Consent for Research Participation

Research Study Title: Families Becoming Healthy Together

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Key Information for You to Consider

The information in this box is a short summary to help you decide if you want to be in this research study. More detailed information is listed later in this form. Please ask questions if there is anything you do not understand. Please take your time. You should not feel rushed or pressured to make a decision.

- **Voluntary Participation**. You should only be in the study if you completely understand the study and want to volunteer. You do not have to be in this study.
- **Purpose**. This research study will determine if a family-based childhood overweight and obesity treatment program, that has goals for healthy eating and physically activity for both the child and adult caregiver, can improve child weight at 18 months.
- **Research Procedures and Activities.** Due to COVID-19, health safety procedures may be put in place during you and your child's participation in the study. This could involve social distancing and wearing a face covering. If you decide to be in the study, we will ask you and your child to complete individual appointments to collect information at 0, 6, 12, and 18 months. These appointments will occur remotely via Zoom. Additionally, you and your child will also be asked to complete 29 program meetings over 18 months. These program meetings will occur remotely via Zoom. Both you and your child will receive goals for diet and physical activity.
- **Duration.** If you agree to be in the study, your participation will last for 18 months. The program will involve 60-minute program meetings via Zoom once a week for months 1 to 4, twice a month for months 5 to 6, once a month for months 7 to 12, and once every two months for months 13 to 18 (for a total of 29 sessions).
- **Benefits**. Possible benefits for you and your child include weight loss, consuming a healthy diet, and being more physically active. Your participation will help us learn more about family-based childhood overweight and obesity treatment that will benefit others in the future.
- **Risks.** Some risks of this study include you and your child may not lose weight, eat healthier, be more active, or maintain weight loss.
- **Alternatives.** Instead of being in the study, you could talk to your or your child's health care provider for possible alternatives for weight management. This could include diets with lower daily calorie recommendations, drug interventions, and surgery.

Why am I being asked to be in this research study?

We are asking you to be in this research study because you have a child living in your house between the ages of 8 and 12 years and you and your child have overweight or obesity according to medical standards.

What is this research study about?

The purpose of this research study is to determine if a family-based childhood obesity treatment program, that has goals for healthy eating and being physically active for both the child and adult caregiver, can improve child weight at 18 months.

Who is conducting this research study?

This study is being conducted by Drs. Raynor and Crouter from the University of Tennessee, Dr. Epstein from the University at Buffalo, Dr. Thomas from the Miriam Hospital, and Dr. Berlin from the University of Memphis.

The research team is receiving funding, from the National Institute of Diabetes and Digestive and Kidney Diseases, which is part of the National Institutes of Health.

How long will I be in the research study?

If you agree to be in the study, your participation will last for 18 months and will involve 60-minute program meetings once a week for months 1 to 4, twice a month for months 5 to 6, once a month for months 7 to 12, and once every two months for months 13 to 18 (for a total of 29 sessions). These meetings will occur online via Zoom.

What will happen if I say "Yes, I want to be in this research study"?

Due to COVID-19, health safety procedures may be put in place during you and your child's participation in the study. This could involve social distancing and wearing a face covering.

For individual appointments at 0, 6, 12, and 18 months to collect measures like, height and weight, tastes tests, and questionnaires, three sessions will occur. For these appointments, we will either mail or drop off at your house all equipment and materials you need for these appointments. The box will include physical activity trackers, questionnaires, and supplies for the taste tests.

For your and your child's first and second session, we will meet online using Zoom. You and your child will eat the provided energy bar before these sessions. In both sessions, you and your child will be asked to taste test different foods, like cookies and fruit, and juices, like lemon and lime. There will be two taste tests, one for food and one for juice. For each of these tests, you will actually taste food or juice 14 times. For each taste, you and your child will put three cotton dental rolls in your mouth, with one on each side of the mouth and one under the tongue. The

rolls will collect saliva during the taste tests. During the taste tests, you and your child will also rate how hungry and full you are and how much you like the foods and juices.

At the first session, which will last about 90 minutes, we will review questionnaires you and your child will be completing after that session. These questionnaires will include information about demographics, food preparation habits, foods you have at home, sleep habits, and routines. It will take about 30 minutes to complete these questionnaires. There will also be a questionnaire about unhealthy practices for weight loss for your child to complete. Children who score high on this questionnaire will require permission from their primary care provider to participate in the study. We will also review the devices you and your child will be wearing around the waist during the next week to measure physical activity. During that same week, you and/or your child will be asked to take pictures of food and drinks you and your child eat with your phone. The pictures should be taken at the start and end (showing food and drink not eaten) of all eating occasions. If you do not have a phone to take these pictures, we will provide one for you. We will call you on three days during the week you are taking pictures and wearing the devices. During the calls, we will ask you to describe the food and drinks you ate during the last 24 hours. We will also ask your child, with your help, to describe the foods and drinks eaten during the last 24 hours. These calls will take about 30 minutes each.

After you and your child have worn the devices and completed the three calls, the second session will occur online via Zoom. At this session all questionnaires will be reviewed. The Zoom session will take 90 minutes. Individual assessment appointments via Zoom will not be audiotaped or recorded for research purposes.

For the third session, we will collect materials from your home including the physical activity trackers, completed questionnaires, and cotton rolls from the taste test. Additionally, we will measure you and your child's height and weight and this will take about 10 minutes.

Following completion of these measures, you and your child will come to 29, 60-minute, family-based childhood overweight and obesity program meetings over 18 months online via Zoom. At the 60-minute meetings, you and the child will attend separate 40-minute adult and child group meetings, and then for the last 20 minutes of the meetings you will meet together with an individual interventionist. The last 20 minutes will allow the interventionist to provide individual treatment to your family. The meeting with the individual interventionist may be at a different time from the scheduled group time.

During the first two weeks of the program, you and your child will have one individual meeting online via Zoom to do a taste test of a food. Like the other taste tastes, you will actually taste food 14 times. For each taste, you and your child will put three cotton dental rolls in your mouth, with one on each side of the mouth and one under the tongue. The rolls will collect saliva during the taste tests. During the taste tests, you and your child will also rate how hungry and full you are and how much you like the food. This appointment will take approximately 40 minutes. This taste test will include a time in which supplies for the taste test will be mailed or dropped off at your front door and a time in which the cotton rolls are picked up from your front door.

At the end of the study, there will be a questionnaire about how COVID-19 has affected your family.

Program meetings will be audiotaped for the purpose of the treatment standardization. Individuals will not be identified in any way and all information will be kept confidential. Tapes will be destroyed within 2 years of completion of the study.

The program uses an eating plan called the Traffic Light Diet. The Traffic Light Diet calls foods high in calories and low in vitamins and minerals RED foods. The Traffic Light Diet has the eating goals of 1000-1500 calories per day and 2 or fewer servings of RED foods per day. The program also has a goal of at least 60 minutes per day of physical activity for children and at least 30 minutes per day of physical activity for adults. You and your child will be asked to keep track of your eating and activity during the 18 months of the program.

You will be randomized, which is like a coin toss, to one of two groups within the program. The two groups are: 1) Family-based Treatment; or 2) Family-based Treatment with Variety Goals. Both groups are the same except for one difference. The Family-based Treatment with Variety Goals group is experimental and has one more food goal. For this goal, families will identify two RED foods, a dinner entrée and snack food, and develop meal plans that use these two foods and limit other RED foods. Two new RED foods will be chosen each month.

What happens if I say "No, I do not want to be in this research study"?

Being in this study is up to you. You can say no now or leave the study later. Either way, your decision won't affect your relationship with the researchers or the University of Tennessee.

Instead of participating in the study, one option available to you is to consult your health care provider for possible alternatives for weight management. Alternative treatments that your health care provider may suggest include diets with lower daily calorie recommendations, drug interventions, and surgery.

What happens if I say "Yes" but change my mind later?

Even if you decide to be in the study now, you can change your mind and stop at any time.

If you decide to stop before the study is completed, you may contact the Healthy Eating and Activity Lab at 865-974-0752 to let us know you would no longer like to participate. Any of your information already collected for the research study will be returned to you if you request it.

Are there any possible risks to me?

It is possible that someone could find out you were in this study or see your study information, but we believe this risk is small because of the procedures we use to protect your information. These procedures are described later in this form.

The diet goals provide a balanced diet, with approximately only 300-500 (child) or 500-1000 kcal (adult caregiver) per day decrease from usual intake, and so you should expect to feel hunger prior to meals. The physical activity goal is for moderate-intensity activities that are to be

increased gradually over time in order to prevent injury. However, it is still possible that you or your child may become injured when starting to be more physically active, but this is a risk for any new physical activity program. A potential risk is that you and your child may not lose weight and maintain the weight loss while in the program. However, this is a potential risk in any overweight and obesity treatment program.

Are there any benefits to being in this research study?

There is a possibility that you and your child may benefit from being in the study, but there is no guarantee. Possible benefits for both you and your child include weight loss, consuming a healthy diet, and being more physically active. Even if you don't benefit from being in the study, your participation will help us learn more about family-based childhood overweight and obesity treatment that will benefit others in the future.

Who can see or use the information collected for this research study?

We will protect the confidentiality of your information by removing any identifying information that would connect you to your data and responses. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there are times when others may need to see the information, we collect about you. These include:

- The Institutional Review Board at the University of Tennessee, Knoxville who oversee research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.
- The National Institute of Diabetes and Digestive and Kidney Diseases, who is the study sponsor paying for this research.
- A description of this study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this study will be posted on this website at the conclusion of the research. No information that can identify you will be posted.

What will happen to my information after this study is over?

We will keep your information to use for future research. Your name and other information that can directly identify you will be kept secure and stored separately from your research data collected as part of the study

We may share your research data with other researchers without asking for your consent again, but it will not contain information that could directly identify you.

Will I be paid for being in this research study?

All caregiver participants will receive a $80, $90, and $110 gift card to Wal-Mart at 6, 12, and 18-month assessments when the height and weight measures, diet and physical activity measures, and questionnaires are fully completed. All caregiver participants will receive a $60, $70, and $80 gift card to Wal-Mart at 6, 12, and 18-month assessments when the taste-tests are fully completed. These will be provided in person or by mail. Participant name and address will be collected in the instances that the gift cards are mailed.

Will it cost me anything to be in this research study?

The only cost to you for this study is money spent on mobile phone costs when submitting digital pictures of food before and after eating occasions.

What else do I need to know?

We may need to stop your participation in the study without your consent if you no longer meet the study's eligibility requirements or if the study is stopped for any reason. Additionally, it is possible that the funding agency, National Institute of Diabetes and Digestive and Kidney Diseases, may choose to end the study. Should this happen, you will receive all benefits earned up to the point of the termination of the study.

If we learn about any new information that may change your mind about being in the study, we will tell you. If that happens, you may be asked to sign a new consent form.

If this study results in clinically-significant results, these results will not be automatically disclosed to participants.

The University of Tennessee does not automatically pay for medical claims or give other compensation for injuries or other problems.

As part of the study, you and your child will be asked to track your eating, activity, and weight over the 18 months of the program. The use of internet-based, third-party applications [MyFitnessPal (eating), Fitbit (activity), Garmin Jr (activity), and Wyze (weight)] is suggested to decrease barriers to tracking and allow researchers to access your tracking data remotely. These applications may use or share your personal information and data for functionality, marketing or analytics purposes or as required by court/law or for law enforcement; collect data related to your location; and use cookies, device identifiers, or other technologies to track some of your activities for the purpose of targeted advertising. In most instances, you do not have to allow the use of your personal information and data for these purposes. You can adjust your privacy settings for each application to disallow the use of your personal information and data in many of these ways.

Additionally, the personal information and data you share with third-party applications is hosted on servers that are not maintained by the University of Tennessee. Third-party applications typically do not disclose their protocols for ensuring the privacy and security of your data. Thus, it is possible that a data breach may occur that is outside the control of the researchers.

You do not have to use digital applications to track your eating, activity, or weight. Tracking may be done using traditional pen and paper methods, if desired. The research team will still ask that

you share your tracking records with them via Zoom, text, email, or phone call. You do not have to use your real information when creating accounts with third party applications. You may decide to use alternative tracking applications (e.g., Apple Watch) with which you are more comfortable.

To read more about the privacy policies of the suggested applications, please visit the websites below:

- MyFitnessPal: https://www.myfitnesspal.com/privacy-policy
- Fitbit: https://www.fitbit.com/global/us/legal/privacy-policy
- Garmin Jr: https://www.garmin.com/en-US/privacy/garminjr/policy/
- Wyze: https://global.wyze.com/en-ph/policies/privacy-policy

Who can answer my questions about this research study?

If you have questions or concerns about this study, or have experienced a research related problem or injury, contact the researcher, Dr. Hollie Raynor at (865) 974-9126, ext. 1 or hraynor@utk.edu.

For questions or concerns about your rights or to speak with someone other than the research team about the study, please contact:

Institutional Review Board
The University of Tennessee, Knoxville
1534 White Avenue
Blount Hall, Room 408
Knoxville, TN 37996-1529
Phone: 865-974-7697
Email: **utkirb@utk.edu**

Authorization to Collect Height and Weight

If you and your child choose to no longer participate and attend program meetings and/or assessments as part of this study, it would still be useful to us to know how you and your child does over the next 18 months. We'd appreciate it if you'd give your authorization for the principal investigator to continue to obtain you and your child's most current height and weight from your primary care provider.

Child height and weight

_____ If my child and I choose to no longer attend program meetings and/or assessments as part of this study, you have my permission to collect my child's most current height and weight from my child's primary care provider.

_____If my child and I choose to no longer attend program meetings and/or assessments as part of this study, you do not have my permission to collect my child's most current height and weight from my child's primary care provider.

Caregiver height and weight

_____ If my child and I choose to no longer attend program meetings and/or assessments as part of this study, you have my permission to collect my most current height and weight from my primary care provider.

_____If my child and I choose to no longer attend program meetings and/or assessments as part of this study, you do not have my permission to collect my most current height and weight from my primary care provider.

Use of Your Identifiable Health Information

A law, called the Health Information Portability and Accountability Act (HIPAA), protects your health information. When choosing to take part in this study, and providing your permission above, you are giving us permission to obtain and use your and/or your child's health information. This health information includes information in your medical records and information that can identify you (like your name, or phone number), so generally this information cannot be used in research without your written permission.

If you give your permission, your health information that will be shared with us and used in the study includes your child height and weight and/or your height and weight

Your health information above will be shared with us by your or your child's health care provider (as stated on the document that you complete for the study).

We may need to share your health information (height and weight) with other people or organizations. Below is a list of those people and organizations and the reasons why they may see or get your health information.

- Members of the research team and other authorized staff at the University of Tennessee, Knoxville who make sure it is safe for you to be in this study, conduct the study and analyze the research data.
- People at the University of Tennessee, Knoxville who oversee and evaluate research. This includes the ethics board and quality improvement program that work to ensure research is conducted properly.
- People from and agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Business offices at the University of Tennessee, Knoxville may be given your name, address, payment amount and related information.
- National Institute of Diabetes and Digestive and Kidney Diseases who is the study sponsor paying for this research.
- Groups monitoring the safety of this study.

Some of these people or organizations that may see or get your health information may not have to follow the same privacy laws and protect your information in the same way that we will. Your health information will not be shared with anyone else without your permission unless all information that can identify you is removed.

Your permission to use and share your health information for this study will continue until the research study ends and will not expire, unless you cancel it sooner. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can I change my mind about the use of my health information?

At any time you may change your mind and withdraw your permission for your health care provider(s) to share or use your health information (height and weight) for the research; however you cannot get back information that was already shared.

To takeback your permission, you must write the researcher and tell him or her of your decision. You should also send a copy of this written notification to your health care providers. In the letter, state that you changed your mind and do not want any more of your health information shared or collected.

Dr. Hollie Raynor, 1215 Cumberland Ave, 229 JHB, Knoxville TN, 37996; hraynor@utk.edu

Once you take away your permission, no new health information will be shared with us. However, health information that has already been collected or shared with us may still be used as necessary to maintain the integrity of the research and as required by law. Also, if you take away your permission, you may not be able to stay in the research study.

You do not have to allow use of your health information. If you do not allow use of your health information, it will not affect your relationship with the researchers, the University of Tennessee, your health care provider(s) or any of the services and benefits you and your family receive from them in any way.

You have the right to see and copy your health information that is shared or used in this study. However in order to complete the research, your access to this information may be restricted during the conduct of the study to maintain the integrity of the research. When the study is completed, you will be able to access to this information.

STATEMENT OF CONSENT

I have read this form and the research study has been explained to me. I have been given the chance to ask questions and my questions have been answered. If I have more questions, I have been told who to contact. By signing this document, I am agreeing to be in this study. I will receive a copy of this document after I sign it.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the study.

Name of Research Team Member	Signature of Research Team Member	Date