RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Low Intensity Weight Loss for Young Adults

VCU IRB NO.: HM20002772

SPONSOR: *National Institute of Diabetes and Digestive Kidney Diseases*

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

You are being asked to take part in this research project because you are between 18 and 25 years of age and you meet the medical criteria for either overweight or obesity. The study is called Low Intensity Weight Loss for Young Adults. This study is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases.

Obesity is a major health problem in the United States, and young adults age 18-25 are at particularly high risk. These years are associated with a variety of unhealthy weight-related behaviors, and more than 40% of 18-25 year olds are already overweight, placing them at increased risk for additional weight gain during these years. Further, weight gain and obesity during young adulthood is associated with an increased risk for diabetes and other heart disease risk factors. Although this age group is at increased risk, very few programs have been developed to specifically target weight loss and healthy lifestyle behaviors during these years.

Low Intensity Weight Loss for Young Adults is a research study looking to test three new approaches to promote weight loss and healthy lifestyle behaviors in young adults. A total of 381 young adults between 18 – 25 years of age will take part in this study. The study will last for 12 months, and all assessments and treatment visits will take place at the OPT for Health Research Center located in the One Capitol Square building, 830 E. Main Street in downtown Richmond, VA.

The study will consist of three groups of volunteers. Participants in all three groups will receive personalized feedback on their weight and physical measurements (e.g., body fat, blood pressure). In addition, all groups will receive one group-based session and one in-person individual session, followed by a 6-month, technology driven lifestyle intervention consisting of core behavioral weight loss information and strategies proven to produce weight loss in previous studies. In addition to weekly lessons, participants

will receive personalized feedback on their progress each week. All groups will focus on healthy eating and physical activity to produce weight loss.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

A total of 381 young adults between 18 – 25 years of age will take part in this study. The intervention will last for 6 months. All in-person treatment sessions and assessments will take place at 830 East Main Street, 6th floor, downtown Richmond, VA. The study will consist of three groups of volunteers. All participants will receive a 6-month healthy lifestyle program, though some aspects of the program will differ based on the group to which you are assigned. Finally, all participants will be asked to complete questionnaires via a secure website at 2 weeks, 2 months, and 4 months, along with 3 follow-up assessment visits at 3, 6, and 12 months after they begin the program. Detailed descriptions of what is involved with each of the assessment visits and the three treatment programs are provided below.

Baseline Screening Visit

This visit will require you to fast for 12 hours, refrain from alcohol for 12 hours, and to refrain from any strenuous activity for 8 hours prior to your appointment. At this visit, your height, weight, blood pressure, waist circumference, body composition, and resting metabolic rate will be measured. Your body composition (amount of fat and lean mass) will be assessed using BIA (bioelectric impedance analysis). You will be asked to continuously wear a physical activity monitor on your wrist for 7 days. The monitor will provide an assessment of the amount of time you spend in sedentary, light, moderate, and vigorous activity throughout each day, as well as sleep quality. You will be asked to return the wrist worn Actigraph device to us at the end of the week. You will be asked to complete a set of questionnaires that ask about your health history and weight-related behaviors, and a member of the study team will meet with you to ask you questions about the study and why you might want to be in the study. Questionnaires can be completed prior to this visit by using a secure link that will be sent to the email account that you have provided to the clinic staff, or at the clinic during your visit. This visit will take between 1.5 and 2 hours, and data collected will be used for two purposes – 1) to determine whether you meet the eligibility criteria for the study, and 2) if eligible, to individualize your goals, dietary and physical activity prescriptions in the study. If you are randomized to the study, you will receive feedback on your individual clinic-based physical assessment measures, diet, and physical activity at your initial treatment session.

Randomization

After completing the baseline assessment visit, those individuals who are found to be eligible for the study will be randomly assigned to one of three groups. By "random" we mean that neither you nor any of the research staff (including your doctor) can select which group you will be in. Using a procedure like flipping a coin, a computer program assigns you to one of the groups. By signing this consent, you are indicating that you are willing to be placed in any of these 3 groups. Requirements for each of these groups and what they will do are described below.

Treatment

Group 1 (Silver):
If you are assigned to Group 1, you will be asked to attend one in-person group session in week 1. This session will last approximately 1.5 hours and you will receive information on the program goals, as well as an overview of behavioral weight loss, healthy eating, and physical activity, and will be oriented to the study website. In week 2, you will be asked to attend an individual meeting with your lifestyle coach to review and further personalize your goals for the program. The group session and individual session will be audio recorded so that content from the session can be coded and analyzed for research and quality control purposes. Individuals will not be identified in any way and all information will be kept confidential. Recordings will be destroyed after review/training or within 3 years of completion of the study, whichever comes first.

In weeks 2-24 you will have access to a secure study website where you will receive your weekly lesson content; this will be viewable on a desktop, tablet or smartphone. You will receive an email each week with a link to take you to the content that is most of interest to you. You will be prompted to log onto the website at least once per week to review the lesson content for that week, and to submit any questions for your lifestyle coach. You will receive weekly, personalized feedback on your performance, as well as the opportunity to discuss with your coach any barriers or challenges you may have in order to help you meet your goals. In addition, you have the option to join a private Facebook group with other members of your intervention group. Participation in this group is voluntary and your decision whether or not to join will in no way impact the other elements of the treatment program you receive.

You will be given a weight loss goal of 1-2 lbs / week and an individualized calorie goal of 1200-1800 calories/day that is designed to help you reach this weight loss goal. You will also be instructed to increase your physical activity to 250 minutes per week, or about 50 minutes on 5 days / week. To help you make these changes you will be asked to record your diet and exercise. You will be encouraged to weigh yourself regularly and provided with a Bluetooth connected scale that will transmit your weight directly to the website via wifi so that you do not need to report this information in order to receive feedback from your coach. The program will teach you ways to reach this weight loss goal, using behavioral skills such as goal setting and self-regulation. To help you practice these core skills and meet your weight loss goals, the program will also offer four weight

loss challenges throughout the program. These challenges will occur over a two-week period and are designed to help you use the information you see on the scale and in your food log to make changes in your behaviors. All challenges will be distributed via email. In addition, the program will focus on important topics such as how to maintain your motivation, eating healthy on a budget, time management, social factors that influence eating, stress management, and how to challenge yourself in your physical activity routine.

Group 2 (Green):
If you are assigned to Group 2, you will be asked to attend one in-person group session in week 1. This session will last approximately 1.5 hours and you will receive information on the program goals, as well as an overview of behavioral weight loss, healthy eating, and physical activity, and will be oriented to the study website. In week 2, you be asked to attend an individual meeting with your lifestyle coach to review and further personalize your goals for the program. The group session and individual session will be audio recorded so that content from the session can be coded and analyzed for research and quality control purposes. Individuals will not be identified in any way and all information will be kept confidential. Recordings will be destroyed after review/training or within 3 years of completion of the study, whichever comes first.

In weeks 2-24 you will have access to a secure study website where you will receive your weekly lesson content; this will be viewable on a desktop, tablet or smartphone. You will receive an email each week with a link to take you to the content that is most of interest to you. You will be prompted to log onto the website at least once per week to review the lesson content for that week, and to submit any questions for your lifestyle coach. You will receive weekly, personalized feedback on your performance as well as the opportunity to discuss with your coach any barriers or challenges you may have in order to help you meet your goals. You will also have the option of attending selected classes offered in the community where you can practice / apply what you have learned through the weekly lessons (e.g., cooking demonstrations, circuit training class).
You will receive a list of locations and vouchers to attend those that are of interest to you. In addition, you have the option to join a private Facebook group with other members of your intervention group. Participation in this group is voluntary and your decision whether or not to join will in no way impact the other elements of the treatment program you receive.

You will be given a weight loss goal of 1-2 lbs / week and an individualized calorie goal of 1200-1800 calories/day that is designed to help you reach this weight loss goal. You will also be instructed to increase your physical activity to 250 minutes per week, or about 50 minutes on 5 days / week. To help you make these changes you will be asked to record your diet and exercise. You will be encouraged to weigh yourself regularly and provided with a Bluetooth connected scale that will transmit your weight directly to the website via wifi so that you do not need to report this information in order to receive feedback from your coach. The program will teach you ways to reach this weight loss

goal, using behavioral skills such as goal setting and self- regulation. To help you practice these core skills and meet your weight loss goals, the program will also offer four weight loss challenges throughout the program. These challenges will occur over a two-week period and are designed to help you use the information you see on the scale and in your food log to make changes in your behaviors. All challenges will be distributed via email. If you meet the challenge, you will be entered into a drawing for a prize that will help you apply the skills you've been learning in the program (e.g., resistance bands you can use at home). Five raffle winners will be drawn for each challenge. In addition, the program will focus on important topics such as how to maintain your motivation, eating healthy on a budget, time management, social factors that influence eating, stress management, and how to challenge yourself in your physical activity routine.

Group 3 (Blue):

If you are assigned Group 3, you will be asked to attend one in-person group session in week 1. This session will last approximately 1.5 hours and you will receive information on the program goals, as well as an overview of behavioral weight loss, healthy eating, and physical activity, and will be oriented to the study website. In week 2 you will be asked to attend an individual meeting with your lifestyle coach to review and further personalize your goals for the program. The group session and individual session will be audio recorded so that content from the session can be coded and analyzed for research and quality control purposes. Individuals will not be identified in any way and all information will be kept confidential. Recordings will be destroyed after review/training or within 3 years of completion of the study, whichever comes first.

In weeks 2-24 you will have access to a secure study website where you will receive your weekly lesson content; this will be viewable on a desktop, tablet, or smartphone. You will receive an email each week with a link to take you to the content that is most of interest to you. You will be prompted to log onto the website at least once per week to review the lesson for that week, and to submit any questions for your lifestyle coach. You will receive weekly, personalized feedback on your performance, as well as the opportunity to discuss with your coach any barriers or challenges you may have in order to meet your goals. You will have the opportunity to receive small monetary incentives in weeks 2-24 for tracking and reporting your weight and calorie intake at least 4 of 7 days that week ($1-10 per week). The maximum amount you are able to earn over the 24-week program is $90. In addition to these weekly incentives, you have the chance to be entered into a raffle for $50 if you lose 5%-10% of your starting body weight, or a raffle for $100 if you lose more than 10% of your starting body weight. Raffles will be conducted at both 3 and 6 months. In addition, you have the option to join a private Facebook group with other members of your intervention group. Participation in this group is voluntary and your decision whether or not to join will in no way impact the other elements of the treatment program you receive.

You will be given a weight loss goal of 1-2 lbs / week and an individualized calorie goal of 1200-1800 calories/day that is designed to help you reach this weight loss goal. You will also be instructed to increase your physical activity to 250 minutes per week, or about 50 minutes on 5 days / week. To help you make these changes you will be asked to record your diet and exercise. You will be encouraged to weigh yourself regularly and provided with a Bluetooth connected scale that will transmit your weight directly to the website via wifi so that you do not need to report this information in order to receive feedback from your coach. The program will teach you ways to reach this weight loss goal, using behavioral skills such as goal setting and self- regulation. To help you practice these core skills and meet your weight loss goals, the program will also offer four weight loss challenges throughout the program. These challenges will occur over a two-week period and are designed to help you use the information you see on the scale and in your food log to make changes in your behaviors. All challenges will be distributed via email. If you meet the weight loss goal associated with the challenge, you will be entered into a raffle drawing for $50. A total of 5 winners will be drawn for each challenge. In addition, the program will focus on important topics such as how to maintain your motivation, eating healthy on a budget, time management, social factors that influence eating, stress management, and how to challenge yourself in your physical activity routine.

Remember that you will not be able to select the group you join. You will be assigned to your group randomly (by chance).

Follow-up Assessments

All participants will be asked to attend clinic visits at 3, 6 and 12 months after beginning the program; these visits will be similar to your baseline assessment visit before you started the program. These visits will require you to fast for 12 hours, refrain from alcohol for 12 hours, and to refrain from any strenuous activity for 8 hours prior to your appointment. For each of these visits, you will have your blood pressure measured, as well as your height, weight, waist circumference, and body composition measured. Your body composition (amount of fat and lean mass) will be assessed using BIA (bioelectric impedance analysis.) You will be asked to continuously wear a physical activity monitor on your wrist for 7 days at 6 and 12 months only. The monitor will provide an assessment of the amount of time you spend in sedentary, light, moderate, and vigorous activity throughout each day, as well as sleep quality. You will be asked to return the wrist worn Actigraph device to us at the end of the week. In addition to the measures listed above, at your 6 month visit, you will have your resting metabolic rate measured again to allow us to personalize goals for you in the maintenance phase. At each of these visits, you will again be asked to complete a series of questionnaires about your health habits and current behaviors. Questionnaires can be completed prior to visits by using a secure link that will be sent to the email account that you have provided

to the clinic staff, or at the clinic during your visit. These follow up visits will take about 60-75 minutes.

You will receive a $50 honorarium for completing each of the 3- and 6-month follow-up visits and a $75 honorarium for completing the 12 month follow-up visit. In addition, you will receive detailed feedback on the results of your clinic-based measurements.

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 are no major risks associated with the program itself or data collection visits. All medical tests and care may involve some minor risks or discomforts. These include:

Blood Pressure Assessment
You may experience temporary discomfort during blood pressure recordings due to the pressure of the blood pressure cuff on your arm or ankle.

Risks of Increasing Physical Activity
Risks involved with increasing your physical activity include, but are not limited to, injuries to the muscles, ligaments, tendons and joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will follow guidelines and safety recommendations for physical activity set forth by the American College of Sports Medicine and by your doctor.

Resting Metabolic Rate Assessment
In order to personalize your goals in this program, you will have your resting metabolic rate determined by indirect calorimetry using an instrument called the Fitmate GS. This measurement involves laying on an adjustable exam table that is slightly elevated at one end while wearing a ventilated canopy over your head. During this time, you should be relaxed, lie still, and breathe normally. You may experience claustrophobia (a fear of enclosed spaces) during the measurement. There is no physical danger involved with these measurements. The Fitmate GS has a well-ventilated canopy that will cover your head and neck. Research staff will remain in the room and monitor you throughout the procedure. At any time, you may easily remove the canopy by lifting it over your head.

Mobile Communication
You may receive text messages from the internet program. You should be aware that it is illegal in the State of Virginia to text while driving. It is also dangerous to pay attention to your cellular phone while driving, walking, or doing any activity that requires your attention. You should continue to exercise good judgment on this while participating in this study. In addition, you should know that a third party service called Clickatell is

needed to send the messages from the internet program and that Clickatell stores your cell number, the date and time of the text and the content of the text message being sent. Your cell phone service provider may also store some or all of this information (see your own provider's data storage policies). As per the Clickatell Privacy Policy (found at https://www.clickatell.com/about-us/terms/privacy-policy/), they only store the data for operational purposes such as reporting and trouble shooting and do not collect or compile personal information for dissemination or sale to outside parties for consumer marketing purposes or host mailings on behalf of third parties. However, as with your cell provider, there is a slight risk that your personal information could be breached. This study will not transmit any other personal information through these texts except for your cell number and updates on your weight and/or exercise programs; you may opt out of these messages at any time.

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:

- 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 psychiatric care
☐ Information about Hepatitis B or C tests
☐ Information about sexually transmitted diseases
☒ Other (specify): The entire research record (e.g., height, weight, blood pressure, waist circumference, body composition, questionnaire data)

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
You may benefit from this program by losing weight, but there is no guarantee that you will achieve this benefit. You may also benefit from the information you learn through your lessons or lifestyle coach about healthy eating and physical activity. You may benefit from the information that you receive at each assessment visit, including information about your weight, blood pressure, body composition, diet, and physical activity. With your signed consent, study staff may contact your primary care physician concerning any medical abnormalities. We also will learn more about which approaches to weight loss are best for this understudied and high risk age group so that this information can be provided to people and the scientific and medical community.

COSTS
Some of the services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include body composition analysis, objective measures of your height, weight, waist circumference, resting metabolic rate and blood pressure, as well as a state of the art healthy lifestyle program. Those services will be paid for by the study and will not be billed to you or your health insurance company. None of the services you receive as part of this research study will be at any cost to you. The only costs associated with your participation in this study are the time you will spend participating in the program and

to attend assessment visits, and in your transportation costs to 830 East Main Street, 6th floor, Richmond, VA, 23219.

PAYMENT FOR PARTICIPATION

You can earn up to a $60 honorarium at the 3-month follow up visit, which is made up of the following:

- $5 for completing brief online questionnaires at 2-weeks
- $5 for completing brief online questionnaires at 2-months
- $50 for completing your clinic visit and questionnaires

You can earn up to a $55 honorarium at the 6-month follow-up visit, which is made up of the following:

- $5 for completing brief online questionnaires at 4-months
- $50 for completing your clinic visit and questionnaires

You will receive a $75 honorarium for completing the 12 month follow-up visit which is made up of your clinic visit and questionnaires.

You will receive up to $5.00 to cover transportation / parking costs associated with your clinic visits. In addition, you will receive detailed feedback on the results of your physical measurements.

In addition, depending on the group to which you are randomized, there is the possibility of winning a reward/prize for completing challenges throughout the treatment program. Specific details are provided in the group-specific sections above.

ALTERNATIVES

Your alternative is to not be in the study. If you choose not to join this study, you may talk to your doctor about the benefits of weight loss, healthy eating, and exercise and other programs to lose weight. You may continue with your usual health care, whether you join the study or not.

CONFIDENTIALITY

Potentially identifiable information about you will consist of audiotapes of your initial treatment sessions, as well as results from your assessment visits and questionnaires.

All medical information will remain confidential to the extent the law allows. The results from the study may be published, but your identity will not be given, and the results will be given for groups of people, not individuals. All study staff will maintain strict confidentiality.

Data is being collected only for research purposes. Your data will be identified by an ID number only (not names or birth dates, or other identifiable information), and stored separately from medical records in a locked research area. All personal identifying

information will be kept in password protected files and these files will be deleted within 3 years after the study is over. Your research record / file, which will be identified by an ID number only and contains the results from your assessment visits, will be kept in a locked file cabinet for 3 years after the study ends and will be destroyed at that time. Access to all data will be limited to study personnel. A data and safety monitoring plan is established and an external safety officer will oversee this study to ensure participant safety and confidentiality.

We will not tell anyone the answers you give us; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research, or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services.

The group and individual in-person treatment sessions you attend will be audio taped, but no names will be recorded. The audio files will be stored in password protected files which can only be accessed by authorized study personnel. Once the information on the recordings has been coded and analyzed for research and quality control purposes, or within 3 years of study completion, the files will be destroyed.

Confidentiality of your identity or information discussed on the optional Facebook group page cannot be guaranteed by the research staff due to the presence of other research participants. Similarly, information you share as part of your initial group session cannot be guaranteed by research staff because other participants are present. However, study volunteers are encouraged to maintain strict confidentiality regarding your information and the information of others who are participating in the program. Additionally, while there are safeguards (such as password protection) to assure the confidentiality of electronic communication (e.g., Facebook, text messages from your mobile device), the confidentiality also cannot be completely guaranteed.

It is also important to keep in mind that while the study team will keep your study information confidential, anything you post on Facebook is technically governed by and can be used by Facebook; therefore, we cannot ensure complete confidentiality of all of your Facebook posts and information. Similarly, you may receive other notifications from Facebook or suggestions and requests about people you may know – this is controlled by Facebook and not the research team. Facebook terms and conditions may be updated periodically; therefore, we highly recommend that you go to https://www.facebook.com/legal/terms to check the latest statement of your rights and responsibilities. These limitations and suggestions apply to other social media sites, as well. The study team may also examine your Facebook group posts throughout the program for the type and nature of the posts. These results may be presented, but if any data are presented the data will not be identified by name, and results will only be presented in a group format.

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.

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 if, as part of this research, we learn that you intend to harm yourself or others, or we learn about real or suspected child or elder abuse. In these instances, the law says that we have to let people in authority know so they can protect the person(s) at risk.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Website will not include information that can identify you. At most, the Web site 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 name will not ever be used in these presentations or papers. In addition, we will also host a "report-back" event at the end of the trial, where we will share the overall results with all former participants. No individual level data or information will be shared. Main results from the trial will also be distributed to all former participants via email, using the email address on file with the study team.

Finally, in the future, identifiers might be removed from the information you provide in this study, and after that removal, the data could be used for other research studies by this study team or another researcher without asking you for additional consent.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to 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. If you decide not to participate, or if you quit the

study, it will not affect the health care services that you normally receive. If you decide to quit the study any time after you have signed this consent form, we will not collect any further data from you. However, any data that was collected prior to your withdrawal from the study will be used for reporting and analysis purposes.

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

- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions (prior to randomization only);
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

If at any point, you choose to withdraw from the research study, please write to Dr. Jessica LaRose, VCU Department of Social and Behavioral Health, PO Box 980149, 830 East Main Street, 4th floor, Richmond, VA, 23219, or Jessica.larose@vcuhealth.org to officially terminate your participation.

QUESTIONS

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

Principal Investigator: Dr. Jessica LaRose
Phone: (804) 628-7521
Email: jessica.larose@vcuhealth.org

The researcher/study staff named above is 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
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
P.O. Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number for general questions, 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 have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed Participant signature Date

_____

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

_____ _____

Signature of Person Conducting Informed Consent Date

_____ _____

Principal Investigator Signature (if different from above) Date