Parental Permission and Child Assent to Participate in a

Research STUDY AT The Children’s Mercy HospitalS

**The Brain, Appetite, Teens, and Exercise (Bate)**

##### WHO IS DOING THIS STUDY?

A study team at Children’s Mercy Hospital and the University of Kansas Medical Center (KUMC) led by Dr. Robin Shook is doing this study. Other health care professionals may help them.

Funding for this study comes from the Marion Merrell Dow Clinical Scholars Award. The study team will not receive any personal payment because of your decision.

We are asking your child 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 decision.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand what happens when adolescents are more or less physically active. This study will measure your child's energy intake, energy expenditure, and body composition.

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

We are asking your child to be part of this research study because he is a healthy, adolescentage 14-17 years old. Up to 40 adolescents will be asked to be part of this study at the Children’s Mercy Hospital and KUMC.

## WHAT WILL HAPPEN TO MY CHILD IN THIS STUDY?

Being in this study involves taking part in an orientation session followed by three initial assessment sessions (a total of 9 hours). Assessment sessions will take place at Children's Mercy Hospital and at KUMC. Your child will also be asked to complete additional activities at home in between sessions 1 and 2 and between sessions 2 and 3. After the initial assessment sessions your child will be randomly assigned to receive a newsletter, which will contain parenting tips, activities, and recipes associated with healthy living and the prevention of Type II diabetes, or they will be assigned to an exercise intervention group in addition to the newsletter). You or your child’s doctor cannot decide which group your child will be assigned to. Your child should take part in this study only if you agree that your child will be in any of the study groups. The exercise intervention will be an organized program that meets approximately 3 days a week to achieve around 180min/week of moderate-intensity exercise. Your child will receive the newsletter or participate in the exercise group for 3 months after the initial assessment sessions, and then they will do a final assessment session that is identical to the first. The study team will collect information from your child’s medical record as a part of this study. If you agree for your child to be in this study, he/she will be in the study for about 4 months.

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

Visit 1: Orientation

This session will take place at the Don Chisholm Center at Children's Mercy, and will last about 1 hour.

* Your child’s height, weight, and blood pressure will be measured.
* You will be asked to complete an online questionnaire about your child's medical history, including a standard self-assessment of their puberty stage, which will take approximately 30 minutes.

Visit 2: Measurement Session

This session will take place in the morning at the Don Chisholm Center at Children's Mercy, and will last about 6 hours. Your child will be asked to stop eating and drinking (except for water) for 12 hours before coming for the visit. These things will happen during the 1st measurement visit:

* Body Scan to evaluate your child's 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, your child 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 your child is wearing hospital scrubs and bare feet. If your child is female a urine pregnancy test will be done prior to the scan as a standard safety precaution.
* Resting Metabolic Rate where we measure the amount of oxygen your child uses for 45 minutes while he 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.
* Meals will be provided. The first meal will be at breakfast. The second meal will be provided 3 hours later and your child can eat as much as he likes.
* Prior to and after the meals, your child will be asked to complete short questionnaires that ask them about his hunger and how full they feel.
* Blood draws to determine blood fats and hormones. Your child will give a blood sample 8 times (two samples before the first meal, at 15 minutes, 45 minutes, 60 minutes, 90 minutes, 120 minutes, and 180 minutes after the meal). To avoid multiple sticks with a needle, a small peripheral venous catheter (IV) will be placed by a nurse. The catheter is a needle stuck once into the arm and is taped to the skin. This allows for multiple blood draws with only 1 needle stick.

Home Assessments

Your child will be asked to complete these assessments at home. The home assessment includes approximately 90 minutes of involvement over a period lasts for 14 days.

* Complete random 24-hour dietary recalls. Someone from the study team will call your child and ask him to report everything he has eaten in the previous 24 hours. Your child will be asked to complete 3 random recalls during the 14 day period. Each recall will take about 30 minutes (90 minutes total).
	+ Your child will specify the time of day during which they would like to receive calls from the dietician (e.g. after school). If a participant cannot answer the phone when a dietician calls, the dietician will attempt the call at a later time. Up to three attempts will be made.
* Wear a small monitor on the upper leg, and a monitor on the wrist, all of which track your child's physical activity. These monitors cannot tell us where your child is at or what your child doing. It only tells us what your child's physical activity level is. Your child will be asked to wear the monitors for 14 days while awake and sleeping.

Visit 3: Physical Activity Session

This session will take place at the Don Chisholm Center at Children's Mercy, and will last about 2 hours. These things will happen during the visit:

* Complete a DXA scan using the same process as Session 1.
* Your child will be asked to participate in a fitness test where he walks/jogs on a treadmill. This test will take 20-30 minutes and will involve exercising at increasing levels of intensity, until your child reaches maximal effort. Your child will wear a blood pressure cuff and a mask to measure heart rate, blood pressure, and breathing throughout the entire test.
* Your child will perform a grip strength test.
* You child will complete questionnaires related to decision-making.

Visit 4: Brain Imaging Session

This session will take place at the Hoglund Brain Imaging Center and KUMC, and will last about 2 hours. These things will happen during the visit:

* Your child will be asked to take a computer-based questionnaire that asks him to rate food and activity items. Food and activity items will be rated by preference, liking, taste, and/ or health value. This questionnaire will take about 30 minutes.
* Your child will then undergo a magnetic resonance imaging (fMRI) test. The fMRI examines how water molecules in the brain behave in a strong magnetic field. The fMRI gives a detailed picture of what the brain looks like, and can also provide information on blood flow, metabolism, and function of the brain. This method is considered to be non-invasive and is commonly used in routine tests of brain structure and function.
* While in the fMRI, your child will complete a computer task. Your child will see pictures of food and activities on the screen, and will rate both foods and activities by preference. This test will measure how the brain responds to making decisions about food. This will take approximately 75 minutes.

Once your child has completed their initial assessment sessions and has been randomized into the newsletter or newsletter + exercise intervention group they will either receive a monthly newsletter containing parenting tips, activities, and recipes, or they will attending a 3x weekly exercise intervention program at the Don Chisholm Center where they will participate in structured exercise (such as treadmill walking or cycling on a stationary bike) with the goal of completing approximately 180min/week of moderate intensity exercise. The actual prescribed dose of exercise for your child may vary, and will be calculated using their body weight. All supervised exercise will occur at the Don Chisholm Center with heart rate, treadmill speed and grade, or cycle ergometer wattage monitored by an exercise specialist every five minutes. We will monitor compliance of the prescribed exercise dose weekly, and if your child is failing to complete at least 90% of their program they will be excluded.

After the three-month newsletter or newsletter + exercise program your child will complete another round of assessment sessions described just as above (without the orientation session), including a measurement session, physical activity session, home assessments, and brain imaging session.



Your child may be excluded from participation in the brain imaging session if they wear braces, but they may still participate in the study.

At the end of the study you will also receive a personalized report and a counseling session with study staff to discuss the results from the measures/tests your child took part in during the study (blood pressure, cholesterol levels, body fat, etc.).

Your child’s samples will be used only for research and will not be sold. Your child’s samples will only be used for research related to this study. You should know that research sometimes results in discoveries that may one day have commercial value. For example, discoveries could eventually lead to new tests, drugs, or other products. Development of new products relies on the study of samples from hundreds or thousands of people, not on any one person. If this happens, neither you nor your child would share in any financial recovery. You and your child will not receive money or other compensation for use of these samples. You will not be informed about future use or results.

When your child reaches adulthood (18 years of age), we will contact him to find out if he wants to give consent for continued participation in this study and/or use of the information and samples. If your child cannot be reached or chooses not to consent, the link between your child’s identifiable information and sample will be destroyed. No identifiable information will be saved. The de-identified physical information will be stored in locked file cabinets and only approved study staff will have access. Electronic documents will be stored on a secure, password protected, hospital server. Blood samples will be kept in the secured biochem lab in the Don Chisholm building

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

While participating in this study your child may experience the following risks or discomforts:

* Risks of drawing blood from your child’s arm include discomfort and/or bruising. There is a very low risk of infection, bleeding, clotting, or fainting.
* Wearing activity monitors poses no known risks. However, your child may feel some discomfort while initially getting used to wearing the monitors. In addition, a small percent of participants have developed a rash associated with the adhesive from the leg activity monitor. If your child experiences any irritation, itching or redness while wearing either monitor, have your child stop wearing the monitor immediately and inform the study staff.
* 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.
* During the fitness test your child will experience an increase in heart rate and blood pressure. Additionally, sweating will occur, and your child may become fatigued, all of which are to be expected with exercise. It is also possible that abnormal responses may occur such as dizziness, unusually high increases in heart rate and blood pressure, and in rare instances, fainting. Trained personnel will be on hand during the fitness test. Emergency equipment is kept in the exercise testing room and all staff have been trained in its use. Following the fitness test, your child may experience muscle soreness for a few days.
* During the study your child will be asked to eat two meals. Please let us know if your child has any food allergies.
* fMRI scanning in general is not associated with any health risks, but it is important that you complete the metal screening form accurately prior to the evaluation. If your child has any internal metal, your child may not be allowed to participate in this study. Some subjects get a feeling of mild claustrophobia during MRI. The MRI unit makes loud noises during the examination. To minimize any possible discomfort from these noises, you and your child will be given earplugs and ear phones. *Whenever a fMRI is done, there is a chance of finding something unexpected and unrelated to the research study that may have some clinical implications. Unexpected findings can have a clear or uncertain clinical significance to your child. Clear clinical significance means that the fMRI shows a problem that may be treatable and we have an understanding of the risks of not treating the problem. Uncertain clinical findings are when the fMRI shows something unusual but we do not know if it might affect the health of your child or treatment may not be available or possible. On this study, you will be informed of any findings of clear clinical significance discovered during the research, but you will not be told of findings of uncertain clinical significance. To help us decide if the findings are of clinical significance to your child, we may review your child’s medical record. If such findings are found, KUMC/CMH staff may contact you by telephone to recommend a visit for you or your child.*
* There is also a slight risk of loss of confidentiality, meaning that someone could know that your child participated in this study if our research records are hacked. Your child’s confidentiality will be protected to the greatest extent possible. Children’s Mercy takes great precaution to maintain the security of their data (more information below).
* There also is a risk to confidentiality when using the internet. By providing your email address and/or text information, 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/text 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/text 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/text.

If your child has any of these problems or changes in the way he 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 keep your child in the study.

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

If you decide for your child to participate in this study, there may be no direct benefit to your child. It is hoped that the information gained in this study will benefit society by understanding what happens when adolescents are more or less active.

##### WHAT ABOUT EXTRA COSTS?

Participation in this study will not result in any extra costs to your child. 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 WILL I OR MY CHILD RECEIVE FOR BEING IN THIS STUDY?

You or your child will receive a total of $250 for participating in the study. Payment of $50 will be issued upon completion of the initial Brian Imaging Session, another $25 at the midpoint of the exercise/newsletter intervention, $75 at the completion of the exercise/newsletter intervention, and the remaining $100 will be issued upon completion of the second Brain Imaging Session. All payments will be electronically loaded onto a CMH Greenphire MasterCard Clincard.

You or your child will receive T-shirts and exercise towels, if randomized to the exercise intervention, valued at <$10.

If the total value of payments/gifts provided to you/your child 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 payment for taking part in the study may affect eligibility for Medicaid or other programs.

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

# WHAT ABOUT CONFIDENTIALITY?

Your child has rights regarding the privacy and confidentiality of his or her 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 child’s PHI is used or disclosed. A research study is one of those situations.

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

* The research team, which includes the study personnel at Children’s Mercy Hospital and the University of Kansas Medical Center (KUMC)
* The Institutional Review Board at The Children’s Mercy Hospitals
* 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;

The research record is separate from your child’s medical record. Information about your child that is obtained during this study will be recorded in a research record and may also be recorded in your child’s medical record. A research record will be created and kept in the Don Chisholm research office. The research record may include documents that have your child’s name, date of birth, date of service, medical record number, account number, social security number, telephone number, email address, and street address. All research records will be maintained in a confidential manner.

Additionally, information to include your child’s name, address, date of birth and social security number will be collected from you for the purpose of compensating your child for study participation. This information will remain indefinitely on Children’s Mercy Hospitals’ secured server. This information is needed for compensation only.

There will be a separate database that will be used to analyze the study information and find out the study results. Information in this database will include a generic study ID number and your child’s physical activity levels, age, and gender.

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

Some people or groups, such as government oversight agencies, who get your child’s identifiable health information might not have to follow the same privacy rules that we follow. We will share your child’s 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 child’s privacy. However, once your child’s information is shared outside of CMH or KUMC, we cannot promise that it will remain private.

You may choose not to sign this permission/assent form and not have your child be in the study.  You may cancel your permission to use and share your child’s 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, or the KUMC IRB, University of Kansas Medical Center 3901 Rainbow Boulevard, Kansas City, KS 66160, in writing. If you cancel your permission, your child may no longer participate in this study. Your child’s 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 child’s PHI may continue to be recorded until the entire study is finished. This may take years. Any study information recorded in your child’s medical record will be kept forever. Unless stated elsewhere in this form, you may not have access to your child’s research record or research test results.

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

Missouri law, a competent minor (less than 18 years old) may consent to his or her own diagnosis or treatment without parental permission for pregnancy (but not abortion), drug or substance abuse, and venereal disease. Negative test results cannot be released to a parent or guardian without the minor’s permission. Positive test results can be discussed with the parent or guardian. Because pregnancy testing is being done as part of this study, this privacy protection is not possible. If participants do not want these test results shared, they should not enroll in the study.

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

Instead of being in this study, you or your child may choose for your child not to participate.

##### WHAT ARE MY CHILD’S RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. Your child does not have to be in this study to receive medical care. If you choose not to have your child participate, there will be no penalty or loss of benefits to which your child is otherwise entitled.

You may withdraw your child from the study at any time without penalty or loss of benefits to which your child is otherwise entitled. We will inform you of any new information that develops during this study. This information may affect your decision to keep your child in the study. If you choose to withdraw your child from the study or if you are asked by your child’s personal doctor to withdraw your child from the study, you must tell the study team as soon as possible.

If you withdraw your child 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. No further information will be collected for the study.

Dr. Robin Shook or the Institutional Review Board may stop the study at any time. The investigator(s) or your child’s doctor may remove your child from the study at any time without your consent.

##### 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. Ms. Amy Papa is the project coordinator of this study and can be reached at 816-234-9230.

You may also call the Children’s Mercy Hospital 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.

Dr. Bruce is in charge of the study at the University of Kansas Medical Center. You may call her at 913-588-7051 with questions at any time during the study.

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

You may also call the University of Kansas Medical Center Human Subjects Committee (HSC) at 913-588-1240 with questions about injury or your child’s rights as a research subject. The HSC is a group of people who review studies to protect the rights of research subjects.

## SPONSOR AND INSTITUTIONAL RESPONSIBILITIES

In the case of illness or injury resulting from this study, treatment is available at The 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. The 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, or your child, are not giving up any legal rights to seek compensation for injury

**PERMISSION OF PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE (LAR)**

Your signature means you agree to the following statements:

* I have had a chance to discuss the study and ask questions. My questions have been answered.
* I understand the purpose, the required procedures, risks and benefits involved if my child participates in the research.
* I understand that my child does not have to be in this study.
* I agree for my child to be in the study.

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Signature of Parent/Legally Authorized Representative Date Relationship to Participant

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

Print name of Parent/LAR

**ASSENT OF MINOR**

Your signature means you agree to the following statements:

* I have been told that I don’t have to be in this research study.
* I can quit the study at any time and no one will be mad at me.
* I agree to be in the study.

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Signature of Participant Date

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Print name of Participant

**STUDY PERSONNEL**

Your signature means you have confirmed that legally effective permission of the parent and assent of the child (when required) has been obtained.

* I have explained the purposes, procedures, and risks involved in this study in detail to the participant and parent/LAR.
* I have answered all questions.
* I attest that, in my judgement, the participant possesses the legal capacity to give informed permission freely.
* I have confirmed the agreement of the participant and obtained their signature documenting that agreement.

Indicate if assent is not obtained for child: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print child name)

\_\_\_ The child **IS** in my opinion capable of assenting to participating in this study.

\_\_\_ The child **IS NOT** capable of assenting because

\_\_ Age (child is less than 7 years old)

\_\_ Limitation in understanding based on child’s condition

\_\_Other, please explain \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature of Person Obtaining Permission/assent Date Time

Print Name of Person Obtaining Permission/assent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**INTERPRETER**

[ ]  Interpreter Used [ ]  Qualified Bilingual Study Staff Used

I was present and provided interpretation services during the signing of this document.

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Signature of Interpreter Date

Printed Name of Interpreter: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Must also sign the translated document)

Relationship of Interpreter to Subject, Father/Mother or Legally Authorized Representative:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_