UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

If you are a parent, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow your child to take part in this study. Therefore, for the rest of the form, the word "you" refers to your child.

If you are an adult, child, or adolescent reading this form, the word "you" refers to you.

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study?

Wellness Achieved Through Changing Habits (The WATCH Study)

3. Who do you call if you have questions about this research study?

Principal Investigator: Michelle Cardel, PhD, MS, RD (352) 273-8811

Other research staff: Darci Miller, MPH, CHES (352) 294-5980

4. Who is paying for this research study?

The sponsors of this study are the National Institutes of Health, WellCare Health Plans Inc., and the Department of Health Outcomes and Biomedical Informatics at the University of Florida.

5. In general, what do you need to know about this research study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to investigate the effects of a remote acceptance-based therapy (ABT) healthy lifestyle/weight loss intervention on teens and to compare them to the effects of enhanced care. The program will be approximately 12 months in duration.

b) What is involved with your participation, and what are the procedures to be followed in the research?

Both Groups: If you decide to participate, you will be asked to fill out questionnaires/surveys about yourself and your health. These surveys also cover information we will ask you to provide about your behaviors, thoughts, and feelings and will include some personal information. Specifically, we will ask about your eating behaviors, life stress, confidence, emotions, current medications, social standing, and relationships. We will also contact you 3 times for 24-hour dietary recalls. You will then receive personalized feedback from a registered dietitian about your diet and activity via Zoom. Once this is complete, we will record health measures from you including height/weight and you will be given an accelerometer (a device which measures your movement and activity levels) to wear and a sleep log to use for a 7-day period, and asked to return them to us. You will then be randomized to either the ABT group or the enhanced care group.

ABT Group: You will be asked to attend 15 remote intervention sessions that are each approximately 90 minutes in length. Intervention sessions will be weekly for the first 2 months, bi-weekly for the next 2 months, and monthly for the following 2 months. Sessions will include nutritional education and physical activity education. They will also seek to build skills in the areas of goal-setting, problem solving, self-monitoring, and decision making.

Enhanced Care Group: You will receive 15 emailed handouts weekly for 2 months, bi-weekly for the next 2 months, and monthly for the following 2 months. These handouts will cover general healthy lifestyle information useful for teens. You will also receive a mid-point nutrition consultation from a registered dietitian about your diet and activity via Zoom.

Both Groups: Upon completion of the study, you will be asked to complete post-treatment assessments (6 months from your initial intervention session), which will be the same as the assessments completed before the intervention. Once you have completed the post-treatment assessments, we will ask you to complete them again 6 months later for a follow-up.

c) What are the likely risks or discomforts to you?

This is a low-risk study, however there is a slight risk that information could be revealed inappropriately or accidentally. You may also experience feelings of stress or anxiety while completing the surveys.

d) What are the likely benefits to you or to others from the research?

This study will assist in the development of future healthy lifestyle/weight loss interventions for teens. Additional potential benefits include the possibility of weight loss, increased self-regulation skills, and improved health.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Appropriate alternative courses of treatment include regular wellness visits to your clinician.

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 website will include a summary of the results. You can search this website at any time.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

This study will not change your normal clinical care.

7. What will be done only because you are in this research study?

Both Groups: If you decide to participate, you will be asked to fill out questionnaires/surveys about yourself and your health. These surveys also cover information we will ask you to provide about your behaviors, thoughts, and feelings and

will include some personal information. Specifically, we will ask about your eating behaviors, life stress, confidence, emotions, current medications, social standing, and relationships. We will also contact you 3 times for 24-hour dietary recalls. You will then receive personalized feedback from a registered dietitian about your diet and activity via Zoom. Once this is complete, we will record health measures from you including height/weight and you will be given an accelerometer (a device which measures your movement and activity levels) to wear and a sleep log to use for a 7-day period, and asked to return them to us. You will then be randomized to either the ABT group or the enhanced care group.

ABT Group: You will be asked to attend 15 remote intervention sessions that are each 90 minutes in length. Intervention sessions will be weekly for the first 2 months, bi-weekly for the next 2 months, and monthly for the following 2 months. Sessions will include nutritional education and physical activity education. They will also seek to build skills in the areas of goal-setting, problem solving, self-monitoring, and decision making.

Enhanced Care Group: You will receive 15 emailed handouts weekly for 2 months, bi-weekly for the next 2 months, and monthly for the following 2 months. These handouts will cover general healthy lifestyle information useful for teens. You will also receive a mid-point nutrition consultation from a registered dietitian about your diet and activity via Zoom.

Both Groups: Upon completion of the study, you will be asked to complete post-treatment assessments (6 months from your initial intervention session), which will be the same as the assessments completed before the intervention. Once you have completed the post-treatment assessments, we will ask you to complete them again 6 months later for a follow-up.

The entire study will be conducted remotely via Zoom.

Any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this research study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

Both Groups: You will be in this research study for a total time of approximately 12 months.

ABT Group: This study includes 2 baseline appointments via Zoomthe monitoring periods assessing your movement using the accelerometer and dietary intake, 15 ABT intervention sessions (each 90 minutes in length), post-treatment, and a 6-month follow-up. Intervention sessions will be weekly for the first 2 months, bi-weekly for the next 2 months, then monthly for the remaining 2 months.

Enhanced Care Group: This study includes 2 baseline appointment via Zoom the monitoring periods assessing your movement using the accelerometer and dietary intake, a mid-point nutrition consultation via Zoom, post-treatment, and a 6-month follow-up.

9. How many people are expected to take part in this research study?

This research study plans to enroll up to 465 participants.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

There is a slight risk that information could be revealed inappropriately or accidentally. Depending upon the nature of this information, such a release could upset or embarrass you. However, we take all possible measures to prevent the release of any private information and all data collected kept in a locked office in a locked cabinet of the Principal Investigator or behind a firewall on a University of Florida protected data management system. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

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 have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing your 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. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your 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. If we learn about child abuse,

or intent to harm yourself or others, we will report that information to the appropriate authorities.

You may also experience feelings of stress or anxiety while completing the questionnaires/surveys

This study may include risks that are unknown at this time.

If you indicate that you are going to hurt yourself or someone else at any time throughout the study, a member of the study team will call '911'.

If your scores during the study indicate that you need assistance with mental wellness or eating disorders, we will provide you with a list of resources.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

This study will assist in the development of future healthy lifestyle/weight loss interventions for adolescents. Additional potential benefits include the possibility of weight loss, increased self-regulation skills, and improved health.

11b. How could others possibly benefit from this study?

Participation in this study will result in your contribution to the good of science and will enhance knowledge in the field. Your participation could assist in development of future healthy lifestyle/weight loss interventions for teens.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals. No identifiable information will be included in presentations at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Your participation in this study is completely voluntary. There is no penalty for not participating.

If you are a student, you have been invited to participate in this research because you meet preliminary enrollment criteria and you are willing to participate. The investigator associated with this project may or may not teach in your college or be associated with courses for which you are enrolled or might be expected to register in the future. Your participation in this study is voluntary and any decision to take part or not participate will in no way affect your grade or class standing.

If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your grade(s), you should discuss this with the dean of your college or you may contact the IRB office at (352) 273-9600.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The Principal Investigator decides that continuation could be harmful to you
- You do not follow the study plan
- Other reasons affecting administration of the research study

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Services

The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related

to this study, please contact Michelle Cardel, PhD, RD (352) 273-8811 or Darci Miller at (352) 294-5980.

Items/Services Not Paid for by the Sponsor

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

15. Will you be paid for taking part in this study?

You will be compensated with a total of $180 throughout your participation in the study.

This will be broken down as follows: $35 after the first two months, $30 after 2nd 2 months, $20 after last 2 months, $25 at post-treatment, $40 for attending 80% of intervention sessions or attending mid-point nutrition consult (depending upon if randomized to ABT or enhanced care group) that will be provided at post-treatment, and $30 at 6-month follow-up.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment, contact the study coordinator.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization, through your signature on this consent form. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information will be created by participating in study procedures, from your study visit and through telephone calls. More specifically, the following information may be collected, used, and shared with others in the research team:

- Height, weight, and responses from questionnaires/surveys

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- The PHI collected throughout the study is needed to investigate the effects of the ABT healthy lifestyle/weight loss intervention and to compare them with the effects of enhanced care in adolescents.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the

researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____
Signature of Person Obtaining Consent & Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

_____ _____
Signature of Adult Consenting & Authorizing for Self Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____
Consent & Authorization Signature Date
of Parent/Legal Representative

_____ _____
Print: Name of Legal Representative Print: Relationship to Participant:

_____
Print: Name of Subject:

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

_____ _____

Assent Signature of Participant Date