The Children's Hospital *of* Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title: Social Media Intervention for Women with Postpartum Depression

IRB#: **14-011491**

Phase III

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Study Sponsor: University of Pennsylvania Research Foundation
Oscar G. and Elsa S. Mayer Family Foundation

You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating. If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in the study if you do not want to. If you take part, you can leave at any time. In the sections that follow, the word "we" means the study doctor and other research staff.

Why are you being asked to take part in this study?

You and your child are being invited to take part in this study because your child is between the ages of 1 and 3 months old and you have screened positive for depressive symptoms.

What is the purpose of this research study?

Raising a baby can be hard and stressful. We have developed a parenting program to help mothers with stress or depression to encourage good behaviors in their babies and form good relationships with them.

How many people will take part?

Up to 90 caregivers and their infants from up to three urban sites affiliated with the Children's Hospital of Philadelphia (CHOP Care Network Karabots, South Philadelphia, and Cobb's Creek) will participate in this study for up to 12 weeks.

What is involved in the study?

If you agree to participate, your participation will be up to 12 weeks, with 8 weeks attending one of the parenting program formats. One format is a traditional in-person meeting with other mothers in a group setting. The other format is based online in a secret Facebook group, and participation will take place through comments and answers to questions that have been posted.

Study Procedures:

If you agree to participate, you will be asked to sign this consent form and complete two study visits in your home or a CHOP facility. In addition, participants will be assigned to one of the two program formats. The procedures for these two groups differ. Your participation will last up to 12 weeks.

Assignment into Groups:

If you agree to participate in this study, you will be assigned to one of the two formats described below by random assignment.

If you consent to participate in this study, you will complete two study visits either at your home or at CHOP. At each study visit, you will complete brief questionnaires that ask about your and your child's characteristics, your level of stress or depression, your parenting competence, and your level of satisfaction with the program. At the final visit, you will complete a questionnaire on your feelings about the group and have a 16-minute video recording taken of you playing with your child. The digital copies of video recordings will be stored on a CHOP-issued, password protected server. Following

analysis by study staff, videos will be destroyed. Only study staff will have access to the videos.

If you are assigned to the in-person format, you will meet with several other mothers weekly for two hours for 8 weeks at a convenient time and location to learn parenting skills designed to help your child develop. If you are assigned to the Facebook format, you will take part in a similar program through a secret Facebook group that you access through your computer or smartphone. All participants will complete survey questions on the material you learn each week, as well as a final survey question at the end of the program. The Table below provides a brief description of the purpose and duration of each visit.

.Visit	Purpose	Main Procedures	Duration
Study Visit 1, 1-2 weeks before Parenting Program	Prepare for the parenting program, complete demographic questionnaire	Demographic questionnaire 1 survey on your level of stress or depression. 1 survey on your parenting competence	1 hour
Parenting Program, meeting weekly for 8 weeks	Improve parenting skills designed to help your child develop	In-person format – weekly meetings with other mothers and facilitators Online format – participation in online Facebook group through posts responding to contact Both groups – weekly acceptability questionnaire	2 hours/week
Study Visit 2, 1-2 weeks after Parenting Program	Gather Feedback	1 survey on your level of stress or depression. 1 survey on your parenting competence 1 survey on your feelings about the group 16 minute video recording of you and your child playing	1-2 hours

What are the risks of this study?

Participating in this study involves minimal risk. The main risk is loss of confidentiality, disclosure of health information, or group members sharing your information outside our parenting group meetings. We will protect your and your child's personal information in the following ways:

- Information that contains your name will be kept separately from study information. We will store information which could identify you on a separate password-protected computer.

- Establish ground rules in the parenting group that asks all members to respect each other's privacy and keep all information heard in the group meetings confidential.

Are there any benefits to taking part in the study?

You and your child may or may not benefit from this study. You may benefit from the parenting program or from receiving assistance with making mental healthcare appointments but this can't be guaranteed. Information from this research will help researchers design better programs to assist caregivers with parenting.

Do you need to give your consent to participate?

Once you read this form and have your questions answered, you will be asked to decide if you wish to participate. If you wish to participate in this study, you must sign this form. A copy will be given to you to keep as a record. Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?
Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?
You can stop being in the study at any time. You do not have to give a reason.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

We need to collect health information about you in order to conduct this study. This includes information about you gained from the parenting classes that are part of this research. We will do our best to keep your personal information private. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation about the study. People and organizations that may inspect and/or copy your

research records to conduct this research, assure the quality of the data, and analyze the data include:

- Members of the research team and other authorized staff at CHOP
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- Representatives of the University of Pennsylvania Research Foundation and Oscar Mayer Family Foundation who are the study sponsors (and will only receive de-identified data)
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. We are also required by law to report any danger to you or others. Information about child abuse or intent to harm self or other will be reported to authorities as required by law.

By law, we are required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be able to protect your health information under the Federal Privacy laws. If permitted by law, they may be able to share it with others without your permission.

The identifiable information from this study will be destroyed after all analyses have been completed. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, you must tell the investigator in writing.

Dr. James Guevara
The Children's Hospital of Philadelphia
General Pediatrics

3535 Market Street, Suite 1531
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

The study sponsors are providing financial support for study incentives.

Will you be paid for taking part in this study?

- Parents/participants in the in-person group will be provided SEPTA tokens for travel, childcare and meals during the weekly meetings.
- Parents/participants in the on-line group will not be provided SEPTA tokens, childcare, or meals.
- Parents in both groups will be paid $30 for the study visit before the parenting program and $50 for the study visit after the parenting program for their time and effort. Both these payments will be in the form of a CHOP pre-loaded debit card.
- If you are sorted to the Facebook group, you will receive payments at the completion of the second in-person study visit or, if you are unable to meet in person for the second study visit, they will be paid via mail.

If you receive payment using a bankcard, the bank will have access to identifiable information.

Who is funding this research study?

The University of Pennsylvania Research Foundation and the Oscar G. and Elsa S. Mayer Family Foundation are providing funding for this study.

Please ask Dr. Guevara if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Guevara at (215)-590-1130. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

If you, the subject and are consenting to participate in the study:

By signing this form, you are indicating that you have had your questions answered and you agree to take part in this research study. You are also agreeing to let CHOP use and share your health information as explained above.

If you, the parent or legal guardian, you are consenting (for yourself and) to allow your child to participate in the study:

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in the research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.
NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject	Date