

Innovative Approaches to Adolescent Obesity Treatment:  
Exploring the Role of Parents

NCT02586090

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## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE:** Innovative Approaches to Adolescent Obesity Treatment: Exploring the Role of Parents

**VCU IRB NO.:** HM20005235

**SPONSOR:** National Institutes of Health

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

### PURPOSE OF THE STUDY

The purpose of this research study is to evaluate the effect of two different approaches to parental involvement in a weight management program for overweight adolescents on 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 85<sup>th</sup> 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.

### DESCRIPTION OF THE STUDY AND YOUR [YOUR CHILD'S] INVOLVEMENT

If you decide that you and your child would like to participate in this research study, you will be invited to an informed consent and orientation meeting. This meeting will include a group of other parents and their adolescents who are also interested in the study. At the meeting, study staff will describe the research study to the group and answer any questions. After hearing about the study and having all of your questions answered, you will be asked to sign this consent form and your child will be asked to sign an assent form.

In this study you will be asked to:

1. Provide information about your feelings, behaviors and relationships.
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 height and weight measured.
5. Bring your child to a medical assessment.
6. Participate in weekly group education sessions with parents of other adolescents in the program.
7. Attend an exercise orientation session at the YMCA with other parents and teens in the study.

8. Attend a cooking class with other parents and teens in the study.
9. Have your physical activity measured by a small device worn on your wrist for approximately 4-7 days (tested at entry and again at 4 months and 7 months). Bring your child for adolescent group sessions once a week for 4 months.
10. Bring your child to exercise sessions once a week for 4 months. This can be on the same day as your parent meeting.
11. Provide support and encouragement for your child participating in the program.

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 approximately 4-7 days (tested at entry and again at 4 months and 7 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.
- Come to 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.
- Attend an exercise orientation session at the YMCA with other teens and parents in the study. Learn and follow an exercise program that will be designed for him/her and exercise at the program's gym at least one time a week for about an hour for 4 months.
- Keep track of his/her eating and exercise choices each day by writing in a log book. Your child will need to bring your log book to the weekly meetings and go over the information with the nutrition or behavior specialists.
- Attend a cooking class with other teens and parents in the study.
- Have his/her weight measured every week to monitor progress.

If you and your adolescent decide to enroll in the study, you will be assigned to either Parent Group A or Parent Group B. Parents in Group A will participate in 16 weekly sessions. Fourteen of these sessions will be parent-only, and two will be together with the adolescents. Parents in Group B will participate in a series of 8 parent-only group education sessions (one session every two weeks), and eight nutrition sessions on alternate weeks together with their adolescents. All parent education 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. Parent and adolescent educational sessions will be digitally recorded for sound only so that study staff can monitor what topic and approaches the groups facilitators 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 and facilitators will be requested to only use first names of subjects during group sessions to further protect confidentiality.

## **STUDY PROCEDURES**

After signing up for the study, you and your child will be provided with a packet of study assessment forms and information and receive instructions for how to complete the forms. You will then be scheduled for intake assessments visits. The assessments include:

- A 1-hour evening 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. At this visit, 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 1-hour evening visit with the behavior specialist to assess the adolescent's emotional status and social support. This may be scheduled on the same day as the dietitian visit. You and your child will both be asked to complete a series of questionnaires before this meeting and bring the completed papers to this visit. It will take about 30 minutes for you and your child to answer these questions.  
A 20-minute visit with an exercise physiologist to complete a physical activity assessment.
- A 1-hour visit for additional measurements and a medical assessment for your adolescent. 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. You should bring the completed forms to your medical visit so that they can be reviewed by one of the medical providers at the visit. The medical provider may ask additional questions to make sure that the information is complete.

- Your child will be examined by a study physician or other 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. 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 to 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 like 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 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.

Once the intake assessments are completed and study staff have received your medical clearance form, the 4-month intervention will begin. For parents in Group A, parents will attend weekly meetings with other parents, while adolescents participate in their own sessions. Parent and teens will have 2 combined meetings. 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 with the program's registered dietician, and on alternate weeks, parents and adolescents will participate in separate behavioral support group sessions lead by a behavioral support specialist (a psychologist or psychology doctoral student). 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. Height and weight measurements will be taken for your child at each weekly group session.

Your child will also participate for 4 months in an after school group exercise session led by an exercise science professional offered each day Monday through Thursday from 5:00 – 8:00 p.m., and Saturday from 9:00 – 11:00 a.m. at the Children’s Hospital of Richmond (CHoR) at VCU’s Healthy Lifestyle Center Gym. Each child is expected to exercise at the Healthy Lifestyles Center gym 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 (treadmill, stationary bike, aerobic games, or group exercise sessions) and 20-30 minutes of strength training (Nautilus resistance training machines, and free weight). Each adolescent’s heart rate will be periodically measured during exercise session to ensure appropriate intensity for health benefits. 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. Your child will be asked to bring these logs to each of the meetings so that they can be reviewed with the study staff. Depending on which Parent Group you are assigned to participate in, you may also be asked to complete similar logs. Log books will be provided by study staff.

During the 4 month period, you and your child will attend two individual visits with the study dietitian to discuss goals and answer your questions. These visits will last about 30 minutes each. One nutrition visit will occur in the second month of the program and the second one will occur in the third month. Your adolescent will also be scheduled to attend two individual visits with a behavioral specialist in the first and fourth months. These sessions will also be about 30 minutes in length. You may be asked to attend and participate in the individual behavioral support for your child if the behavioral support staff feel that it would be helpful for your child.

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.

After you and your child complete the first 4-months of the program, all of the assessments done at baseline will be repeated, and you will continue to work on your diet and exercise goals on your own. At month 7, you and your child will return to the Healthy Lifestyles Center to repeat these assessments again. If you are not able to attend the 4-month and 7-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 physical exam will not be repeated at 7 months.

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

TEENS + STUDY VISIT SCHEDULE		
Pre-intervention Visits	<b>Visit 1: Orientation Night</b>	
	<u>Activities at the Healthy Lifestyles Center</u> <ul style="list-style-type: none"> <li>Group overview of study</li> <li>Individual meeting for consent/assent</li> <li>Receive 3-day food log and instructions</li> <li>Height and weight measurements</li> <li>Complete brief survey measures</li> </ul>	<u>Items to Complete at home</u> <ul style="list-style-type: none"> <li>Online surveys</li> <li>Paper medical history form (teen and parent)</li> <li>Parent and teen 3-day food logs</li> <li>Parent medical clearance form</li> </ul>
	<b>Visit 2: Medical Visit</b>	
	<ul style="list-style-type: none"> <li>Teen physical exam and physician review of parent and teen medical histories</li> </ul>	
Intervention Visits	<b>Visit 3: Baseline Visit</b>	
	<ul style="list-style-type: none"> <li>Turn in parent medical clearance form</li> <li>Height and weight measurements</li> <li>Receive accelerometers</li> <li>Meet with dietitian to review 3-day food logs</li> <li>Meet with behavior specialist to review surveys</li> <li>Meet with the exercise staff to complete an activity recall</li> </ul>	
Intervention Visits	<b>Visits 4-19: Weekly Visits for 16 Weeks</b>	
	<ul style="list-style-type: none"> <li>Height and weight measurements</li> <li>For Group A, parents and teens meet separately, yet concurrently, each week in their own group; with the exception of 2 nutrition groups when parents and teens will meet together. For Group B, parents and teens meet separately every 2 weeks, then together on alternate weeks for nutrition groups</li> <li>Review of daily food and exercise journals</li> <li>Teens exercise for 1 hour (teens may exercise at the HLC gym more than once a week)</li> <li>Attend 1 monthly individual session for a total of 2 nutrition and 2 behavior sessions.</li> </ul>	
Mid-Intervention	<b>Visit 8: Month 2 Assessments</b>	
	<u>Items to complete at home prior to assessment visit:</u> <ul style="list-style-type: none"> <li>Online surveys</li> </ul>	<u>Activities at the Healthy Lifestyles Center</u> <ul style="list-style-type: none"> <li>Height and Weight Measurements</li> <li>Meet with behavior specialist to review surveys</li> </ul>
Post-Intervention Visits	<b>Visit 20: Month 4 Assessments</b>	
	<u>Items to complete at home prior to assessment visit:</u> <ul style="list-style-type: none"> <li>Online surveys</li> <li>Parent and teen 3-day food logs</li> </ul>	<u>Activities at the Healthy Lifestyles Center</u> <ul style="list-style-type: none"> <li>Height and Weight Measurements</li> <li>Receive accelerometers</li> <li>Meet with exercise staff to complete activity recall</li> <li>Meet with dietitian to review 3-day food logs</li> <li>Meet with behavior specialist to review surveys</li> </ul>
	<b>Visit 21: Complete Month 4 Assessment</b>	
	<ul style="list-style-type: none"> <li>Return accelerometers and receive 4-month visit payment</li> </ul>	

	<b>Visit 22: Month 7 Assessments</b>
	<ul style="list-style-type: none"> <li>• Height and weight measurements</li> <li>• Receive accelerometers</li> <li>• Meet with exercise staff to complete activity recall</li> <li>• Meet with dietitian to review 3-day food logs</li> <li>• Meet with behavior specialist to review surveys</li> </ul>
	<b>Visit 23: Complete Study</b>
	<ul style="list-style-type: none"> <li>• Return accelerometers and receive final study payment</li> </ul>

If one of the TEENS+ behavior specialists is concerned that behavioral or emotional difficulties may be negatively impacting your child's well-being, additional psychological evaluation by a mental health provider outside of the TEENS program may be required. In these cases, recommendations for treatment and further participation in the TEENS program will be determined on an individual basis with guidance from the mental health provider.

If you discontinue your participation in the study prior to the completion of the study, a study staff member may contact you to obtain information about the reason for your absence or withdrawal to help us identify areas for program improvement.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

## **RISKS AND DISCOMFORTS**

There is little risk to you or your child with participation in this study. On occasion, some people may experience light-headedness (dizziness), shortness of breath, racing heartbeat or nausea while exercising, which typically lasts for only a short time. Additionally, when beginning a new exercise program or increasing the intensity of exercise, most people experience muscle soreness or stiffness that will improve after a few days. Rarely, these symptoms may continue or become severe, requiring further medical attention.

As with any exercise program, there is a potential risk for injury if your child falls or does not perform the exercise correctly. A professional will always be present during the exercise sessions at the Healthy Lifestyles Center to ensure that your child is performing the exercises safely. These professionals are trained in exercise physiology and have training in CPR and first aid. If your child receives any injury or experiences unusual responses to exercise that affects his or her ability to exercise, clearance from a specialist or pediatrician will be required prior to resuming the exercise program.

Some participants with asthma may experience wheezing or shortness of breath during or after an exercise session. All teens with a history of asthma are cautioned to bring the appropriate rescue medications to all exercise sessions. Any adolescent whose asthma symptoms are worse with repeated activity should contact their pediatric health care provider for further evaluation.



Depending on which Parent Group you are assigned to participate in, you may also be encouraged to increase your own physical activity through an exercise program. Unlike your child's exercise program which will include participation in supervised sessions at the Healthy Lifestyle Center's gym, you will be expected to complete these activities at home or at another location you chose such as a local gym. While you are enrolled in the program, you and your child participating in the study will receive a free membership with a local YMCA, and will attend one group orientation and exercise session at the YMCA. Increasing physical activity may be associated with potential risks of injury of other serious medical conditions based on your age, gender, and overall health. You should discuss if there are any specific risks with such a program with your health care provider before starting this research study.

Another possible risk for you and your child would be severe weight loss. Parents should notify study investigators or staff if they are concerned that they or their child are losing weight rapidly, if they notice changes in their child's behavior or if their child develops strange eating patterns.

There is no guarantee that you or your child will lose weight from being in this study. You may lose weight, stay the same, or gain more weight while you are in this study.

Sometimes talking about issues related to emotions or weight may cause you or your child to become upset. You and your child do not have to talk about any topics or answer any questions that he or she does not want to talk about. If the behavior specialist feels that your child is deeply disturbed by an emotional issue, or is dealing with issues in an unhealthy manner, you will be given names of counselors that you may contact to get your child help in dealing with these issues.

If you (or your daughter) are pregnant or become pregnant, there is no foreseeable risk to you or the fetus by being in this study. However, pregnant women or teens are not allowed to continue to participate in the study as a result of the impact of pregnancy on body weight.

## **USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION**

### **Authority to Request Protected Health Information**

The following people and/or groups may request my Protected Health Information:

- Principal Investigator and Research Staff
- Study Sponsor
- Research Collaborators
- Institutional Review Boards
- Data Safety Monitoring Boards
- Government/Health Agencies
- Others as Required by Law

### **Authority to Release Protected Health Information**

The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:

- Health Care Providers at the VCUHS
- Principal Investigator and Research Staff

- Study Sponsor
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Research Collaborators
- Institutional Review Boards
- Government/Health Agencies

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

### Type of Information that may be Released

The following types of information may be used for the conduct of this research:

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Complete health record   | <input type="checkbox"/> Diagnosis & treatment codes                     | <input type="checkbox"/> Discharge summary    |
| <input checked="" type="checkbox"/> History and physical exam   | <input checked="" type="checkbox"/> Consultation reports                 | <input type="checkbox"/> Progress notes       |
| <input type="checkbox"/> Laboratory test results  | <input type="checkbox"/> X-ray reports                                   | <input type="checkbox"/> X-ray films / images |
| <input type="checkbox"/> Photographs, videotapes  | <input type="checkbox"/> Complete billing record                         | <input type="checkbox"/> Itemized bill        |
| <input type="checkbox"/> Information about drug or alcohol abuse  | <input type="checkbox"/> Information about Hepatitis B or C tests        |   |
| <input checked="" type="checkbox"/> Information about psychiatric care  | <input type="checkbox"/> Information about sexually transmitted diseases |   |
| <input checked="" type="checkbox"/> Other (specify): Clearance for safe participation in a weight loss program to include exercise and caloric restriction. |  |   |

### Expiration of This Authorization

- ☒ This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.
- ☐ This research study involves the use of a Data or Tissue Repository (bank) and will never expire.
- ☐ Other (specify):

### Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your or your child's protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you and your child for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

### BENEFITS TO YOU AND OTHERS

There is no guarantee that you or your child will receive any medical benefits from being in this study. However, the information from this research study may lead to a better treatment in the future for overweight children and adolescents that could reduce health problems. It may also help us design prevention efforts specifically targeted to children and adolescents.

Your child may benefit from the physical exams and other study procedures that will include diet and exercise education. You and your child may also benefit from improved health and fitness as a result of following the diet and exercise recommendations.

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

### **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.

### **PAYMENT FOR PARTICIPATION**

While you are enrolled in the program, you and your child participating in the study will receive a free membership with a local YMCA. The YMCA has the discretion to end a membership at any time. Parents will receive a cash payment of up to \$20.00 for the 2-month assessment, up to \$40.00 upon completion of the 4-month assessments, and an additional payment of up to \$50.00 upon completion of the 7-month assessments. The payment is for the parent to use at his or her discretion. There will be no payment for parents who participated in the study but did not complete the assessments.

You may be asked to provide your social security number in order to receive payment for your participation. 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. Your social security number is required by federal law. It will not be included in any information collected about you for this research. Your social security number will be kept confidential and will only be used in order to process payment.

### **ALTERNATIVES**

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.

### **CONFIDENTIALITY**

Potentially identifiable information about you and your family members will consist of, demographic information, questionnaire responses, nutrition profiles, interview notes, medical history and examination notes, body measurements, accelerometer readings and audiotapes of group sessions. Data is being collected only for research purposes.

Confidentiality of personal information about you and your child– including medical records and personal research data gathered in connection with this study will be maintained in a manner consistent with federal and state laws and regulations. You and your child’s data will be stored separately from medical records in a locked research area. All personal identifying information will be kept in password protected files and names will be removed from the data file one year after completion of the study. Data queries will have names removed. Digital audiotapes of group sessions will be stored on a secure server behind a firewall. Sessions will not be transcribed. Only first names will be used during the group sessions to protect privacy. Paper records of lab results, questionnaires, interview and visit notes will be kept in a locked file cabinet indefinitely. Access to all data will be limited to study personnel. Data files might be periodically reviewed by research subject advocates at VCU’s Clinical Research Center to ensure that all safety measures are being followed.

We will not tell anyone the answers you and your child give us; however, information from the study and information from your medical assessment and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Federal Food and Drug Administration, or the Department of Health and Human Services or other regulatory bodies. 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 sent to the YMCA to promote safe physical activity. 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.

What we find from this study may be presented at meetings or published in papers, but your or your child’s name will not ever be used in these presentations or papers.

If a study faculty or staff member becomes aware of ongoing abuse involving the participant or another child, state law requires that this information must be reported to Child Protective Services. Additionally, if a specific and immediate threat to cause serious bodily injury or death to oneself or another person is communicated during the interview or intervention, state law requires that appropriate steps must be taken to protect the potential victim, which includes reporting the threat to appropriate authorities. Lastly, should your personal information be subpoenaed by a court of law, program faculty or staff are required to comply and produce the requested information.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> 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.

#### **IF AN INJURY OR ILLNESS HAPPENS**

If you or your child is injured by, or becomes 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.

### **VOLUNTARY PARTICIPATION AND WITHDRAWAL**

You and your child do not have to participate in this study. If you do participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study. Your decision will not change your future medical care at this site or institution.

Your participation in this study may be stopped at any time by the study staff 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 time of participating in the study.
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

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.

### **QUESTIONS**

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**  
**P.O. Box 980140**  
**Richmond, VA 23298-0140**  
**(804) 527-4756**

**Edmond Wickham, M.D., M.P.H.**  
**Study Medically Responsible Investigator**  
**VCU Departments of Internal Medicine and Pediatrics**

**P.O. Box 980111**  
**Richmond, VA 23298-0111**  
**Telephone: (804) 827-0453**

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

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

Office of Research and Innovation  
Virginia Commonwealth University  
800 East Leigh Street, Suite 3000  
P.O. 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 with someone else. General information about participation in research studies can also be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

### CONSENT

I and my child have been given the chance to read this consent form carefully. I understand the information about this study. Questions that I asked about the study have been answered. My signature says that I am willing to participate, and am willing for my child to participate in this study. I will receive a copy of the consent form once I have signed it.

\_\_\_\_\_  
Child Name Printed

\_\_\_\_\_  
Name of Parent or Legal Guardian (printed)

\_\_\_\_\_  
Relationship to Child

\_\_\_\_\_  
Parent or Legal Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Second Parent or Legal Guardian (printed)

\_\_\_\_\_  
Relationship to Child

\_\_\_\_\_  
Second Parent or Legal Guardian Signature

\_\_\_\_\_  
Date

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Name of Person Conducting Informed Consent  
Discussion/Witness  
(Printed)

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Date

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Signature of Person Conducting Informed Consent  
Discussion/Witness

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Date

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Principal Investigator Signature (if different from above)

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Date