may give us the time of day, duration, which app is being used on your phone, whether screen is on/off, and battery status. This application does not log any information about the private content of your phone use. In other words, while it may note when certain apps are running – such as Internet browser, Facebook, etc. – it cannot and does not track any contacts made through those apps, what is posted on social media, the content of emails or texts, phone numbers dialed or messages/calls received, etc.

As further explanation, the Avicenna app records the time that the smartphone's screen turns on or off (screen state data). It does not record the content of the screen or the reason it was turned on or off. The Avicenna app also records the battery status of your smartphone, which provides information on your device's charging, discharging, and power consumption (battery status data).

The Chronicle app for both iOS and Android devices poses few risks to participants with regards to loss of confidentiality; it has already been trialed in populations after passing Institutional Review Board review and does not drain the battery, increase the likelihood of viruses, or cause the participants' device to break. Because there is the possibility of data breach, either from the Methodic server or our servers, all storage and data transmission will be planned with the highest level of security. Methodic uses the highest possible security encryption to protect data, and complies with HIPAA Security Rule, which establishes technical specifications for applications that work with protected health information online. All data is stored securely at rest encrypted with AES-256. Researchers can control who can access the device use data online by assigning and revoking user permissions or by defining user roles. For this study, there will be no identifiable data on Methodic servers as participants will log into the app using their study ID number, and only the study team (not Methodic) will have access to the master list that links participants' identities to their ID numbers. Methodic uses the highest possible security encryption to protect data, and complies with HIPAA Security Rule, which establishes technical specifications for applications that work with protected health information online. Methodic's infrastructure is built on HIPAA and CJIS compliant services such as Amazon EBS (Elastic Block Storage), which uses virtual hard drives encrypted with Amazon KMS (Key Management System). All data is stored securely at rest encrypted with AES-256. Methodic uses tamper resistant audit logs that record every time someone reads or accesses the data.

If you own an iPhone and are asked to also install the RealizD app, you will not enter any personal identifying information during the install, which will further protect the confidentiality of your data. RealizD does not collect personal identifiers, but may collect information such as the type of mobile device used and operating system. Your phone use data via the RealizD app is only stored locally on your phone. You will be asked to export and email anonymous device use data to the study team, which we will download onto secure computers or servers. The RealizD data that is stored on your phone will be deleted when you remove the RealizD app from your phone. Your phone use RealizD data that you shared with us will be maintained by us as described earlier.

If you own an iPhone and are asked to also install the Avicenna app, you will not enter any personal identifying information during the install, which will further protect the confidentiality of your data. Avicenna does not collect personal identifiers but may collect information such as the type of mobile

device used and operating system. On iOS devices, applications are often terminated by the operating system when running in the background, which can interrupt the data collection process. To prevent this, the app must keep the location sensor active in the background. Therefore, participants must grant location permissions. However, no location data is collected by the app. All services on Avicenna servers are located behind a firewall. All traffic between the app and the server is encrypted via SSL/TLS 1.2 and is sent through HTTPS. Avicenna also encrypts the data at rest. Thus, all data collected by Avicenna is encrypted at all times. Avicenna is compliant with PEPEDA, HIPAA, GDPR, and FDA CFR Part 11.

Although your data and responses are confidential, we are required by law to report suspected child abuse and any potential risk of harm to yourself or others. If you express, describe, or show actions involving or with suspected child abuse or harm to yourself or others in survey open response fields, during interviews or video observations, or during any virtual or physical interaction with the study team, we will report this information to the local authorities and/or local child abuse or suicide risk hotline.

Voluntary Nature of Participation: You do not have to participate in this research project. If you agree to participate, you can discontinue participation at any time without penalty. Any questions you may find objectionable, you are not required to answer. If you no longer want your phone use to be measured, you may uninstall the phone tracking app.

Questions about the Research: If you have any questions about this research project, you can contact Dr. Brandon McDaniel and his study team at 260-266-7247 or via email at EMBRACE@parkview.com. If you have questions about your rights as a subject/research participant in this research or concerns about the treatment of research participants, you can contact the Parkview Health Institutional Review Board at 260-266-8195 or via email at irbcoordinators@Parkview.com.