COVER PAGE

Official Title of the Study: Breastfeeding Support and Weight Management for Black Women: A Dual Intervention

ClinicalTrials.gov ID: NCT03480048

Date (of most recent IRB approval for document contents): Feb 28, 2018

	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:
APPROVAL PERIOD Feb 28, 2018 – Feb 27, 2019 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** **Mothers Allied with Mothers Around Breastfeeding Encouragement And Renewed Health (Mama Bear)**	

Gwen Alexander, Ph.D.
Research Scientist
Henry Ford Health System
Public Health Sciences
1 Ford Place, 5C
Detroit MI 48202

1. WHY IS THIS RESEARCH BEING DONE?

The purposes of this study are to 1) learn what kinds of support will help women meet their goals for breastfeeding and weight management after their baby is born and 2) to test mom's urine and blood for nutrition factors that may help us understand how breastfeeding and weight loss after a baby is born affects the health of mothers and their baby. You are being asked to take part in this research study because you are an African American woman in the later months of your pregnancy and you said you were interested in breastfeeding your baby. We will enroll about 80 women in this research study at Henry Ford Health System (HFHS). This study is funded by the National Institutes of Health (NIH R21) and is a group project between HFHS and Michigan State University (MSU).

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be two groups in the study. The group you are assigned to will be chosen by chance (like flipping a coin). Both groups will get educational information about how to get a healthy start for both mom and baby. One group will get written information, and the other group will get information from an online program and will have in-person visits from a community health worker.

Women in both groups will be asked to:

1) Answer survey questions three (3) times during the 6-month study. Have your height, weight and body composition measured three (3) times during the 6-month study. Body composition will be measured with a bioelectrical impedance analysis (BIA) scale that sends a small current through your body that you can't feel. This information will be collected from you either at the NCO clinic or at your home.
2) Have some urine (from the sample you give your doctor during your visit) collected two (2) times during the 6-month study (today and at your routine doctor visit that will be about 6 weeks after your baby is born). Your urine will be tested for iodine and some environmental chemicals that interfere with iodine uptake into the thyroid gland (including perchlorate which is found in many products and thiocyanate which is found in cigarette smoke and some foods).

3) Have some extra blood (2-4 teaspoons or 10-20 ml) collected and stored two (2) times during the 6-month study (today and at your routine doctor visit that will be about 6 weeks after your baby is born). Your blood will be tested for nutrition factors (including ferritin which measures your iron status and carotenoid concentrations which estimates your fruit and vegetable intake), and other factors (including thyroid hormone).
4) Allow your medical records from pregnancy, labor and delivery and your baby's medical records to be reviewed by the research team.
5) Researchers will collect health and other information concerning the birth of your child as reported to the Michigan Department of Health and Human Services (MDHHS) at the time of your child's birth. In order to locate your baby's birth certificate, research staff will request your social security number.

All of the procedures at these data collection visits are extra – these are things that you will not do if you choose not to participate in the study. None of these data collection procedures are experimental. If your identifiable specimens or health information are selected for use in additional research, you will be contacted for permission.

All women:

At visit 1, which will be today, if you choose to participate, you will have the following procedures: we will measure your height, weight and body composition, and ask you if we can collect some urine and blood. If you choose not to participate in this collection, you may still enroll.

At visit 2, which will be by telephone, a researcher will call you—within the next week or two— and ask you some survey questions about your social situation, your diet and physical activity habits (about 25 minutes to complete).

At visits 3 and 4, after your baby is born, we will meet you at NCO or at your home to measure your weight and ask you the same survey questions and a few more about what you are feeding your baby (about 25 minutes to complete).

- Visit 3 will be when your baby is about 4-8 weeks old.
- Visit 4 will be when your baby is about 20 weeks (5 months old).

We will try to schedule these study visits at the same time you come to see your doctor or your baby's doctor, but if that doesn't work, we will ask your permission to schedule a visit at your home.

For women in the group that gets information from the online program: You will receive information and be encouraged to use an online program to record activities related to returning to your pre-baby weight. You will also have one-on-one visits, at your home and by telephone, with a community health worker to talk about infant feeding and your weight before and after the baby is born. These visits are extra beyond your

regular prenatal care at HFHS and after your baby is born. The visits by the community health worker and the use of the online program are new ways to offer support to pregnant women and new moms. We are testing these ways of communicating with women to understand how best to support women like you after a new baby is born.

3. WHAT ARE THE RISKS OF THE STUDY?

We do not expect any increase in physical, psychological, social, legal nor economic risks to you or your baby from being in this study. You should tell the person obtaining your consent about any other medical research studies you are involved in right now. It is not expected that you will have any complications or discomforts from being in this study. There may be risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The potential benefits to you for taking part in this study include all of the many health and emotional benefits associated with either breastfeeding or weight management or both. You may also benefit from the feeling of being involved in an important study that may help improve two important health activities among African American women – breastfeeding and postpartum weight management.

5. WHAT OTHER OPTIONS ARE THERE?

Your participation in this study is completely voluntary. You have the right to refuse to be in the study or to stop at any time without affecting your present or future medical care. At this time, there is no known other study like this one. If you wish, you may talk to your doctor about your other choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We on our study team may collect and use:

- Your existing medical records.
- New health information about you and your baby created during this study.
- Health insurance and other billing information.

We (HFHS) may release this information, using your study identification without names attached, to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research.
- The research sponsor National Institutes of Health.
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.
- The Michigan State University Human Research Protection Program.

Once your de-identified information (no name attached) has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at your research study information that is not in your medical record.

HFHS or others in this research group may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will not expire at the end of this research study. The research records will be maintained for a minimum of 3 years after the end of the study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected.

If you would like to talk about this study or withdraw for any reason, you may contact the principal investigator, Gwen Alexander, Ph.D., at (313) 874-6737 or the HFHS IRB Coordinator (313) 916-2024 to cancel your consent and we will send you a form to sign or you can send a written and dated notice to the principal investigator at the address listed on the first page of this form.

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for

your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Gwen Alexander, Ph.D., or her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Gwen Alexander at (313) 874-6737. There is no federal, state or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. Youi and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

If you have questions about your rights as a research subject, you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB (Institutional Review Board) is a group of people at HFHS who review all of the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

While this is not anticipated due to the nature of this study, the Principal Investigator can end your participation in the research study at any time. The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

If you consent to participate and data collection begins, you will be given gift cards at four different times during the study to thank you for participating. You will receive:

- $20 gift card today
- $30 gift card after your phone interview that will be within a few weeks after today's visit
- $50 gift card after the study visit when your baby is about six weeks old and
- $50 gift card after completion of the final survey when your baby is about five months old.

We will also provide you with some non-monetary gifts (like a teddy bear). If you complete the study, you will receive a total of $150 to thank you. If you do not finish the study, you will be given the gift cards for the parts of the study that you did complete.

13. CONSENT

You have read this consent form or it has been read and explained to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

Signature of Subject	Date	Time
Print Name of Subject		
Witness to Signature	Date	Time
Print Name of Person Obtaining Consent		
Signature of Person Obtaining Consent	Date	Time

Procedures Manual cover page

MAMA BEAR

Procedures Manual

Mama Bear Procedures Manual Table of Contents page

The purpose of the Mama Bear study is:

- to learn what kinds of support will help women meet their goals for breastfeeding and weight management after their baby is born
- to understand how breastfeeding and weight loss after a baby is born affects the health of mothers and their baby.

Table of Contents

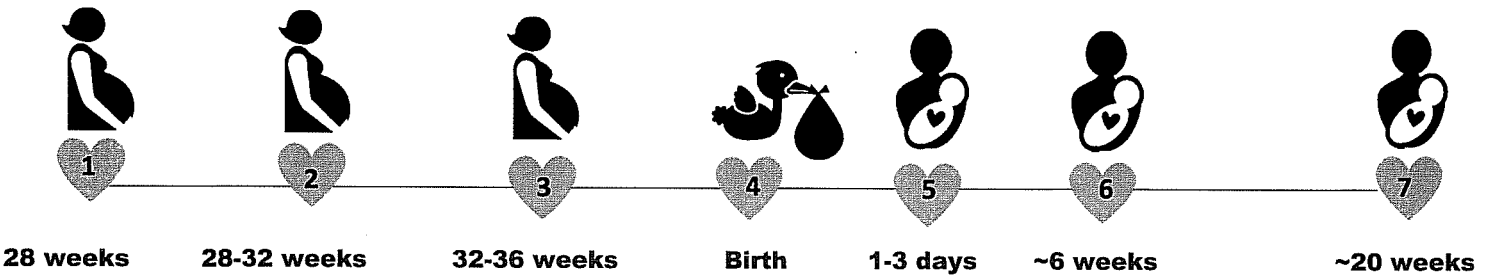
General Documents

Intervention Group Only Documents

same as header

Mama Bear Study Activities Timeline

Funding is 4/1/16-3/31/18 (with extension through 3/31/19)



	Time	Location	Activities (Staff Responsible)	Incentive
1	~28 weeks	NCO Clinic	• Pre-screening (N) • Eligibility, consent, weight, blood, urine (DC) & (N if time permits)	$20
2	28-32 weeks	Phone	• Baseline survey data collection (DC)	N/A
	Randomization into Intervention Group or Usual Care Group			
3	32-36 weeks	**Home or NCO Clinic***	• **Intro to program, breastfeeding support * (CHW)**	$30
		NCO Clinic	• Usual Care group (DC) & (N if time permits)	
4	Birth		• All participants receive a congratulations letter and a Baby Bear board book via mail (Claire)	N/A
5	1-3 days postpartum	**Home***	• **Breastfeeding support, self-care tips* (CHW)**	N/A
6	~6 weeks postpartum	NCO Clinic	• Weight & Survey (DC, CHW) & (N if time permits) • **Intro to mobile app*** (DC, CHW) & (N if time permits)	$50
7	~20 weeks Postpartum	Home	• Data collection to include measured weight (DC)	$50

Key

* **<u>Intervention group only</u>; includes additional contact as needed until baby is 20 weeks old**

* Envelope to include gift card and MYBABY insert- to be picked up in clinic

N: Nurses (Kristine Walton and Khara Grant)

DC: Data Collectors (Tangi and Minh Anh)

CHW: Community Health Workers (Felicia Lane and Nada Dickinson)

Incentive Plans for Participants in Both Study Arms

10/9/2017

Mama Bear Incentive Plan for Participants in Both Study Arms (Intervention and Usual Care)

1. Enrollment: $20 gift card + Mama Bear water bottle
2. Phone Survey: $30 gift card
3. Soon after baby is born: Baby Bear board book (or notebook customized with Mama Bear logo)
4. ~6 week (4-8 week) postpartum clinic visit: $50 gift card
5. ~20 week postpartum clinic or home visit: $50 gift card

Additional Incentives for the Intervention Participants

1. Diapers and wipes (at early postpartum visit)
2. Bathroom scale (at 6 week postpartum visit)
3. Small "prizes" for using the online platform

Mama Bear Clinic Recruitment

Guidelines for Nurses

Procedures:

A. Obtaining Informed Consent

1. Approach women presenting for prenatal care who meet the following criteria:
    - African American
    - 24-32 weeks gestation
    - Scheduled for the one hour glucose challenge test this visit
    - Single gestation
    - No known fetal or chromosomal anomalies
    - Fluent in English and able to complete consent process
2. Ask permission to speak with them about a study that they might enjoy being a part of.
3. If a woman agrees to learn more about the study, provide her with the flyer
4. Script:
    - *Thank you for giving me a few minutes of your time. I will briefly explain the study, and if you decide you would like to participate, I have a consent form for you to sign. First, I will ask you a few questions to make sure you are eligible. [COMPLETE ALL ELIGIBILITY QUESTIONS ON THE IPAD IN THE MAMA BEAR REDCAP PROGRAM. PROCEED ONLY IF PARTICIPANT MEETS ALL ELIGIBILITY CRITERIA].*
    - *I see that you are planning to breastfeed your baby, and we want to support you in doing this, in every way we can. Also, I know that most women, after having a baby, want to get back in shape, get back to their regular weight, and be able to wear the clothes they wore before they got pregnant.*
    - *This study may be able to help both with breastfeeding, and getting back in shape after having your baby. It's called Mama Bear, and the study is designed to find out if assistance from peer counsellors can help overcome any difficulties you might encounter with breastfeeding, and if an app that you can use on your phone to track your diet and exercise, can help you with weight loss.*
    - *Some women do just fine with breastfeeding and weight loss, without any special assistance, and others find that adding that extra assistance really helps. This study will assist researchers to determine if the extra assistance I described might be something that can be offered to all women. For now, for women who decide to join the study, half the women will get the extra help I described, and half will get written information. That is how we determine if the extra in-person help really makes a difference. Women in both groups will meet with study staff to answer some questions and have their weight and body composition measured.*
    - *I also have two special requests as part of this research. First, you are going to have your blood drawn for the blood sugar test, and I would like to get two extra tubes (about 2 teaspoons) of blood drawn at the same time, so you do not have to get poked (another needle stick) again. Second, you are going to give a urine sample, so I would like to get a small amount of your urine from that cup, for this research study.*
    - *Finally, because we appreciate the extra time you are giving to help with this study, you will receive a $30.00 gift card today if you decide you want to participate, and additional cash or gift cards as you complete later visits in the study.*

5. If the woman gives verbal agreement after this explanation, have her read the consent, and sign two consent forms. One will be given to the study participant, and the other one will be kept in her study file.
6. Have the participant sign the Gift Card Voucher and provide her with the $30.00 gift card. Record the card on the Gift Card Distribution Form. Then complete all parts of the enrolment interview on the iPad in REDCap.
7. Explain to the participant that she will be contacted within the next week by a Mama Bear staff member from Henry Ford, who will conduct an interview over the phone. Confirm with patient that it is ok to leave a message (not sure if this is necessary but usually a good idea since this is related to her pregnancy). After that, she will be mailed $20 in cash and some information about what she can expect next from the study.

B. **Obtaining Weight, Body Composition, Blood and Urine Specimens** *(for all handling of biological fluids, use gloves, and employ good hand washing techniques)*

1. Weight and Body Composition
    a. Utilize the Tanita research study scale provided to measure the participant's weight and body composition.
    b. Select "One-Step" Mode and input required data:
        - Enter weight of clothing- *1.0 kg (preset)*
        - Enter Study ID number
        - Enter Body type- "Standard"
        - Enter Gender- Female
        - Enter age
        - Enter height

    c. Have the participant remove any outerwear garments (coat, hat, scarf, gloves), and remove her socks or stockings.
    d. In the presence of the participant, clean the foot pads on the scale with alcohol wipes
    e. Have her step on the scale with her bare feet.
    f. Print results and record the weight and body composition on the data collection form on the study iPad.
2. Blood
    a. Use the labels provided to write the ID number, date and time of the blood collection
    b. Place one label on the red top tube, and one on the lavender top tube.
    c. Hand both tubes to the participant ask her to take them with her to the lab so that her blood can be collected in these tubes at the same time that she is getting her blood drawn for the blood sugar test.
    d. When the participant returns with the blood filled tubes, place them in a specimen collection bag, seal, and place the bag in the refrigerator.

3. Urine
    a. Use the label provided to write the ID number, date and time of the urine specimen collection.
    b. Place the label on a urine vial provided for the study.
    c. Have the participant hand you the cup with her freshly voided urine once she steps out of the restroom.
    d. Pour a small amount of that urine into the pre-labelled urine vial and cap tightly.
    e. Return the original cup of urine for testing with the dipstick.
    f. Place the study urine vial in the bio-storage bag, close and seal, and then put the urine specimen into the refrigerator.

C. Transporting Specimens

1. Towards the end of the work day, call the One Ford Place lab contact number to inform the staff that Mama Bear study specimens will be delivered. Give an approximate time of arrival.
2. Place all research specimens collected for the day in the cooler provider.

3. Transport the specimens, by car, to One Ford Place and pull into a space along the curb in front of the entrance. Call the lab the notify them of your arrival. Carry the specimen into the front lobby and hand to the lab representative.

(alternative: Mama Bear 031017_4)

The Mama Bear flyer with description Mama Bear 031017_4

The Mama Bear flyer (as shown below) is used by nurses when approaching patients in the clinic to see if they are interested in meeting with research staff. For more information, see Mama Bear Recruitment Procedures, Section A 3.

MAMA BEAR

Mothers Allied with Mothers Around

Breastfeeding Encouragement And Renewed Health

Mama Bear helps moms reach their breastfeeding goals and lose weight after giving birth.

Help moms like you have a healthy future. Join the Mama Bear research study today!
Call: (313) 874-6324
Email: chooker1@hfhs.org

Front

Mama Bear is provided at no cost to you.

MAMA BEAR

Who Can Participate?

- African American women
- At least 18 years of age
- Pregnant (about 28 weeks)
- Interested in breastfeeding
- Reliable internet access (by smartphone, tablet, or computer)

What's Involved:

- Receive up up to $150 after completing 6 months of fun!
- During the 6 months you'll be asked:
  - to answer survey questions
  - have your height, weight, and body composition measured
  - give urine and blood at usual collection times
  - give permission for review of baby's and your medical records

Our goal is to help moms and babies have a healthy start!

MICHIGAN STATE UNIVERSITY
College of Human Medicine

Henry Ford Health System

Offered in Partnership Between Henry Ford Health System and Michigan State University. Funded by the National Institutes of Health.

Back

Same as header

MAMA BEAR: Recruitment Script (with opt-out guidance for blood collection)

Procedures:

A. Obtaining Informed Consent

1. Approach women presenting for prenatal care, as identified by the research nurse, who meet the following criteria:

    - African American
    - 24-32 weeks gestation
    - Scheduled for the one hour glucose challenge test this visit
    - Single gestation
    - No known fetal or chromosomal anomalies
    - Fluent in English and able to complete consent process

2. Ask permission to speak with them about a new study that they might enjoy being a part of.

3. If a woman agrees to learn more about the study, provide her with the flyer.

4. Script:
    - *Thank you for giving me about 8 – 10 minutes of your time. I will briefly explain the new study, and if you decide you would like to participate, I have a consent form for you to sign. First, I will ask you a few questions to make sure you are eligible. [COMPLETE ALL ELIGIBILITY QUESTIONS ON THE IPAD IN THE MAMA BEAR REDCAP PROGRAM. PROCEED ONLY IF PARTICIPANT MEETS ALL ELIGIBILITY CRITERIA].*

        - *It looks like you are <u>not</u> eligible for our study. Thank you for your time this morning. We are only able to invite women who meet the study guidelines for eligibility. Best of luck with your pregnancy. Thank you. OR*

        - *It looks like you are eligible for our study. I'll continue telling you about it.*

    - *I see that you are planning to breastfeed your baby, and we want to support you in doing this, in every way we can. Also, I know that most women, after having a baby, want to get back in shape, get back to their regular weight, and be able to wear the clothes they wore before they got pregnant.*

    - *This new study offers a program that may help both with breastfeeding, and getting back in shape after having your baby. It's called Mama Bear, and the study is designed to find out if assistance from community health workers who will stay in contact from before the baby's arrival to 5 months after the baby arrives, can help overcome any challenges you might have with breastfeeding, and if an app that you can use on your phone to track your diet and physical activities, can help you with losing some weight <u>after</u> the baby is born.*

    - *Some women do just fine with breastfeeding and weight loss, without any special help, and others find that adding that extra assistance really helps. This study will help researchers to determine if the extra assistance I described might be something that can be offered to all women. For now, for women who decide to join the study, half the women will get the extra help I described, and half will get written information. That is how we determine if the extra in-person help really makes a difference. Women in both groups will meet with study staff to answer some questions and have their weight and body composition measured.*

    - *I also have two special requests as part of this research. First, today as part of your regular appointment, you are scheduled to have your blood drawn for the blood sugar test. If you agree to be in the MAMA BEAR study, we would need to get two small extra tubes (about 2 teaspoons) of*

blood drawn at the same time. Second, as part of your regular appointment today, you are scheduled to give a urine sample. If you agree to participate, I would need to get a small amount of your urine from that cup ***during this visit today, and get blood and urine samples again at a 6 week postpartum visit****, for this research study. [RECRUITERS PLEASE USE THE FOLLOWING LANGUAGE IF A WOMAN IS HESITANT ABOUT GIVING SAMPLES FOR THE STUDY] – "If you prefer not to give the two extra tubes of blood or urine samples, you may still participate in the study."*

- *As I mentioned before, the MAMA BEAR study will be connecting with women before the baby arrives and through the first 5 months after the baby is born. We would be asking a set of questions at three time points – soon after enrolling today – before the baby is born (by phone); about 6 weeks after the baby comes (on the phone to answer some questions and then here in the clinic to get your weight measured and give some blood and urine samples), and then again when your baby is about 5 months old (here in the clinic or in your home, to answer some questions and get your weight measured). We will be providing money as incentives for participation throughout these next several months to people who enroll.*

- *Part of the incentive for enrolling includes a $20.00 gift card* ***today*** *if you decide you want to participate* ***for the 7 months of this MAMA Bear Study****, and an additional $30 gift card once the next step is complete (a 30 minute phone survey). This survey is part of enrollment. Future incentives (gift cards) will be provided after each of the next study visits, one after you complete a phone survey and then come to the clinic around 6 weeks postpartum ($50), and the final one around 5 months after the baby is born ($50).*

- ***Would you agree to participate in the MAMA Bear Study? Do you have any questions?***

5. If the woman gives verbal agreement after this explanation, talk through the consent form, and allow time for her to read the consent, and sign two consent forms. Give one to the study participant, and the other one will be kept in her study file.
   - Ask: Would you be willing to give the small sample of your blood and urine today and again at your 6-week postpartum clinic visit?
6. Have the participant sign the Gift Card Voucher and provide her with the $20.00 gift card. Record the card on the Gift Card Distribution Form. Then complete all parts of the enrollment interview on the iPad in REDCap
   - **If the woman says she will give the blood and urine, say you will walk with her to the lab where her scheduled blood draw and urine sample will be collected.**
   - **If the woman says she does not want to give the blood or urine, make a note in REDCap that she is opting out of this protocol element and tell her that she may need to remind them at her 6-week postpartum visit if they still don't want to give blood and urine then.**
7. Tell the woman that she will be contacted within the next week by a Mama Bear staff member from Henry Ford Health System, who will complete the enrollment process by completing an interview over the phone**. Confirm with the patient that it is ok to leave a message and ask her to make sure to check her messages and call us back when she can**. After that step, she will be contacted again to give her more information about what to expect next from the study and to make plans for her to pick up another $30 gift card either from one of the community health workers or someone else from our Mama Bear study staff.

B. **Obtaining Weight, Body Composition, Blood and Urine Specimens** *(for all handling of biological fluids, use gloves, and employ good hand washing techniques)*

1. Weight and Body Composition
   a. Utilize the Tanita research study scale provided to measure the participant's weight and body composition.
   b. Select "One-Step" Mode and input required data:
      - Enter weight of clothing- *1.0 kg (preset)*
      - Enter Study ID number
      - Enter Body type- "Standard"

- Enter Gender- Female
- Enter age
- Enter height

c. Have the participant remove any outerwear garments (coat, hat, scarf, gloves), and remove her socks or stockings.
d. In the presence of the participant, clean the foot pads on the scale with alcohol wipes
e. Have her step on the scale with her bare feet.
f. Print results and record the weight and body composition on the data collection form on the study iPad.

2. Blood
   a. Use the labels provided to write the ID number, date and time of the blood collection
   b. Place one label on the red top tube, and one on the lavender top tube.
   c. Hand both tubes to the participant ask her to take them with her to the lab so that her blood can be collected in these tubes at the same time that she is getting her blood drawn for the blood sugar test.
   d. When the participant returns with the blood filled tubes, place them in a specimen collection bag, seal, and place the bag in the refrigerator.

3. Urine
   a. Use the label provided to write the ID number, date and time of the urine specimen collection.
   b. Place the label on a urine vial provided for the study.
   c. Have the participant hand you the cup with her freshly voided urine once she steps out of the restroom.
   d. Pour a small amount of that urine into the pre-labelled urine vial and cap tightly.
   e. Return the original cup of urine for testing with the dipstick.
   f. Place the study urine vial in the bio-storage bag, close and seal, and then put the urine specimen into the refrigerator.

C. Transporting Specimens (for Research Nurses)

1. Towards the end of the work day, call the One Ford Place lab contact number to inform the staff that Mama Bear study specimens will be delivered. Give an approximate time of arrival.
2. Place all research specimens collected for the day in the cooler provider.
3. Transport the specimens, by car, to One Ford Place and pull into a space along the curb in front of the entrance. Call the lab the notify them of your arrival. Carry the specimen into the front lobby and hand to the lab representative.

PCF_Alexander_10403 Supporting doc_1

	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:

APPROVAL PERIOD Sep 22, 2017 – Mar 19, 2018 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** **Mothers Allied with Mothers Around Breastfeeding Encouragement And Renewed Health (Mama Bear)**

Gwen Alexander, Ph.D.
Research Scientist
Henry Ford Health System
Public Health Sciences
1 Ford Place, 5C
Detroit MI 48202

1. WHY IS THIS RESEARCH BEING DONE?

The purposes of this study are to 1) learn what kinds of support will help women meet their goals for breastfeeding and weight management after their baby is born and 2) to test mom's urine and blood for nutrition factors that may help us understand how breastfeeding and weight loss after a baby is born affects the health of mothers and their baby. You are being asked to take part in this research study because you are an African American woman in the later months of your pregnancy and you said you were interested in breastfeeding your baby. We will enroll about 80 women in this research study at Henry Ford Health System (HFHS). This study is funded by the National Institutes of Health (NIH R21) and is a group project between HFHS and Michigan State University (MSU).

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be two groups in the study. The group you are assigned to will be chosen by chance (like flipping a coin). Both groups will get educational information about how to get a healthy start for both mom and baby. One group will get written information, and the other group will get information from an online program and will have in-person visits from a community health worker.

Women in both groups will be asked to:

1) Answer survey questions three (3) times during the 6-month study. Have your height, weight and body composition measured three (3) times during the 6-month study. Body composition will be measured with a bioelectrical impedance analysis (BIA) scale that sends a small current through your body that you can't feel. This information will be collected from you either at the NCO clinic or at your home.
2) Have some urine (from the sample you give your doctor during your visit) collected two (2) times during the 6-month study (today and at your routine doctor visit that will be about 6 weeks after your baby is born). Your urine will be tested for iodine and some environmental chemicals that interfere with iodine uptake into the thyroid gland (including perchlorate which is found in many products and thiocyanate which is found in cigarette smoke and some foods).

3) Have some extra blood (2-4 teaspoons or 10-20 ml) collected and stored two (2) times during the 6-month study (today and at your routine doctor visit that will be about 6 weeks after your baby is born). Your blood will be tested for nutrition factors (including ferritin which measures your iron status and carotenoid concentrations which estimates your fruit and vegetable intake), and other factors (including thyroid hormone).
4) Allow your medical records from pregnancy, labor and delivery and your baby's medical records to be reviewed by the research team.
5) Researchers will collect health and other information concerning the birth of your child as reported to the Michigan Department of Health and Human Services (MDHHS) at the time of your child's birth. In order to locate your baby's birth certificate, research staff will request your social security number.

All of the procedures at these data collection visits are extra – these are things that you will not do if you choose not to participate in the study. None of these data collection procedures are experimental. If your identifiable specimens or health information are selected for use in additional research, you will be contacted for permission.

All women:

At visit 1, which will be today, if you choose to participate, you will have the following procedures: we will measure your height, weight and body composition, and ask you if we can collect some urine and blood. If you choose not to participate in this collection, you may still enroll.

At visit 2, which will be by telephone, a researcher will call you—within the next week or two— and ask you some survey questions about your social situation, your diet and physical activity habits (about 25 minutes to complete).

At visits 3 and 4, after your baby is born, we will meet you at NCO or at your home to measure your weight and ask you the same survey questions and a few more about what you are feeding your baby (about 25 minutes to complete).

- Visit 3 will be when your baby is about 4-8 weeks old.
- Visit 4 will be when your baby is about 20 weeks (5 months old).

We will try to schedule these study visits at the same time you come to see your doctor or your baby's doctor, but if that doesn't work, we will ask your permission to schedule a visit at your home.

For women in the group that gets information from the online program: You will receive information and be encouraged to use an online program to record activities related to returning to your pre-baby weight. You will also have one-on-one visits, at your home and by telephone, with a community health worker to talk about infant feeding and your weight before and after the baby is born. These visits are extra beyond your

regular prenatal care at HFHS and after your baby is born. The visits by the community health worker and the use of the online program are new ways to offer support to pregnant women and new moms. We are testing these ways of communicating with women to understand how best to support women like you after a new baby is born.

3. WHAT ARE THE RISKS OF THE STUDY?

We do not expect any increase in physical, psychological, social, legal nor economic risks to you or your baby from being in this study. You should tell the person obtaining your consent about any other medical research studies you are involved in right now. It is not expected that you will have any complications or discomforts from being in this study. There may be risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The potential benefits to you for taking part in this study include all of the many health and emotional benefits associated with either breastfeeding or weight management or both. You may also benefit from the feeling of being involved in an important study that may help improve two important health activities among African American women – breastfeeding and postpartum weight management.

5. WHAT OTHER OPTIONS ARE THERE?

Your participation in this study is completely voluntary. You have the right to refuse to be in the study or to stop at any time without affecting your present or future medical care. At this time, there is no known other study like this one. If you wish, you may talk to your doctor about your other choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We on our study team may collect and use:

- Your existing medical records.
- New health information about you and your baby created during this study.
- Health insurance and other billing information.

We (HFHS) may release this information, using your study identification without names attached, to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research.
- The research sponsor National Institutes of Health.
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.
- The Michigan State University Human Research Protection Program.

Once your de-identified information (no name attached) has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at your research study information that is not in your medical record.

HFHS or others in this research group may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will not expire at the end of this research study. The research records will be maintained for a minimum of 3 years after the end of the study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected.

If you would like to talk about this study or withdraw for any reason, you may contact the principal investigator, Gwen Alexander, Ph.D., at (313) 874-6737 or the HFHS IRB Coordinator (313) 916-2024 to cancel your consent and we will send you a form to sign or you can send a written and dated notice to the principal investigator at the address listed on the first page of this form.

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for

your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Gwen Alexander, Ph.D., or her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Gwen Alexander at (313) 874-6737. There is no federal, state or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. Youi and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

If you have questions about your rights as a research subject, you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB (Institutional Review Board) is a group of people at HFHS who review all of the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

While this is not anticipated due to the nature of this study, the Principal Investigator can end your participation in the research study at any time. The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

Henry Ford Health System	**CONSENT TO PARTICIPATE IN A RESEARCH STUDY** (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:

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12. WILL I BE PAID TO PARTICIPATE?

If you consent to participate and data collection begins, you will be given gift cards at four different times during the study to thank you for participating. You will receive:

- $20 gift card today
- $30 gift card after your phone interview that will be within a few weeks after today's visit
- $50 gift card after the study visit when your baby is about six weeks old and
- $50 gift card after completion of the final survey when your baby is about five months old.

We will also provide you with some non-monetary gifts (like a teddy bear). If you complete the study, you will receive a total of $150 to thank you. If you do not finish the study, you will be given the gift cards for the parts of the study that you did complete.

13. CONSENT

You have read this consent form or it has been read and explained to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

Signature of Subject	Date	Time
Print Name of Subject		
Witness to Signature	Date	Time
Print Name of Person Obtaining Consent		
Signature of Person Obtaining Consent	Date	Time

A. Procedures:

Purpose of this document

This document should be used when contacting participants for the study: Mama Bear . Direct phone contact with participants should be initiated as soon as possible after consent is obtained in the clinic during pregnancy around 28 weeks gestation.

Steps in phone call contact

- Initiate call. Let the phone ring 7 times
- If answering machine appears, leave message explaining who you are and when you will contact them again.
- When call is complete complete REDCap Checklist
- If the participant calls and reaches you, start from **step 3** of the script

B. Telephone script

STEP 1 | INITIAL CONTACT

Hello. I am first name from HFHS and I'm part of the Mama Bear Study Team. May I please speak to insert participant's name.

When [desired person is on the phone]	My name is First Name and I am a data collector calling on behalf of Henry Ford Health System with the Mama Bear Study. On "Time when consent was obtained" you agreed to participate in the Mama Bear study and the nurse told you that you would receive a call to collect some information from you. Is now a good time to talk more about the Mama Bear study and collect some information from you? **IF NO, GO TO STEP 2** **IF YES, GO TO STEP 3**
If desired person is not available	Is there a better day and time to reach [Ms]_____? Note days and times and enter into REDCap Thank you for your assistance. I will try to call back then.
If desired person is in distress or does not have capacity	I am sorry to hear cause of distress and I hope this call has not caused you further distress. *If participant becomes distressed, do not continue with question below.* Do you feel comfortable continuing this call? **IF YES, GO TO STEP 3** **IF NO.** Okay. Is there a better day and time I can call you back? I need to collect some information – what is the best time and day to call you back in the next few days? Thank you. Make note in REDCap

STEP 2 | INITAIL CONTACT CONTINUED

If interrupted or call back later	Is there a better day and time I can call you back? **IF INTERRUPTED.** Okay. Thank you. Myself or include names of other data collectors of the team will try to call back then. Note days and times and enter into REDCap
If refusal	**IF NO/NOT INTERESTED**. Okay. Thank you for your time. **End Call.** Note and enter into REDCap

Version Number 1			

STEP 3 | PARTICIPATION DETAILS

STEP 3	The Mama Bear study would like your help to find the best ways to help moms and babies stay healthy. Participation in this study is completely voluntary and will involve contact at multiple points over the course of 6 months. Initially, in the clinic, you signed a consent form and received a copy of it to take home. Now, we want to ask you some qustions during this phone call. Do you mind if I proceed? **IF NO/NOT INTERESTED.** Okay. May I ask why you are not interested anymore? Thank you for your time. **End Call.** Note and enter into REDCap **IF YES, GO TO STEP 4**

STEP 4 | USE OF INFORMATION

STEP 4	Your answers will be kept completely confidential. We will make sure that the information we collect from you is kept private and used only for the research study we are discussing. If you do not agree to continue the phone call, or if you do not want to participate in the research project, it will not affect your care or any future care you may have at Henry Ford Health System.

STEP 5 | QUESTIONNAIRE

STEP 5	As a participant in the Mama Bear Study , you will be asked to complete questionnaires about feeding your baby and also about other topics related to your health and pregnancy. There are no right or wrong answers. We want to hear about your experiences. The questionnaire will take about 25 minutes of your time, depending on how many of the questions apply to your situation. **IF YES** Continue questionnaire and go to **STEP 6** *Ensure that you indicate how participants are to answer each question at the beginning of the questions (ie strongly disagree to strongly agree)* *Ensure you check the participant is happy to continue with the questionnaire at approximately 15 minute intervals.* ***BE PREPARED TO PROBE IF THE RESPONDENT ANSWERS OUTSIDE OF THE CATEGORIES PROVIDED. PROBE USING THE ANSWER CATEGORIES ONLY; DO NOT INTERPRET FOR THE PARTICIPANT.*** **IF NO** Thank them for their time and indicate you plan to keep the information you have collected so far and request them to provide you another time to finish the survey questions. Also, encourage them that upon their completion they will receive a mailed incentive ($20 Walmart gift card).

Version Number 1		Date	

STEP 6 | ENDING THE CALL

STEP 6	Thank you again for your time and interest in the Mama Bear study. Do you have any questions? As we mentioned when you enrolled, we will be calling you from time to time to collect more information from you and see how you are doing. Either I or my colleague will be calling you again in about **[# of weeks]**. Let me check again. Is **[day/time]** still the best time to reach you? We will keep trying, so thanks for connecting with us when we try to reach you. I would like to confirm I have your mailing address details correct. Depending on which group you are in, we will either mail your gift card or someone will call you to make arrangements to deliver it to you in-person. We are only able to mail this one time, so please make sure this is an address where you can pick up your mail for at least the next week or so. Again, my name is first name. If you have any questions after this phone call you can contact me on insert contact number based at HFHS. Thank you for your time today. Goodbye. **End Call.**

Initial Phone Contact

Hello. I am first name from HFHS and I'm part of the Mama Bear Study Team. May I please speak to insert participant's name.

Hello [Ms/Mrs]_____. My name is (Data collectors Name), and I am calling from HFHS (Henry Ford Health System Research) and I'm part of the Mama Bear Study Team. I am following up for your participation in the Mama Bear Study you enrolled in at your prenatal care visit at New Center One on (insert date of enrollment). I would like to schedule a time that is convenient for you to answer some questions on the phone. I'd like to schedule it for next week and we'll need about 25 minutes. Our records show that the best days and times for you are (insert best days and times from REDCap). Does next (insert best time) work for you? Thank you, I'll call you then.

If no contact is made and voicemail is available:

"Hello, this message is for_____. My name is (Data collectors Name), and I am calling from HFHS (Henry Ford Health System Research) and I'm part of the Mama Bear Study Team. I am following up for your participation in the Mama Bear Study. Your participation is our study is very important. Could you please call us at XXX-XXX-XXXX or my direct number at XXX-XXX-XXXX? Please leave your name, phone number and a good day and time for us to reach you. I will contact you again in a week for your participation in this study. Thank you"

Same as header

Data Collector Protocol

Data Collection Protocol

On the event grid within REDCap it will display all the records including questionnaires, form by form, for the particular events for one Participant ID. There is a "legend for status icons", where you can view the status of each form which can guide "work flow" for a particular participant. Listed are the questionnaire forms that will be collected at each point of data collection.

Questionnaire Forms	Baseline Phone Call	~6 Week Post-Partum	20 Week Post-Partum
Demographics	X		
Health	X		
Weight Change Goals PhenX Toolkit	X		X
Breastfeeding Benefits	X		
IFPS II	X		
IPAQ	X		X
Breastfeeding Self-Efficacy Scale	X	X	X
Edinburgh Depression Scale	X	X	X
HBSS	X	X	X
Fruit And Vegetable Inventory			
PSQI	X		X
Phenx Fiber Intake	X		X
Phenx Healthy Food Environments	X		X
Phenx Physical Activity Neighborhood Environment	X		X
Breastfeeding Intensity		X	X
Repeated Weight Measure		X	X
Checklist Baseline Data Collection	X		
Checklist 6Wk Postpartum Home Visit		X	
Checklist 20Wk Postpartum Home Visit			X

Contact and Scheduling

1. In REDCap view the "Record Status Dashboard" to identify participants who are approaching the point of data collection following consent.
2. Use the "Telephone script protocol" when contacting participants for the first time.
3. Document any and all forms of contact made with the participant in the "Contact log" on REDCap. Be sure to capture date, time of call, details pertaining to call, and initials.

Baseline Data Collection

1. Identify the participants that have consented to participate in the study by using REDCap's Record Status Dashboard.
2. Contact the participant within **one week** to collect baseline data.
3. Use the "Telephone script protocol" when contacting participants.
4. After speaking with the participant and completing baseline data collection, complete the "Checklist" following the call on the REDCap **web version**.
5. As each form is **completed** in REDCap move status of form to "unverified".

Contact and Scheduling

1. In REDCap view the "Record Status Dashboard" to identify participants who are approaching the point of data collection (~6 weeks and 20 weeks' post-partum). Visit Reports may be downloaded or provided that will project the "scheduled date" for the participant's visit to be completed. Either upon monitoring or receipt of those reports, the ~6-week or 20-week post-partum visit should be **scheduled immediately**.
2. Open the participant ID, contact the participant to schedule a mutually agreed date and time to collect data. Use the "Telephone script protocol" to guide your call. During scheduling, be sure to confirm their address for upcoming appointment. The Schedule Generator should be used to find the participant and generate a schedule of upcoming visits for data collection at specific time points which can be tracked on the calendar (this can only be used in the web version).

Clinic Visits

~6-week post-partum data collection should occur at the clinic visit. This visit may occur for the participant anywhere between 2-8 wks post-partum.

After the participants' baby is born, contact the participant reminding them to schedule their post-partum visit at the clinic with the nurses. Ask the participant if the time scheduled would also be convenient for data-collection following the appointment. Document contact made within the "Contact log" on REDCap with details listed above. After the participants appointment has been scheduled, call participant 24hrs prior to their appointment providing them with a reminder of the appointment and that you will also meet with them during that visit.

If for some reason data collection cannot occur during the clinic visit, **document the reason within the contact log and PLAN for completing visit**. The next option for completing the visit would be over the phone and last option would be going to the participants home.

Possible reasons may include: No data collector available during clinic appointment, time was inconvenient for participant, or missed appointment.

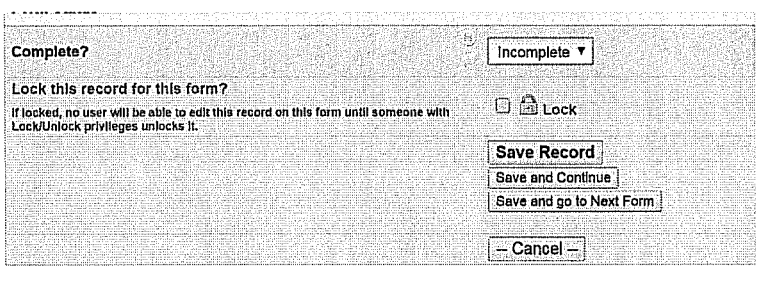
Home Visits

- **Before Visit**

  Before leaving office, identify the participant ID and download the appropriate forms onto the mobile application. Use REDCap mobile application on IPADS to collect data at 20 weeks' post-partum. Before heading to the visit, be sure IPAD is completely charged.

- **During Visit**

  Click on the Participant ID, find specific event for data collection, scroll to the bubble (displayed gray) and click to begin particular survey. Ask participant questions as stated within forms and document in the IPAD. Be **sure** to "save and continue" **often** as moving through the different forms. Once you have reached end of form, be sure to change status of form to "unverified" and save.



Be sure to take the participant's weight using the Tanita SC-240 scale. Follow the Bioelectric Impedance Analysis Protocol.

- **After visit**

  Within **1 day** of completing visit, connect to internet to sync all documents that were completed in field on the mobile application to the full REDCap server. The mobile application will have an option that will appear to "sync/upload forms" for participants.

  Within **1 day** of the completed visit, complete the "Checklist 20-week post-partum Home Visit" within the **web version** REDCap system.

* All checklist need to be completed in the **web version** of REDCap

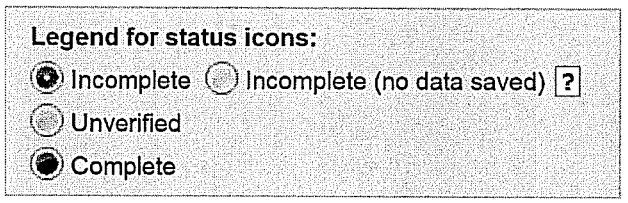
*In the case of an emergency and the data collected has not been synced, such as IPAD turning off because of low battery, use the "Send Emergency Data Dump" that appears at the bottom of the REDCap mobile application, which will send all data collected to the full server.

*Any time a change is made or something new is documented, **make sure** it is saved and save often.

Form Completion Tracking

As information is collected in REDCap, keep track of completion of forms by switching the status of the form being complete. This can also be used to guide work flow of upcoming events and scheduling participant home visits.

- Incomplete= not complete
- Unverified= complete, but needs review by Project Manager
- Complete= After verified by Project Manager

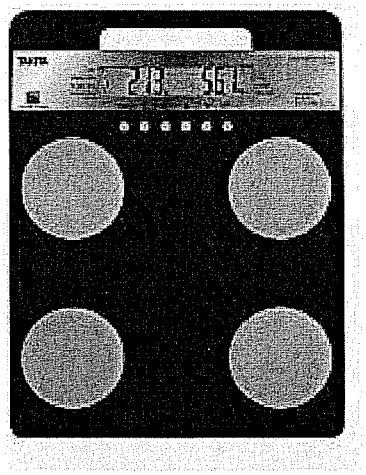


Bioelectrical Impedance Analysis

Definition: Bioelectrical Impedance Analysis (BIA) estimates body composition by measuring the electrical impedance of body tissues. It assesses total body water content.

Equipment: Tanita SC-240 (see Fig. 7)
NOTE: Total body water of participants will be measured using leg-to-leg bioelectrical impedance analysis. "In this system, two footpad electrodes (pressure contact) are incorporated into the platform of a precision electronic scale. A person's measurements are taken while in a standing position with the electrodes in contact with bare feet. The body monitor/analyzer automatically measures weight and then impedance. Computer software (a microprocessor) imbedded in the product uses the measured impedance, the subject's gender, height, fitness level, age (which have been programmed), and the weight to determine body fat percentage based on equation formulas." (Tanita website: http://www.tanita.com/en/tanita-publications/)

Figure 1. Tanita SC-240 for measurement of BIA and weight.



Examinee Preparation: Administer the questions in Measured Anthropometry in REDCap to determine if the participant meets any of the exclusion criteria. If the participant is pregnant or has a pacemaker or automatic defibrillator, they should be excluded from the BIA assessment as indicated by REDCap. NOTE: False teeth and hearing aids do not have to be removed. NOTE: Participants can drink reasonable amount of water before the BIA measurement to avoid dehydration.

NOTE: If participant is unable to independently stand on the BIA machine with both feet flat, she will not be able to participate in this part of the study. If the reason she cannot participate in the BIA measurement is apparent or volunteered by the participant, e.g. foot is in a cast; include this information in the comment field in the Measured Anthropometry section of REDCap.

Measurement Method:

Step 1. Administer BIA screening questions (R section 'Measured Anthropometry' in the main questionnaire) to make sure if the participant will be eligible for BIA measurement. Weight and BIA are measured at the same time as components of the one-time output method of the Tanita SC-240 instrument.

Step 2. Before the BIA measurement, open the Tanita Health Ware software.

Step 3. Sync the scale and computer

- Open Tanita Health Ware software
- Select "Done" from the User Profile menu that appears
- Turn on the BIA scale. You should see a flashing "0 kg" on the screen.
  - If the scale is not in kilograms, press and hold "Enter/Zero"
    - Use the up/down arrows until it flashes "SET 5"
    - Press "Enter/Zero"
    - Use the up/down arrows until you see "0. KG"
    - Press "Enter/Zero"
    - Turn off the BIA scale
    - Turn on the BIA scale. You should now see "0 kg" flashing.

- Choose 'File'
  - Choose Health Ware Options
  - Choose SC-240 from the list of possible units
  - Click "control scale remotely"
  - Click "connect" and step on scale when it beeps
  - Remain on scale until the computer indicates that it is successfully communicating with the scale
  - Click "ok" and then "ok" again to exit this menu

If this method *does not work*, then:

- Uncheck "control scale remotely"
- Click "connect"
- When the timer starts on the computer screen, go to the BIA scale
  - Press "Enter/Zero"
  - Press the down arrow once to select female figure on left side of screen
  - Press "Enter/Zero"
  - Use the up/down arrows to select age
  - Press "Enter/Zero"
  - Use the up/down arrows to select height (in cm)
  - Press "Enter/Zero"
  - Wait until the arrow on the right-hand side points to "Step on"
  - Step on the scale
  - Wait until the computer displays a successful completion
  - Step off the scale

NOTE: Step 3 is only applicable to Tanita Health Ware software that is newly installed. Once Step 3 is completed, it can be omitted during future measurements.

Step 4. Enter a new user*

- In main Health Ware window, click "Users" on the toolbar
  - Choose "add user"
  - Enter user information
    - Put the first name (capitalize the first letter) and the capitalized first initial of the last name in the "Name" field.
    - User ID should be study ID
    - Change units to "Metric" and then enter height – this way it will correspond with the height measured earlier
    - Birthday, gender, and height MUST be correct; the body fat measurement is drastically different if they are not
    - Click "ok" to exit this menu

NOTE: the user profile can be created for a participant prior to Visit #1. Height must still be entered at time of interview.

Step 5. Obtain new measurements*

- In main Health Ware window:
  - Check to make sure the correct user profile is selected. This is shown in the upper left corner of the Health Ware window, just below the 'file' menu. If the correct

profile is not chosen, click the arrow next to the profile name and choose the correct one
    - Click the "New Measurement" button
- On the BIA scale:
    - Press "Enter/Zero"
    - Press the down arrow once to select female figure on left side of screen
    - Press "Enter/Zero"
    - Use the up/down arrows to select age
    - Press "Enter/Zero"
    - Use the up/down arrows to select height (in cm)
    - Press "Enter/Zero"

Step 6. Ask the participant to take off her socks for BIA measurement if she has socks on.

NOTE: It is OK for the participants to wear socks for weight measurement but it is not OK for the participant to wear socks for BIA measurement.

REDCap Mobile Application Protocol

REDCap Mobile Application

Glossary of terms used in this document

"REDCap" = desktop/laptop version. NOT mobile version or mobile device/interface

"REDCap server" = data storage device at Michigan State University. NOT mobile device

"REDCap Mobile App", "App", "mobile app" = all relate to the user experience on the mobile tablet or smart phone.

"Main REDCap project" = this is the same as the desktop/laptop version. NOT mobile version or mobile device/interface

"Record" = subject/participant/patient

Screen Shots

In the screen shots below the name of the REDCap project is "Test Mobile App".

About the Mobile App

The REDCap Mobile App adds provides users with a tool for offline data collection, particularly in environments with poor or no internet connectivity. The Mobile App cannot be used on its own, but is a companion app that must be used alongside REDCap itself. All users of the Mobile App must already be a MSU-REDCap user before using the Mobile App for the Study.

The REDCap mobile app is an app that can be installed on a tablet or cell phone (Mac or Android) so that data may then be collected for a REDCap project in an offline fashion on that device. This data may be synced back to the project on the MSU REDCap server when a reliable internet service becomes available.

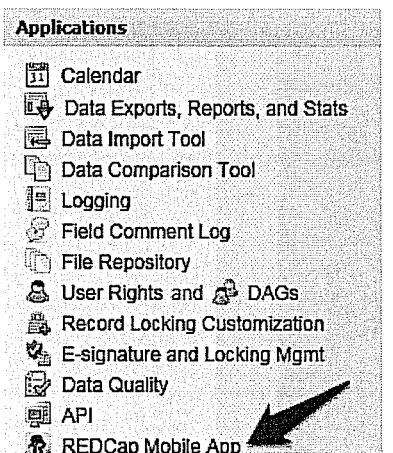
Setting up the REDCap Mobile App on your mobile device

1. DEVICE/ONLINE: Download the REDCap Mobile App onto the mobile device that will be used to collect data off-line. The app can be found at AppleStore for Apple devices, or Googleplay for android devices.

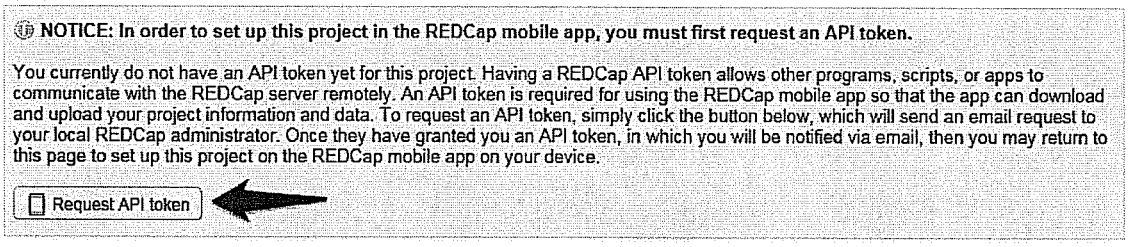
2. COMPUTER/ONLINE: Send a request to the MSU-BRIC data manager to modify your REDCap account to be enabled for using the REDCap Mobile App.

3. COMPUTER/ONLINE: Open REDCap on your computer, open the Study project, go to the left margin menu and open "REDCap Mobile App".

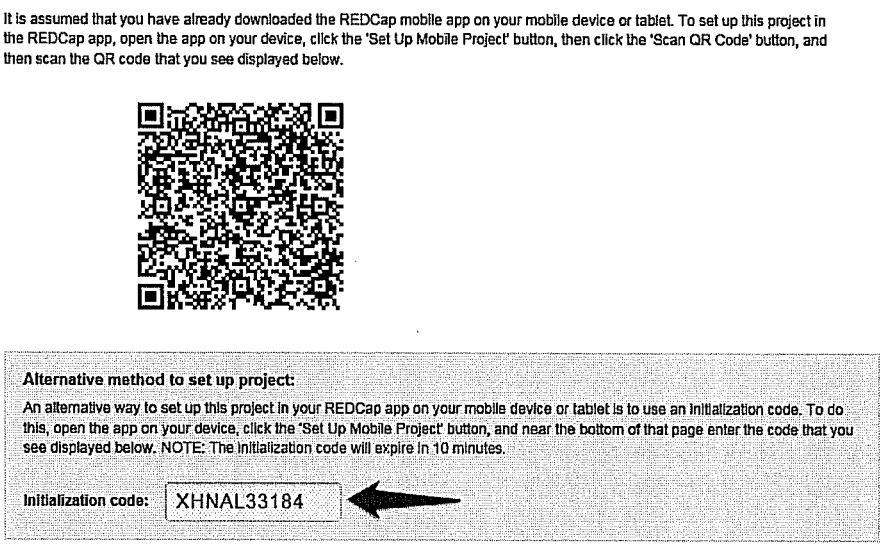
4. Follow the directions for set up, which are found on the Set Up Project in Mobil App" tab. The instructions require an 'API



Request', which is sent to the MSU-BRIC Data Manager.



5. After you receive the API from the MSU-BRIC Data Manager, continue to complete the Set Up steps.



Overview: Collecting data using the REDCap Mobile App

1. OFFLINE: **Collect data** from participants using the Mobile App offline.
2. ONLINE: **Send collected data back to the REDCap server.**
3. ONLINE: **Refresh the project** on the Mobile App.

Detail: Send collected data back to the REDCap server

When you return to an online environment (e.g. back in your office with

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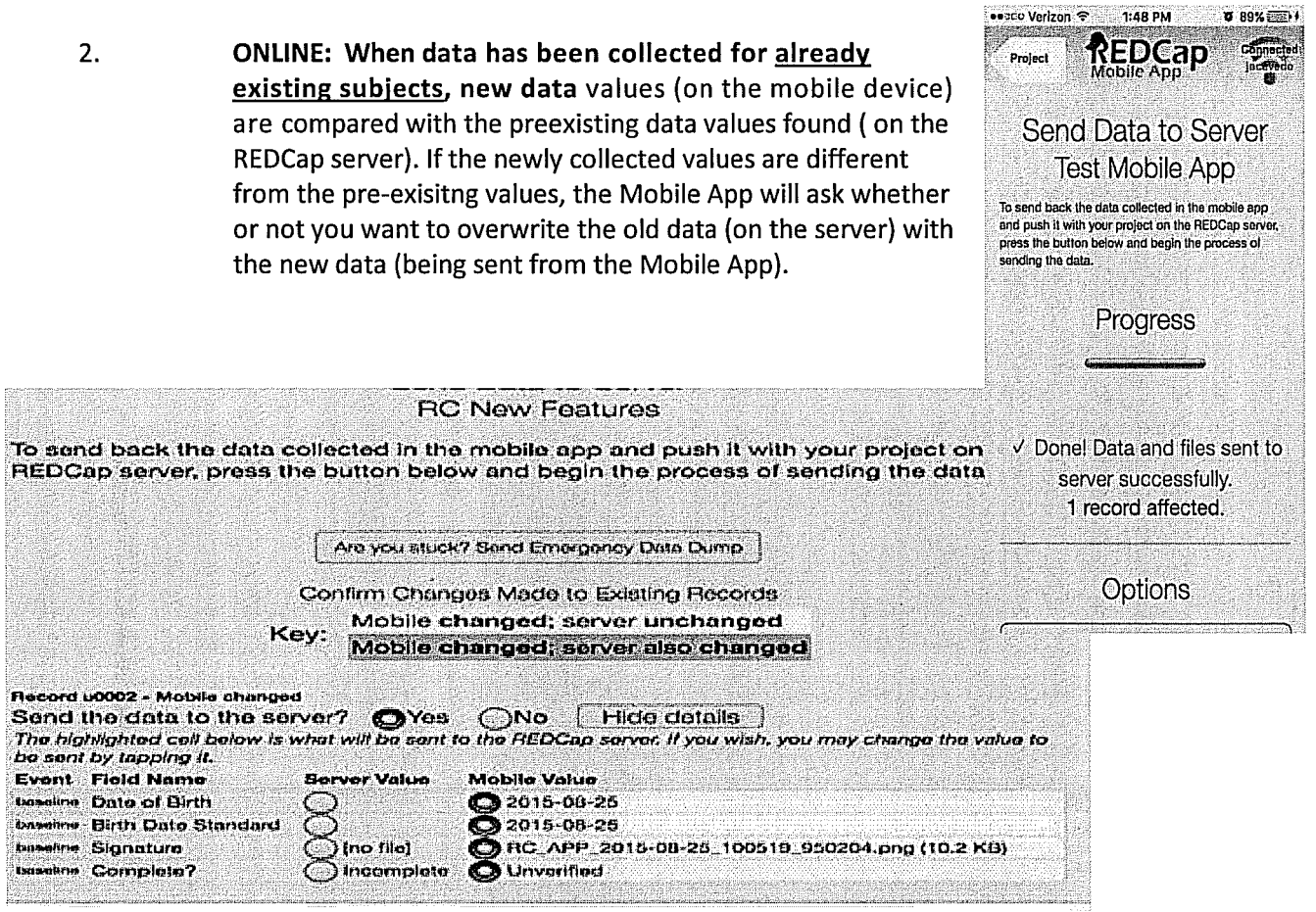

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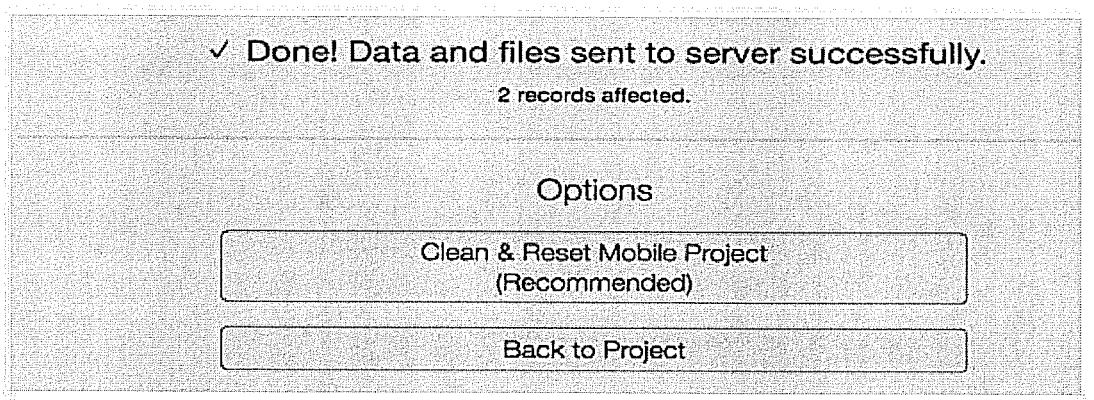

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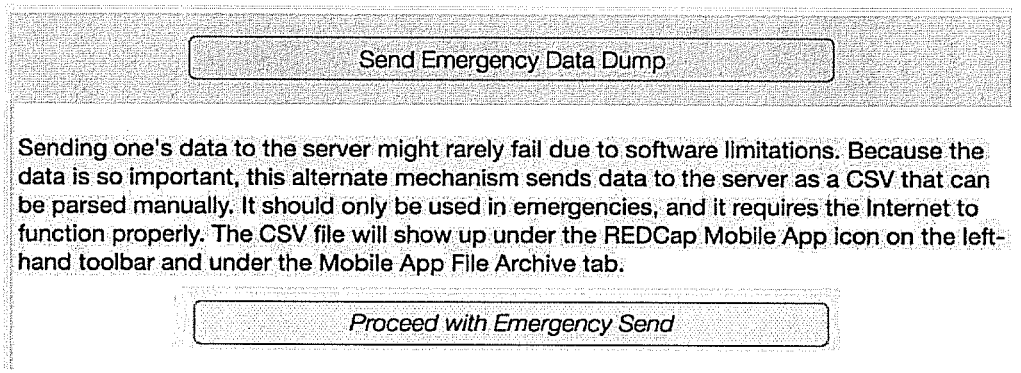


SERVER Visits Report FAQ

The **Visits Report** displays upcoming appointment dates based upon the birth date of the baby.

When the baby's date of birth is entered into the REDCap "**Baby Data**" form, the expected dates for upcoming events are populated into this report for easy "at a glance" viewing. The expected dates for upcoming appointments are based upon REDCap's "Days Offset" for each visit. The Study protocol's schedule of visits is determined at the Project setup, prior to collection of data.

Contents

Why do I care about this report?

- The **Visits Report** is used to display an expected (or rough draft) schedule of upcoming visits with the participant and to track the progress of completing these visits. It provides an "at a glance" look at each participant and tells what that person has completed, and when her next event is to be scheduled.

What does the report tell me?

- The **Visits Report** tells you what you need to do next. It can be used to coordinate scheduling of participants for upcoming events, by telling you what each participant's next event is, and when the study requires it to be accomplished.

How is the schedule determined?

- At the set-up of the Project, the BRIC Study Coordinator, in conjunction with the Principal Investigator, sets up a sequence of events for each participant in the study. This is based upon REDCap's "Days Offset" feature. For example: In this study, a 2-week postpartum visit is required. REDCap will set up to track 14 "Days Offset" from the baby's date of birth to schedule that visit. This projected date of visit will be displayed in this schedule.

What does "Days Offset" mean?

- "Days Offset" is the number of days before or after the "Index Event." These days are determined by the BRIC Study Coordinator, in conjunction with the Principal Investigator, and are used for scheduling activity and data collection schedules within the study.

What is an "Event"?

- An "Event" in REDCap means a specific visit or step in the study protocol.

What is an "Index Event"?

- The "Index Event" is a designated event, or field, that is the basis for calculating dates and schedules in REDCap. In this study, the "Index Event" is the baby's Date of Birth. All future events in REDCap are determined and calculated in relation to that fixed event.

What happens if I change the "Index Event"?

- Once data on a form are entered, and the form is saved in REDCap (by pushing the "Save" button on the bottom of the page), the **Visits Report** begins to calculate the schedule of events for that participant. If the specific **"Index Event"** (in this study it is the Baby's Date of Birth) is changed, e.g. a data entry error is discovered later, the entering of the corrected date will cause REDCap to recalculate and overwrite the expected visit dates and schedule. It is very important to enter the correct date (the "Index Event") properly the first time, so scheduling errors do not occur.

What forms do the data come from?

- The data can come from any of the Study forms. In the example of this study, the baby's date of birth is collected in the form titled "Baby Data." The completion date of scheduled events will come from the forms where that particular data is collected. The actual dates projected for the **Visits Report** are calculated behind-the-scenes by REDCap, based upon the days offset.

How do I make/request other reports?

- The BRIC Study Coordinator can assist in creating or updating reports. If the PI or Research Person(s) need to have access to creating reports, that can be arranged through the BRIC Study Coordinator.

I only see blank information. Why is that?

- All data displayed in the **Visits Report** is triggered by the "Index Event" being entered into the proper form. In this study, if the "Baby's Date of Birth" is not entered there will be only blank data shown for that study participant. Similarly, the actual completion dates for the projected activities displayed in the report are filled in only after the data are entered into the appropriate forms. If the report fields are empty, that means the data have not been entered in the study forms.

Why do I only see the ID#, and not the name?

- For participant security, only the assigned ID# is shown. This helps control the privacy of participants. Authorized users may still access the participants' names as needed.

Why don't I see all of the participants?

- Only participants with a properly entered "Index Event" will show in the report. If a participant's data does not include this information, the report will not display that participant.

Why does it say I can't enter the information on a tablet? What do I do now?

- REDCap Mobile, the application used to run the data collection on tablets and mobile devices, is a great tool, but it is still being developed and improved. At this moment, data used as "Index Events" do not translate properly from mobile devices into the laptop/desktop application. As a result, if the "Index Event" – or other specified data – is entered on a mobile device/tablet, the reports will not function properly. Many institutions and entities are working to improve this issue. **Currently, the "Index Event" must be entered via a laptop/desktop in order for the reports to function.**

How do I run this report?

- On the left had side of the REDCap screen, you will find a section labeled "Reports." (This feature is currently only available on the laptop/desktop version of REDCap.) The **Visits Report** is listed there. The report is dynamic and will automatically update whenever it is selected. This report will always show the most current data available.

How do I use this report in Excel?

- Once you select the report to run, you will see a button labeled "Export Report." Clicking on this button will enable you to select the application you would like to export the data into. Excel, and many popular statistics software, is listed as an option. The export feature also allows important "de-identification" options.

How do I sort the report so I can use it easier?

- Reports will sort in the order chosen at report creation. If a different order is required, a new report should be created or the report should be exported and sorted through an external application.

Kerver Randomizaton Process Logistics (Revised copy

RANDOMIZATION PROCESS/LOGISTICS

1. BRIC Prepare randomization table
   Packet ID# (sequential)/ group assignment (T or C)
   Randomization scheme: block randomization with random block size

2. BRIC Email randomization table to Claire/Claire's supervisor, Michelle Groesbeck. [Claire and her supervisor are ~~is~~ unblinded.]

3. ~~Claire~~Michelle Create packets
   Insert appropriate material (T or C) based on the randomization table.
   Label with Packet ID# on outside of packet.
   Deliver packets (in numerical order) to Data Collectors (DCs)

4. DC Complete baseline data collection.
   Retrieve next numbered packet. Use packets in sequential order.
   On Checklist Baseline Data Collection Phone Call FORM enter the Packet ID# for each Participant.
   Address the Packet with the Participant's mailing address.
   Record on the paper log sheet for each Packet ready for mailing:
   PacketID#/Participant Initials/Date packet mailed

5. ~~Claire~~Gayle?? View the Packet GroupAssnmnt REPORT on a daily basis.
   Open the Intervention FORM for each Participant listed in the report and enter the Group Assignment (T or C) for the given Packet ID#, by using the randomization table.
   Note: The report and form are blinded to all but Claire and Interventionists

Comment [JK1]: Does Gayle also have access?

6. Interventionist
   View the Ready for Intervention Scheduling REPORT on a daily basis.
   Participants listed in the report are ready to be schedule for intervention visits.
   Note: This report is blinded to all but Claire and Interventionists.

Same as header

MAMA Bear Peer Counselors (MBPC) Protocol

Prenatal One-on-One Visit and phone contacts

Script for first visit:

- **Thank you for taking time to meet with me today! Today I plan to talk with you about your goals for breastfeeding your baby, and share some resources that may be helpful to you in the future. We can also discuss any concerns you have regarding breastfeeding, or certain breastfeeding topics that you would like to learn more about.**

- **To begin, I'd like to understand your views on breastfeeding.**
  Ask one or more of the following, depending on individual needs:
  - **Do you have other children?**
    - If yes, ask: **Have you breastfed before?**
  - **What have you heard about breastfeeding?**
  - **What are your goals for breastfeeding your baby?**
  - **Do you have any concerns about breastfeeding?**

- **I think you might find the Coffective app helpful in supporting your breastfeeding goals. Have you heard about it? It's designed to help moms get off to a good start breastfeeding their babies, and to help them with concerns or problems if they should happen along the way.** *Show short intro video (1:24): https://vimeo.com/127838520. Show second video if time allows (5:41):* https://vimeo.com/127839660

- **Let's download the Coffective app to your phone and I will show you how to use it.** *If mother forgot her phone or you experience technical difficulties, refer to the Coffective website to show her the app features. Ask if she would like you to text her the link to where she can find it: http://www.coffective.com/ Make a plan for her to download the app when she gets home, and to discuss it at the next phone contact.*

- **Coffective also has a great checklist for helping you communicate your goals with your healthcare team when you deliver your baby. Sometimes you don't feel much like talking when you get to the hospital, so this checklist is helpful because you can simply hand it to the staff when you arrive. It can help them understand how to help you with your breastfeeding goals right after your baby is born. You can also share it with your significant other and/or your support persons. Having everyone "on the same page" is a great way to begin!**

- **During the completion of the Coffective checklist, address early postpartum topics applicable to mother, which are provided:**
  1. **Falling in love with your baby**

2. **Preparing for breastfeeding, benefits and expectations at hospital**
3. **Building your team**
4. **Benefits of exclusive breastfeeding**
5. **First hour after birth**
6. **Importance of rooming in**
7. **Breastfeeding positions**
8. **Protecting your milk**
9. **Feeding cues**
10. **Recommended duration (6 months) for exclusive breastfeeding**

**Remember not to provide medical advice, diagnose conditions, and to yield situations outside of your scope of practice. See "Scope of Practice for Peer Counselors" and "Yield List."*

- **Do you have any questions so far?**
  **Remember not to provide medical advice, diagnose conditions, and to yield situations outside of your scope of practice. See "Scope of Practice for Peer Counselors" and "Yield List."*

- **After your baby is born, it can be challenging to take care of yourself. Planning ahead can help you and your baby stay healthy and have less stress during those first few weeks. Some of the things you can do now are:**
  - **Thinking about your short and long term goals**
  - **Planning ahead for good nutrition despite being tired and busy**
    - *Example: preparing some frozen meals rich in lean proteins and vegetables.*
  - **Thinking of ways to get adequate rest**
    - *Example: sleeping when the baby sleeps*
  - **Enlisting the help of support persons**
    - *Example: listing three support persons and contact info in your booklet*
    - *Example: brainstorming ways in which your support persons could help you, such as grocery shopping, breastfeeding latch help, breastfeeding positioning help, laundry, or coming to hold the baby for a few hours while you sleep. Help with household chores and meals can allow you time to focus on rest and breastfeeding.*
  - **Think about and set goals for weight management**
    Ask the following questions as they apply:
    - **What do you feel your ideal weight is?**
    - **What was your pre-pregnancy weight?**
    - **What has your weight gain been during your pregnancy?**
    - **Have you been able to be as active during pregnancy as you were before pregnancy?**
    - **Has your doctor discussed his/her typical guidelines regarding resuming physical activity following birth?**

- **Do you have any concerns regarding weight management during or after pregnancy?**

- **Please write down any questions you might have. I'll be contacting you every 2 weeks by phone/text to see how you're doing.**
  - *After the visit, begin texting mother every 2 weeks to answer questions, provide additional education and support with breastfeeding and their healthy lifestyle goals*
  - *Any **contact** made with mother should be documented in RedCap System*

- **Once your baby is born, the postpartum home visit should be completed within 1-3 days after birth. Please contact me as soon as possible after your delivery so we can plan the visit.** *Make sure she has your accurate contact information handy.*

<u>Postpartum home visits and phone contacts</u>

- *Home visits should be completed within 1-3 days postpartum, and again at 6 weeks postpartum.*

- **Congratulations! How did the birth go?**

Listen attentively as she shares her birth story, asking open-ended questions as appropriate. Examples:

- **How did breastfeeding go in the hospital?**
- **Let's review your short term breastfeeding goals.** *Read through her goals together.*
- **In what ways were the hospital staff and your support persons supportive of your breastfeeding goals?**
- **How is breastfeeding going so far?**
- **Do you have any concerns or questions?**

- *Based on mother's responses, review Breastfeeding Support Topics as needed:*
  1. **Latch and positioning**
  2. **Feeding cues and normal infant feeding patterns**
  3. **Emotional challenges**
  4. **Breast and nipple care**
  5. **How to know baby is getting enough breast milk** *(diapers, weight gain over time)*

- **Let's take a few minutes to review your long term breastfeeding goals.**
  - *Read through her goals together.*
  - *Provide reinforcement of exclusive breastfeeding benefits and recommended duration (the first 6 months).* **As we discussed at our first visit, breastfeeding exclusively for the first 6 months provides many benefits to both you and your baby.** *List and discuss benefits. Remind mother that exclusive breastfeeding is only feeding baby breastmilk, either at the breast or pumped and given in a*

bottle. No water, juice, cow's milk, formula, or solids like baby cereal or baby food.

- **One of those benefits is weight loss, because your body is using extra calories to make milk. If you breastfeed exclusively for the first 6 months, that is equivalent to 90,000 calories! That's equal to over 650 scoops of ice cream!**

- *Provide participant with the reminder to utilize the Coffective app as needed.*

- *From initial weight management and healthy lifestyle goals established with participant you may provide relevant educational materials which can be obtained from:*
  - USDA- Choose MyPlate
    - https://www.choosemyplate.gov/ten-tips
  - Exercise Guide for Post-partum mothers
    - http://makeyourbodywork.com/postpartum-exercise-guide/

- **Our next home visit will be when your baby is 6 weeks old, around the time of your 6 week postpartum check up with your doctor/midwife. Let's plan a date and time.**

- **Keep in mind that additional home visits can be done as needed if you request them. If you're having problems or unsure of something, just ask! I'm here to help you. I will be calling you monthly, but if questions arise before my call or visit, please feel free to contact me.** *After breastfeeding has been established, Mama Bear Peer Counselors will make* ***monthly*** *calls and continue to track in RedCap.*

  - *In those calls, follow up on usage of weight management application and Healthy Lifestyle goals set.*

- *At 6 week visit, discuss the use of a scale. Instruct mother not to use it daily, because inches are lost before pounds.*

Reminders

- MBPCs will call Gayle Shipp, CLS after their first couple of postnatal home visits to discuss any questions they could not answer and/or to debrief about the entire visit.
- MBPCs will also have access to a contracted Lactation Consultant to assist with any breastfeeding challenges they cannot resolve.
- MBPCs have a "Yield List" that indicates when they Yield to a Lactation Expert or Health Care Provider.

Educational Materials and Resources available for visits

Prenatal Breastfeeding Education

Coffective Checklist
Coffective Counseling sheets
Breastfeeding Matters fact sheets
Express Yourself fact sheet
Making Milk-Yes You can fact sheet
Feeding Your New Baby-Eating Smart-Being Active

Postpartum Breastfeeding Education

Getting Milk from Mom to Baby fact sheet
Making it Work fact sheet
Diaper Diary

Healthy Lifestyle Prenatal/Post-Partum

- https://www.womenshealth.gov/breastfeeding/index.html?from=AtoZ
- https://www.womenshealth.gov/itsonlynatural/
- https://www.womenshealth.gov/files/assets/docs/breastfeeding/itsonlynatural/breastfeedingguide-africanamerican-english.pdf

USDA- Choose MyPlate

- https://www.choosemyplate.gov/ten-tips

Exercise Guide for Post-partum mothers

- http://makeyourbodywork.com/postpartum-exercise-guide/

Postpartum Birth Control Education

Same as header

Interventionist Protocol

Contact and Scheduling

1. In REDCap view the "Record Status Dashboard" to identify participants who are approaching the point of scheduling either a (Prenatal visit, Early Postpartum Visit, or 6 Week Postpartum Visit). Visit Reports can be drafted that will project the "scheduled date" for the participant's home/clinic visit to be completed. Upon either monitoring or receipt of those reports, visits should be **scheduled immediately**.

2. Open the participant ID, contact the participant to schedule a mutually agreed date and time. During scheduling, be sure to confirm their address and telephone number for upcoming appointment. The Schedule Generator should be used to find the participant and generate a schedule of upcoming visits at specific time points, which can be tracked on the calendar (this can only be used in the web version).

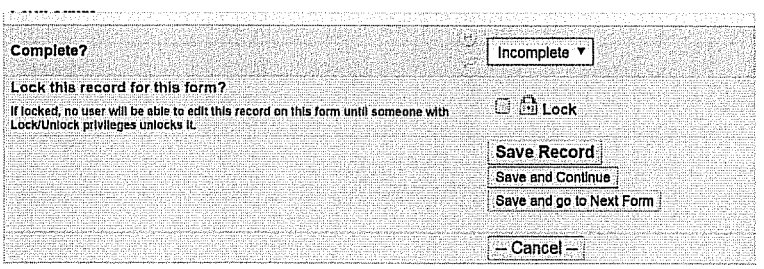
Visits

- **Before Visit**

  Before leaving office, identify the participant ID and download onto the mobile application. Before heading to the visit, be sure IPAD is completely charged.

- **After Visit**

  Within **1 day** of completing visit, complete either the "Checklist Prenatal Home Visit" or "Checklist Early Post-Partum Home Visit" or "Checklist 6-week post-partum Home Visit" within the **web version** REDCap system. Click on the Participant ID, find specific Checklist (Prenatal, Early Post-partum, 6 week Post-partum), scroll to the bubble (displayed gray) and click to begin completing the form based on the previous visit. Once you have reached end of form, be sure to change status of form to "Complete" and save.



Following the Prenatal Visit: Participant Interactions/ Call Log

After the Prenatal home/clinic visit, contact mother's **bi-weekly** to answer questions, provide additional education and support with breastfeeding and their healthy lifestyle goals set. Any **contact** (phone call, text message, home/ clinic visit) made with mother and topics discussed should be documented in the form "Participant Interaction". Once you have reached end of form, be sure to change the status of form to "**Complete**" and **save**.

***During any contact, if the mother has delivered her infant. Please complete the form "Baby Data".**

Following the Early Postpartum Visit: Participant Interactions/ Call Log

Following the **Early Postpartum Visit** and breastfeeding is established; Interventionist's will make **monthly** calls and track in RedCap. Any **contact** (phone call, text message, home/ clinic visit) made with mother and topics discussed should be documented in the subsequent form "Participant Interaction". Once you have reached end of form, be sure to change status of form to "**Complete**" and **save**.

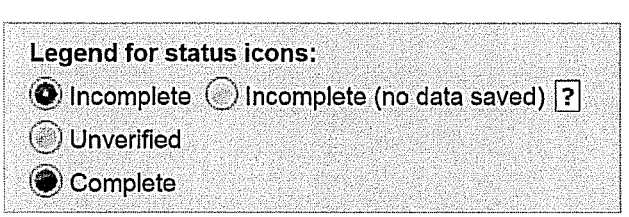
*If using the IPAD, while collecting information and In the case of an emergency where information collected has not been synced, such as IPAD turning off because of low battery, use the "Send Emergency Data Dump" that appears at the bottom of the REDCap mobile application, which will send all data collected to the full server.

*Any time a change is made or something new is documented, **make sure** it is saved.

Form Completion Tracking

As information is collected in REDCap, keep track of the completion of those forms by switching the "status" of the form being complete. This can also be used to guide work flow of upcoming events and scheduling participant home visits.

- Incomplete= not complete
- Unverified= complete, but needs review by Project Manager
- Complete= After verified by Project Manager



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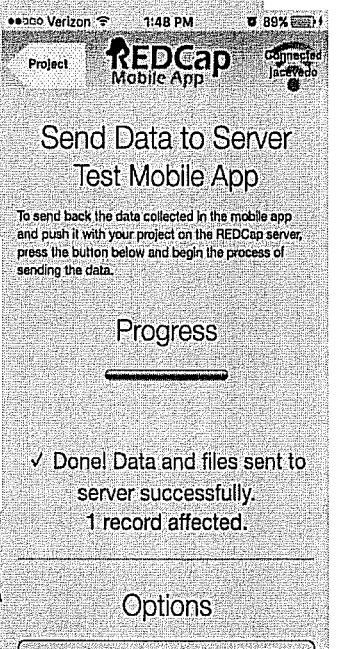

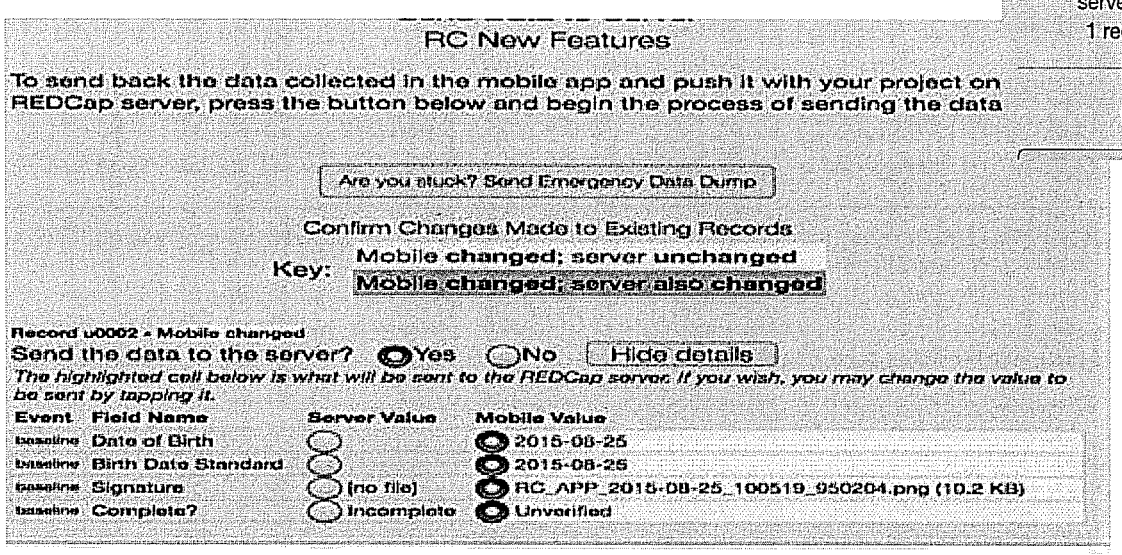

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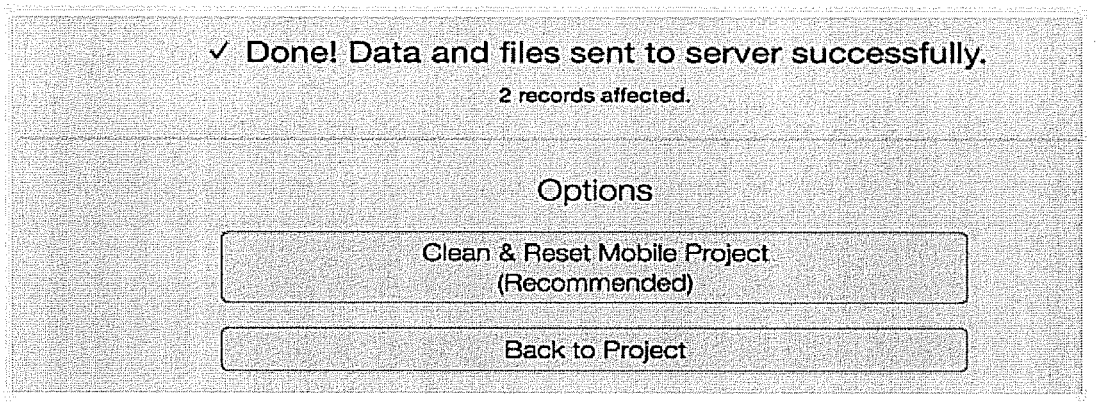

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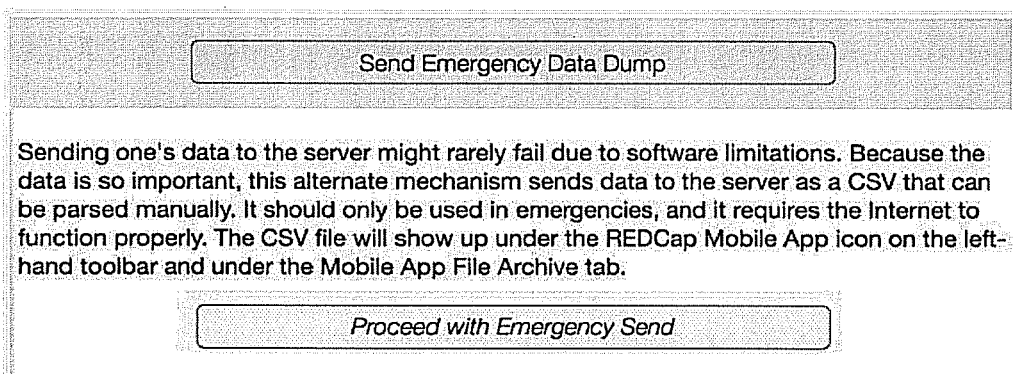


Henry Ford Hospital Detroit
Community Check list

We're Prepared!

Learn best practices. Decide what you want. Tell your care team your wishes.
Being prepared helps you and your new baby have a great hospital stay.

My Name _____ **Source** Henry Ford Hospital Detroit

(Where I received the checklist.)

Build My Team

My Champion(s):	_____	☐
My Doctor/Midwife:	_____	☐
My Baby's Doctor:	_____	☐
My WIC: N/A	_____	☐
My Home Visitor: N/A	_____	☐
Other:	_____	☐

POSTPARTUM APPOINTMENTS

DATE ___/___/___ TIME ___:___ AM PM
DATE ___/___/___ TIME ___:___ AM PM
DATE ___/___/___ TIME ___:___ AM PM
DATE ___/___/___ TIME ___:___ AM PM
DATE ___/___/___ TIME ___:___ AM PM

REFERENCE	PRACTICES	OFFERS	I'M PREPARED & WANT	I RECEIVED
Plan	Wait At Least 39 Weeks	☑	☐	☐
	Comfort During Labor	☑	☐	☐
Fall In Love	Skin To Skin Right After Birth	☑	☐	☐
	Delayed Routine Procedures	☑	☐	☐
	Magical First Hour Without Interruptions	☑	☐	☐
	Help With Baby's First Feed	☑	☐	☐
Nourish	Help Learning How to Breastfeed	☑	☐	☐
	Help Learning How to Hand Express Milk	☑	☐	☐
Keep Baby Close	Keep My Baby In The Room With Me	☑	☐	☐
	Continued Skin to Skin	☑	☐	☐
	My Quiet Hours: FROM ___:___ AM PM TO ___:___ AM PM	☑	☐	☐
Learn Your Baby	Feed My Baby on Cue	☑	☐	☐
	Comforting My Baby	☑	☐	☐
Protect	No Pacifiers or Bottles	☑	☐	☐
	No Formula (Unless Medically Necessary)	☑	☐	☐

MOTHERS: *Consider sharing this with your care team, including WIC.*

Baby's Name: _____

Birthdate: ____ / ____ / ____ Gestational Age: _____

Birth Weight: _____ Length: _____ Head Circ. _____

Discharge Date: ____ / ____ / ____ Weight: _____

At Discharge Baby Has Been: ☐ Breastfed ☐ Formula Fed ☐ Combination

Notes: _____

Mom's Postpartum HCT/HG: _____ Weight: _____

Stay Connected with Local Resources

Your Detroit Health Department

Together Toward a Healthier Detroit

The Detroit Health Department wants to make Detroit a city where all babies have an opportunity to be healthy and well. We are here to link you and your family to information, services and community resources, and to share important information for your and your baby's health.

MY BABY helps you remember six important health facts:

Make it to Your Due Date: Your care team is there to help you carry your pregnancy full term.

Your Medical Home: Make sure you have a primary care doctor.

Baby's Medical Home: Find a pediatrician for your baby by your third trimester of pregnancy.

ABC'S of Safe Sleep: Remember to put your baby to sleep Alone, on her or his Back, in a Crib – and do not Smoke.

Breastfeeding: Mommy's milk is best – breastfeed!

Your Choice: Plan 18 months between pregnancies for your and your baby's good health.

Health Department Services for Moms, Babies & Families

- Women, Infants and Children (WIC) Nutrition Program
- Immunizations
- Lead screening and case management
- Vision and hearing screening
- Children's Special Health Care Services
- 961-Baby Maternal Child Health Referral Hotline
- Safe sleep education
- Car seat safety education

CITY OF DETROIT — DETROIT Health Department

Michigan WIC

WIC provides nutritional services, breastfeeding support and supplemental food for pregnant women, new mothers, infants and children. Families of four can qualify with incomes up to $44K. Contact your local agency at:

Detroit Health Department WIC: (313) 831-5141

Detroit Urban League WIC: (313) 831-5141 ext. 42

Wayne County WIC: (313) 865-4631

Macomb County WIC: (586) 469-5471

AIHFS (American Indian Health and Family Services) WIC:
(313) 876-4555
There are other WIC agencies to choose from:
Call 1-800-BIRTH-26 or visit *www.michigan.gov/wic.*

Children's Special Healthcare Services 1 (800) 359-3722

A program within the Michigan Department of Health and Human Services for children with special health care needs and their families. Over 2,700 diagnoses qualify.

Home Visiting Services

Home visiting agencies provide one on one services to mothers in the community, in their home or in other settings. The Maternal Infant Health Program (MIHP) provides in-home visits to all pregnant women and infants on Medicaid. Other agencies serve first-time mothers. Still others provide guidance and assistance during crisis.

IHP Healthy Start Detroit MIHP: (313) 309-9340

Infant Mortality Program: (313) 369-5730
Sponsored by St. John Providence

Nurse Family Partnership: (313) 319-5717
Home visiting for first time mothers with income limits

Early Head Start: *www.detroitheadstart.com*

Wayne County HUB: 1-844-321-GROW connects families to home visiting and crisis services

DHealth 961-BABY: Parenting and Family Health Hotline
There are other MIHP's to choose from: visit *www.michigan.gov/mihp.*

Other Community Resources

Make Your Date Detroit: (313) 577-1000 A comprehensive prenatal and educational program for the families of Detroit
www.makeyourdate.org

Women Inspired Neighborhood Network: (313) 874-4581
www.winnetworkdetroit.org

Black Mothers' Breastfeeding Association: (800) 313-6141
Breastfeeding peer counselors, doulas and support groups

Focus HOPE Doula and Breastfeeding Services: (313) 494-4425 Peer to peer support before, during and after pregnancy

Wayne County Breastfeeding Coalition: info@wcbfc.org
Breastfeeding events and connections to resources

United Way 211: Call 211, a 24/7 hotline for basic needs and other health resources

Henry Ford Hospital - Detroit

Henry Ford Health System — Henry Ford Hospital

In-Patient Lactation Services: (313) 916-8363
Routine visits on maternity floor and NICU avalabile 6 days per week

Prenatal Breastfeeding Classes: 1-800-746-9473
Breastfeeding basics (benefits, making milk, position/latch, common problems)

Lactation Consultant Warm Line: (313) 916-8363
24-hour phone line to speak/leave message with a lactation consultant

Women's Health Clinic Breastfeeding Peer Counselor Support:
1-800-746-9473 Mother-to-mother support at New Center One and Ford Road Women's Health Clinic

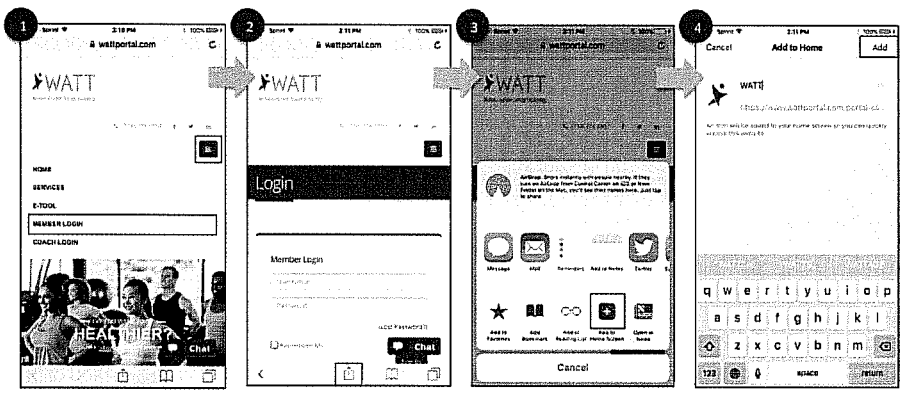
User_WATT Mobile

Download Instruction

To quickly access WATT on your mobile device (smartphone, tablet, etc.), follow the steps below to create an icon on the home screen of your device.

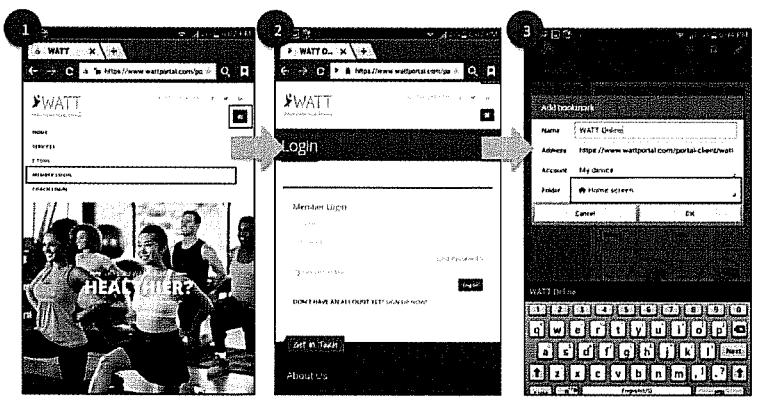
Apple iOS Devices

1. Open your internet browser and visit your program or project site. Once on the site, click on the site's menu icon and go to the "Login" page.
2. Click the "Download" button on the menu of your browser.
3. Select "Add to Home Screen" from the list of download and saving options.
4. Click "Add" to save the icon to your device's home screen.



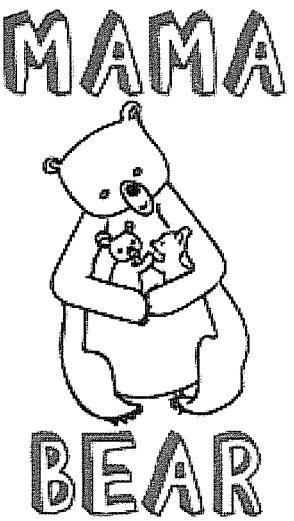
Android Devices

1. Open your internet browser and visit your program or project site. Once on the site, click on the site's menu icon and go to the "Login" page.
2. Click the "Bookmark" button on the top menu of your internet browser.
3. Select "Add Bookmark" from the list of download and saving options.
4. Select the "Home Screen" folder to save the icon to your device's home screen.



Additional resources and training materials are available, such as:

- The "Diet for a Healthy Breastfeeding Mom" powerpoint (slides shown on the next page)
- The "Orientation Handbook for Peer Counselors" purple binders (see binder cover below)



Mothers
Allied with
Mothers
Around
Breastfeeding
Encouragement
And
Renewed Health

MAMA BEAR

Orientation Handbook for Peer Counselors

Training CHW. 11.23.

Diet for a Healthy Breastfeeding Mom

Tips and suggestions for reference when working with Breastfeeding Mothers in MAMA Bear Study

Presented by: Gayle Shipp MS. CLS. PHP

Eat a well-balanced diet for *your* health

- Breast milk can meet baby's nutritional needs even when not eating perfectly.
- Baby won't be harmed by occasional dietary lapses doesn't mean that MOM won't suffer.
- Body draws on its reserves, which can eventually become depleted.
- Encourage: Eating small meals with healthy snacks in between – the way she may have done during pregnancy –good way to keep your hunger in check and energy level high.

Don't count calories & Aim for slow and steady weight loss

- Most women who are breastfeeding need about 500 calories more than moms who aren't – that's a total of 2,000 to 2,500 calories per day.
- Encourage mom to follow **hunger** as a guide to how much need to eat.
- Encourage mom to lose weight **gradually** and plan to return to pre-pregnancy weight within 1 yr.
- Most women can safely lose 1 pound each week by combining a healthy diet with moderate exercise.
- Large drop in calorie intake can affect milk supply, discourage going on a crash diet to lose weight quickly.

Include a variety of health foods & Choose Good Fats

- ☐ Encourage eating a mix of carbohydrates protein, and fat at meals keeps you feeling full longer and supplies the nutrients your body needs.
- ☐ Encourage consumption of Complex carbs like whole grains and cereals
- ☐ Fresh fruits and vegetables not only provide more nutrition than processed starches and sugars, they provide longer-lasting energy
- ☐ Limit saturated fats and avoid trans fats, both of which are considered unhealthy

Take extra steps to avoid contaminants

- Minimize:
  - Pesticides
  - Insecticides
  - other chemicals that you ingest can make their way into your breast milk.

Go easy on the alcohol

- ❑ If mom decides to consume an alcoholic drink; encourage her to either breastfeed her baby or express her milk first and store it for later.
- ❑ After consumption of alcohol; encourage her to wait at least two hours before breastfeeding her baby or she may need to "pump and dump."

Drink plenty of water and limit caffeine

- Good guideline to follow is drink to satisfy thirst
- Most experts suggest that nursing moms limit their consumption of caffeine (including coffee, tea, soft drinks, energy drinks, chocolate, and coffee ice cream) to no more than 300 mg per day. That's about as much as you'd get in three 5-ounce cups of coffee. You may want to drink even less if you're nursing a newborn or preterm baby

Keep taking your vitamins

- ❑ Encourage the continuance of prenatal vitamin while breastfeeding
- ❑ A supplement doesn't take the place of a well-balanced diet, but it can provide some extra insurance on those days when taking care of the new baby especially if it keeps mom from eating as well as she'd like

Additional Resources

- https://www.womenshealth.gov/breastfeeding/index.html?from=AtoZ
- https://www.womenshealth.gov/itsonlynatural/
- https://www.womenshealth.gov/files/assets/docs/breastfeeding/itsonlynatural/breastfeedingguide-africanamerican-english.pdf

USDA- Choose MyPlate

- https://www.choosemyplate.gov/ten-tips

Exercise Guide for Post-partum mothers

- http://makeyourbodywork.com/postpartum-exercise-guide/

Reference

- http://www.babycenter.com/0_diet-for-a-healthy-breastfeeding-mom_3565.bc

Analysis Plan:

Aim 1: Feasibility of recruitment and retention: Feasibility will be assessed at multiple points: enrollment rate (percent of eligible and approached women); percent of participants for whom study staff is notified of hospital admission for birth; percent of participants completing each additional data collection point. By compartmentalizing our feasibility assessment in this R21 exploratory/developmental project, we will be better able to target specific areas for refinement to inform our planned phase III trial. Retention will be assessed by the percent of participants who complete the 20 week postpartum data collection visit.

Aim 2: Acceptability will be measured at each data collection point using a brief questionnaire developed by the research team that will allow participants to rate the value and utility of the intervention content and give their opinions about the format, ease of use, and delivery method. Control group participants will be asked a similar set of questions to compare satisfaction with usual care practices. Engagement will be assessed as percent of intervention arm participants completing each planned intervention contact and by the frequency of log-ins to the online system, use of web/mobile-based tracking tools, and interactions with peer counselors. Feasibility and acceptability will be assessed separately from, but also in relation to the primary outcomes of breastfeeding duration and weight retention. For example, we will assess the number of women who discontinue BFing but continue tracking diet and exercise. These results will guide our structured interview questions planned for the final data collection visit (20 wks postpartum).

Aim 3: Estimate the preliminary effect size of the intervention relative to a) the control group (at 20 weeks postpartum) and secondarily to b) patients in the same health system who are not enrolled in our study (via electronic medical records at 6 weeks postpartum) on: (1) breastfeeding duration, and (2) postpartum weight retention. Statistical Analyses: Subjects will be randomized to treatment (TRT) or control (CNT). Adequacy of the randomization: Randomization adequacy will be tested by comparing relevant baseline maternal and infant characteristics between the two study arms. Where substantive differences exist, they will be controlled for in subsequent analyses. We will test the degree of similarity, however, following Altman we will be guided by the degree of dissimilarity, not strict statistical significance. Outcomes and Analysis: The data on *n* participants are denoted by with outcome and explanatory variables in the *i*-th participant. The two main outcomes are: (1) Duration of breastfeeding assessed by number of days postpartum at infant weaning (possible range=0-140 d), and (2) Weight retention assessed by the ratio of the maternal weight at 20 weeks postpartum to the pre-pregnancy weight. Both outcomes are regarded as continuous and will be analyzed using linear models. If data are found to be skewed, a logarithmic or square-root transformation *g* will be applied to . To assess the effect of treatment on outcome we will fit the model and test the hypothesis where is the coefficient for the TRT group indicator, with CNT as referent. Results will be presented as (1) a point estimate and 95% confidence interval for , with and without regression-adjustment and (2) a standard two-sample t-test of $_0 H$.
Statistical Power: With a total sample size of 80 women randomized to TNT, CNT we can detect at least a moderate effect size of 0.65 (i.e., in units of standard deviation) with power of 80% (2-sided test, alpha=0.05). Our objective, however, is the estimation of effect size rather than testing for significance.