CONSENT to Participate in a

Research STUDY AT Children’s Mercy HOSPITALS

## Sable Indirect Calorimetry Device Validation Study

**SUMMARY** (Details of this information are in the sections below)

We are asking you to be in this research study. Being in a research study is completely voluntary, and your choice will not affect your regular medical care. This research study is done to validate a new convenient and affordable measurement system for resting metabolic rate (RMR), or calories burned at rest, that utilizes a tent. The following things are part of this study: questionnaires, height and weight assessment, DXA scan, and both a hood RMR test and tent RMR test given in a random order. Being in this study will take approximately 2 hours over one study visit. The biggest risks from being in this study are low level radiation from the DXA (less than you would receive on a flight from New York to Los Angeles), loss of confidentiality, and some participants experience a slight feeling of claustrophobia from the hood RMR. There may/may not be direct benefit to being in this study. Instead of being in this study, you can continue to get regular medical care.

##### WHO IS DOING THIS STUDY?

A study team led by Dr. Robin Shook is doing this study. Other health care professionals may help them.

Sable Industries is working with Children’s Mercy Hospitals to do this research study. Some funding for this study comes from the Sable Industries. The study team will not receive any personal payment because of your decision.

We are asking you to be a part of this research study. Please read the information below and ask questions about anything that you do not understand before you make a choice.

## WHY IS THIS STUDY BEING DONE?

Resting metabolic rate (RMR) plays an important role in health. Testing RMR reliably and validly is a valuable tool for health researchers. The purpose of this research study is to validate a new system that is more affordable and convenient for researchers to measure RMR in adolescents and young adults.

##### WHO CAN BE IN THIS STUDY?

We are asking your child to be a part of this research study because he or she is a healthy volunteer between the ages of 13 and 17 years old, with a body mass index between the 5th and 95th percentile.

Up to 60 children and adults will be in this study. Up to 60 children and adults, ages 13 through 18, will be asked to be in this study at Children’s Mercy Hospitals.

## WHAT WILL HAPPEN TO ME IN THIS STUDY?

Being in this study involves one visit to the Don Chisholm Center where the study team will go over Informed Consent, ask you some questions, assess your height and weight, complete a DXA, and then do both a hood and tent RMR in randomized order. If you agree to be in this study, your participation will last for approximately 2 hours.

If you decide to be in this study, the following things will happen:

* We will ask you questions about your medical history, health, and the medicines you are taking to see if you can be in the study. Your medical records may be reviewed to assess your health.
* You will be asked to complete some questionnaires on a computer. These questionnaires will take about 10 minutes to complete. You will be asked about: demographic information, physical activity level, academic grade level, and last menstrual cycle (females only).
* Your height and weight will be measured.
* Body Scan to evaluate your body composition and amount of fat. This is called a DXA scan (dual energy x-ray absorptiometry scan) and it is a type of X-ray scan used to measure body composition (lean body mass and fat composition). DXA is a non-invasive procedure that involves approximately 1/3 the radiation in a normal chest X-ray and less than you would receive in a flight from New York to Los Angeles. During the scan, you will be asked to lie on a table. A detector will be slowly passed over his body. The entire procedure should take approximately 10 – 20 minutes. This measurement will occur while you are wearing hospital scrubs and bare feet. If you are a female a urine pregnancy test will be done prior to the scan as a standard safety precaution.
* Two Resting Metabolic Rate (RMR) tests, where we measure the amount of oxygen your child uses for 30 minutes while he/she is lying down. Your child will lie down on a bed and a canopy will be placed over the head to measure the amount of air that is breathed in and out. The canopy has a hole in it to allow for your child to breathe in normal room air during the entire test. Your child will also lay down in a standard camping tent on a cot to measure the amount of air that is breathed in and out. The tent has a hole in it to allow for your child to breathe in normal room air during the entire test. These two RMR tests will be randomized in their order.
* Information collected for this study will be shared with Sable Industries.
* You will be given the results of the testing done for this research study. These tests include the results of your DXA scan and RMR tests.

Optional Future Research Contact:

* You will be asked whether we may contact you in the future about taking part in future research studies related to your disease or condition. Your decision will not affect your ability to be in this research study and will not affect your routine care. If you decide to allow us to contact you in the future for other research opportunities, we will keep your name, phone number, and your medical record number in a separate Research Registry. You will be able to mark your choice at the end of this form.

**WHAT ARE THE RISKS** **OF THE STUDY?**

There are certain risks in this study. These risks may include:

* While the radiation used for the body scan (DXA scan) has no observable radiological or biological effect, there is always a risk associated with radiation exposure.
* We do not know what effect the DXA might have on a pregnant woman, an unborn baby, or a breastfeeding baby. Women of childbearing potential will be tested for pregnancy prior to a DXA scan.
* There is a slight risk of loss of confidentiality. Your confidentiality will be protected to the greatest extent possible.
* There also is a risk to confidentiality when using the internet. By providing your email, the study team may communicate with you regarding setting up appointments, sending copies of permission/assent forms and any other non-clinical, study related communication. Please be aware of the following:
* Corresponding through email is not a secure method of sending information and others may be able to access the information sent.
* The information may not be secure if storing or viewing the permission/assent document on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena.
* Information that is sent through e-mail may be kept on the Hospital's or your service provider's (Google,

Yahoo, MSN, etc) network servers. Unlike paper copies, e-copies delivered directly to your PED may not be able to be permanently removed.

* The Hospital is not liable for any security breaches of your information sent by email.

If you have any of these problems or changes in the way you feels, you should tell the investigator or other study personnel as soon as possible.

There may be risks we don’t know about right now. We will tell you about any new information that might change your decision to stay in the study.

## WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

There may be no direct benefit to you from being in this research study. By being in this study, you may help researchers find better treatments for children and adults with determining the accuracy of an affordable and convenient alternative for assessing RMR in the future.

##### WHAT ABOUT EXTRA COSTS?

There is no cost to you for participating in this study. Basic expenses such as transportation and the personal time it will take to come to all of the study visits will be your responsibility.

# WHAT ABOUT CONFIDENTIALITY?

You have rights regarding the privacy and confidentiality of your health information. When health information includes identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers) that link it directly to an individual, it is called protected health information (PHI). Federal laws require that PHI be kept secure and private. In certain situations, federal law also requires that you approve how your PHI is used or disclosed. A research study is one of those situations.

By signing this consent form, you are permitting the following people to have access to your medical record and use your PHI for the research purposes described in this form. You are also permitting your PHI to be shared with everyone listed below:

* The research team, which includes persons involved in this study at Children’s Mercy Hospitals;
* Sable Industries and the people or groups hired to help perform this study;
* The Institutional Review Board at Children’s Mercy Hospitals
* Other researchers, hospitals, and institutions that are part of this study and their Institutional Review Boards;
* People from organizations that provide independent accreditation and oversight of hospitals and research;
* Government/regulatory agencies (both US and international), such as the Office for Human Research Protections, whose job it is to protect human subjects and oversee the conduct of research; and

The research record is separate from your medical record. Information about you that is obtained during this study will be recorded in a research record and may also be recorded in your medical record. A research record will be created and kept in the Don Chisholm Center Energy Balance research office. The research record may include documents that have your name, assigned study ID number, home street address, telephone number, medical record number, hospital account number, social security or individual taxpayer identification (ITIN) number (as required for payment), date of birth, dates of service, email address. All research records will be maintained in a confidential manner.

Additionally, information to include your name, address, date of birth and social security number will be collected from you for the purpose of compensating you for study participation. This information will remain on the Greenphire secure server 7 years after study closure and then will be destroyed. This information is needed for tax purposes related to compensation only.

Portions of that research medical record will be sent to Sable Industries. This information sent to Sable Industries will include your assigned study ID number, date of birth, dates of measurement.

By signing this consent form, you are allowing your health information to be recorded in the research record. You are also permitting your research record and medical record to be shared with everyone listed above.

Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. We will share your health information only when we must, will only share the information that is needed, and will ask anyone who receives it from us to protect your privacy. However, once your information is shared outside of CMH we cannot promise that it will remain private.

You may choose not to sign this consent form and not be in the study.  You may cancel your permission to use and share your PHI at any time by contacting the study personnel listed on this form.  You may also contact Children’s Mercy Hospitals Health Information Management (HIM) in writing.  If you cancel your permission, you may no longer participate in this study. Your PHI that has already been collected for the study may still be used; however, no new information will be collected except information related to adverse events or other safety issues.

If you do not cancel your permission, your PHI may continue to be recorded until the entire study is finished. This may take years. Any study information recorded in your medical record will be kept forever. Unless stated elsewhere in this form, you may not have access to your research record or research test results.

Results of this study may be made public. If made public, you will not be identified in any publications or presentations.

##### WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?

Instead of being in this study, you may choose not to be in the study.

###### WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?

You will receive $50 payable as a cash or gift card upon completion of the study.  Maximum compensation for participating in the study is $50.

If you do not complete the study, you will be compensated for the visits that were completed.  You will not be compensated for any unscheduled visits*.*

If the total value of payments to you from Children’s Mercy Hospitals totals more than $600 in any calendar year, the hospital must report this to the IRS on a Form 1099 with the recipient’s social security number (SSN) or individual tax identification number (ITIN).  You will receive a copy of this tax form.  Accepting payments for taking part in the study may affect eligibility for Medicaid or other programs.

Children’s Mercy Hospitals can only make payments if we have your SSN or ITIN Number, name, address, and date of birth.  If you do not provide this information, you can still participate in the research study; however, you will not receive payments. Your SSN or ITIN Number will be maintained in a secure manner.

##### WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. You do not have to be in this study to receive medical care. If you choose not to be in this study or withdraw from this study, there will be no penalty or loss of benefits to which you are otherwise entitled.

We will inform you of any new information that we find out during this study. This information may affect your decision to stay in the study. If you choose to withdraw from (quit) the study or if you are asked by your personal doctor to withdraw from the study, you must tell the study team as soon as possible.

If you withdraw from the study early for any reason, the information that already has been collected will be kept in the research study and included in the data analysis/ de-identified and cannot be traced back to you. No further information will be collected for the study.

Dr. Robin Shook the Sable Industries, the Institutional Review Board or the FDAmay stop the study at any time. The investigator(s), your doctor, or Sable Industries may remove you from the study at any time without your permission.

##### WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Robin Shook is in charge of this research study. You may call Dr. Shook at 816-234-9443 with questions at any time during the study. You may also call Kelli Snow, the study coordinator, at 816-234-9322 with any questions you may have.

You should call Dr. Shook if you believe that you are sicker or have suffered injury of any kind as a result of being in this research study.

You may also call Children’s Mercy Hospitals’ Pediatric Institutional Review Board (IRB) at (816) 701-4358 with questions or complaints about this study. The IRB is a committee of physicians, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

## SPONSOR AND INSTITUTIONAL RESPONSIBILITIES

In the case of illness or injury resulting from this study, treatment is available at Children’s Mercy Hospitals, but will be provided at the usual charge.  Payment for this treatment will be your responsibility. The hospital may not bill insurance or other third party payers for this care. Children’s Mercy Hospitals does not have funds set aside to pay research participants if the research results in injury. By signing this form, you are not giving up any legal rights to seek compensation for injury.

**CONSENT OF SUBJECT**

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. I consent to be in this research study. A copy of this signed form will be given to me.

**Optional Future Research Contact:**

Please only complete if you want your child’s name to be added to the Research Registry.

My/My child’s name may be added to the Center for Children’s Healthy Lifestyles and Nutrition’s research registry so that I might be contacted in the future if I am eligible for a future study.

\_\_\_\_\_ Initials

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_

Signature of Adult Date

##### STUDY PERSONNEL

I have explained the purposes, procedures, and risks involved in this study in detail to:

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Print name(s) of Subject

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Signature of Person Obtaining Consent Date Time

Print Name of Person Obtaining Consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_