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.** If you decide to be in the study, we will ask you and your child to attend individual appointments at the Healthy Eating and Activity Laboratory at the University of Tennessee to collect information at 0, 6, 12, and 18 months. You and your child will also be asked to come to 29 program meetings over 18 months. 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 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).
- **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.

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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).

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

If you agree to be in this study, you and your child will attend two individual appointments at the Healthy Eating and Activity Laboratory at the University of Tennessee every 6 months for 18 months. These appointments will take 60 to 90 minutes each. Before these appointments, we will give you and your child an energy bar to eat. At the first appointment we will collect you and your child's height and weight. At each appointment, you and your child will also 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 appointment, you and your child will be given questionnaires to take home and complete. 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. You and your child will also be given devices to wear 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

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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, you will came back to the second appointment to bring back the devices that measured physical activity and the phone you may have used to take pictures. Your questionnaires that you completed at home will be reviewed.

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. These meetings will take place at the Healthy Eating and Activity Laboratory at the University of Tennessee. 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.

During the first two weeks of the program, you and your child will have one individual meeting 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.

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.

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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.

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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 $50, $60, and $75 gift card to Wal-Mart when the 6, 12, and 18-month assessments are fully completed, respectively. This will be provided in person if data are all collected at that time or by mail, after all measures have been collected – whichever occurs first. Compensation will only be given if all procedures have been completed. 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 transportation to and from the program meetings and assessments. Additionally, there may be 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.

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) 974-6259 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

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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

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