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CASE WESTERN RESERVE UNIVERSITY EST. 1826

# INFORMED CONSENT DOCUMENT

## Nourishing Beginnings:
## Addressing Food Insecurity During Pregnancy in High Risk Populations

You are being asked to participate in a research study about healthy food access and nutrition among pregnant people receiving Community Health Worker support as part of Better Health Partnership's Pathways HUB. Researchers at Case Western Reserve University are conducting this study. Participants will be approached for enrollment based on study eligibility requirements. Your participation is completely voluntary and if you choose not to participate, it will not affect the care you receive with the Better Health Partnership HUB Pathways, the benefits you receive, or your eligibility to receive other services.

## KEY INFORMATION

### Purpose

We are doing this research in partnership with Better Health Partnership and the Greater Cleveland Food Bank to see if an intervention that helps address food access and nutritional needs of pregnant people (either by providing food delivery or by providing additional financial support to purchase healthy foods) can help to improve both mom and baby health outcomes, by reducing stress and anxiety that are sometimes associated with trying to eat healthy during pregnancy.

### Procedures and Duration

If you choose to participate, you will be enrolled in the study that will last 12-18 months and you will be randomly assigned to one of two intervention groups aimed to help you access healthy foods during your pregnancy.

Neither your community health worker nor the project team can control which group you are assigned. The project involves two different groups because we want to understand if one approach works better than the other, although we believe both will be beneficial. The two groups are of equal value in what we are providing to you as part of your involvement in the study. Individuals in both groups will receive access to and support from a community health worker provided by the Better Health Partnership HUB Pathways program. All participants will also receive a kitchen needs assessment. If the assessment shows that you need tools to help prepare food at home, the study may provide basic supplies to you.

The groups will be different in the following ways:

Group 1: Participants in this group will receive a tailor-made box of nutritious groceries from the Greater Cleveland Food Bank, delivered to your home every two weeks. The food included in each box will be tailored to your individual food preferences with help from the community health worker in choosing healthy food options. Food is also selected so that multiple meals can be made from each food box, enough to feed a family of 4.

Group 2: Participants in this group will receive a modest amount of financial support twice a month to assist with healthy food purchases **as well as** support from a study team member in identifying healthy food retail

options within your neighborhood or accessible with a car or bus. The financial support is $25 every two weeks, which will be placed on a reloadable gift card.

We will collect information from you four times throughout the study; first, after you have agreed to participate in the research study by signing the consent form, second, in the middle of your pregnancy, third, near your delivery date, and finally, six months after you have delivered your baby. Every two weeks, we will ask you to respond to a short text survey to give the project team feedback on the intervention you are getting. This feedback will be very helpful informing the future implementation of the program

As part of the study, we will ask you to do the following:

1. Complete a few short surveys which ask about your current nutritional needs, where you shop for food, your thoughts and feelings, and your levels of stress. You will be asked to complete these questions at the beginning of the study, around your delivery date and then 6 months after delivery.
2. Complete three 24-hour dietary recalls over the telephone with a member of the study team, once at the beginning of the study, once near the time of delivery and once at the end of the study. You will be helped to recall what you ate in the past 24 hour prior to the call, which is then entered into a computer program that analyzes the nutritional composition of the foods. You will receive $25 for each completed set of three recalls, placed on a reloadable gift card.
3. Work with your Community Health Worker to complete the Kitchen Tool Assessment and determine if there are items you need in your kitchen in order to cook and eat better (up to $100).
4. Answer a few short questions every other week about the intervention you receive, such as the quality of the food in the boxes, your ability to find healthy food to purchase, etc. You may answer these questions via a link to a secure web-based survey that will be texted to you, or by phone, whichever you prefer. This information will be extremely important for allowing us to make changes to the intervention during the study.

In addition to the data you provide to us, your consent will allow the study team the ability to track your data through other entities:

- Work with your insurance provider to confirm your birth outcomes. This will be used to ensure accurate details on the birth weight, gestational age, and other relevant birth outcomes.
- Work with the Greater Cleveland Food Bank to document the food you received through the intervention. This will be used to analyze the types of food that are associated with positive birth outcomes in the study.
- Work with Vincent Payment Solutions to understand how much money from your gift card was used at stores that sell food. (We will not be able to see what you purchased, only where you made purchases with the card).

## Reasons You Might Choose to Volunteer for This Study

Your participation is completely voluntary. Participation in this study may inform what resources the government or medical insurance companies may support and provide for at-risk pregnant moms. Participation in this study could also provide food, healthy food navigation and/or small amounts of monetary compensation; as well as additional one-on-one time spent with your assigned Better Health Community Health Worker.

## Reasons You Might Choose Not to Volunteer for This Study

The risks to participating in this study are low. The risks include loss of confidentiality and the time burden associated with participating. Participation in this study requires filling out additional study surveys and more time spent with your Better Health Community Health Worker, and you might choose not to participate if you do not have the time or desire to complete those extra activities.

## Voluntary Participation

If you decide to participate in this study, it should be because you want to volunteer. There is no penalty or loss of benefits for not participating. You can change your mind at any time.

# DETAILED CONSENT

## Foreseeable Risks and Discomforts

There are no known risks, harms or discomforts associated with this study beyond those encountered in normal daily life. The possible risk and/or discomfort associated with the procedures described in this study include: loss of confidentiality. To keep the risk low, your personal information (name, phone number) will not be linked with or stored with the data that are collected for the purposes of this study.

Your study information and results will be stored by an assigned number instead of your name, and your data will be encrypted or protected in a computer. The medical and research information recorded about you will be used by the study team at Case Western Reserve University, Better Health Partnership, and the Greater Cleveland FoodBank to evaluate the effects of the intervention. Access to your information is granted only to the site principal investigator, Dr. Elaine Borawski and approved faculty and staff working on the study.

## Compensation

There will be no costs for you to participate. In addition to the resources you receive as part of your intervention group, you will receive a $25 gift card for the completion of the NDSR (24 hour dietary recalls) (three times over the course of the study).

## Alternative(s) to Participation

The only alternative to participation is simply not to participate.

## Voluntary Nature of the Study

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with your health care provider, Better Health Partnership, Case Western Reserve University, or the Greater Cleveland Food Bank. There is no penalty, loss of benefits, changes in medical care, or service eligibility for not participating or for discontinuing your participation. You are free to end your participation in the study at any time. If you wish to stop participating, we ask you to contact the researchers by calling Better Health Partnership at 216-778-7525.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI must be made in writing to the Principal Investigator.

## Confidentiality

Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Research records will be kept in a secure location and access will be limited to the researchers, the University review board responsible for protecting human participants, and regulatory agencies In any sort of report we might publish, we will not include any information that will make it possible to identify a participant.

However, you should understand that in cases where we suspect elder or child abuse or neglect or imminent harm to self or others, we will take the necessary action in an effort to prevent such harm or injury, including reporting to authorities.

## Subject Identifiable Information

Some information that identifies you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. Better Health Partnership will have access to your identifiable information as part of normal operating procedures of the Community Health Worker HUB.

Research staff at CWRU will only have access to the study data linked to a unique study ID and not to information that will connect your identity to information you provide for the study. A separate list of names and addresses will be used by CWRU research staff for payment purposes and will not be connected to your study data. Research staff will be provided a transaction record for purchases made on the reloadable gift card (merchant name and amount) but individual purchases are not recorded. If you wish to receive a copy of the study results, your address may be used to send the study report. The file containing your name and address will be destroyed after the completion of the study and after you receive a report of the study results.

Greater Cleveland Food Bank will utilize your name and address in order to arrange for food delivery. Your phone number will be used to send a text with a secure link to a survey. The Greater Cleveland Food Bank, as part of their standard operating procedures, will track food delivery in Pantrytrak using the Pantrytrak account associated with your household, or will create an account for your household if one does not exist.

***Data Storage:*** All research data will be maintained in a secure location. Only authorized individuals will have access to it. Any electronic research data will be stored electronically in an encrypted file. A study dataset will be stored in a secured, encrypted REDCap database. REDCap is a software that is built for managing secure research projects.

***Data Retention:*** The researchers intend to keep the research data until the research is published and/or presented. Your identifiable information collected for this research may have the identifiers removed and be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. However, any new studies would be required to obtain IRB approval to proceed with any studies outside the original intent of this study.

## Contacts and Questions

The lead researcher conducting this study is Dr. Elaine Borawski. If you have any additional questions, concerns or complaints about the study, you may contact Dr. Elaine Borawski at exb11@case.edu, (216) 368-1024; Christopher Mundorf at cmundorf@metrohealth.org, (330) 414-4189; or Alissa Glenn at aglenn@clevelandfoodbank.org, (216) 738-7261.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: (1) questions, concerns or complaints regarding this study, (2) research participant rights, (3) research-related injuries, or (4) other human subjects issues, please contact Case Western Reserve University's Institutional Review Board at (216) 368-4514 or write: Case Western Reserve University; Institutional Review Board; 10900 Euclid Ave.; Cleveland, OH 44106-7230.

## Future Studies

Sometimes a study investigator may wish to contact participants to ask about participating in another study or to provide additional information for research. Can the Nourishing Beginnings study team can utilize your contact information to contact you for these purposes? You can decide at that time if you are interested in additional participation. Check one of the following:

____ Yes, it is ok for the Nourishing Beginnings team to contact me for future studies.

____ No, I do not want to be contacted once my participation has concluded..

## Statement of Consent

Your written consent certifies the following:

- You are at least 18 years of age.
- You have read (or been read) the information provided above.
- You agree to be randomly assigned into one of the two intervention groups.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

You will be given a copy of this form for your records.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Obtaining Consent Date