Evaluating Technology Enabled Services in Perinatal Depression

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ONLINE CONSENT FORM INTRODUCTION

Hi there! Before you get started with the study, we'd like to share some important information about the study and obtain your permission to participate.

Please take the time to read this information carefully. At the end of certain sections, there will be corresponding comprehension questions. These will help to reinforce key points we'd like you to be aware of before consenting to participate in this research study. If you have any questions feel free to discuss this with your care manager, or any of the research study staff.

SECTION 1: ABOUT THIS RESEARCH STUDY

Title of Research Study: Evaluating Technology Enabled Services in COMPASS

Primary Investigator(s): Emily Miller, MD, MPH, and David C. Mohr, PhD

Supported By: This research is supported by funding made available through the National Institutes of Health.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Dr. Mohr, an investigator on this study, has a financial relationship with a company that is commercializing the IntelliCare apps and may benefit from this study in the future.

Key Information about this research study

The following is a short summary of this study to help you decide whether to be a part of this study. The purpose of this study is to evaluate how the addition of digital resources like mental health smartphone apps, websites, and other digital communication tools can support people experiencing perinatal (during pregnancy and up to 12 months postpartum) depression. If you join the study, you will be asked to do two main things:

1. Interact with digital resources designed to provide mental health support.
2. Complete research surveys online. You may also be invited to complete optional telephone interviews.

We expect that you will be in this research study for 12 weeks. The primary risk of participation is the possibility that you will experience distress or fatigue while completing the research interviews or questionnaires. You have the option to stop a research survey at any time without penalty. The main benefit is helping researchers improve services for people who may experience perinatal depression in the future.

Why am I being asked to take part in this research study?
You are being invited to take part in this research study because you are at least 18 years old, and you are a patient at Northwestern Medicine receiving care through the COMPASS care team, which serves patients from the perinatal and obstetrics clinics. You have a smartphone and have expressed interest in using digital resources as an experimental add-on to enhance the services you are already receiving through the COMPASS care team.

Why is this research being done?
Providers from Northwestern Medicine's perinatal and obstetrics clinics and researchers from Northwestern University's Center for Behavioral Intervention Technologies (CBITs) aim to evaluate how the addition of mental health smartphone apps and other digital resources can support people experiencing symptoms of perinatal depression.

This study will give researchers the opportunity to explore how apps, websites, and digital communication tools work for patients who use them as an experimental add-on to the services they are already receiving through the COMPASS care team.

The purpose of this study is to evaluate how the addition of digital resources can help patients manage symptoms of perinatal depression.

How many people will be in this study?
We expect to recruit 100 people for this research study.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Question: My participation in this research study is voluntary.

Is this statement true or false?
(A) True
(B) False

SECTION 2: HOW TO JOIN AND WHAT YOU'LL BE ASKED TO DO

What happens if I say "Yes, I want to be in this research"?
After you read this consent form and agree to participate by digitally signing the form, you will receive information about completing the initial online survey. Once you complete the initial survey, your care manager will contact you to help you get set up with the digital resources.

How does the study experience differ for each participant?

As a participant you will be assigned to one of two groups:

If you are assigned to group 1, you will be invited to use a mental health app called IntelliCare and receive support from your care manager through text messaging. You will be asked to complete the following tasks during the 12-week study.

- Download the IntelliCare app and use it for a few minutes each day. The IntelliCare app teaches people skills they can use to manage stress, depression, and anxiety. The modules in the IntelliCare app may help you celebrate your accomplishments, learn new skills to solve problems and improve your mood, identify, and change your negative thoughts, identify your strengths, and help you find meaning in your daily activities, and change negative feelings that come from worrying.
- Stay in touch with your care manager who will coach you on how to use the IntelliCare app: At the beginning of the study, your care manager will help you download the IntelliCare app during a phone call and develop a plan for how you can use the IntelliCare app to manage stress, depression, and/or anxiety. You will be offered the option to communicate with your care manager via text messaging. Your care manager will be able to provide additional support and coaching for using IntelliCare apps via text message. Messaging support might include general encouragement, light technical support, addressing barriers to app use, reinforcing attempts to implement new skills in daily life, and supporting self-management of medications and behavior. As a note, once you have completed the research study you will no longer have access to text message your care manager.
- Complete in-app surveys about your mental health: Every two weeks, spend about five minutes answering questions in the app that will help your care manager understand how you are doing so they can best support you.

The IntelliCare application was developed by researchers at Northwestern University's Center for Behavioral Intervention Technologies (CBITs) and is now managed by a company named Adaptive Health. Northwestern University has an agreement in place with Adaptive Health to make the app available to you through this study. Adaptive Health has agreed to protect your information. See section 5 under the heading **"Privacy & Confidentiality"** for more information about how Adaptive Health will manage information gathered during the study.

If you are assigned to group 2, you will continue to receive standard care through the COMPASS program and you will receive access to a website that contains information about managing perinatal depression. Your care manager will help direct you to the website initially and then you will access information on the site on your own, as needed. The website is managed by the research team at Northwestern University.

You will not be able to pick which group you end up in, nor will the study staff get to choose. Your group assignment is made by the computer, and it is entirely up to chance (random). This method helps ensure the research study is fair.

Question: Who chooses which study group I end up in? (Multiple choice) (A) I get to choose which group I'd like to be in (B) The computer randomly assigns me to a group

(C) Study staff choose my group assignment
(D) None of the above choices

Online Surveys (All Participants)
Once enrolled in the study you will be asked to complete research surveys online. You will be asked to complete 3 online surveys. The first survey will be sent to you soon after you consent to participate in the study. You will receive additional surveys 6 and 12 weeks after you join the study. The surveys will take approximately 30 minutes to complete and will include questions about your mood, your health and your opinions about the COMPASS program and the digital resources you will receive as part of this study.

Optional Usability/User-Feedback Interviews (Group 1 Only)
If you are assigned to group 1, you will be invited to complete optional paid telephone interviews to provide additional feedback about your experience using the IntelliCare app and working with your care manager. If you are interested in providing additional feedback, you will be contacted by study staff to schedule the optional interview session(s) via telephone or video conferencing software. Completing the additional telephone interviews is completely voluntary. Whether or not you agree to complete the additional interviews will not affect your overall participation in the study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to do the following things over the 12-week study period:

- Complete three paid online surveys.
- Complete an initial phone call with your COMPASS care manager to get set up with the digital mental health resources that are part of this study.
- **Stay in touch with your COMPASS** care manager.
- Let the research team know if you are interested in completing optional telephone interviews.

SECTION 3: RISKS, BENEFITS, RIGHTS, AND ALTERNATIVES TO PARTICIPATING IN THIS STUDY

Will being in this study help me in anyway?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

- Learning helpful strategies to manage stress and mood.
- Access to tools that may help you develop positive health behaviors and habits.
- Easier access to your COMPASS care manager through text messaging.

Is there any way being in this study could be bad for me?
The risks of harm from being in this study are minimal. Participants might feel upset or become tired while completing the study surveys. Participants can take a break or stop a study survey at any time. There is a chance that IntelliCare might not be effective at improving symptoms of depression. We consider this risk to be minimal because all treatments come with the risk that they will not work for some. There are additional risks related to using IntelliCare on a smartphone. Participants who do not have unlimited text message and/or cellular data plans

may be charged for overages. We encourage you to discuss your plan with research staff before enrolling in the study. There is also the potential for loss of confidentiality if someone else were to use your phone and read information you have entered into the apps and/or messages you have sent to your care manager. We recommend setting up a PIN (personal identification number) for your phone to reduce confidentiality risks. If you do not have a PIN set up for your phone and do not know how to, the research team will share information that will help you set one up. The researchers also have procedures in place to protect the information you provide. See the section 4 under the heading titled: **"Privacy & Confidentiality"**

Can I be removed from the research without my OK?
The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if your care manager determines that you would benefit from receiving a higher level of care, or if you are not able to complete study procedures.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can remove you from the study. You may be asked as why you chose to withdraw.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. All data collected up to that point will be secured appropriately and access to the data limited to study team members and carefully managed.

Question: Should you choose to discontinue your study participation, when could you do so?
- **(A)** At any point in time
- **(B)** Only at the end of the study
- **(C)** Only after the half-way point of the study
- **(D)** None of the above choices

SECTION 4: INFORMATION THAT WILL BE GATHERED AND HOW IT WILL BE HANDLED

What information will be collected for the research?
Study data will include information that you provide through study assessments (*surveys and interviews), interactions with your care manager and study staff (via phone, email, and text message), and your app or website usage. Research team members who are trained to protect your data will also gather some de-identified information from your medical record (this is covered in greater detail in the section 6 describing HIPAA Authorization). Please note that study assessments and other interactions such as interviews with study staff may be audio

recorded, and the audio recordings will be included as study data. To protect your privacy, study staff will not ask you to state your name or share other identifying information on the audio recording.

*Please note, your care manager will not see your responses to the online surveys and interviews that you may complete as part of the research.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. Your direct identifiers (for example name or email) will be removed from your data before it is published. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

Question: Once I sign the consent form, the study's researchers may share information collected about me to study staff, collaborators, and others. The researchers will remove direct personal identifiers like my name, address, or telephone number before the data is published.

Is this statement true or false?
(A) True
(B) False

Privacy & Confidentiality
We take your privacy very seriously. As part of our commitment to your privacy, you have been assigned a unique study ID that will follow you throughout the course of the study. Any study data containing your name or other information that could directly identify you is kept in secure, password protected, and locked locations.

If you are assigned to group 1, once you download the IntelliCare app, your mobile phone will collect and transmit data on your app usage. You will be able to enter information into the IntelliCare app (for example journal entries). Your care manager may enter certain information about you into the IntelliCare system, and send you text messages through the system, to tailor the program to your needs. The IntelliCare system is managed by Adaptive Health (a software contractor supporting this research). Adaptive Health will store only the minimum amount of identifying information needed to create and maintain your user account, and your information is stored on secure servers for your protection. Adaptive Health agrees to protect your information and will erase any identifying information about you after this research is complete. If you would like to review their privacy policy or terms and conditions, we've provided the links below:
https://www.adaptive-health.com/privacy
https://www.adaptive-health.com/terms

If you are assigned to group 2, once you start using the website, we will keep track of how often you use the site and what information you access on the site. Your website usage data will be stored in secure Northwestern University online platforms.

Certificate 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. Identifiable information that could still be disclosed beyond the research team: 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.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

Limits to Confidentiality
While we take measures to protect your confidentiality, we may be required to break confidentiality if you were to tell us something that leads us to believe that you may be a danger to yourself or to others, or share information suggesting abuse or neglect of a minor, an older adult, or disabled individual. In those instances, we may need to disclose that information to keep everyone safe.

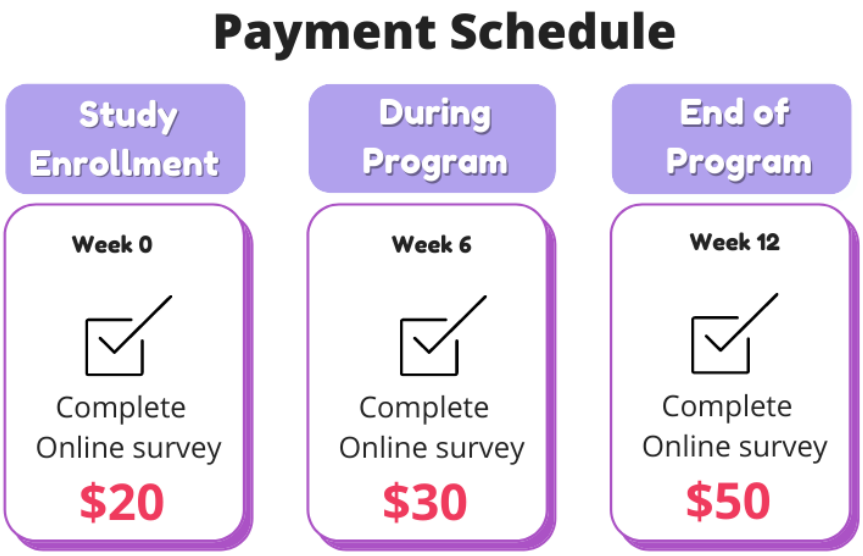
Question: When would the research staff have to break confidentiality?
- **(A)** If I mention information about the abuse or neglect of a minor, elderly person, or disabled individual
- **(B)** If I disclose information about being in imminent danger of harming myself or others
- **(C)** If my records were to be subpoenaed by the court
- **(D)** A and B
- **(E)** All of the above choices

SECTION 5: COSTS, PAYMENTS, AND STUDY CONTACT INFORMATION

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you. All costs required for this study will be paid for by a grant from the sponsor, the National Institute of Mental Health.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. You will not be charged for use of the IntelliCare apps and messaging. The IntelliCare apps will use a small about of data, so there is a slight chance that you may experience data overages while participating in the study, although we do not expect this to happen. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Payment
Research Surveys (All Participants)
If you agree to take part in this research study, we will pay you for your time and effort for each survey that you complete. You will be paid $20 for the initial survey, $30 for the week 6 survey, and $50 for the week 12 survey, for a total of up to $100.



Optional Telephone Interviews (Group 1 Only)
If you are assigned to group 1, and you agree to complete one or more of the optional telephone interviews, you will be paid an additional $25 for each 30-60 minute interview you complete. Approximately 10 participants will be invited to complete app usability interviews at weeks 2, 4, and 6. All participants assigned to group 1 will be invited to complete a coaching user feedback interview at week 6. The table below shows the payment schedule for the interviews:

Interview Schedule	Week 2	Week 4	Week 6
App Usability Interview	$25	$25	$25
Coaching Feedback Interview			$25

Payment Methods

Depending on Northwestern University payment guidelines, and availability at the time of your participation, payments to participants will be paid in one of the following ways:

- Gift card: The following gift card payment methods are only available to participants earning no more than $100 per calendar year.
    - Amazon.com gift card: You would be sent a code to your email address that will allow you to redeem an Amazon.com gift card. Gift Cards may only be redeemed toward the purchase of eligible goods and services provided by Amazon.com. You must create an account with Amazon to use the card. No fees apply to Amazon Gift Cards and the balance will not expire.
    - PNC Stored Value (Visa) Card: If you do not have an Amazon account or do not wish to be paid through Amazon, you may request a Stored Value (Visa) Card instead. The cards may be virtual or physical as per your preference.
- Check: Participants earning more than $100 per calendar year must be paid by check. Checks require a signed W9 form and will be mailed to your mailing address.
- Through Northwestern University (NU) Payroll if you are an NU employee

To process your payment, the study team may gather your name, email address, mailing address, date of birth, and social security number. Please allow approximately 2-4 weeks for your payments to be processed. A Form 1099 will be sent to you if your total payments (from this study and other Northwestern University studies) are $600 or more in a calendar year.

Whom can I talk to?

Your care manager is involved in this research study. Your care manager is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

If you have questions, concerns, or complaints, or think the research has hurt you, talk to any member of the study team or you can contact the person managing this research study, Joshua Santiago, at 312-503-1249, Monday -Friday, 9-5pm with any questions about this research study.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

- You want to get information or provide input about this research.

SECTION 6: HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes de-identified health information in your medical records. Your health information we may collect and use for this research includes:

- Medical history (including obstetric information)
- Problem list (which may include things like HIV testing results, substance abuse information, and mental health information)
- Records about medication or drugs
- Mental Health information: mental health diagnoses and assessment information, and information about encounters with mental health providers.

This information will be de-identified and will be stored separately from any identifying information such as your name. You have the right to inspect and copy the mental health records that will be collected as part of this study.

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

This consent expires on 3/31/2025. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity, and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

However, Illinois law does not allow the re-release of mental health information by the receivers of the information except in precise situations allowed by law.

Also, Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of substance use disorder information unless further disclosure of this information is expressly permitted by written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire on 3/31/2025.

Although you may revoke consent to participate in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PIs Name: David C. Mohr
Institution: Northwestern University Feinberg School of Medicine, Center for Behavioral Intervention Technologies
Department: Preventive Medicine
Address: 750 N Lake Shore Drive, 10th Floor, Chicago Illinois 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

SIGNATURE SECTION

Optional Elements:
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	**I disagree**	
_____	_____	The researchers may contact me to participate in additional interviews throughout the study.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Consent Summary:
I have read this form and I understand the research study. I have been told whom to contact if I have questions. I agree to participate in the research study described above; this is signified by typing my name in the space provided.

Your typed name will serve as your digital signature. Typing your name will indicate your consent to take part in this research. You can print a copy of this signed document or ask the research team to provide you a copy.

Subject's name:
Please type your FULL legal name. Your typed name will serve as your digital signature.
Date: