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Wake Forest University
School of Medicine

Department/Section of Implementation Science

KIDS POWERUP PILOT AND FEASIBILITY STUDY

Informed Consent Form to Participate in Research
Katherine Sauder, PhD, Principal Investigator

SUMMARY

This is a consent form to participate in a research study for children and a parent. This form tells you about the study. This form also asks for your consent for you (the parent or primary caregiver aged 18 years or older) to participate in the research study. It also asks for your consent for your child to participate in the research study.

You are invited to participate in a research study. The purpose of this research is learn more about how programs promoting either health or science can benefit your child and you. You are invited to be in this study because you live in the Bennett, Colorado area or a rural area in North Carolina. Your participation in this research will involve 2 visits and last about 7 months.

Participation in this study will involve completing two research visits for you and your child involving questionnaires (parent), a physical exam (child and parent), a blood sample (child and parent), and a device measuring activity (child). Between these two visits, you will receive activity kits in the mail for you and your child to complete together. You will either receive 6 kits teaching about science or 16 kits teaching about health. You will also meet every 3-4 weeks with a study team member to talk about the kits. All research studies involve some risks. A risk to this study that you should be aware of is discomfort with the blood sampling. You and/or your child can deny any part of the data collection process. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include talking to your doctor about your child's health. You will not lose any services, benefits, or rights you would normally have if you chose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you have a child aged 7-10 years and live in the Bennett, Colorado area or a rural area in North Carolina . Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to learn more about how programs promoting either health or science can benefit your child and you.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 75 parents and 75 children at this research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If your child joins the study, your child will complete data collection visits at the beginning and end of the study. Depending on your preference and staff availability, you will self-collect these elements with virtual guidance from trained staff, or trained staff will collect them during in-person visits. At these two visits, you and your child will:

1. Complete questionnaires about your family, including education, health and medical history questions. Complete questionnaires about your child's diet and activity. At the second data collection visit, we will ask you questions about your child's experience in the study. At the second visit, we will also ask you to complete the same questionnaires on your diet and activity.

2. Complete a physical exam. We will measure height and weight and measure the amount of vitamins in the skin with a finger scan. The finger scan will shine a light on the finger.

It does not hurt or feel uncomfortable. These measures will be done on your child at the first visit; and both you and your child at the second visit.

3. Obtain a fasting blood sample (no food or drink except water in the prior 8 hours) from your child's arm. We will put a button-shaped plastic device on the upper arm, below the shoulder. This device makes a small cut in the skin of the arm and collects the blood in a tube. We will use this blood sample to measure markers of sugar intake and metabolism. We may need to use two devices to collect enough blood for these tests. The total amount of blood drawn with each device is about ¼ of a teaspoon. These blood samples will be taken from your child at the first visit, and from both you and your child at the second visit. You do not need to fast for your blood sample at the second visit.

4. Wear an accelerometer. This is a small activity monitor on an elastic band that is worn around the wrist for 7 days to record their activity. This monitor will be worn by your child at the first visit. At the second visit, both you and your child will wear monitors.

After the first data collection visit, you will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

The science group will receive 6 activity kits teaching about science. The kits will be mailed to the home every month for 6 months. This group will also meet with a study team member up to 6 times to talk about the kits. These meetings will be by phone or text.

The health group will receive 16 activity kits teaching about physical health. The kits will be mailed to the home every 1-2 weeks for 6 months. This group will also meet with a study team member up to 9 times to talk about the kits and health goals. These meetings can be in person or online (like Zoom).

As part of this research study, you may be audio-recorded during the phone calls with the staff or at the end of the study when we ask you about your experience. This is being done to make sure staff are following procedures correctly, and to understand how you felt about the program and the kits you received. These recordings will be considered Protected Health Information if they contain information that identifies you. You understand that you may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the recording before it is used, but doing so may affect your eligibility to remain in the research study. You should also understand that you will not be able to inspect, review, or approve the recordings or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the recording used in this research study:

_____ I would like the recordings of me to be destroyed once their use in this study is finished. I understand that destroying the recordings at the end of this study will not affect any prior use of the recordings.

____ The recordings of me can be kept for use in future studies provided they are kept secure, and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

How Long Will I Be in the Study?

You will be in the study for about 7 months.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first. If you stop participating in the study, you will not receive any more kits in the mail, phone calls from the staff, or complete the research visits.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the study include:

- Discomfort or pain during the blood collection. The risks of blood sampling include psychological discomfort, mild pain, lightheadedness, soreness, bruising and infection at the site of the sampling. All these risks are extremely rare.
- Sharing private information about your family may be uncomfortable.
- Your child may be hungry at the data collection visits because they are asked to fast for 8 hours prior to the visit.
- There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be learning about science or physical health with your child.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you have the option of not participating in this study.

WHAT ARE THE COSTS?

All study costs, including any study products or procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

TEXT MESSAGE COMMUNICATION. I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that

I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive up to $200 for participating in this study. This consists of:

- $50 for the first visit
- $25 for the blood sample from your child at the first visit
- $50 for the second visit
- $25 for the blood sample from your child at the second visit
- $50 for the surveys, measurements, and blood sample from you at the second visit

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the American Diabetes Association. The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

- Research visit and research test records
- Blood samples and the resulting data

- Dietary intake data
- Physical activity data

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research (University of Colorado, University of Alaska Fairbanks); central laboratories, reading centers or analysis centers (ExamOne, Quest Diagnostics); the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries; iBIO Institute who makes the science kits.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes, or other recorded media that identify you, unless we have your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire.

You can tell Dr. Sauder that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Katherine Sauder, PhD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

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 Web site at any time.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Wake Forest University
School of Medicine

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Katherine Sauder at [redacted] or [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Printed Name of Minor: _____

Parent's Name (Printed):_____

Parent's Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm