MINDFULNESS-BASED INTERVENTION FOR DEPRESSION AND INSULIN RESISTANCE IN ADOLESCENTS

PARTICIPANT INFORMED CONSENT FORM

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Key Information

Please read all the information below and ask questions about anything you don't understand before deciding if you want to take part.

You (you= you/your child) are being asked to be in a research study. Participation in Research is voluntary.

Purpose of the Study: We are doing this study to learn more about how taking part in different adolescent group programs could improve mood, lessen stress, and decrease insulin resistance among teenagers at risk for diabetes.

Procedures: If you agree to participate, the following will happen:

- You will have two screening visits to make sure you are eligible to join this study.
- If you are eligible, you will be randomly assigned to one of three groups. You cannot choose which group you will be in. The programs for all three groups are the same length.
- You will be asked to make 6 1-hour long groups meetings over about 6 weeks, either remotely or at one of the study sites. What happens at each meeting will vary depending on which program you are in.
- About 1 week after your program ends, you will be asked to take place in a focus group to give feedback on the program. This may happen in-person or over video-conferencing.
- You will participate in two follow-up sessions, one about 2 weeks after group program ends and one about 1 year after you started the group program, where we will repeat the procedures done during screening. These visits will take place at the study sites.

Risks: Participation in research involves possible risks including the following: pain and/or bruising from blood draw, feeling discomfort due to physical exams, and emotional stress from sharing in the group sessions.

Benefits: There is no guarantee that your health will improve if you join this study. This study may lead to information that could help patients and health care providers in the future.

Alternatives: You may be able to receive any of the treatments in this study without participating in this study. Please discuss standard treatment and care options with your doctor.

Detailed Consent

We invite you ("you" means you/your child) to take part in a research study that is taking place at **Children's Hospital Colorado** (Aurora, CO), **Colorado State University** (Fort Collins, CO), the **Uniformed Services University** (Bethesda, MD), and **Children's National Medical Center** (Washington, D.C.). We are partnering with the National Center for Complementary and Integrative Health and Office of the Director of the National Institutes of Health to conduct this study. This form provides you with information about the study. A member of the research team will describe the study to you and answer your questions. Please read the information below and ask us any questions about anything you don't understand before deciding whether or not to take part. It is up to you to decide if you'd like to volunteer for this study.

Why is this study being done?

You have been identified as being at possible risk for the development of **type 2 diabetes**. Type 2 diabetes is a chronic disease that makes people more likely to get serious health problems like heart disease, kidney problems, vision problems, and stroke. People with diabetes live for a shorter time than people without diabetes. Type 2 diabetes is the most common type of diabetes in adults. However, there has been a concerning rise of type 2 diabetes in teenagers. Diabetes is inherited, meaning that it runs in families. Depending on how many family members you have with diabetes, your chances of developing diabetes may be as much as 6 times the chances of someone who does not have family members with diabetes.

A major way type 2 diabetes develops is through **insulin resistance**. Insulin is an important chemical the body makes to help keep blood sugar normal. When you eat, sugar enters the bloodstream. Blood insulin levels normally increase to help the body's tissues use sugar. Normally, once the sugar from food you eat enters the body's cells, blood insulin drops to a very low level. Insulin resistance means that insulin isn't working as well as it should to help sugar enter the body's cells. When there is insulin resistance, blood insulin levels stay high even when you have not eaten anything. If insulin resistance gets bad enough, there may be high blood sugars even when the blood insulin level is quite high. Over time, worsening insulin resistance can lead to diabetes.

Type 2 diabetes is preventable. A main way to prevent diabetes is to improve insulin resistance. Research shows that maintaining a healthy diet and physical activity improves insulin resistance. Studies also show that a person's mood is related to insulin resistance. In particular, people who feel depressed or stressed have worse insulin resistance than people who do not feel depressed or stressed. Some research studies show that decreasing feelings of depression and stress improves insulin resistance. But, we do not know for certain if this works, especially for teenagers.

Up to **120 teenage boys and girls** will participate in this study. All volunteers who enroll in the study must: 1) be 12 to 17 years old, 2) have a body mass index (BMI) – a ratio of a person's weight to how tall they are – at or above the 85th percentile compared to other boys or girls their age, 3) have family members with diabetes, 4) report symptoms of depression such as feeling sad, down, or grouchy, and 5) be in good general health.

The **purpose** of this study is to find out whether taking part in different adolescent group programs could be a feasible and acceptable way to improve mood, lessen stress, and decrease insulin resistance among teenagers, at risk for diabetes, in different parts of the country (Colorado, Maryland, and Washington, D.C.).

What happens if I join this study?

Study activities will take place at **one of these four locations**: (1) Children's Hospital Colorado in Aurora, CO, (2) Colorado State University in Fort Collins, CO, (3) Uniformed Services University of the Health Sciences in Bethesda, MD, or (4) Children's National Medical Center in Washington, D.C. We will also ask you to do some **research activities at home**. There are **three overall parts to this study**. The **first** part is a screening phase to determine if you qualify for the study. In the **second** part, if you qualify for the study, you will be assigned, at random, to one of three different group programs: 1) a mindfulness-based group program 2) a cognitive-behavioral therapy group program or 2) a health education group program. The mindfulness-based group program is a research intervention, and not a program that you would typically receive as a part of standard care. The cognitive-behavioral therapy group program is considered standard care for prevention and treatment of depression. The health education group program is considered standard care for providing adolescents with general health knowledge. The programs meet once a week for 6 weeks and will either take place at one of the four study locations (Children's Colorado, Colorado State University, Uniformed Services University, or Children's National), or will be held remotely via video conferencing software. You would need to agree to be assigned to any of the programs to take part in this study. To decide which group program you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. The **third** part of this study is a focus group when the program ends, and two follow-up appointments, about 6 weeks after your program ends and again, about 1 year later. We describe each of these parts in detail below. After a participant joins the study, they can decide to quit or stop during any of these parts, at any time.

Part 1: Screening

The screening phase is to determine if the study is a good fit for you. This part involves two screening appointments, plus additional home activities.

Screening Appointment #1

The first screening may be scheduled using remote video or phone conferencing or, may be scheduled in-person at one of the study locations: Children's Hospital Colorado, Colorado State University, the Uniformed Services University, or Children's National Medical Center. The first screening appointment will take approximately **3 hours** to complete. A parent/guardian will need to be present and participate during this first screening visit. During the first screening visit, we will do the following **5 things**:

1. **Consent form**. We will go over this consent form in detail, review all parts of the study, and ask you to sign the consent form if you would like to participate. If the visit is done remotely, you will be asked to "e-sign" the consent. We will make a hard copy of the signed forms, electronic copy, or both available for you to access for your records.
2. **Body measurements**. We will measure your height and weight or, if you are at home, will ask you to measure how tall you are and how much you weigh.
3. **Medical history**. We will obtain a medical history, including the assessment of parental (guardian) medical and psychiatric illness. We will ask adolescent girls to report if they are pregnant or suspect that they could be pregnant. If you are pregnant, you will be unable to participate in the study.
4. **Surveys and interviews**. We will ask you to answer survey questions about your mood, stress, behaviors, and relationships. Questionnaires that your parent/guardian fill out ask for them to describe your behaviors. These surveys and questionnaires are always done electronically if your visit is in person or done remotely. However, if you prefer paper forms, we will be glad to make those available to you instead. We will interview you regarding your mood and psychological health. These interviews will be audio-recorded.
5. **Home collection instructions**. Last, we will give you the supplies and go over the instructions for some home activities – these are described in the next section.

Home Activities

After the first screening appointment, we will ask you to do the following research study activities at home:

1. **Activity belt**. We will ask you to wear a small device, called an accelerometer, on your hip, for 7 days in a row. This device will measure your movement or how active you are. You should always wear the device. However, you should remove the device when showering or bathing as the device is not waterproof. If you go swimming, you should remove the device and put it back on after swimming. We will give your family a **work sheet** so that you can record when you wore the device and activities like going to bed and waking up.
2. **Saliva (spit) samples**. We will ask you to put a **small cotton swab** in your mouth for 90 seconds at a time so that we can measure the amount of stress hormones in your saliva (spit). We will ask you to do this **7 times throughout 2 separate days**: (1) immediately when you wake up in the morning, (2) 2 minutes after waking up (3) 15 minutes after waking up, (4) 30 minutes after waking up, (5) 45 minutes after waking up, (6) at 4:00 pm in the afternoon, and (7) at bedtime, right before you go to sleep. We will ask you to pick **one weekday and one weekend day** to collect saliva.

Screening Appointment #2

For the second screening appointment, **you will need to come to one of the four study locations**: Children's Hospital Colorado in Aurora, CO, Colorado State University in Fort Collins, CO, the Uniformed Services University in Bethesda, MD, or Children's National Medical Center in Washington, D.C. This visit will start in the morning, around **8:00 am**, and will take approximately **6 hours** to complete. We will ask that you **not have anything to eat or drink (other than water) after 10:00 pm on the night before and the morning of** coming to your appointment. During the second screening visit, we will do these things:

1. **Body measurements**. We will measure your **height**, **weight**, and **waist circumference**. We also will measure the amount of fat in your body using a device called a "**Bod Pod**." We will ask you to sit inside the Bod Pod for about 10 minutes. The whole test takes about 15 minutes. This machine determines body fat by measuring air movement and does not cause children any discomfort. You will need to bring a tight-fitting swimsuit to the appointment for the Bod Pod test or you will be measured clothed only in underwear. Please make sure your swimsuit has no ruffles on it.
2. **Physical exam**. The medical provider will perform a brief physical exam. You may need to remove your clothes briefly for the physical exam. The exam will include checking your stage of puberty (examination of the breasts, testes, and pubic hair). We also will ask you to complete a survey to rate your stage of puberty from your perspective. Depending upon the medical provider's schedule, the physical exam may be scheduled at the first or second screening appointment.
3. **Blood drawing**. We will draw a small amount of blood (no more than 3 tablespoons) using a small needle placed into a vein in your arm or hand to make sure that your blood sugar (also called "glucose") has a normal value. We also will measure your insulin so that we can estimate your insulin resistance. At approximately 9:30 am, we will ask you to drink sugar water (one name for this is "Glucola"). After you drink the sugar water, we will draw another small blood sample (approximately one-half teaspoon) 2 hours (or 120 minutes) later to measure how hormones in the body, like insulin, respond to the intake of sugar. Before we draw blood, we will offer to put a special cream called ELA Max, Anusol, or another non-prescription "numbing cream" on your arm to make blood drawing hurt less. You can have the needle placed into a vein two times – once before you drink the sugar water (when you're "fasting") and again, 2 hours later. Or, we can draw blood using an intravenous line (IV). The IV insertion consists of a small plastic tube being inserted into a vein of your arm in order to obtain blood samples. The IV stays in the arm or hand until after the second, 2-hour blood draw is completed, and then it would be removed. If we find anything unusual on these blood tests, we will inform you and/or your doctor. If you are found to have a serious health problem, such as type 2 diabetes, we will refer you for more intensive treatment and exclude you from participating in this study. In the case where blood cannot be drawn, the study team may use a finger stick test to measure glucose levels of your child.
4. **Test meal**. You will be provided with a lunch meal, made up of foods that most teenagers like, and asked to eat until you are no longer hungry. Then, we will ask you to taste and rate the flavor of a variety of snack foods. You will be asked to rate your feelings before and after eating the lunch meal and the snacks. If you do not like enough of the foods (e.g., if you are vegetarian or vegan), you may be asked to skip this portion.

5. **Speech and math tasks**. You will participate in a speech task and then work on a brief math problem. You will have some downtime to rest before these activities. During this rest period, you will be able to read some magazines. Before and during these tasks (about 6 times), we will ask you to rate your feelings on a brief form. We will also measure your heart rate and blood pressure, with a cuff that goes around your upper arm, during this activity.
6. **Surveys and interview**. We will ask you to answer some additional surveys about your health and well-being and we also will interview you about how you eat. These surveys and interview can be done during the visit, but also may be completed remotely on a computer, by secure video-conferencing, and/or by phone. The surveys are done electronically. However, if you prefer paper forms, we will be glad to make those available to you instead.

Part 2: Group Program

If you are eligible to participate after the screening phase, you will be randomly assigned to participate in one of three different group programs: (1) a mindfulness-based group program, (2) a cognitive-behavioral group program, or (3) a health education group program. **Randomly assigned means that neither you nor your parents/guardians get to pick which program you take part in**. We will ask you about your preference for which program you would prefer, but we will not use that preference to inform which group program you get – it will be like rolling the dice.

All of the programs involve approximately **1-hour weekly meetings for 6 weeks in a row**. The 6 sessions may be spread over a slightly longer period (e.g., 7 weeks) if the program overlaps with a holiday. The group meetings either will take place remotely, using a secure video-conferencing software or will take place at one of the study locations, either the Children's Hospital Colorado, Colorado State University, the Uniformed Services University, or Children's National Medical Center. Each program will have approximately 5 teenagers between 12 and 17 years of age in the group. All of the programs will be led by a psychologist. Just before or after the group sessions, we will ask you about your mood, what you liked or did not like about the session, and also, how you are getting along with your group leader and group members.

Here is a description of each group program:

(1) Mindfulness-based program: This program is called **"Learning to BREATHE."** Learning to BREATHE is a group program developed for teenagers to learn "mindfulness skills:" exercises that help a person pay attention to how they are feeling in the present moment. Exercises include activities such as a "body scan," yoga, and meditation. This program is considered a research intervention, meaning that it is not a program that you would typically receive as part of standard care.

(2) Cognitive-behavioral therapy program: This program is called the **"Blues Program."** The Blues Program was designed for teenagers to prevent the development of clinical depression. Meetings focus on teaching how to recognize how feelings, thoughts, and behaviors are interconnected. Coping skills are taught for how to improve mood and how to deal more effectively with stressful events. This program is considered standard care for prevention and treatment of depression.

(3) Health education program: This **"Health Knowledge"** program was designed for teaching teenagers information on how to lead a healthier life. Topics include improving nutrition, exercise, and body image, avoiding alcohol, drug, and tobacco use, recognizing domestic violence and improving conflict resolution, and identifying signs of clinical depression and suicide. This program is considered standard care for providing adolescents with general health knowledge.

Part 3: Focus Group and Follow-ups

Approximately 1 week after the group sessions end, we also will ask you to take part in a "**focus group**." This will be a group discussion with the same teenagers who took part in your group program. This focus group discussion will last approximately 1 hour and will be scheduled at your study location, in-person, or via secure video conferencing. We will ask about your experiences participating in the group program, including what you liked and what you did not like. This information will help our team make the programs even better.

There will be two follow-up assessments. One will take place within about 2 weeks after the group program ends ("**6-week follow-up**") and the other will take place about 1 year after you started the group program ("**1-year follow-up**"). At each of these time points, we will ask you to return to Children's Hospital Colorado, Colorado State University, the Uniformed Services University, or Children's National Medical Center.

At both the **6-week follow-up** and the **1-year follow-up visits**, we will ask you to repeat the body measurements, surveys and interviews, blood drawing, lunch meal, snacks taste test, and the speech and math tasks. The medical history will be updated at both follow-up visits, but we will only repeat the physical puberty examination at the 1-year appointment, unless there is a health concern earlier. At both the 6-week and 1-year follow-up periods, we will ask you to repeat the **home activities**, meaning to re-wear the activity belt device and to collect saliva (spit) at home. If it is indicated, the interviews and surveys also can be completed from home, using secure, remote video conferencing or phone.

What are the possible discomforts or risks?

1. **Blood drawing**. A hollow needle/plastic tube will be placed in your arm for taking blood samples. The total amount of blood that will be taken is no more than 3 tablespoons. If you choose to have an IV, it will be left in for about 2 hours. When the needle goes into a vein, it hurts for a short time. Also, there may be a minor discomfort of having the plastic tube taped to your arm. In about 1 in 10 cases, a small amount of bleeding under the skin will produce a bruise. The risk of a small blood clot forming in the vein is about 1 in 100, while the risk of infection or significant blood loss is 1 in 1000. The risk of fainting is very small.
2. **Fasting**. You will not be able to have anything to eat or drink, other than water, the night before the second screening visit and the night before both of the two follow-up visits after the group program, including the morning of those appointments. You may feel hungry or cranky until you are able to eat, after the blood test is done.
3. **Body measurements**. The body measurements used in this study have no known risk. The measurement of body fat by the Bod Pod takes about 15 minutes total, and it is not associated with any discomfort, other than the inconvenience of being in underwear or a bathing suit while the measurements are taken.
4. **Physical examination**. A medical provider will examine you briefly with your clothes off. Measures will be taken to protect your privacy, but some adolescents may find this examination embarrassing.
5. **Activity belt devices**. There is no known risk to wearing the accelerometers or activity belt devices. Wearing the device may feel inconvenient. You can remove it when you are doing water-based activities like swimming or showering.
6. **Saliva**. Saliva samples may be inconvenient but entail no risk.
7. **Surveys and interviews**. Filling out surveys and answering interview questions involve no risk, but some individuals may feel uncomfortable being asked how they feel about themselves. You do not have to answer any question that makes you feel uncomfortable. Just let the researcher know that you'd like to skip that question.
8. **Speech and math tasks**. Completing the speech task and math problem may cause some temporary emotional stress. Typically, this stress does not last long. However, if there is evidence of severe distress, you will be referred for a consultation with a mental health professional and referred for outside treatment as recommended. During these tasks, we will measure your blood pressure and heart rate. The type of stress experienced is similar to what you might experience in daily life (for example, taking a test or having your blood pressure measured at the doctor's office).
9. **Group program sessions and focus group**. Some adolescents may feel uncomfortable talking about personal information during the program sessions or sharing their thoughts and feelings during the focus group, but you only have to share if you are comfortable doing so.

What are the possible benefits of the study?

This study is designed for the researchers to learn if it is feasible and acceptable for adolescents at risk for type 2 diabetes, in different parts of the U.S. (Colorado, Maryland, Washington, D.C.), to take part in mindfulness or cognitive-behavioral group programs that could improve mood, lessen stress, and improve insulin resistance, or whether taking part in a health education program is just as helpful.

Possible benefits from participating in this study include: (i) improvement in insulin resistance, (ii) reduction in the risk of developing type 2 diabetes, (iii) improvement in mood, and/or (iv) increased knowledge with regard to leading a healthier life. However, we do not know how well the group programs work to improve insulin resistance. Therefore, it is possible that there will be no direct benefit to you or the benefit(s) may be only temporary.

Are there alternative treatments?

There may be other ways of intervening to help you decrease your risk of developing type 2 diabetes. These other ways include nutrition education, weight or lifestyle management, or psychotherapy that could help you improve your mood and/or improve insulin resistance. You could also choose to get no interventions at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being paid for by a grant from the National Center for Complementary and Integrative Health and the Office of the Director of the National Institutes of Health.

Will I be paid for being in the study?

If you leave the study early, or we have to take you out of the study, you will be paid only for the parts that you completed. If you decide that you want to stop doing a part of the study at any time, you will be reimbursed for the visits you complete.

This study provides payment to adolescents for participation. In order to meet requirements of the Internal Revenue Service (IRS), we must report these payments as income. You will be asked to provide your social security or tax identification number to meet these IRS regulations. Colorado State University requires an additional form to receive payments for participating. If you are participating at Colorado State University, you will be asked to complete this additional form. Children's Hospital Colorado uses a debit card payment system. Each time you complete the requirements for payment, the cash value will be loaded onto the card. We are required to keep a record of your payments.

You will be paid for taking part in the study, as follows:

Timeline/Order of Research Intervals for Each Participant	Amount
Screening/baseline visits	$150
Baseline saliva/spit (2 collection days)	$24 ($12 per day)
Baseline activity belt (7 collection days)	$35 ($5 per day)
Group bonus incentive (5 or more group sessions)	$50
Follow-up focus group (about 1 week after program ends)	$25
6-week follow-up visit	$150
6-week follow-up saliva/spit (2 collection days)	$24 ($12 per day)
6-week follow-up activity belt (7 collection days)	$35 ($5 per day)
1-year follow-up visit	$150
1-year follow-up saliva/spit (2 collection days)	$24 ($12 per day)
1-year follow-up activity belt (7 collection days)	$35 ($5 per day)
Total Possible Per Participant	**$702**

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

Your participation in this study may be stopped by the investigators at any time, with or without your consent. For example, if you develop a medical or psychiatric problem that requires treatment, you will be referred for treatment and might not continue in the study.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call your doctor immediately. The Children's Hospital Colorado, Colorado State University, Uniformed Services University, and Children's National have no plan to pay for a physical or psychological injury. If you are injured or hurt during this study, you may call Dr. Lauren Shomaker at (970) 491-3217. We will arrange for to get you medical care if you have an injury that is caused by this research or if any conditions are discovered, physical or mental health, that require additional health care of follow-up. You or your insurance company will have to pay for that care.

Who do I call if I have questions?

The primary researcher carrying out this study is Dr. Lauren Shomaker at Colorado State University. Dr. Megan Kelsey at Children's Hospital Colorado, Dr. Marian Tanofsky-Kraff at the Uniformed Services University, and Dr. Eleanor Mackey at the Children's National Medical Center are also carrying out this research.

You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call:

Colorado State University: Dr. Lauren Shomaker at (970) 491-3217 or write to her at: 1570 Campus Delivery, Fort Collins, CO 80523.

Children's Hospital Colorado: Dr. Megan Kelsey at (720) 777-0991 or write to her at: 13123 East 16th Ave, B265, Aurora, CO 80045.

Uniformed Services University: Dr. Marian Tanofsky-Kraff at (301) 295-1482 or write to her at: 4301 Jones Bridge Road, Bethesda, MD 20814.

Children's National Medical Center: Dr. Eleanor Mackey at (202) 476-5307 or write to her at: 111 Michigan Avenue NW, Washington, D.C., 20010.

You will be given a copy of this form to keep. You can also call the research coordinator team for all of the sites **at (970) 413-4410**, with questions.

You may have questions about your rights as someone in this study. You can call any of the researchers listed above with questions. You can also call the **Colorado Multiple Institutional Review Board at (303) 724-1055**.

Who will see my research information?

The universities and hospital(s) that are part of this study have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Anschutz Medical Campus
- Children's Hospital Colorado
- Colorado State University
- Uniformed Services University of the Health Sciences
- Children's National Medical Center

The Children's Hospital Colorado and Children's National Medical Center share a medical record system with other healthcare systems; therefore it is also possible that your information could be viewed by healthcare professionals outside of these specific organizations.

We cannot do this study without your permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not join this study. We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside of University of Colorado Anschutz, Children's Hospital Colorado, Colorado State University, the Uniformed Services University of the Health Sciences, and Children's National Medical Center, and its affiliates may not be covered by this promise. We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's primary investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Lauren B. Shomaker
1570 Campus Delivery
Fort Collins, CO 80523

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the National Center for Complementary and Integrative Health, the National Institutes of Health Office of the Director, the Food and Drug Administration and the Office of Human Research Protections that protect research subjects
- People at the Colorado Multiple Institutional Review Board
- The study primary investigator and the rest of the study team
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- The financial management teams at each of the institutions may request an audit of research expenditures; for financial audits, only the fact that you participated would be shared, not any research data

It is important for you to know that **some things we cannot keep private:**

- If you give us any information about child or elder abuse or neglect we have to report that to the proper authorities
- We also have to report if you are a danger to yourself or others
- If you report a medical or psychiatric problem that, in the opinion of the investigators, may require treatment, this information may be discussed with your parent or guardian, with or without your consent. You will be referred for treatment and might not continue in the study.

We might talk about this research study at scientific meetings. We might also print the results of this research study in relevant academic or scientific journals. But we will always keep the names of the research participants, like you, private.

You have the right to request access to your personal health information from the investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

The investigator (or staff acting on behalf of the investigator) will also make all or some of the following health information about you available to:

- The research teams at Children's Hospital Colorado, Colorado State University, Uniformed Services University, and Children's National Medical Center involved in running this study
- Your medical providers
- Independent contractors who will be involved in reviewing the fidelity of group interventions
- An independent monitoring committee involved in overseeing data collection and participant safety
- The research organization contracted by the study sponsor to monitor the conduct of all aspects of the study

Information about you that will be seen, collected, used and disclosed in this study:

- Name and demographic information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, psychological testing, procedure results, and so forth
- Body measurements
- Blood drawing laboratory values
- Cortisol and other hormones measured in saliva
- Physical activity measurements
- Psychological surveys and information, including audio-recordings, provided in interviews and group sessions
- Behavioral tasks

What happens to data collected in this study?

Scientists at Colorado State University, Children's Hospital Colorado, the Uniformed Services University, and Children's National Medical Center involved in this study work to find the causes and cures of disease. The data and samples collected from you during this study are important to this study and to future research. If you join this study:

- The data and blood and saliva are given by you to the investigators for this research and so no longer belong to you
- Both the investigators and any sponsor of this research may study your data and samples collected from you
- If data are in a form that identifies you, the institutions involved in this study may use those data for future research **only** with your consent or Institutional Review Board approval
- Any product or idea created by the researchers working on this study will not belong to you
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings. These protections apply only to your research records. The protections do not apply to your medical records. The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research
- If required by Federal, State or local laws
- If necessary for your medical treatment, with your consent
- For other scientific research conducted in compliance with Federal regulation,

- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child or elder abuse or domestic violence, and required communicable disease reporting
- Or, under other circumstances with your consent

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Photography, Video, and Audio Recordings

In this study, we will be video recording during the speech task with a video camera. We will keep this information secure and private. Interviews, group program sessions, and focus groups will be audio-recorded. Recordings will be immediately downloaded after interviews or sessions to each site's secure server, via password protected computers in each laboratory, and recordings on the devices will then be deleted. Recordings will only be used for research and training purposes for carrying out this research study.

Permission to contact for future research

I give my permission for my study staff to contact me in the future to ask me or my family to take part in more research.

_____YES or _____NO _____Initials

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand and authorize the access, use and disclosure of my information as stated in this form. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study. A signed and dated copy of this form will be made available upon request.

Signature: _____ Date: _____

Print Name: _____

Consent form explained by: _____ Date: _____

Print Name: _____ Time: _____: _____AM / PM

Witness Signature: _____ Date: _____

Witness Print Name: _____

Witness of signature x

Witness of consent process x

Signature: _____ Date:_____

(Child Participant 12-17 years old; ***In addition*** to Parent Signature)

Print Name: _____