RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: The Effect of Family Based Adolescent Obesity Treatment on Eating Pathology Risk during Emerging Adulthood

PRINCPLE INVESTIGATOR: Melanie K. Bean, PhD, Associate Professor, 804-827-8336

NOTE: In this consent form, "you" always refers to the research participant. Both adolescents and parents will be participants in this study.

ABOUT THIS CONSENT FORM

You 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 situation.**

This research participant information and consent form is meant to assist you in thinking about whether or not you 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 not to 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

Why is this study being done?

The purpose of this research study is to evaluate the long-term effects for adolescents and parents after participating in TEENS, a family-based behavioral weight loss treatment. More specifically, this research will examine how to support healthy weight management and eating disorder prevention during the transition through adolescence and emerging adulthood. You are being asked to participate in this study because you are approaching or have recently completed the 2-year (24-month) assessment for the TEENS Program.

What will happen if I participate?

If you choose to enroll in this study, you will be asked to meet with a study staff member for approximately 1 hour in-person or via Zoom on three separate occasions: at the 2-year, 3-year, and 4-year assessment visits. During these interviews, you will be asked questions about weight

management, the changing role of parents and the home environment, cultural beliefs about weight management, and adolescents developing independence.

We won't share adolescent answers with their parent, nor will we share parent answers with their adolescent. These interviews will be audio-recorded. All identifiable information will be removed from the records and recordings will be deleted after they have been transcribed.

Your family's total participation time in this study will last up to six hours (1-hour interview for parent, 1-hour interview for teen at 3 separate time points). Approximately 160 individuals will participate in this study. We ask that both the parent and adolescent participate. If only one of you wants to or can participate, please decline participation.

What alternative procedures are available?

You have the option to complete your interview(s) virtually using Zoom if that is preferred over completing your interview(s) in-person with study staff. Talk to the study staff about what is the best option for you and your child.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. None of the activities are considered experimental.

Risks and Discomforts	Benefits to You and Others
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. The interview may contain questions that are sensitive and personal in nature and may make you feel uncomfortable or embarrassed. You may refuse to answer any question that makes you feel uncomfortable. 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.	There is no guarantee that you or your child will receive any benefits from being in this study. However, we hope the information learned from this study will provide more information about better ways to support adolescents with overweight who are transitioning to young adulthood.

WHAT ARE THE COSTS?

All costs associated with the study will be covered by the study sponsor

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be compensated in cash for completing study interviews. Adolescents and caregivers will each receive $50 at 2-years, 3-years, and 4-years. If you complete interviews in person, you will also be reimbursed for travel at the federal mileage rate.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually 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.

CAN I STOP BEING IN THE STUDY?

You 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.

We may withdraw you from the study if:

- the study staff thinks it is necessary for the subject's mental health and safety;
- the sponsor stops the study; or
- administrative reasons

HOW WILL INFORMATION ABOUT ME 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:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

We will not tell anyone the answers your child gives us. However, 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.

We will not return any individual results of the research to you.

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.

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

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Melanie Bean, Principle Investigator
melanie.bean@vcuhealth.org
(804) 827-8336
and/or
Sarah Farthing, Research Coordinator
sarah.malone@vcuhealth.org
(804) 527-4756

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human-research/

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/OR PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent form and permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form 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 form and permission form for my records.

Signature Block for Enrolling Adult Participants	
_____ 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) *Study team – verify that this individual is the child's parent or legal guardian.*	
_____ **Required** First Parent/Legal Guardian Signature	_____ Date
_____ **Optional** Second Parent /Legal Guardian's Signature	_____ Date
_____ Name of Person Conducting Parental Permission Discussion (Printed)	
_____ Signature of Person Conducting Parental Permission Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Enrolling Child Participants – Verbal Assent by Child
STATEMENT OF ASSENT BY CHILD PARTICIPANT The person doing this research study has explained what will happen to me if I participate in this study. Saying "yes" means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.