The Role of Parents in Adolescent Obesity Treatment: Randomized Control Trial of TEENS+

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CONSENT AND PARENT PERMISSION FORM

STUDY TITLE: The Role of Parents in Adolescent Obesity Treatment: Randomized Control Trial of TEENS+

VCU INVESTIGATOR: Melanie K. Bean, PhD, Associate Professor of Pediatrics and Psychology

SPONSOR: National Institutes of Health

ABOUT THIS CONSENT AND PARENT PERMISSION FORM

You and your child are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your child and your situation.**

This consent and parent permission form is meant to assist you in thinking about whether or not you and your child want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

The purpose of this research study is to evaluate the effect of two different approaches to parental involvement in a weight management program for adolescents with overweight and obesity. Specifically, this research is examining the impact of each approach on adolescent body weight and healthy behaviors in the adolescents. You are being asked to participate in this study because you have an adolescent child age 12-16 years that has a Body Mass Index (BMI) above the 85th percentile. The BMI used to determine your child's eligibility was calculated from your child's height and weight measurements. The percentile is determined by charting the BMI value against your child's age on a standardized growth chart.

If you and your adolescent decide to enroll in the study, you will be randomly assigned (like the flip of a coin) to either Parent Group A or Parent Group B. Parents in both groups will participate in 16 weekly sessions. In Group A, all of these sessions will be parent-only. Parents in Group B will participate in a series of 8 parent-only group education sessions, and 8 nutrition education sessions with their adolescent. All parent educations sessions will last 60 to 90 minutes and be held in the evenings. The topics covered in these sessions will be different based on whether you are assigned to participate in Group A or B.

Parents in Group A will be assigned a program of customized daily calorie and nutritional goals designed to produce weight loss for the parents. Parents in Group A will also receive

instruction on exercise and self-monitoring activities. Parents in Group A will have their weight measured every week. Parents in Group B will learn parenting strategies to support their child and to implement dietary and physical activity changes for the family. You will not know which group you will participate in until you and your child have decided to participate in the study and finished all baseline testing.

You will be in a group with up to 15 parents and their adolescents of the same gender as your child. Approximately 210 parent/child pairs (420 individuals) will participate in this study.

In this study, you will be asked to do the following things:

1. Provide demographic information about yourself and your child.
2. Provide information about your medical history, current health, eating habits, and exercise choices.
3. Have your health care provider complete a medical clearance form that states it is safe for you to participate in a weight management program that focuses on improving your eating choices and increasing your physical activity.
4. Have your child's health care provider complete a medical clearance form that states it is safe for your child to participate in a weight management program that focuses on improving your eating choices and increasing physical activity. As an alternative, you may bring your child to a medical assessment at the Pediatric Endocrinology Clinic at the Children's Hospital of Richmond at VCU the beginning of the study.
5. Participate in 16 weekly group education sessions with parents of other adolescents in the program, and sometimes with your teen and other adolescents.
6. Participate in an optional monthly group exercise session with other parents and teens in your group.
7. Encourage your child to participate in exercise sessions at least once a week for 4 months.
8. Encourage your child to participate in adolescent group sessions once a week for 4 months, and one individual session per month.
9. Participate in a cooking class taught by Mise en Place cooking school with other parents and teens in the study.
10. Have your height and weight measured at the beginning of the study, and again at 2 months, 4 months, 8 months and 12 months. If you are randomized to Group A, you will also have your weight measured before each of the 16 weekly educational sessions.
11. Take surveys and answer questions about your feelings, behaviors and relationships.
12. Have your physical activity measured by a small device worn on your wrist for 7 days (tested at entry and again at 4, 8 and 12 months).
13. Keep a diary about your food choices and exercise, or about the ways you supported your child's efforts to lose weight, depending on the group you are in.

Your child will be asked to:

- Be seen by doctors, diet specialists, exercise specialists and behavior specialists.
- Have his/her physical activity measured by a small device worn on the wrist for 7 days (tested at entry and again at 4 months, 8 months and 12 months).
- Answer some questions on paper forms and at individual meetings with a dietitian and behavior specialist that will help us to understand things like eating habits, exercise choices, what your child's life is like and how he/she feels about things.
- Participate in weekly meetings with the behavior specialists and the dietitian for 4 months. For the behavior meetings, your child will also be with other teens in the program at the same time. Separate meetings will be held for boys and girls. For the nutrition meetings, depending on which study group you are in, your child may be in a group with other teens, or in a group with other teens and parents at the same time. These meetings will occur once a week in the afternoons or evenings and last about 1 hour. During the meetings, staff will help your child learn about healthy eating and exercise, help set goals to improve his/her health and lose weight, and monitor progress in reaching these goals.
- Participate in 4 individual sessions with the behavior support specialist or dietitian (one per month).
- Learn and follow an exercise program that will be designed for him/her and exercise at least one time a week for about an hour for 4 months.
- Participate in an optional monthly group exercise session with other parents and teens in your group.
- Keep track of his/her eating and exercise choices each day using an online application. Your child will go over the information with the nutrition or behavior specialists.
- Participate in a cooking class with other teens and parents in the study.
- Measure his/her weight every week to monitor progress.

It will take approximately 2-4 weeks to complete the preliminary (baseline) measures for the study. The intervention portion of the study will last 16 weeks, and there will be 3 follow-up visits after the intervention is completed: one at the end of the intervention, one 4 months after completing the intervention and another 8 months after completing the intervention. Therefore, your participation in this study will last up to 13 months.

After the study ends, there is an option to participate in three additional follow-up assessments at 24 months, 36 months, and 48 months after you start the program.

You may be provided with information about your and your child's weight measurements during the study. Feedback will be provided at weekly meetings to help you and your child progress toward the goals that are established based on the group that you are randomized to.

If you and your child decide not to enter this study, your child can receive the usual care that he or she would receive even if not in the study. This includes online resources, books or videos, gyms or other public exercise programs, public weight-loss programs, or private weight loss

counselors or dietitians. The study staff will discuss these options with you. You and your child do not have to participate in this study to be treated for overweight.

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Most Common Risks and Discomforts	Benefits to You and Others
• Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You or your child may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue. Increased physical activity may worsen existing medical conditions. • Weight change may require adjustments to medications. • A focus on diet and weight could be upsetting for some people, and might result in increased depression, or resorting to unhealthy behaviors in attempts to succeed at weight loss. • Participation in research might involve some loss of privacy. There is a small risk that someone outside the study could see and misuse information about you or your child. • The study questionnaires ask personal questions that are sensitive in nature and may make you feel uncomfortable. • Some teens may be uncomfortable about the medical exam. • The activity monitor may be irritating to wear, or may cause embarrassment for some people. There may be safety concerns for some kinds of work or sports activities. • Health behavior change may generate increased conflict among family members.	There is some evidence that lifestyle intervention with exercise, nutrition education and behavioral support is effective in helping people lose weight. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you and your child. This study may help the investigators learn things that may help other people in the future. There is no guarantee that you or your child will receive any benefits from being in this study. However possible benefits include improved health and fitness. We hope the information learned from this study will provide more information about better ways to treat children and adolescents with overweight.

Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF MY CHILD AND I PARTICIPATE IN THE STUDY?

After signing up for the study, you and your child will be scheduled for intake assessment visits. If you are not able to attend the assessment visits at the Healthy Lifestyles Center, some visits may be conducted virtually, or at an alternative location. The assessments include:

- A 1-hour visit with the dietitian to review your and your adolescent's food diary and eating patterns. You and your adolescent will both have your height and weight measured by study staff. You and your adolescent will also be provided with an activity monitor to be worn on the wrist for 1 week. The activity monitor measures your level of physical activity but does not report your specific location. Study staff will collect the activity monitors from you and your child after the week period ends.
- A 20-minute visit with an exercise physiologist to complete a physical activity assessment.
- Completing online questionnaires about family demographics, eating and exercise habits, emotions, social support, parenting style, home environment, parent-child relationship, and current health practices.
- A 1-hour visit for a medical assessment, if you have opted to have your child's medical clearance done by a study medical provider. If your child is male, the detailed physical examination performed on your child will include a testicular exam for the presence of inguinal hernias. Prior to this visit, you will be asked to complete a questionnaire about your child's health including medical conditions, surgeries, current medications and recent or severe symptoms. You will complete a separate questionnaire about your own health history. The medical provider may ask additional questions to make sure that the information is complete. If the physician determines that your child has a health problem that needs attention by a specialist or your pediatrician, you will need to obtain the referral and have the condition evaluated. If necessary, you may need to provide written clearance from a specialist or pediatric health care provider that it is safe for your child to participate in this study. If the medical clearance cannot be completed before the rest of the program starts, you and your child may not be able to continue with the research program. In such cases, your family may be able participate in a future group if others are being offered.

Before you or your child can participate in the intervention, you must have a medical release form completed by a medical provider who is familiar with your health, medical conditions and treatment that states that he or she feels that it would be safe for you to potentially participate in either of the Parent groups. The medical release form describes how you may be asked to participate in a parent group that would encourage you to make changes to your own eating patterns to promote a healthy weight loss and increase your own physical activity levels through an exercise program. If your medical provider feels that it is not safe for you to participate in such a program, you and your child will not be able to participate in this study. As part of this process, you should specifically discuss if your health care provider has any concerns

about your risk for injury or any other complications with increasing your physical activity level and losing weight. You should also discuss if there are specific exercises and activities that you should avoid. Lastly, be sure to discuss how changes in your dietary habits, activity levels and weight may require changes to your medications or other medical treatments and arrange a plan for follow-up while you are in the study.

You will need to have your health care provider complete this form and make sure it is returned to the study coordinator during the time period that the other baseline assessments are being completed. You and your child will not be able to start the intervention until this form has been completed.

If you qualify for the study, you will be randomly assigned (like the flip of a coin) to be in/receive either Group A or Group B. You have an equal chance of being assigned to any one of the groups.

Once the intake assessments are completed and study staff have received your medical clearance form, the 4-month intervention will begin. All sessions will be led by trained behavior coaches. For parents in Group A, parents will attend weekly meetings with up to 15 other parents, while adolescents participate in their own sessions with up to 15 other teens. For Parents in Group B, nutrition and behavior support groups will be rotated each week. In this group, parents and teens will participate with other families in a total of 8 nutrition education group sessions, and on alternate weeks, parents and adolescents will participate in separate behavioral support group sessions. Nutrition education sessions will cover topics such as food groups, portion sizes and food labels, and behavioral support groups will cover topics such as making healthy choices, social situations, goal setting, role-modeling, barriers and solutions, dealing with setbacks, self-monitoring and willpower. Separate behavioral support sessions will be held for adolescents who are males and females. Each group nutrition and behavioral support sessions will be held in the early evening and last approximately 60 minutes. Weight measurements will be recorded for your child at each weekly group session.

Your child will also participate for 4 months in individual and group exercise sessions led by an exercise science professional offered each week. Each child is expected to exercise a minimum of one time each week. Each exercise session will last about 1 hour. After an appropriate warm-up, a typical exercise session will include 20-30 minutes of cardiovascular activity and 20-30 minutes of strength training. At the end of the exercise session, your child will engage in a brief cool-down.

During the 4 month period, your child will be asked to complete a log with their eating choices and calories and physical activities. These logs will be reviewed weekly with the study staff. Depending on which Parent Group you are assigned to participate in, you may also be asked to complete similar logs.

During the 4 month period, your child will participate in two individual visits with the study dietitian to discuss goals and answer your questions, and two individual visits with the behavior

coach to provide individual support. These visits will last about 30 minutes each and occur monthly.

After you and your child complete the first 2 months of the program, a brief assessment will be conducted, consisting of fasting height and weight measurements, and completion of a subset of the questionnaires completed at baseline. It will take approximately 30 minutes to complete the questionnaires, and 10 minutes for the height and weight measurements. Measurements may be taken in-person, or reported virtually.

After you and your child complete the first 4-months of the program, all of the assessments done at baseline (with the exception of the physical exam) will be repeated with the addition of an exit survey for you and your child to provide feedback about your experience, and you will continue to work on your diet and exercise goals on your own. At month 8 and month 12, you and your child will repeat these assessments again, with the exception of the exit survey. If you are not able to attend the 4-month, 8-month or 12-month assessment visits at the Healthy Lifestyles Center, we may work with you to find a mutually acceptable alternative for obtaining height and weight measurements. In this case, you and your child may or may not be provided with activity monitors.

The optional 24, 36 and 48 month assessments will include some of the measures that are done at month 8 and month 12.

The following table is a summary of what will happen at each visit during your study participation.

TEENS + STUDY VISIT SCHEDULE		
Pre-intervention Visits	**Visit 1: Orientation**	
	• Overview of study • Individual meeting for consent/assent • • Height and weight measurements •	•
	Visit 2: Medical Visit (if receiving clearance from study physician)	
	• Teen physical exam and physician review of parent and teen medical histories	
	Visit 3: Baseline Assessments	
	• Turn in parent and teen (if applicable) medical clearance form • Height and weight measurements • Wear accelerometers • Meet with staff to review 3-day food logs and sleep logs • Complete online surveys • Meet with staff to complete an activity recall	
Intervention Visits	**Visits 4-19: Weekly Visits for 16 Weeks**	
	• Weight measurements • For Group A, parents and teens meet separately, yet concurrently, each week in their own group. For Group B, parents and teens meet separately every 2 weeks, then together on alternate weeks for nutrition groups • Review of daily food and exercise journals • Teens exercise for 1 hour (teens may exercise more than once a week) • Attend 1 monthly individual session for a total of 2 nutrition and 2 behavior sessions.	
Assessment Visit	**Visit 20: 4 Month Assessments**	
	• Height and weight measurements • Wear accelerometers • Meet with staff to review 3-day food logs and sleep logs • Complete online surveys • Meet with staff to complete an activity recall	
Assessment Visit	**Visit 21: 8 Month Assessments**	
	• Height and weight measurements • Wear accelerometers • Meet with staff to review 3-day food logs and sleep logs • Complete online surveys • Meet with staff to complete an activity recall	
Assessment Visit	**Visit 22: 12 Month Assessments**	
	• Height and weight measurements • Wear accelerometers • Meet with staff to review 3-day food logs and sleep logs • Complete online surveys • Meet with staff to complete an activity recall	

	Visit 23: Optional Long-Term Assessments at Month 24

As se	• Height and weight measurements • Meet with study staff to review 3-day food logs and sleep logs • Complete online surveys • Wear accelerometers
Assessment Visit	**Visit 24: Optional Long-Term Assessments at Month 36**
	• Height and weight measurements • Meet with study staff to review 3-day food logs and sleep logs • Complete online surveys • Wear accelerometers
Assessment Visit	**Visit 25: Optional Long-Term Assessments at Month 48**
	• Height and weight measurements • Meet with study staff to review 3-day food logs and sleep logs • Complete online surveys • Wear accelerometers

WHAT ALTERNATIVES ARE AVAILABLE?

Lifestyle modification including exercise, nutrition and behavioral support are the cornerstone of treatment for overweight adolescents. You may choose as an alternative to obtain those services from other sources in your community. You can seek health information online, purchase books or videos, join gyms or other public exercise programs, enroll in a public weight-loss program, or see private weight loss counselors or dietitians. The study staff will discuss these options with you. You and your child do not have to participate in this study to be treated for overweight.

Although many of the surveys are provided in an online format, you and your child will also have the option to paper surveys if that is preferred. Ask the study staff if you or your child would like paper surveys.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no guarantee that you or your child will receive any benefits from being in this study. However possible benefits include weight loss and improved health and fitness. We hope the information learned from this study will provide more information about better ways to treat children and adolescents with overweight and obesity.

WHAT RISKS AND DISCOMFORTS COULD MY CHILD AND I EXPERIENCE FROM BEING IN THE STUDY?

Your or your child's condition may not get better or may become worse while you are in this study.

Possible Risks Associated with Exercise

Likely (More than a 50% chance that this will happen)

- Physical discomfort
- Fatigue

- Sore Muscles
- Increased heart rate

Occasional (Between a 1-10% chance that this will happen)

- Strained or pulled muscles
- Accidental injuries such as falling
- Nausea
- Shortness of breath
- Worsening of an existing medical condition

Rare (Less than a 1% chance that this will happen)

- Chest pain
- Shortness of breath

Possible Risks Associated with Weight Loss Intervention

Occasional (Between a 1-10% chance that this will happen)

- Embarrassment or emotional upset

Rare (Less than a 1% chance that this will happen)

- Development of unhealthy eating behavior
- Severe weight loss
- Physiological changes required changes in medication doses

Possible Risks Associated with Physical Exam for Adolescent

Occasional (Between a 1-10% chance that this will happen)

- Embarrassment or emotional upset

Non-Physical Risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you or your child. Because the activity monitors are worn on the wrist, they are visible if not covered by clothing, and may generate curiosity if seen in public. For some people, this can cause embarrassment or frustration. Some kinds of work or sports activities may not permit the monitors for safety reasons.

Questionnaires may contain questions that are sensitive in nature. You and your child may refuse to answer any question that makes you feel uncomfortable.

Your child may be embarrassed by the physical exam. Your child may refuse the physical exam, but will not be able to participate in the study without this clearance to participate in the exercise program.

You may not be randomized into the study arm that you would prefer to be in, and feel disappointed. You may learn things about yourself that you did not know before and that could affect how you think about yourself. It is possible that conflicts may arise in relationships due to efforts to make lifestyle changes.

WHAT ARE THE COSTS?
There are no costs associated with participating in this study other than the time you and your child will spend at appointments and filling out questionnaires. Any medical costs associated with obtaining medical clearance for safe participation in the Parent Groups will not be paid for by the study. If you bring your child to a specialist following the results of testing conducted for this study, those medical expenses will also not be paid for by the study. Those visits will be billed to your insurance company or handled the same way as your normal medical care.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?
Parents will receive a cash payment of $25.00 for completion of all of the 2-month assessment measures, $50.00 for completion of all of the 4-month assessment measures, $75.00 for completion of all of the 8-month assessment measures, and $100.00 for completion of all of the 12-month assessment measures. Payment for families that complete the optional long-term assessment measures is $125.00 for the 24-month, $150.00 for 36-month, and $200.00 for 48-month assessment measures. If the adolescent has reached age 18 at the time of the assessment, the payment will be divided to provide half of the total amount to the parent and half to the child. For partial completion of measures at any timepoint, payment will be ½ of the amount specified at each timepoint; however, no payment will be made if fasting height and weight measurements are not obtained. Additionally, you will be reimbursed for all travel for this study at the federal mileage rate.

Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

While you are enrolled in the program, you and your child participating in the study will receive a free membership with a local YMCA. A full year YMCA membership is valued at $900.00. The YMCA has the discretion to end a membership at any time. You and your teen will also attend a cooking class valued at $50.00, and will periodically receive group incentives valued up to $30.00, and opportunities to win raffle prizes valued up to $15.00.

If you and/or your child do not have access to a device (e.g., tablet, laptop or similar) or internet, then the study staff may provide you with a device, mobile hotspot and/or monthly data package for the 4-month intervention.

Please be aware that the investigative team and the University may receive money for the conduct of this study.

WHAT HAPPENS IF I OR MY CHILD IS INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?
If you or your child are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth

University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN MY CHILD AND I STOP BEING IN THE STUDY?
You and your child can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study before the final regularly scheduled visit, you may be asked by the study doctor to make a visit for some final end of study procedures.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the study staff thinks it is necessary for your or your child's physical or mental health and safety;
- you or your child have not followed study instructions;
- you or your child miss appointments without calling to cancel or reschedule.
- you or your child, if female, becomes pregnant during the intervention portion of the study;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

HOW WILL INFORMATION ABOUT ME AND MY CHILD BE PROTECTED?
VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

Parent and adolescent educational sessions and individual sessions will be digitally recorded for sound only so that study staff can monitor what topic and approaches the groups facilitators and behavior coaches are using. These recordings will be kept on a secure server and will be destroyed within 5 years after the study results are published. Group participants, facilitators and behavior coaches will be requested to only use first names of subjects during group and individual sessions to further protect confidentiality.

If you and your child choose to participate in the scholarship with local YMCA, general information regarding your child's fitness level and TEENS exercise plan will be provided to you to bring to the YMCA to promote safe physical activity. The YMCA will provide us only with the dates that you and your child have scanned in your TEENS membership card.

When you or your child are in a group with other TEENS study participants, they will hear what you say, and may or may not tell someone else. Only first names will be use in group sessions to protect privacy.

We will not tell anyone the answers your child gives us. But, if your child tells us that someone is hurting her or him, or that she might hurt herself or someone else, the law says that we must let people in authority know so they can protect your child. If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

Project findings and reports prepared for dissemination will not contain information which can reasonably be expected to be identifiable.

A description of this clinical trial will be 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 Website will include a summary of the results. You can search this Web site at any time.
In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: child abuse or neglect, a specific and immediate threat to cause serious bodily injury or death to oneself or another person, or including research data in the medical record.

OPTION FOR CONTACT TO COMPLETE LONG-TERM ASSESSMENTS

After you complete the 1-year study, we would like to contact you to see if you would be interested in completing the 24, 36 and 48-month long-term assessments. Please indicate below if you are willing to be contacted about these assessments.

_____Yes
_____No

OPTIONAL CONTACT FOR FUTURE RESEARCH STUDIES

We would like to contact you in the future to see if you would be interested in participating in another research study. Please indicate below if you are willing to be contacted about any future research studies.

_____Yes
_____No

OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES

After you and your child have enrolled in the study, you may be asked for consent and permission to store your data and your child's data in a research registry (Children's Hospital of Richmond Healthy Lifestyle Registry) that has been established by Dr. Wickham to use for future investigations into the causes, effects, and treatments for obesity and other weight-related health conditions. If you are interested in donating data to the registry, you and your child will be provided with separate consent and assent forms specific to the registry. If you are not interested in information about the registry, or decide that you do not want to donate data to the registry, this will not have any impact on your or your child's ability to participate in this study, and will not impact your future health care at VCU.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research, contact:

Melanie K Bean, PhD
Study Principal Investigator

VCU Department of Pediatrics
Box 980140
Richmond, VA 23298-0140
(804) 527-4756

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT AND PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent and permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent and permission form, I have not waived any of the legal rights or benefits to which I and/or my child otherwise would be entitled. My signature indicates that I freely consent to participate and/or give permission for my child to participate in this research study. I will receive a copy of the consent and permission form for my records.

_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants - Parent/Guardian Permission	
_____ Name of Child/Youth Participant	
_____ Name of First Parent/Legal Guardian (Printed)	
_____ **Required** First Parent/Legal Guardian Signature	_____ Date
_____ **Optional** Second Parent /Legal Guardian's Signature	_____ Date