The Role of Medically Tailored Groceries in Mitigating Food Insecurity and Improving Pregnancy Outcomes Through Clinic-Community Partnerships

April 19, 2025

Informed Consent Documents

INFORMED CONSENT DOCUMENT (METROHEALTH)

Nourishing Tomorrow Research Study
The Role of Medically Tailored Groceries in Reducing Food Insecurity and Improving Pregnancy Outcomes

You are being asked to participate in Nourishing Tomorrow, a research study about healthy food access and nutrition during pregnancy. Researchers at Case Western Reserve University are conducting this study. Your participation is voluntary and if you choose not to participate, it will not affect the care you receive from your prenatal provider at MetroHealth, the benefits you receive, or your eligibility to receive other services.

KEY INFORMATION

Purpose

We are doing this research in partnership with University Hospitals, MetroHealth and the Greater Cleveland Food Bank to see if a program that improves access to healthy food during pregnancy can help to ensure a healthy pregnancy and baby by reducing stress and anxiety that are sometimes associated with trying to eat healthy during pregnancy.

Procedures and Duration

If you choose to participate and complete the baseline data collection, you will be enrolled in the Nourishing Tomorrow study that will follow you until 6 months after the baby is born. Once you complete the baseline data collection, you will be randomly assigned to one of three intervention groups aimed to help you access healthy foods during your pregnancy. Neither your prenatal health care provider nor the community health worker (CHW) who is helping to recruit can control which group you are assigned. The project involves three different groups because we want to understand if one approach works better than the other, although we believe all three will be beneficial. The groups are of equal value in what we are providing to you as part of your involvement in the study. All participants will also receive cooking tools to provide you with basic supplies to help you prepare food at home, as well as helpful educational materials around eating healthy during pregnancy.

The groups will be different in the following ways:

Group 1: Participants in this group will receive medically tailored groceries provided by the Food as Medicine program at MetroHealth. This is the same program that you were initially referred to by your provider. You will make an appointment and meet with a dietitian who will discuss your dietary needs during pregnancy and help you to choose groceries for you and your family at the Food as Medicine clinic. You will have access to a new box of tailored groceries every two weeks. Upon arrival each time, you will also receive important educational resources about preparing food at home and eating healthy during your pregnancy. While the study will end 6 months after delivery, you will have the options to continue in the program for an additional 6 months.

Group 2: Participants in this group will receive a box(es) of medically tailored groceries from the Greater Cleveland Food Bank, delivered to your home every two weeks. The groceries included in each box and the recipes you can make from the foods are chosen by a registered dietitian; however, your food preferences will be considered in selecting groceries for you specifically where possible. The boxes will include enough food to make multiple meals, enough to feed a family of 4. In addition, with each delivery you will also receive helpful educational handouts about eating healthy during pregnancy. As with group #1, the study will end 6 months after delivery, you will have the options to continue to receive the delivered food boxes directly from the GCFB for an additional 6 months.

Group 3: Participants in this group will receive everything that Group 2 receives – home delivered, medically tailored groceries with recipes matching the foods in the box. However, in addition, this group will receive personalized education and support around food safety and storage, meal preparation, new recipes, and a host of resources to support healthy eating during pregnancy. Similar to Group 2, this group will have the option to continue receiving the delivered food boxes directly from the GCFB after the end of the study, for an additional 6 months.

Should you not complete the baseline data collection (described below), you will not be randomized and will be contacted by the Food as Medicine team at MetroHealth.

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

1. Complete a few short surveys (approximately 20 minutes each) 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. You will receive $25 for each completed survey, deposited to your Cash App account.
2. Complete two 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 asked about what you ate in the past 24 hours, which is then entered into a computer program that analyzes the nutritional composition of the foods. You will receive $50 for each completed set of two recalls, deposited into your Cash App account. Over the course of the study, you would complete a total of six dietary recalls for a total of $150.
3. Complete the Cooking Tools 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, what you liked and did not like, etc. This information will be extremely important for allowing us to make changes to the intervention during the study.

Should you not complete data collection activities, you may be withdrawn from the study and the medically tailored groceries, particularly the home delivered option, may be discontinued.

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

- Your health care provider will share a limited amount of information about you and your health such as your address and phone number, age and gender and your prior pregnancy history.
- Data about your prenatal care visits, pregnancy complications and birth outcomes will be extracted from your medical record and shared with the Nourishing Tomorrow study team. This will be used to ensure accurate details on the birth weight, gestational age, and other relevant birth outcomes.

- The Food as Medicine program MetroHealth and the Greater Cleveland Food Bank will 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. The Greater Cleveland Food Bank will also provide data about the number of times you receive food from a food pantry both as part of and separate from Nourishing Tomorrow.

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 Nourishing Tomorrow 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 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.

Anticipated Benefits

The possible benefits you may experience from this study include receiving medically tailored groceries bi-weekly as well as additional individual support provided through the interventions.

Compensation

There will be no costs for you to participate. As discussed above, in addition to the resources you receive as part of your intervention group, you will receive a small amount of money for some data collection activities.

The Accounting Department at MetroHealth will be given your name, address, and Social Security number to process payment for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

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, University Hospitals, MetroHealth Medical Center, Case Western Reserve University, or the Greater Cleveland Food Bank. You may stop participating in the study at any time, but if you are assigned to the home delivered groceries options, you will no longer receive the groceries at your home and will be given the option to pick up groceries at the Food is Medicine Clinics associated with your provider. If you choose to leave the study, you may keep any of the cooking tools or resources provided. If you wish to stop participating, we ask you to contact the researchers by calling the research team at Case Western Reserve University at 216-368-1024.

Privacy of Protected Health Information (PHI)

The Health Insurance Portability & Accountability Act (HIPAA) is a federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of Case Western Reserve University, University Hospitals/MetroHealth, and the Greater Cleveland Food Bank. **This Authorization form is specifically for a research study entitled "Nourishing Tomorrow" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information.** In order for the Principal Investigator, Elaine Borawski, PhD, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on the care you receive at MetroHealth. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at Case Western Reserve University and the Greater Cleveland Food Bank, who are working on this research project will know that you are in a research study, and they will see and use your PHI, provided by your health care provider, extracted from your medical record. This will include the following PHI about you: name, phone number, address (for program tracking), age, gender your prior pregnancy history, prenatal care visits, pregnancy complications and birth outcome data such as birth weight, gestational age, pregnancy and delivery complications and NICU admissions.

Your name, address and phone number will be used by the Greater Cleveland Food Bank to arrange for food delivery and text links to follow-up questions about food delivery. The GCFB will also provide data about other food assistance you receive through the Pantry Trak system. Case Western Reserve University will use your name and address in order to arrange for payments associated with the study (for the compensation for data collection activities as described in the Informed Consent document). All other information you provide for the purposes of this study will be linked only by a unique study ID and not to your identity or other PHI. Your access to your PHI may be limited during the study to protect the study results. Your PHI will not be shared with any other groups/persons outside of those listed above.

Your permission to use and disclose your PHI does not expire. However, **you have the right to change your mind at any time and revoke your authorization.** If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization, you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Elaine Borawski, PhD, at exb11@case.edu or at The Department of Nutrition, Biomedical Research Building, 9th Fl & WG-48, 2109 Adelbert Rd, Cleveland, OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the University's Director of Privacy Management, Lisa Palazzo at lisa.palazzo@case.edu or 216-368-4286, or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office for Civil Rights, US Department of Health and Human Services, 233 N. Michigan Ave., Suite 240, Chicago, IL 60601.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. Case Western Reserve University, the Greater Cleveland Food Bank, and MetroHealth are committed to protecting your confidentiality.

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 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

Upon receiving from your health provided, Case Western Reserve University will have access to your identifiable information as part of normal operating procedures of the HUB. Some information that identifies you will be removed and replaced with a code, a study ID. A list linking the study ID and your identifiable information will be kept separate from the research data.

Your name, address and phone numbers will be used at various times to conduct study activities such as arranging for food delivery and cooking tools delivery, sending text surveys, and conducting additional data collection via the Parent Survey and the 24-hour food recalls. The study will also utilize your Cash App account information so that money can deposited as compensation for completion of data collection activities as described above. This information will not be stored with other study data you provide. The file containing your name and address will be destroyed after the completion of the study and after you receive a report of the Nourishing Tomorrow study results.

Greater Cleveland Food Bank will also use your name and address as part of their standard operating procedures to track food delivery using a national computer system called PantryTrak.

Data Storage: All research data will be maintained in a secure location. Only authorized individuals will have access to it. A Nourishing Tomorrow study dataset will be stored in a secured software database called REDCap. Each member of the research staff will only have access to what is absolutely necessary in order to do their work.

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 that would require additional information from you would be required to obtain IRB approval to proceed with any studies outside the original intent of this study.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contacts and Questions

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

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.

Local Study Team Contact(s) for Questions About the Study

Whom do I call if I have questions or problems?

If you have questions about any part of the study now or in the future, or if you wish to communicate concerns or a complaint, you should contact Dr. Kelly Gibson, who may be reached at (216) 778 7076. If you experience any side effects or injuries while participating in this study, please contact Patricia Hardy, who may be reached at (216) 778 1733. For after hours, weekends and/or holidays, call Patricia Hardy, at (216) 339-2756. Any written communications with the study team may be sent to Dr. Kelly Gibson 2500 Metrohealth Dr, Suite G240, Cleveland, OH 44109.

If you have any questions about your rights as a research participant, or if you wish to express any concerns or complaints, please contact The MetroHealth System's Institutional Review Board—a group of people who review the research to protect your rights—at (216) 778 2021.

Compensation in Case of Injury/Availability of Treatment for Injury

It is important that you tell Dr. Kelly Gibson, the lead study investigator at MetroHealth, if you think that you have been injured because of taking part in this study. You can call her at 216-778-7076.

If you are injured as a result of being in this study, the costs for medical treatment may be billed to you or your health insurance plan. Health insurance plans may or may not cover costs for treatment of research-related injuries. If you have insurance, you should check with your health insurance plan before deciding to participate in this research study. If your health insurance plan covers some or all of the treatment costs, you may still be responsible for any co-pays or deductibles required by your plan.

MetroHealth has not committed to pay you or to pay for your treatment if you suffer an injury as a result of being in the study. There are no plans for MetroHealth to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research-related injuries. However, you are not waiving any legal rights by signing this form, including the right to seek compensation for an injury.

Clinical Trials.gov

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

Also, by signing this form, you are allowing the researchers for this study to use and disclose your protected health information (PHI) in the manner described fully in the detailed written consent document and you confirm that you have received a copy of that document for your records.

Signature of Research Participant (captured electronically via REDCap)	Print Name of Research Participant	Date
Signature of Witness (captured electronically via REDCap)	Print Name of Witness	Date

INFORMED CONSENT DOCUMENT (UNIVERSITY HOSPITALS)

Nourishing Tomorrow Research Study
The Role of Medically Tailored Groceries in Reducing Food Insecurity and Improving Pregnancy Outcomes

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KEY INFORMATION

Purpose

We are doing this research in partnership with University Hospitals, MetroHealth and the Greater Cleveland Food Bank to see if a program that improves access to healthy food during pregnancy can help to ensure a healthy pregnancy and baby by reducing stress and anxiety that are sometimes associated with trying to eat healthy during pregnancy.

Procedures and Duration

If you choose to participate and complete the baseline data collection, you will be enrolled in the Nourishing Tomorrow study that will follow you until 6 months after the baby is born. Once you complete the baseline data collection, you will be randomly assigned to one of three intervention groups aimed to help you access healthy foods during your pregnancy. Neither your prenatal health care provider nor the community health worker (CHW) who is helping to recruit can control which group you are assigned. The project involves three different groups because we want to understand if one approach works better than the other, although we believe all three will be beneficial. The groups are of equal value in what we are providing to you as part of your involvement in the study. All participants will also receive cooking tools to provide you with basic supplies to help you prepare food at home, as well as helpful educational materials around eating healthy during pregnancy.

The groups will be different in the following ways:

Group 1: Participants in this group will receive medically tailored groceries provided by the Food for Life program at University Hospitals. This is the same program that you were initially referred to by your provider. You will make an appointment and meet with a dietitian who will discuss your dietary needs during pregnancy and help you to choose groceries for you and your family at the Food for Life market. You will have access to a new box of tailored groceries every two weeks. Upon arrival each time, you will also receive important educational resources about preparing food at home and eating healthy during your pregnancy. While the study will end 6 months after delivery, you will have the options to continue in the program for an additional 6 months.

Group 2: Participants in this group will receive a box(es) of medically tailored groceries from the Greater Cleveland Food Bank, delivered to your home every two weeks. The groceries included in each box and the

recipes you can make from the foods are chosen by a registered dietitian; however, your food preferences will be considered in selecting groceries for you specifically where possible. The boxes will include enough food to make multiple meals, enough to feed a family of 4. In addition, with each delivery you will also receive helpful educational handouts about eating healthy during pregnancy. As with group #1, the study will end 6 months after delivery, you will have the options to continue to receive the delivered food boxes directly from the GCFB for an additional 6 months.

Group 3: Participants in this group will receive everything that Group 2 receives – home delivered, medically tailored groceries with recipes matching the foods in the box. However, in addition, this group will receive personalized education and support around food safety and storage, meal preparation, new recipes, and a host of resources to support healthy eating during pregnancy. Similar to Group 2, this group will have the option to continue receiving the delivered food boxes directly from the GCFB after the end of the study, for an additional 6 months.

Should you not complete the baseline data collection (described below), you will not be randomized and will be referred back to the Food is Life program at University Hospitals.

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

1. Complete a few short surveys (approximately 30 minutes each) 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. You will receive $25 for each completed survey, deposited to your Cash App account.
2. Complete two 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 asked about what you ate in the past 24 hours, which is then entered into a computer program that analyzes the nutritional composition of the foods. You will receive $50 for each completed set of two recalls, deposited into your Cash App account. Over the course of the study, you would complete a total of six dietary recalls for a total of $150.
3. Complete the Cooking Tools 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, what you liked and did not like, etc. This information will be extremely important for allowing us to make changes to the intervention during the study.

Should you not complete data collection activities, you may be withdrawn from the study and the medically tailored groceries, particularly the home delivered option, may be discontinued.

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

- Your health care provider will share a limited amount of information about you and your health such as your address and phone number, age, race, and your prior pregnancy history.
- Data about your prenatal care visits, pregnancy complications and birth outcomes will be extracted from your medical record and shared with the Nourishing Tomorrow study team. This will be used to ensure accurate details on the birth weight, gestational age, and other relevant birth outcomes.
- The Food for Life program at UH and the Greater Cleveland Food Bank will 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. The Greater Cleveland Food Bank will also

provide data about the number of times you receive food from a food pantry both as part of and separate from Nourishing Tomorrow.

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 Nourishing Tomorrow 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 to evaluate the effects of the intervention. Access to your information is granted only to the site principal investigator, Dr. Christopher Nau and approved faculty and staff working on the study.

Anticipated Benefits

The possible benefits you may experience from this study include receiving medically tailored groceries bi-weekly as well as additional individual support provided through the interventions.

Compensation

There will be no costs for you to participate. As discussed above, in addition to the resources you receive as part of your intervention group, you will receive a small amount of money for some data collection activities.

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, University Hospitals, Case Western Reserve University, or the Greater Cleveland Food Bank. You may stop participating in the study at any time, but if you are assigned to the home delivered groceries options, you will no longer receive the groceries at your home and will be given the option to pick up groceries at the Food for Life market at University Hospitals. If you choose to leave the study, you may keep any of the cooking tools or resources provided. If you wish to stop participating, we ask you to contact the researchers by calling the research team at Case Western Reserve University at 216-368-1024.

Privacy of Protected Health Information (PHI)

The Health Insurance Portability & Accountability Act (HIPAA) is a federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of Case Western Reserve University, University Hospitals/MetroHealth, and the Greater Cleveland Food Bank. This Authorization form is specifically for a research study entitled "Nourishing Tomorrow" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator,

Elaine Borawski, PhD, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on the care you receive at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at University Hospitals, Case Western Reserve University and the Greater Cleveland Food Bank who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: name, phone number, address (for program tracking), age, race, your prior pregnancy history, prenatal care visits, pregnancy complications and birth outcome data such as birth weight, gestational age, pregnancy and delivery complications and NICU admissions. Your name, address and phone number will be used by the Greater Cleveland Food Bank to arrange for food delivery and text links to follow-up questions about food delivery. The GCFB will also provide data about other food assistance you receive through the Pantry Trak system. Case Western Reserve University will use your name and address to arrange for payments associated with the study (for the compensation for data collection activities as described in the Informed Consent document). All other information you provide for the purposes of this study will be linked only by a unique study ID and not to your identity or other PHI. Your access to your PHI may be limited during the study to protect the study results. Your PHI will not be shared with any other groups/persons outside of those listed above. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research:

- The Department of Health and Human Services
- Other Institutional Review Boards
- Data Safety and Monitoring Committee
- Other staff from the Principal Investigator's medical practice group that are involved in the research
- University Hospitals, including the Clinical Research Center and the Law Department; any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation, and Government representatives or Federal agencies, when required by law.

It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, **you have the right to change your mind at any time and revoke your authorization.** If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization, you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Dr. Christopher Nau, MD
Department of Obstetrics & Gynecology
11100 Euclid Ave, Cleveland, OH 44106.
Christopher.nau@uhhospitals.org

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights,

OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. Case Western Reserve University, the Greater Cleveland Food Bank, University Hospitals, and MetroHealth are committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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 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

Upon receiving from your health provided, Case Western Reserve University will have access to your identifiable information as part of normal operating procedures of the HUB. Some information that identifies you will be removed and replaced with a code, a study ID. A list linking the study ID and your identifiable information will be kept separate from the research data.

Your name, address and phone numbers will be used at various times to conduct study activities such as arranging for food delivery and cooking tools delivery, sending text surveys, and conducting additional data collection via the Parent Survey and the 24-hour food recalls. The study will also utilize your Cash App account information so that money can deposited as compensation for completion of data collection activities as described above. This information will not be stored with other study data you provide. The file containing your name and address will be destroyed after the completion of the study and after you receive a report of the Nourishing Tomorrow study results.

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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 that would require additional information from you would be required to obtain IRB approval to proceed with any studies outside the original intent of this study.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contacts and Questions

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

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.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

Also, by signing this form, you are allowing the researchers for this study to use and disclose your protected health information (PHI) in the manner described fully in the detailed written consent document and you confirm that you have received a copy of that document for your records.

Signature of Research Participant (captured electronically via REDCap)	Print Name of Research Participant	Date
Signature of Witness (captured electronically via REDCap)	Print Name of Witness	Date