Title: The Role of High Intensity Interval Training in the Treatment of Adolescent Obesity

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RESEARCH SUBJECT INFORMATION CONSENT and PARENT PERMISSION FORM

TITLE: The Role of High Intensity Interval Training in the Treatment of Adolescent Obesity

VCU IRB NO.: HM20010365

INVESTIGATOR: Edmond P. Wickham, MD, MPH

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.

In this consent form, "you" always refers to the research participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

PURPOSE OF THE STUDY

The purpose of this research study is to evaluate the effects of two different exercise training methods, high-intensity interval training (HIIT) and moderate-intensity continuous training (CMIT) on adolescents who are trying to lose weight by participating in a behavioral weight management program. 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 95th 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 to be in this study, you will be asked to sign this consent and permission form, and your child will be asked to sign an assent form after you have had all your questions answered and understand what will happen to you and your child. If another parent would like to participate, he/she must sign a separate consent form.

Your participation in this study will last up to 4 months. Approximately 56 adolescents and their parent will participate in this study.

You will be randomly assigned (like the flip of a coin) to receive either a high-intensity exercise program (HIIT) or a continuous moderate-intensity exercise program (CMIT). You have an equal chance of being assigned to either group.

In this study, you will be asked to:

1. Provide information about your education, household income and insurance status.
2. Provide information about the availability of exercise equipment at your home.
3. Have your height and weight measured.
4. Bring your child to a medical assessment.
5. Bring your child for and for laboratory testing.
6. Have your physical activity measured by a small device worn on your wrist for approximately 7 days (tested at entry and again at 12 weeks and 16 weeks) and record sleep time and wake-up time for each day the device is worn.
7. Bring your child to exercise sessions three times a week and behavioral weight-management sessions one time a week for 12 weeks.
8. Attend one introductory session for parents at the beginning of the program and participate in at least a portion of each of the weekly behavioral weight management sessions with your adolescent. Specifically, you will be asked to attend the entire visit for three nutrition-focused sessions and the wrap-up segment of the nine other sessions.
9. Provide support and encouragement for your child participating in the program.
10. Complete an Exit Survey at the end of the intervention to provide feedback about the study.

Your child will be asked to:

- Be seen by doctors, diet specialists, exercise specialists and behavior specialists.
- Have a physical exam including assessment of pubertal development performed by a study medical provider.
- Have height, weight body circumference and body fat measured.
- Have two types of body composition tests taken.
- Provide blood samples for lab tests after fasting for 12 hours.
- Have a sugar metabolism test called an oral glucose tolerance test that requires collection of a blood sample every 30 minutes for 2 hours after drinking a sweet drink.
- If your child is a female, she will also have a pregnancy test performed using a urine sample.
- Have an electrocardiogram (ECG).
- 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 12 weeks and 16 weeks), and record sleep time and wake-up time for each day that the device is worn.
- Have a maximal graded fitness test performed on a treadmill.
- 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 the Healthy Lifestyles Center gym to exercise three times a week for 12 weeks.
- Come to weekly meetings with the behavior specialists and the dietitian for 12 weeks. These meetings will 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.
- Keep track of his/her eating and exercise choices each day by writing in a log book.
- Complete an Exit Survey at the end of the 12 weeks to provide feedback on how he/she felt about the study.

If you and your adolescent decide to enroll in the study, your child will be randomly assigned to either the HIIT treatment or the CMIT treatment. All of the exercise sessions will consist of walking, jogging, or running on a treadmill. Adolescents in the HIIT treatment will participate in treadmill exercise in 1-minute intervals of challenging intensities with recovery periods in between, gradually increasing the number of intervals over the course of the study. Adolescents in the CMIT treatment will participate in a constant moderate intensity treadmill exercise, gradually increasing the duration of the exercise over the course of the study. You will not know which group your child will participate in until you and your child have decided to participate in the study and finished all baseline testing.

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 and samples 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 and samples 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 or samples 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.

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 and your adolescent will also be provided with an activity monitor to be worn on the wrist for 1 week, and a sleep tracker to record your sleep hours during that 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. You will then be scheduled for several intake assessments visits. The assessments include:

- A 1-hour evening visit with the dietitian to review your adolescent's food diary and eating patterns. Before attending this visit, you will be asked to assist your adolescent in keeping a record of any food and beverages that he/she consumes for a period of three days. You will be given a log sheet to assist in recording your adolescent's dietary intake.
- 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 1-hour visit with an exercise physiologist to complete the adolescent's maximum graded exercise test and physical activity assessments. The exercise test involves having your child walk briskly and/or run on a treadmill while breathing into a plastic tube. At several time points, the required effort will be increased, so that the heart will beat faster. The approximate time of the exercise test is 12 minutes, with a cool down period for your child's heart rate to recover. Your child may be very tired at the end of this test. If your child becomes distressed in any way or develops any abnormal responses, the test will be stopped. If your child is unable to work at an effort that suggests that he or she achieved a near maximal effort during the fitness testing based on heart, your child will be asked to repeat the test. If your child is still unable to reach maximal effort for the initial test, participation in the study will not be continued.
- A 1-hour visit for a review of your adolescent's medical history, and a physical examination 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, family history of medical conditions and recent or severe symptoms. 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. The detailed physical examination performed on your child will include a non-invasive assessment of how far your child has progressed through puberty since these changes can impact some of the test results obtained as part of the study. 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.

- A 2-hour morning visit for additional measurements and fasting blood samples for your adolescent. At this visit, your child will have his or her blood pressure, heart rate, body composition and waist and hip circumference measurements taken. Your child's body composition will be determined using a bioimpedance measurement. For this measurement, adhesive pads will be placed on your child to measure the resistance of the body to an electrical current too small to be felt. Your child will also have another type of body composition measurement using a dual energy x-ray absorptiometery (DXA) to measure fat mass, fat-free mass, bone mineral density and percent body fat. The dosage of radiation from the DXA test is small (less than 1/30th of a standard x-ray). The bioimpedance and DXA measurements will be taken at baseline and 12 weeks. Your height and weight will also be measured at this visit.

- Blood samples will be obtained for lab tests for your child. The samples will be collected after your child has been fasting for 12 hours. Part of the blood sample will be tested for fasting glucose and insulin, and blood lipids. After the fasting samples are collected, your child will complete an oral glucose tolerance test to measure how his/her body responds to sugar. This test also screens for diabetes or pre-diabetes. For this test, your child will drink a very sweet solution and blood samples will be taken at 30 minute intervals during 2 hours after drinking the solution. To allow for blood sample collection without inserting a new needle each time a sample is collected, a plastic intravenous (IV) catheter will be inserted in a vein in one of your child's arms so that several blood samples can be drawn over the 2-hour period. The blood work and oral glucose tolerance test will be repeated at 12 weeks. Approximately 5 teaspoons (25 cc) of blood will be collected from a vein in the arm with a sterile needle at each of 2 visits for a total of 10 teaspoons (50 cc) for both visits. If you provide separate permission for your child to participate in the Healthy Lifestyles Registry, an additional teaspoon (5cc) of blood will be collected at each of the 2 lab visits (for a total of 12 teaspoons or60 cc for the entire study) and stored for later testing of different proteins and hormones including those that can be altered by food choices or that may influence body weight, metabolism, and sensations of hunger and fullness.

- Your child will also be given an electrocardiography (ECG) test at the first visit to the lab. This test is designed to evaluate the presence or absence of significant heart problems and/or measure the physical fitness of your child for the exercise program. For this test, adhesive electrocardiogram (ECG) electrodes (sticky pads connected to a machine by wires) will be placed on your child's chest so that we can monitor the heart. During the performance of the ECG test, the electrocardiogram will be monitored. If any physician involved in this study has

concerns about your child's heart or other suspected health problems based on the results of the ECG test, lab work, or medical exam, you will be instructed to contact your child's pediatrician to obtain a referral as needed for further evaluation.

Once the intake assessments are completed, you will attend a 60- minute introductory session with a behavior coach; then the 3-month intervention with your adolescent will begin. Adolescents will exercise at the study gym 3 evenings a week for 12 weeks. On one of those evenings he/she will also attend a 60-minute behavioral weight management session; 9 with a behavior coach, and 3 with a dietitian. Your child's weight will be measured at each of the weekly sessions. You will join your teen for the 3 sessions with the dietitian. After each of the individual sessions your teen attends with the behavior coach, you will be asked to join the session to review your adolescent's individual goals, and identify some parent support goals. Dietary sessions will provide customized calorie and nutritional goals designed to produce weight loss. Behavior sessions will help adolescents with strategies to succeed with diet and exercise changes, and will help parents with strategies to support their child's efforts. Parent and adolescent educational sessions will be digitally recorded for sound only so that study staff can monitor what topic and approaches the 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.

Your child will also participate for 12 weeks in an after-school exercise session led by an exercise science professional offered each day Monday through Thursday from 4:00 – 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 three times each week. During the exercise session, your adolescent will wear a heart rate monitor to ensure the appropriate intensity for health benefits. After your child has participated in the exercise program for 6 weeks, another graded exercise test will be done.

Adolescents in the HIIT treatment will begin with a 5-minute warm-up on a treadmill. Then activity will be increased to begin the alternating 1 minute segments of high and low (recovery) intensity. For the first 2 weeks, 4 intervals of alternating intensities will be performed. For each subsequent 2-week period, one interval will be added, reaching a total of 10 intervals (20 minutes) during weeks 11 and 12. At the end of the exercise session, there will be a 5-minute cool-down. The total time for exercise will range from approximately 20 minutes in the initial phase of participation, to 30 minutes at weeks 11 and 12.

Adolescents in the CMIT treatment will also begin with a 5 minute warm-up, and then progress to the treadmill speed and grade to reach the target heart rate. For the first two weeks, activity at the target heart rate will be sustained for 15 minutes. For each subsequent 2-week period, 4 minutes will be added to the exercise session reaching a

total of 40 minutes at weeks 11 and 12. At the end of the exercise session, there will be a 5 minute cool-down. The total time for exercise will range from approximately 25 minutes in the initial phase of participation, to 50 minutes at weeks 11 and 12.

During the exercise sessions, staff will periodically ask your child to rate how hard he/she feels like she is working and feeling using simple numeric scales. After 5 of the exercise sessions, you and your child will be asked to remain at the Healthy Lifestyles Center for 20 minutes after completing the activity. After that time, the staff will ask your child to answer a few brief questions about his/her enjoyment of the exercise activity and his/her confidence in being able to continue to participate in the type of exercise training to which they are assigned. One extended exercise sessions will occur during weeks 1, 2, 4, 8 and 12 of the program.

During the 12-week period, your child will be asked to complete a log with his or her eating choices and calories and physical activities. You may need to assist your child in completing these logs. You will also be asked to track specific ways that you helped your child achieve his or her goals. You and your child will be asked to bring these logs to each of the meetings so that they can be reviewed with the study staff. Log books will be provided by study staff.

After your child completes the first 12 weeks of the program, all the assessments done at baseline will be repeated, and he/she will continue to work on his/her diet and exercise goals on his/her own. At 16 weeks, you and your child will return to the Healthy Lifestyles Center to repeat height and weight measurements. Your adolescent's body composition will be repeated using bioimpedance. You and your adolescent will complete surveys and meet with the dietitian to review a 3-day food log of your child's intake. You and your adolescent will also wear the physical activity monitors for a week. The physical exam will not be repeated at 12 or 16 weeks.

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

<table>
<tr><th></th><th colspan="2">STUDY VISIT SCHEDULE</th></tr>
<tr><td rowspan="6">Pre-intervention Visits</td><td colspan="2">Informed Consent Night</td></tr>
<tr><td><u>Activities at the Healthy Lifestyles Center</u>
• Individual meeting for consent/assent
• Receive 3-day food log and instructions
• Height and weight measurements
• Complete brief survey measures</td><td><u>Items to Complete at home</u>
• Online surveys
• Paper medical history form
• Teen 3-day food logs</td></tr>
<tr><td colspan="2">Baseline Assessments (over a 3 week period)</td></tr>
<tr><td colspan="2">• Lab work, ECG, bioimpedance and DXA
• Teen physical exam and physician review of teen medical history.
• Meet with dietitian to review the 3-day food log, behavior specialist to review surveys and exercise staff to complete fitness test and activity recall.
• Parent and teen to wear activity monitor and record sleep hours for 1 week.</td></tr>
<tr><td colspan="2">Introductory Session</td></tr>
<tr><td colspan="2">• Parent attends a 60-minute session with behavior coach</td></tr>
<tr><td rowspan="2">Intervention Visits</td><td colspan="2">Intervention: Visits 3 times per week for 12 Weeks</td></tr>
<tr><td colspan="2">• Weekly individual session for teen with weight measurements (parent has partial-full participation in these sessions).
• Review of teen daily food and exercise journals, and parent logs.
• Teens exercise sessions at the Healthy Lifestyles Center three days a week.
• Graded exercise test repeated after 6 weeks.</td></tr>
<tr><td rowspan="4">Post-Intervention Visits</td><td colspan="2">12 Week Post-Intervention Assessments (over a 2 week period)</td></tr>
<tr><td colspan="2">• Lab work, ECG, bioimpedance and DXA
• Meet with dietitian to review 3-day food logs, behavior specialist to review surveys and exercise staff to complete fitness test and activity recall.
• Parent and teen to wear activity monitor and record sleep hours for 1 week.</td></tr>
<tr><td colspan="2">16 Week Follow-up Assessments</td></tr>
<tr><td colspan="2">• Height, weight and bioimpedance measurements
• Wear activity monitor for 1 week
• Meet with dietitian to review 3-day food logs and behavior specialist to review surveys and exercise staff to complete fitness test and activity recall.
• Parent and teen to wear activity monitor for 1 week.</td></tr>
</table>

If one of the 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 study may be required. In these cases, recommendations for treatment and further participation in the study 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.

You will be asked to return the activity monitor after testing is complete. If you are unable to return the study site for any reason, staff will work with you to find a mutually acceptable alternative for returning the monitors.

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. The risks in obtaining blood samples include the chance of pain, bruising or, on occasions, fainting or infection at the site where blood is drawn. Adolescents may experience nausea and vomiting from drinking the concentrated sugar solution.

As a participant in this study, your child will receive extra radiation from the DXA studies that are for research purposes only (not for his or her direct clinical benefit). The radiation dose from these studies is less than 1% of the annual permissible occupational exposure level for radiation workers. The National Council on Radiation Protection and Measurements has set permissible occupational radiation exposure limits for many radiologists, technologists, and scientists who work with radiation and are exposed nearly every day. These limits are defined as the dose of radiation that, in light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his/her lifetime. The risk of this amount of occupational exposure to radiation is, thus, considered to be very small and less than that associated with normal everyday activities. The radiation dose mentioned is what your child will receive from the research component of this study only and does not include any exposure he or she may have received or will receive in the future from other tests.

If your child is female, she will have a urine pregnancy test prior to DXA body composition testing. If the test is positive, nursing staff will stop further testing and contact the Principal Investigator immediately. The Principal Investigator or another medical investigator with the study will first discuss the results of the test with the child in person. Every effort will be made to assist the child in engaging parent(s) regarding the results so the pregnancy can be managed in accordance with the child's wishes. This

may result in psychological stress. In addition, pregnant teens will not be allowed to continue to participate in the study because of the impact of pregnancy on body weight.

Potential risks of cardiorespiratory fitness testing and exercise training are 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. Based on the recommendations of your child's doctor, the exercise method may be modified.

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.

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

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.

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

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

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
- Study Sponsor
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Principal Investigator and Research Staff
- 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:

☐ Complete health record ☐ Diagnosis & treatment codes ☐ Discharge summary
☒ History and physical exam ☒ Consultation reports ☐ Progress notes
☒ Laboratory test results ☒ X-ray reports ☒ X-ray films / images
☐ Photographs, videotapes ☐ Complete billing record ☐ Itemized bill
☐ Information about drug or alcohol abuse ☐ Information about Hepatitis B or C tests
☒ Information about psychiatric care ☐ Information about sexually transmitted diseases
☒ 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 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 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 children and adolescents with obesity 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, lab tests, and other study procedures that will include diet and exercise education. With your authorization, we can send your physician the results of any tests that may be necessary for further medical treatment. 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 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
You and your child will have access to a scholarship at your local YMCA from the 9th to the 16th week that you are participating in the study. Your child will receive small health-related incentives valued at less than $15.00 for reaching certain goals during the study. Parents will receive a cash payment of up to $40.00 upon completion of the 12-week assessments, and an additional payment of up to $50.00 upon completion of the 16-week assessments. There will be no payment for parents who participated in the study but did not complete all study assessments. Also, once all study assessments are completed, your child will be offered an optional exercise training session at the study facility valued at $40.00 to provide more exercise options that may not have been

included as part of the study intervention, such as weight lifting. This optional session must be completed within 2 weeks of final study assessments.

You will be asked to provide your social security number 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 to process payment.

ALTERNATIVES
Lifestyle modification including exercise, nutrition and behavioral support are the cornerstone of treatment for obesity. 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 behavior and nutrition 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 behavior and nutrition 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 or the Institutional Review Board 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 exercise plan will be sent to the YMCA to promote safe physical activity. When you or your child are in the waiting room or gym at the Healthy Lifestyles Center with other study participants, they will hear what you say, and may or may not tell someone else.

We can provide you with a copy of your child's lab results at your request. If you would like to have your child's lab results sent to his/her pediatrician, you will be asked to sign a VCU Health System release form for this purpose.

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, 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.

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.

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.

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 resulting from 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.
- 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 end of study procedures.

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

Edmond Wickham, M.D., M.P.H.
Study Principal 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/human_research/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

_____ _____

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

_____ _____

Signature of Person Conducting Informed Consent Discussion/Witness Date

_____ _____

Principal Investigator Signature (if different from above) Date