CONSENT FORM

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Thomas Robinson, Department of Pediatrics, 3145 Porter Drive (MC:5395), Palo Alto, CA 94304; phone: 650-723-5895

CONCISE SUMMARY

This research will test whether adding brief educational activities will improve the success of families participating in pediatric weight management. Weight, height and other health measures will be collected from you and/or your child(ren) before, during and after the program. Your participation is voluntary and we expect minimal risks.

DESCRIPTION

You and your child are invited to participate in a research study of activities to help improve the success of pediatric healthy weight programs. We are enrolling children 10 to 15.9 years of age with a body mass index (BMI) above the 95th percentile and their parents/guardians. You will participate in a six-month, behavioral weight control program that meets weekly in a group of families. Each weekly session lasts about 90 minutes. Children and at least one parent/guardian will participate. It also includes a set of nine brief (about 20 minutes) online activities for you and/or your child that include watching videos, completing writing assignments, or answering questions about your thoughts, feelings, eating, and physical activity. All participating families will receive the same behavioral weight control sessions but you will be randomly assigned (like flipping a coin) to receive one of two versions of the online activities. Both versions take approximately the same amount of time and include similar activities. You and your child will also be asked to complete study measurements with a researcher before starting the program, about 3 months after starting the program, about six months after starting the program, and about twelve months after starting the program (the end of the study). A total of about 200 families with parents/guardians and children will participate in the study.

CHILD MEASURES

At the start of the study and after six and 12 months, we will measure your child's height, weight, waist circumference, triceps skinfold, and give them surveys about how they spend their time, physical activity, screen use, eating, sleep, puberty status, beliefs, moods, and feelings. They will also complete an online survey of everything they ate in a day on three different days and wear a physical activity monitor for 7 days. You will be told the results of your child's height and weight measures. After 3 months, your child will complete only the surveys.

ADULT MEASURES

These include your height, weight and surveys about your household food and eating habits, physical activity, screen use, and beliefs and feelings, and your child's medical

diagnoses and medications. At the beginning of the study, we will also ask about your child's primary household composition, your income, education, and race/ethnicity. At follow-up visits, we will ask you whether you or your child had any injuries or illnesses and ask if your child has been diagnosed with any new medical problems or has started taking any new prescription medications.

TIME INVOLVEMENT: Your participation in this study will last about 12 months. Weight control sessions are 90 minutes each, every week for six months. The online activities will be about 20 minutes or less each. The measurement visits, before the start of the program, after 6 months, and after 12 months, are each expected to last approximately 60-90 minutes. Children's eating surveys are expected to take 15-30 minutes each and they will wear the activity monitor for one week each time. The surveys after 3 months are expected to take 30 minutes to complete.

FUTURE USE OF PRIVATE INFORMATION

Research using private information is an important way to try to understand human health and disease. You are being given this information because the investigator wants to save information you provide us in this study for future research. Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

RISKS AND BENEFITS: There are minimal risks associated with this study. It is possible that increasing physical activity may be associated with an increased risk of injuries. You and your child may benefit from this study by engaging in activities that may help your child and family make healthful behavior changes. Other children, families, and the public may also benefit from the scientific knowledge learned from this study. We cannot and do not guarantee or promise that you or your child will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your employment/medical care.

PAYMENTS/COSTS: Your family will receive a gift card for completing surveys after about 3 months ($25 per family) for completing all the measures after about 6 months ($50 per family), and for completing all measures after about 12 months ($100 per family). There is no cost to you for participating in this study. However, depending on your mobile phone carrier and plan, you may be charged for text messages. You may request to receive notifications from us as emails instead of text messages.

PARTICIPANT'S RIGHTS:

If you have read this form and have decided to participate in this project, please understand your and your child's participation is voluntary and you and your child have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

You have the right to refuse to answer any questions or to participate in any part of the study.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as disclosure of names, contact information, birthdates, height, weight and survey answers.

Authorization To Use Your Health Information For Research Purposes

We would like your permission to use information that you and your child provide to assist health research at Stanford University. Because information about you and your child and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

Your and your child's health information will be used to evaluate the effects of brief online educational activities designed to improve outcomes in a pediatric weight control program. The results may be presented or published to scientific and public audiences. Some of the information may be shared with other researchers and the National Institutes of Health. You and your child will not be identified by name.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you and your child will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you and your child decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health

information in this study, you must write to: Dr. Thomas Robinson, Department of Pediatrics, 3145 Porter Drive (MC:5395), Palo Alto, CA 94304.

What Personal Information Will Be Obtained, Used or Disclosed?
Your and your child's health information related to this study, may be used or disclosed in connection with this research study. For example, these include but are not limited to: your and your child's name, phone numbers, addresses, email addresses, birthdates, and measurements of height and weight, waist circumference, triceps skinfold thickness, physical activity monitoring, written and verbal responses, and survey answers.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Thomas Robinson, MD, MPH
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff working on the study

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The U.S. National Institutes of Health
- Your and/or your child's health care providers, if you share their names and contact information with us.
- Other Stanford researchers and collaborators
- Other researchers and collaborators outside of Stanford for scientific purposes, but only after removing your and your child's name and other personal identifiers
- Twilio (your cell phone number to send you text messages and reminders)

Your and your child's information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2099 or when all analysis from the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____
Please enter YOUR name

_____
Please enter YOUR CHILD's name

You are signing as a Legally Authorized Representative (LAR) for this child. Please describe your authority to act for this child:

- ○ Parent
- ○ Guardian
- ○ Conservator

_____ _____
Your signature as a Legally Authorized Representative (LAR) Date

SMS Authorization
This study would like to use your mobile phone number to send you important messages regarding this study, such as links to surveys, appointment reminders, activities or other scheduled data.

Please enter your SMS-enabled mobile phone number: ____ - _____ - _____.

WITHDRAWAL FROM STUDY
The Protocol Director may withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant, you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

SPONSOR: The National Institutes of Health is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury
All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer,

managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital. You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION:
Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Thomas Robinson. You may contact him now or later at 650-723-5895.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Thomas Robinson at (650) 723-5895.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Stanford Healthy Goals Contact: If you need to reach the study staff for any reason, please contact the Stanford Healthy Goals study team at (650) 721-3078 or healthygoals@stanford.edu.

FUTURE STUDIES:
May we also contact you about future studies that may be of interest to you? ____ Yes ____ No

To consent for **YOUR CHILD** to participate, please complete below.

_____
Please enter YOUR name

_____
Please enter YOUR CHILD's name

You are completing this consent as a Legally Authorized Representative (LAR) for this child. Please describe your authority to act for this child:

- ○ Parent
- ○ Guardian
- ○ Conservator

_____ _____

Your signature as a Legally Authorized Representative (LAR) Date

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The IRB determined that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404, in accordance with 45 CFR 46.408(b).

_____ _____

(If available) Signature of Other Parent or Guardian Date

_____

Print Name of Other Parent or Guardian

Authority to Act for Participant

- ○ Parent
- ○ Guardian
- ○ Conservator