UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:	Evaluating screening adherence between chatbot and attention control
Study sponsor:	National Institute of Mental Health (1R43MH130293-01A1)
Principal Investigators:	Maria Muzik, M.D., M.S., Department of Psychiatry, University of Michigan
	Marianna Kerppola, M.B.A., M.S., Poisera, Inc.
Study Coordinators:	Nicole Miller, L.M.S.W., Department of Psychiatry, University of Michigan
	Olivia Oates, B.A., Department of Psychiatry, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You can talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will indicate you have read this form by clicking “I agree to participate” at the end of this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about improving health and well-being. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer direct benefits to participants. They also come with different levels of risks, depending on the type of study. You may need to consider other requirements, such as completing surveys or participating in interviews. Think about these aspects as you make your decision to participate in this study.

This study is examining if pregnant women find the Moment for Parents mobile app to be helpful for their emotional well-being. Participants in this study will use the Moment for Parents app and share what they think about it through a survey and an interview. This research will help us improve the Moment for Parents app to support the emotional well-being and mental health of pregnant women.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, there is a small risk of loss of confidentiality and some risk of discomfort with some of the topics discussed in the Moment for Parents app or during the interview. This research poses no risk to the health of your baby. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by helping you learn strategies to cope with your emotions during pregnancy and motherhood. More information will be provided later in this document.

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Pregnancy and postpartum can be a time of significant changes to your emotional well-being and mental health. Pregnant and postpartum women who struggle with their mental health may feel uncomfortable sharing their feelings with healthcare providers. This study aims to explore whether using a chatbot within the Moment for Parents app can provide pregnant and postpartum women a safe and supportive space for them to express and process their feelings. By improving how we monitor and support mental and emotional health during pregnancy and postpartum, this research could lead to better mental health outcomes for both mothers and their babies.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You can join this research if you:

- are pregnant or up to 12 months postpartum (i.e., after giving birth)
- are at least 18 years old.
- live in Michigan.
- own a smartphone with internet access.
- can read, write, and understand English.

3.2 How many people are expected to take part in this study?

We will have at least 160 pregnant and postpartum women in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to join, you will get free, unlimited access to the Moment for Parents app. There will be two versions of the app. When you join, you will be randomly assigned to one of two groups.

Each group will have different features and resources in the app. This study is trying to understand which version encourages moms to continue mental health screenings over time.

You can use the app as much or as little as you like.

After using the app for one week, we'll ask you to take a survey about your experience with the app. We will email or text you the survey. It should take no longer than 5 minutes.

We'll also invite some participants based on their survey responses to do a short interview with us. If you agree, we'll ask about your thoughts on the Moment for Parents app or why you stopped using it.

At the beginning of the interview, the interviewer will ask where you are located and the contact information for a loved one. We will only use this information if the interviewer is concerned for your safety or someone else's. The interviews will last 30 minutes and be done on Zoom. You can only join if you agree to be audio-recorded during the interview.

We will keep your information confidential. We will not share the information you give us or share on the app. We will not link the information you give us to your name, email address, or phone number.

We may share the results for scientific reasons. Before we use the data, we will remove and destroy anything that can identify you, like your name, email, and phone number.

As a participant in this research study, you are responsible for using the app from enrollment to 12 weeks post-enrollment, completing the survey, and if you are invited, participating in the interview. If you continue to use the app past 12 weeks, we will still collect data from your responses. If you suspect that participating in this research has harmed you in any way, please contact the individuals listed in Section 10.

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

You can use the app as much or as little as you like. On average, it takes 5-10 minutes to use all the features in the app each day. Every other week, the app will prompt you to complete a brief assessment of your emotions and mental health, which can take up to 3 additional minutes.

This study will collect your app usage data from enrollment to 12 weeks post-enrollmentafter downloading the app.

After one week, you will be asked to complete an online survey about your experience with the app, estimated to take no longer than 5 minutes.

We'll also invite some participants based on their survey responses to do a short interview with us. If you agree, we'll ask about your thoughts on the Moment for Parents app or why you stopped using it. The interview will last approximately 30 minutes and be conducted via Zoom.

4.3 When will my participation in the study be over?

Your participation in the study will end after you complete the survey and interview and no longer use the app.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

This research poses no risk to the health of your baby.

While using the Moment for Parents app, there is a small risk you might feel uncomfortable with some of the topics discussed with the chatbot. You are allowed to skip any questions that you do not wish to answer.

During the interview, there is a small risk you might feel uncomfortable about the topics discussed. You are allowed to skip any questions that you do not wish to answer. If the interviewer is concerned about your safety, steps will be taken to ensure you receive appropriate support.

During the study, there is a small risk that your information could become exposed or unprotected. For example, there is a risk of discrimination by employers or insurance providers if your mental health data

were linked to your name, email address, phone number, or emergency contact information and disclosed to unauthorized persons. The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research. Risks associated with your regular medical treatment should be discussed with your regular doctor.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

During the study, the chatbot in the Moment for Parents app will ask about your mental health every other week. If your answers suggest that you are struggling with your mental health, a behavioral health counselor from MC3 Perinatal will contact you and provide access to free mental health support.

If you become upset during the interview, the interviewer will encourage you to contact your doctor and will assist you in finding one if needed. Additionally, the interviewer will provide you with information about emergency services and local hospitals. If your responses suggest that you are in immediate danger, the interviewer will take necessary actions, such as contacting local authorities or arranging emergency transportation to the hospital. The interviewer will follow up within 24 hours to ensure you have received the help you need.

If you suspect that participating in this research has harmed you in any way, please contact the individuals listed in Section 10.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may benefit from the information you learn about pregnancy, parenthood, and mental health during this study. For example, you will learn strategies to cope with emotions and navigate changes during pregnancy and parenthood.

You will also have the opportunity to access free mental health support, if needed. The information gathered from this study could lead to improvements in the app, potentially benefiting other pregnant women in the future by providing them with better support and resources for mental and emotional well-being.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

If you decide not to take part in this study, you have the option to seek support or resources as needed from your current healthcare providers. Participation in this study is entirely voluntary, and choosing not to participate will not affect your access to other services or your relationship with your healthcare providers.

7. ENDING THE STUDY

7.1 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 decide to leave the study before it is finished, you can notify the researchers via email at team@momentforparents.com. In an interview, you can quit by telling the interviewer that you would like to stop the interview. 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.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There are no consequences if you decide to leave the study before it is finished. You can withdraw from, or quit, this research study at any time. This will not affect your relationship with Poisera, the company that made the Moment for Parents app. If you decide to quit, we will delete any data we have about you within two weeks.

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

The researchers may need to end your participation in the study if the study is suspended or canceled. The researchers can end your participation should we discover that you do not fit the eligibility criteria.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

You do not have to pay anything to participate in this study. We will not bill your health plan for participating in this study.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

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

All participants will also be entered into a raffle to win one of four $50 e-gift cards after the study ends.

Participants who complete an interview will also receive a $30 e-gift card.

E-gift cards will be provided through Tango card, where you can choose your preferred gift card. Here is a list of e-gift card options available through Tango card.

8.3 Who could profit or financially benefit from the study results?

Poisera Inc. is the company that developed the Moment for Parents app being studied in this research. Poisera Inc. could benefit financially from the results of this study.

Marianna Kerppola owns stock in Poisera Inc. and has created the Moment for Parents app being studied. She could gain financially from the results of this study. To make sure there's no conflict of interest, we will share this information with everyone involved in the project, including partners and team members. We will also share this information with the public.

The University of Michigan is an owner and Dr. Maria Muzik is a creator of copyrighted material that is licensed to Poisera Inc. This means the University of Michigan and Dr. Maria Muzik could gain financially from the results of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF PARTICIPANT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?

Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., chatbot conversation data).

Your research information will be stored electronically in an encrypted, password-protected cloud-based database. The term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards. Only Marianna Kerppola, CEO of Poisera Inc., and Preston Stosur-Bassett, CTO of Poisera Inc., have password access to this cloud-based database.

Your name, email, and phone number will only be shared with MC3 Perinatal if your responses to the bi-weekly mental health questions suggest you are struggling with your mental health. An MC3 Perinatal Behavioral Health Counselor will contact you to provide free mental health support. Poisera will use a password-protected AWS folder to share your information with MC3. MC3 will enter your information, along with any additional health information they request in a HIPAA compliant system

For users who do not screen positive, Poisera will share de-identified data with MC3, including demographics (week of gestation, age, race, ethnicity, and insurance status), the number of chatbot interactions (chats started and completed with dates), mental health screening results, average chat satisfaction ratings (by user and topic), engagement rate (average number of chats completed per active user over daily, weekly, or monthly intervals), retention rate (proportion of active users relative to the total enrolled users), and totals for enrolled and active users of the Moment for Parents app. For users who do screen positive for symptoms of depression, anxiety, and/or suicidality via mental health screenings, Poisera will share identifiable information, such as first names, email addresses, phone numbers (if available), and emergency contact information, along with the number of chatbot interactions (chats started and completed with dates), chat topics selected (with dates), chat satisfaction ratings (per topic), and mental health screening results. Additionally, MC3 will share engagement data for these users, including screening intake data (e.g., PHQ-9 and GAD-7 scores, self-rated concerns, and traumatic birth ratings (as applicable),

IPV and SUD risk, and changes over time), referral paths, the number of women connected to BHC services, the number who accept and consistently enroll in services, and service results.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, if your responses to the mental health questions suggest you may harm yourself or others, we may share information when appropriate. We may also share your information with other researchers.
- 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 and of some communicable diseases.
- 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).
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://www.era.nih.gov/erahelp/CoC_Ext/Content/A-Introduction/Introduction.htm

Adult Abuse: If you tell us or we learn something that makes us believe that you or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies.

Child Abuse: If you tell us or we learn something that makes us believe that your child or others have been or may be abused or neglected, we may, and in some cases must, report that information to the appropriate agencies.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Agreeing to participate in this study gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). The following PHI about you may be obtained during this study:

- Demographic information
- Personal identifiers
- Mental health history and symptoms

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.

- The researchers may need the information to determine if you may need additional mental health support.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner and for quality improvement purposes.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

If your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission does not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Maria Muzik
Mailing Address: 4250 Plymouth Rd. Ann Arbor, Michigan 48105
Email: mmuzik@umich.edu

Study Coordinator: Olivia Oates
Mailing Address:4250 Plymouth Rd. Ann Arbor, Michigan 48105
Email: oolivia@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Once you click “I agree to participate”, you will receive a copy of this informed consent document.

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

12.1 What is meant by the storage, future research use, and sharing of study participants’ medical information and leftover samples (sometimes referred to as biospecimens) taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information to use in future research. These future research uses take different basic forms, which are described below. The medical information may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

12.2-A: Storage, use, and sharing of data in all research subject to the Common Rule (45 CFR 46 Subpart A)

For purposes of this research, Poisera Inc., its collaborators, and associated research partners will receive various types of information based on each participant's screening results. For all users, basic demographic information will be shared, including week of gestation, age, race, ethnicity, and insurance status, along with screening results. For participants who screen positive for potentially struggling with their mental health additional contact information, such as first names, email addresses, and phone numbers (if available), will be shared along with their screening scores.

For those screening positive and using MC3 services, MC3 will also share engagement data. This includes initial screening intake data, such as PHQ-9 and GAD-7 scores, self-rated concerns, traumatic birth ratings (as applicable), and risk indicators for intimate partner violence (IPV) and substance use disorder (SUD), with follow-up to monitor changes over time. Additionally, referral pathways and service engagement information—such as the number of women connected to Behavioral Health Consultation (BHC) services and data on consistent service participation—will be shared. Finally, treatment outcomes will be documented to assess the effectiveness of these services. This data sharing will support ongoing research activities and analysis related to treatment engagement and outcomes among users of MC3 services.

In addition, after any remaining identifiers are removed from your coded private information, the information could be used for future research studies and shared with other researchers without your additional informed consent.

In each of the situations described below, you may later change your mind and withdraw your consent to the storage, use, and sharing of your information even if you give consent now, provided that the information can still be identified as yours, has not already been used or shared, or has not been added to your medical record. Keep in mind, however, that any information that has already been used or shared with other researchers, as well as any information that has been added to your medical record, cannot be recovered, or deleted.

Keep in mind, too, that in cases where giving us your permission to store, use, or share your information is necessary in order for you to participate in this study, changing your mind later and withdrawing your consent to that storage, use, or sharing will also mean that you can no longer take part in the study, and we will remove you unless your participation has already ended.

12.2-B: Storage, use, and sharing of data in all research subject to the Common Rule (45 CFR 46 Subpart A)

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different.

Once we have shared information about you with other researchers, we will not be able to get it back.

Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information.

We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you.

Researchers who wish to access your information must obtain permission to access your information.

You will not find out the results or directly benefit from future research utilizing your information. Sharing your information may contribute to research that helps others in the future.

Permitting us to store and share your information is a condition of participating in this study. If you do not want us to share your de-identified information with other researchers, you should not take part in this study.

13. SIGNATURES

I understand the information printed on this form. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.