Official Title: Feasibility of Delivering a Digital Behavioral Intervention to Increase Diet Quality Among Women Receiving WIC Benefits

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DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
**ADULT**
***Healthy Roots: a digital behavioral intervention to increase diet quality and WIC retention among parents and caregivers receiving WIC benefits.***

We are running a study to develop and test a digital intervention We want to see if it can increase the use of WIC benefits. We also want to improve the food and drinks parents and caregivers eat and drink. You will get a set of goals and use your mobile phone totrack each goal over time. We will give you feedback just right for you based on the datayou send to us. The study is three months long. The greatest risks of this study include the possibility of loss of confidentiality. If want to learn more about this study, please continue to read below.

We are asking you to join this study because you:
1) are at least 18 years old;
2) are currently receiving WIC nutrition benefits;
3) are willing to send and receive text messages;
4) are the parent or caregiver of a child who is2 years old or younger; and
5) have a smartphone.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. Please ask about any words or information that you do not clearly understand. You may ask the study staff to read the consent form to you. You may talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, worries, and other important information about the study are listed below.

Please tell the study staff if you are taking part in another research study.

A grant from the National Institutes of Health will sponsor this study. Portions of Dr. Melissa Kay's and her research team's salaries will be paid by this grant.

**WHO WILL BE IN CHARGE OF THIS STUDY?**
Dr. Melissa Kay is the principal investigator for this study. You will continue to get your care from your WIC provider. We will ask you to answer some questions about the foods you eat. Based on your answers, we may recommend you consult with your WIC provider.

**WHY IS THIS STUDY BEING DONE?**
We want to test a new digital health tool to see if it helps caregivers use their WIC benefits. We also want to see if it helps care givers make healthy food choices.

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## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 60 people will take part in this study. We will ask ten of these participants to take part in interviews following the study.

## WHAT IS INVOLVED IN THE STUDY?

You will be asked to complete surveys about yourself and the foods you eat. We will send a link to these surveys in email and text message. It should take you about 30-45 minutes to complete these surveys.
One survey will be the Automated Self-Administered 24-hour Dietary Assessment Tool (ASA-24). It will capture all the foods and drinks you had in the past 24 hours. The study team will provide you with login information for the ASA-24. We will ask you to complete 2 of these before you begin the study. You will be compensated after each one you complete. If you would like, the research team can schedule an onboarding call with you via phone call or Zoom (video conferencing), based on your preference.

Once all surveys are complete, we will assign behavior change goals, such as 'choose beans instead of red meat once this week'. You will use your phone to tell us how you are doing with your goals, and we will send you personalized feedback. We will also send you motivational messages to support your behavior change efforts.

After three months, we will ask you -to complete another set of surveys about the foods you eat and your behaviors. We will ask you to complete 2 of these and you will be compensated after each one you complete. We will also ask you to participate in a phone or video call (using Zoom). We will conduct a brief interview with you to ask you what you thought of the Healthy Roots study.

## HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for three months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

## WHAT ARE THE RISKS OF THE STUDY?

The activities we ask you to do (such as eating healthy foods) have very little risk to your body. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study. You may stop your participation in this study at any time.

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The ASA-24 website used for the study is developed and maintained by the National Cancer Institute for use by researchers. As with any website that you visit there may be potential security risks and Duke cannot guarantee that the website/software is free of risk. In general, it is recommended that you run a current operating system (OS) on your computer or phone, review the privacy/security settings on your web browsers, run antivirus software, make sure that your connection is encrypted (look for the lock icon when you connect), and log off of websites when you are done.

The information we gather will be kept in a database on password-protected computers at Duke and a remote secure database. These databases will be accessible only by research staff at Duke who are on Healthy Roots. The information we collect will be used only for this study. Only study staff approved by the Duke Institutional Review Board (IRB) will be able to see your information. None of your data will ever be sent to third parties except as described in this consent form, with your permission, or as may be required by law.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
There may be direct health benefits to you for taking part in the study. The study will help you follow national diet recommendations from the Dietary Guidelines for Americans. The activities we recommend (such as eating healthy) may be beneficial for your health and the health of your family. While participating in our study, we hope that you will learn ways to eat healthy and reduce the risk of obesity for you and your child. We hope that in the future the information learned from this study will benefit other families.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Duke University Health System (DUHS) Institutional Review Board.

In order to keep in touch with you, we will collect phone numbers and an email address where you can be reached. This information will be encrypted and stored in a remote secure database.

Following your participation in the study, we may ask you to participate in a secure, one-time phone interview to hear your thoughts about the study. These phone interviews will be digitally-recorded and professionally transcribed by a Duke-approved vendor that has privacy

protections to safeguard your information. The audio files will then be stored in our study folders within Duke-protected online servers.

Text messaging does not provide a completely secure and confidential means of communication. Data sent via text message will pass through a text message software program called Twilio, which is integrated with Duke REDCap. No data will be stored on Twilio's servers; these data will be stored in Duke REDCap. After the study is over, a version of your data *without* personal information (e.g., your responses to survey questionnaires without your name or other identifiable information attached) will be stored on Duke University's secure cloud platform, Duke Box.

The study results will be retained in your research record at Duke for at least six years after the study is completed. At that time, the research information may be destroyed or information identifying you may be removed from such study results at DUHS.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. We will report results about the whole group.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) You have consented to the disclosure, including for your medical treatment; or
3) The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your

own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

**WHAT ARE THE COSTS TO YOU?**
There are no costs to you to participate in this study. However, there may be costs involved in text messages sent or received, depending on your mobile carrier and plan.

**WHAT ABOUT COMPENSATION?**
You will receive reimbursements of up to $55 for your time in the form of Walmart gift cards. An additional $15 will be added for those who complete the additional study follow-up interview.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Melissa Kay at 919-613-8397 during regular business hours.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data

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that have already been collected for study purposes will be retained unless you request otherwise.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at Duke or Piedmont Health. If you do decide to withdraw, we ask that you contact Dr. Kay by email and let her know that you are withdrawing from the study. Her e-mail address is melissa.kay@duke.edu. If you choose to withdraw from this research study, you will be asked to complete a brief survey about your experience in the study and reasons for withdrawal.

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

A description of this research study is available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kay at (919) 613-8397 during regular business hours.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Institutional Review Board (IRB) Office at 919-668-5111.

**STATEMENT OF CONSENT**
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form by email."

_____
REDCap E-signature and Date