OHIOHEALTH

CONSENT FORM (Maternal Version)

TITLE OF STUDY: HAPPY HEALTHY LOVED

PRINCIPAL INVESTIGATOR: MARIE COOPER, RNC-LRN, BSN, MBA

We are conducting a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in the study. This consent form serves two purposes. First, it provides information on the procedures and risks involved in the clinical trial, so that you can decide if you want to take part in the study.

Second, this form will ask for your permission to use and release the medical information that we will get from you during this study. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. If you have any questions, you can ask your study nurse for more explanation.

The OhioHealth Foundation, Denison University and Claremont McKenna College are sponsoring this study.

We ask you to take part in this study because you have recently given birth to your first child and have indicated a preference for breastfeeding, and are a patient at an OhioHealth hospital.

WHY IS THIS STUDY BEING DONE?

We are conducting this study to compare two approaches to supporting and educating parents in the first six weeks postpartum. We designed the program for couples who recently became parents of a newborn infant. We believe the tablet and text message intervention we developed will improve the likelihood of successful breastfeeding and help parents cope positively with the transition to parenthood.

WHAT IS INVESTIGATIONAL ABOUT THIS STUDY?

We are developing a new approach to preparing parents for the first six weeks of parenthood. We will deliver this new approach to teaching using mobile phone text messaging, which is investigational.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 400 people (200 mothers and 200 partners) will take part in this study through Riverside Methodist Hospital, Doctors Hospital, and Grant Medical Center.

Participant's Initials ____

What Will Happen In The Study?

We will ask you to complete a series of survey questions about yourself, which will include questions about your feelings, attitudes, and behaviors. This series of surveys will take about 30 minutes of your time.

Following the survey, we will assign you and your partner to one of two groups to get parenthood preparation and support, using a specific teaching strategy. Regardless of the teaching strategy group that you are assigned to, you will get all usual care and information that is typically given to OhioHealth patients about infant feeding, positive adjustment to parenthood, and postpartum mental health. We may deliver this information through iPad or video, personal instruction and written form. You will also receive brief content delivered by text message regularly over the first six weeks postpartum. This content may be short 2-3 minute teaching videos or other teaching or motivational information. A computer will assign participants to groups through a randomization process after you complete the initial surveys so that neither the investigators nor participants will know which participants will get teaching method.

We will ask you to provide a small hair sample after you complete the first survey questions. The hair sample is a cluster of full length strands of hair about 3 - 5mm wide, which is about half the diameter of a pencil eraser. The research staff will tie the hair together with a piece of floss before cutting close to the scalp. We will use the hair sample to measure your cortisol level. Some researchers believe that the mother's cortisol level is an indicator of how much stress she may have had during pregnancy.

Future Use of Information or Samples: We will not share your information and/or biological samples with other researchers or use them for future research studies, even if all of the information that can identify you personally has been removed.

Genome Sequencing of Biological Samples: Your development, including your traits (e.g., eye color, hair color, etc.) and sometimes your predisposition to disease, is influenced by your DNA. The entire collection of all of your DNA is called your genome. Researchers often use a technology called sequencing to look at your DNA. Whole Genome Sequencing (WGS) is when researchers look at all of the DNA in your genome. Researchers understand what some of your DNA means, but we do not yet understand what all of it means. In the future, we will not use your biological samples for investigations involving whole genome sequencing.

Commercial Use of Biological Samples: Biological samples can be valuable to researchers to use for the discovery of new treatments and product development.

We will not share your samples with any outside entity, such as private companies, government agencies, or other research institutions other than the universities sponsoring this study (Denison University and Claremont McKenna College) for the purposes of this research study.

Participant's Initials ____

At the end of six weeks, we will ask you to complete a second survey online that asks many of the same type of questions you answered on the first survey. Six months postpartum, we will send an email with a link to a third survey with similar items.

In order to participate, both members of a couple must independently consent to the study. The in-hospital education will include your partner. You will each receive text messages separately and complete your own individual surveys. All individual survey responses will be completed separately and individual item responses will not be shared with your partner.

After enrolling, if one member of a couple chooses to discontinue study involvement, it will not affect the other participant's enrollment.

How Long Will I Be In The Study?

You will be in the study for up to six months. The active text message program will finish in six weeks, and the follow up survey will be sent at six months. Once you have completed the six month survey, your participation will end.

Your study nurse may decide to take you off this study if you stop responding to the text or email surveys.

You can stop being a part of this study at any time. However, if you decide to stop being in the study, please talk to the study representative first. There are no serious risks of sudden withdrawal from the study.

What Are The Risks Of The Study?

While on the study, you are at risk for the following risks. You should discuss these with the study representative.

Risks related to *psychosocial education programs* include:

Common:

- It is possible that a question may make you feel uncomfortable. Participating with a partner, it is possible that you will disagree with something said by your partner. You do not have to answer any question that makes you uncomfortable.

Uncommon, but serious:

- It is possible that a breach of confidentiality would occur. While the research team has taken substantial efforts to protect the privacy of your information (outlined in next section), delivery of information via mobile phone text is susceptible to the possibility of

a confidentiality breach. You would be informed immediately if such a breach were to occur and we would take every effort to recover and protect the information.

- It is unexpected, but possible, that the education program will have an unintended adverse effect on your breastfeeding or mental health. If you feel that this is the case, please contact study coordinators listed at the end of this consent form to report your experience. They will help connect you with appropriate support and discontinue your study involvement.

Rare:

- While rare, physical violence as a result of disagreement with a partner would be a serious risk. If you are considering participating with a partner, please do not invite them to participate if you would feel that disagreeing with them would risk physical or emotional harm to you. Remember that you do not have to answer any question that makes you uncomfortable. Research or hospital staff are willing to discretely provide you with domestic violence resources if you do not feel safe with your partner.

YOU SHOULD REPORT ANY OF THESE PROBLEMS TO THE STUDY NURSE IMMEDIATELY SO THAT APPROPRIATE CARE CAN BE GIVEN. SIDE EFFECTS OTHER THAN THOSE LISTED HERE MAY ALSO OCCUR. TALK TO THE STUDY NURSE ABOUT ANY SIDE EFFECT THAT SEEMS UNUSUAL OR THAT IS ESPECIALLY BOTHERSOME TO YOU.

You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.

If the researchers discover information that may have an impact on your non-research related medical treatment, this information will be shared with you at the time of discovery or your next follow-up with the study doctors.

Are There Benefits To Taking Part In The Study?

If you agree to be part of this study, your answers may help develop programs that could help other parents like you in the future. It is possible, but not certain, that you may find the information and support included in the study to be or beneficial for your health.

What Other Options Are There?

Instead of being in this study, you may choose not to participate. Your decision will not affect your care or relationship with this hospital. If you choose not to participate, you will still receive standard education and support provided as part of routine postpartum care at the hospital.

Participant's Initials ____

What Are The Costs?

There are no direct costs associated with this study. However, depending on your mobile phone plan and usage, you may incur costs associated with the text message program. As many as five text messages per week for the first six weeks of parenthood will be sent. The participant incentive of $75 in total gift cards is designed to account for this potential cost. If this amount of messaging will be a substantial financial burden to you, you may consider choosing not to participate in the study. You will be responsible for any costs associated with receipt of text messages on your mobile phone plan.

Taking part in this study will not lead to added costs to you or your insurance company. Non-routine costs required by the study will be paid by the sponsor.

While you are in this study, you may receive tests, procedures, and exams that are standard medical care. This standard medical care may or may not be covered by your medical insurance.

If your medical insurance does not pay for this standard medical care, you will be responsible for the cost of medical care related to your condition, including but not limited to tests, deductibles, co-payments, study nurse and clinic fees, hospitalization and procedures.

What If An Injury Occurs Because of the Study Treatment?

There is no treatment given in this study, only education. If you feel especially upset or distressed due to any questions asked in the study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of psychological distress. You or your insurance company will be charged for continuing medical care and/or hospitalization.

Compensation?

You will receive a $25 retail gift card for your participation today, at the completion of the in hospital program and survey. You will receive a second $25 gift card following the 6-week follow up survey completion. You will receive a third $25 gift card following the 6-months follow up survey completion. If you are participating with a co-parent, he or she will receive separate compensation for study participation.

What Information Will Be Collected From Me For Use In The Study?

We will ask your name along with some basic demographic information about you. We will also ask for your contact information (phone number, address, email) so that we can contact you with survey and gift card information. Survey items will ask about your attitudes, emotions, and

behaviors. We may ask you for information related to your medical history and treatment prior to this study or obtain this information from your medical record.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. For example, the electronic surveys you complete undergo encryption and strict password protection in a secure, professional system (REDCap). Additionally, your responses in the iPad-based education program are encrypted and securely stored in a password protected server. Additionally, we are using a third-party vendor (3C) to send the automated text messages to participants. All information provided to 3C for intervention purposes is encrypted and has strict password protections. 3C adheres to standards of the Health Insurance Portability and Accountability Act (HIPAA).

This survey includes questions about depressive symptoms and suicidal thoughts. In the event that your survey responses indicate a risk for a current depressive episode, you will be provided with education and treatment resources to connect you with area providers. Additionally, if you indicate that you are at risk of harm to yourself or another person, steps will be taken to ensure your safety. We will notify the nurse attending your partner who will follow up with you directly. Depending on the level of risk, this may include contacting your primary care physician, another medical professional, emergency services, and/or family members.

By signing this consent, you agree that we can contact your primary health provider, another medical professional, emergency services, and/or family members if we detect a risk for depression or suicide during the screening or study period. Failure to agree to notification of your primary health care provider or an alternative provider who can ensure your immediate safety will render you ineligible for this study.

Your study number will be used rather than your name as an identifier on your study records or any photocopies of those records.

All survey responses will be reported as summaries rather than individual cases.

If you sign this form and take part in this study, the study staff will be authorized to use the information described above to carry out the purposes of the research study. The study staff will also be authorized to disclose the information described above to all of the following parties involved in the research study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- OhioHealth Institutional Review Board # 1

Participant's Initials ____

- Sponsor (OhioHealth Foundation, Denison University Research Foundation, and Claremont McKenna College)
- The U.S. Food and Drug Administration (FDA) and other government agencies.
- The Department of Health and Human Services Office of Human Subject Research Protections
- The Centers for Medicare and Medicaid Services (CMS)
- The financial agent for CMS
- OhioHealth Research and Innovation Institute Office of Regulatory Compliance
- The office of Erin Henshaw, Denison University

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Once your information is disclosed to the study sponsors, the IRB or the government agencies described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by federal privacy regulations.

If we publish the information we learn from this study in a medical journal, you will not be identified by name or in any other way.

Do I Have the Right to Decline Authorization?

You have the right to decline to sign this authorization to use/disclose your personal information. If you decline, you will not be able to take part in this research study. Except as described herein, if you decline to sign this authorization, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

How Long Will My Authorization Remain In Effect?

The authorization for use and disclosure of your information will remain in effect until January 1 2021.

Can I Withdraw My Authorization?

You may withdraw your authorization at any time by sending a written request to the Principal Investigator at:

Marie Cooper RNC-LRN, BSN, MBA, Director of Women's Health Services,
Riverside Methodist Hospital 3545 Olentangy River Road, Columbus, Ohio 43214.
Phone: 614-566-5117

If you withdraw your authorization:

- Your participation in the study will end

Participant's Initials ____

Your medical information that has already been used and disclosed prior to withdrawing your authorization remains a part of the research study data.

While the research study is in progress, your access to your study records will be temporarily suspended. Afterwards, you have the right to see and copy the medical information collected from you in the course of the study, for as long as that information is maintained by the study staff and other entities subject to federal privacy regulations.

What Are My Rights as a Participant?

The study coordinator has answered your questions. You can ask the study coordinator questions at any time.

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about important new information that may affect your health, welfare and willingness to stay in this study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or a research-related injury, contact the study principle investigator Marie Cooper at 614-566-5117.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the OhioHealth Corporation Office of Ethics and Compliance at 614-544-4200.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Research Compliance at 614-544-4200 or the Office of Regulatory Compliance at 614-566-1748.

Statement Of Consent And Authorization

I hereby freely and voluntarily consent to take part in the research study described above. This consent is given based on the verbal and written information provided and the understanding that I am medically and physically qualified to take part in this study. I am free to ask questions at any time.

I have the option to decline to take part or to withdraw from the study at any time without incurring any penalty or loss of benefits otherwise available, including medical care at this institution.

Participant's Initials ____

My signature below indicates that I voluntarily agree to take part in this study and that I authorize the use and disclosure of my information in connection with the study. I will receive a signed copy of this consent and authorization form.

_____	_____	_____
Participant Signature	Date	Time
_____	_____	_____
	Date	Time
Person Obtaining Consent		
_____	_____	
Investigator Signature	Date	

Participant's Initials ____