Northeastern

**Informed Consent Form**

Northeastern University, Department of Psychology

Name of Investigators: Charles Hillman, Ph.D.

Title of Project: Sympathetic nervous system mediation of acute exercise effects on childhood brain and cognition

**Informed Consent to Participate in a Research Study**

We are inviting you and your child to take part in a research study. This form will tell you about the study, but I will explain it to you first. You may ask me any questions that you have. Please ask me to stop at any time and I will take time to explain. When you are ready to decide, you may tell me if you want to participate or not. You do not have to participate if you do not want to. If you decide to participate, I will ask you to sign this statement and will give you a copy to keep for your records.

**Key Information**

- Your consent is being sought for your child's participation in a research project and their participation is voluntary.
- The purpose of this research is to better understand how exercise may influence how children think.
- The anticipated amount of total time of the lab portion of the study is 12 hours. You and your child will be asked to visit the lab on four separate days. The first lab visit will last approximately 2.5 hours; the second, third, and fourth visits will last 3 hours.
- **The procedures that you will be asked to complete include:**
  - Answering a health history and demographics questionnaire, health and questionnaires about your child's development and readiness to exercise.
- **The procedures that your child will be asked to complete include:**
  - **Visit 1:**
    - Answering questions about pictures, their feelings, what they eat and how much they sleep;
    - Playing computer games and completing school activities such as reading, spelling and math;
    - Have their height and weight measured, and complete a body scan; and
    - Participating in a maximal exercise test, which measures their fitness level by having them walk or run on a treadmill at a vigorous pace. During the maximal exercise test, your child's breathing and heart rate will measured by wearing a mask that collects the air that they breathe out and a heart rate monitor that goes around their chest.
  - **Visits 2, 3, and 4**
    - Wearing an EEG (electroencephalogram) cap and a heart rate monitor that measures bodily reactions through non-invasive sensors placed on the head and chest.
    - Provide saliva samples throughout the visit.
    - Playing computer games and completing school activities



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- Exercise on a treadmill, perform a class like speech, or sit quietly; and
- Following the exercise, speech, or rest sessions, your child will again complete similar computerized tasks and complete school activities.

- The possible risks or discomforts of the study are minimal. There is a possibility that during or after participation in any exercise, your child may have an injury to joints or muscles, or have muscle soreness or fatigue. Rest breaks will be incorporated into each study session. In addition, it will be made clear to your child that they can ask for a break or stop at any time.
- There will be no direct benefit to you or your child for taking part in this study.

**Why is my child being asked to take part in this research study?**

We are asking your child to be in this study because they are between the ages of 9-10 years old.

**Why am I being asked to take part in this research study?**

We are asking your child to be in this study because they are a between the ages of 9 and 10 years old.

**Why is this research study being done?**

The purpose of this research is to better understand how exercise may influence the brain.

**What will I be asked to do?**

Today, your child will be asked to complete a questionnaire that measures his/her intelligence. This questionnaire is administered by an experimenter and will ask your child to look at pictures or read words and indicate their meaning. Your child will also complete several questionnaires. In addition, you will be asked to complete a health history and demographics questionnaire, a questionnaire that determines your child's readiness to exercise, and a physical maturation questionnaire. Following the questionnaires about your child, there are a few questionnaires that we will ask you to complete about yourself (ie, the parent) about your health history. Your child will then participate in a maximal exercise test, which measures their fitness level by having them walk/run on a treadmill at a vigorous pace. Your child will be given an orientation to the equipment necessary for the exercise test. S/he will have a chance to practice on the treadmill prior to testing. This test should not last longer than 10 minutes, and will be supervised by a minimum of three people who are certified in Cardiopulmonary Resuscitation (CPR) and First Aid. Then your child will have a DXA scan. This scan is used to measure body composition. This scan takes 10 minutes and simply requires them to lie still on a table. At the conclusion of the first visit, your child will be asked to wear two accelerometers for 7 days. The staff will instruct your child on how to wear the accelerometers.

<u>Visits 2-4</u>

During the next three visits, your child will do the same thing each day, with only one different activity each time. At each visit, they will wear a heart rate monitor so that we can measure the intensity of their activity. We will ask them to provide 4 saliva samples (by drooling into a tube)



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during each visit to measure their sympathetic nervous system. The saliva measures do not have clinical or diagnostic relevance. They will also wear a cap that measures their bodily reactions through sensors placed on their head. The experimenter will explain to your child how the cap will be placed on their head. The cap is painless and harmless. It merely measures the electrical signals naturally produced by the body. Next, they will complete a computer task while wearing the cap. Your child will be asked to press buttons during the computer tasks. Then, s/he will (1) exercise at a moderate-to-hard pace, (2) sit quietly for 25 minutes, or (3) complete a speaking and math test. During the exercise session, we will adjust the incline on the treadmill to keep them at a constant intensity. S/he will have a chance to practice on the treadmill prior to the start of exercise. The exercise session may also involve circuits of exercises (such as jumping jacks, lunges, etc.). Finally, your child will be asked to complete the same computer task again while wearing the cap, as well as an academic test. If at any time your child finds any of these procedures uncomfortable, you are free to discontinue their participation in the study.

Optional Additional Visit

In addition, you can also choose to have your child participate in an optional blood draw. If you and your child decide to participate in the OPTIONAL day, your child will be asked to perform an overnight fast and refrain from eating or drinking for 8-10 hours prior to the morning of testing. Venous blood (~ 3 tablespoons) will be drawn from the antecubital vein by certified nurse. A blood draw will not be attempted more than twice if the first try is unsuccessful. Blood will be assessed to determine various metabolic factors that may related to the brain, including, but not limited to, glucose, lipids (total cholesterol, low-density lipoprotein, high density lipoprotein, and triglycerides), plasma brain-derived neurotrophic factor (BDNF), essential fatty acids, alpha amylase, and cortisol. After the blood draw is completed, you child will be offered a light snack and refreshment.

**Where will this take place and how much of my time will it take?**

This study will take place in the Cognitive & Brain Health Laboratory in the Interdisciplinary Science and Engineering Complex at Northeastern University, located at 805 Columbus Avenue, Boston, MA 02120. If you decide to take part in this study, we will ask you and your child to visit with us on four (or five) different days. You will be here for about two hours on each day. If your child participates in the optional blood draw, this visit will last about 20 minutes.

**Will there be any risk or discomfort to me?**

All procedures, techniques, equipment, and measures to be used in the study are routinely used in educational and research settings involving human subjects. No individual methodological element is new, untested, or of questionable safety for the health and general wellbeing of human subjects.

When individuals who have been sedentary engage in exercise testing, there is a chance of minor injury and likely some discomfort due to the high use of large muscle groups. However, no major injuries are expected. There is a very small chance that sudden death or heart problems can occur





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while exercising. As noted, this is very rare in children and the benefits of exercise outweigh the risks.

During the DXA scan, your child will be exposed to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 3000 μGy each year. The effective dose from the DXA procedure is about 3μGy. At this dose level, no harmful effects of radiation have been documented suggesting the risk is negligible.

Children may feel anxiety or pain during the optional blood draw. Bruising, bleeding, soreness, or in rare instances, fainting or infection may occur as a result of the needle sticks to obtain blood from your child's vein. This risk is minimized by having qualified individuals draw their blood, only collecting as much as is needed for the study, and making sure they are okay after their blood is drawn and before they leave the lab. Risks are further minimized by the use of sterile procedures and equipment at all times. There is also a possibility of dizziness and lightheadedness associated with blood draws. However, your child will be seated or lying down during and immediately following the blood draw, which will reduce the possibility of injury from a fall. Due to having to fast for 10 hours, there is risk of dehydration, fainting, dizziness and weakness. This risk in minimized by drinking of water prior to the blood draw.

It is possible that during the completion of the parent questionnaires, some sensitive and personal questions may arise. You do not have to complete questions that you choose not to answer. If you would like to seek follow up advice regarding these questionnaires, a list of resources is provided below:

National Alliance of Mental Illness Massachusetts (http://namimass.org/resources/children-families)

National Eating Disorders Helpline: info@NationalEatingDisorders.org; 1-800-931-2237

**Will I benefit by being in this research?**

There will be no direct benefit to you for taking part in this study. However, information gained from this study may help scientists to better understand how your brain responds to exercise.

**Who will see the information about me?**

Your part in this study will be confidential. Only researchers on this study will see the information about your child. No reports or publications will occur that can identify you in any way as being part of this project. Confidentiality is assured for all participants regarding any responses and information provided. All data collected will be coded using numbers so that no individual data will be identifiable. To ensure confidentiality and anonymity during the study, each participant will be assigned a subject ID, and participants will be identified by this identification number only. The master list will be kept on the hard drive of a password protected microcomputer. The list will be destroyed when the study has ceased. Signed consent forms and the identity key will be stored separately from each other and from any data in a locked filing cabinet.



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In rare instances, authorized people may request to see research information about you and other people in this study. This is done only to be sure that research is being conducted properly. We would only permit people who are authorized by organizations such as the Northeastern University Institutional Review Board to see this information.

**Future use of data:** Your and your child's de-identified information could be used for future research **without additional informed consent.**

**What will happen if I suffer any harm from this research?**

In the event of physical injury resulting from this research study, immediate medical treatment is available from several health care providers in the area. However, Northeastern University does not provide medical or hospitalization insurance coverage for participants in this research, nor will any special arrangements will be made for compensation or for payment for treatment solely because of your child's participation in this research, except as required by law. If at any time, day or night, you experience adverse physical symptoms, you should immediately contact your personal physician or emergency personnel (i.e., dial 911).

**Can I stop my participation in this study?**

Your participation in this research is completely voluntary. You do not have to participate if you do not want to and you can refuse to answer any question. Even if you begin the study, you may quit at any time. If you do not want to participate or decide to quit, you will not lose any rights, benefits, or services that you would otherwise have.

**Who can I contact if I have questions or problems?**

If you have any questions about this study, please feel free to contact Dr. Lauren Raine (l.raine@northeastern.edu), or the Principal Investigator, Dr. Charles Hillman (617.373.8342, c.hilman@northeastern.edu).

**Who can I contact about my rights as a participant?**

If you have any questions about your rights in this research, you may contact Nan C. Regina, Director, Human Subject Research Protection, Mail Stop: 560-177, 360 Huntington Avenue, Northeastern University, Boston, MA 02115. Tel: 617.373.4588, Email: n.regina@neu.edu. You may call anonymously if you wish.

**Will I be paid for my participation?**

As an incentive, and appreciation for contributing your time to this study, your child will be paid $20/hour for your participation as soon as you complete the study. Your child will be paid an additional $20 if they participate in the optional blood draw. Even if the optional blood draw is unsuccessful, your child will still be compensated for their time and effort. If you decide to withdraw from the study early, your child will be paid for their time, rounded up to the closest half hour.



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**Will it cost me anything to participate?**

Participation in this study is free.

**Is there anything else I need to know?**

No. Do you have any questions?

**I agree to have myself and my child take part in this research.**

_____

**NAME OF CHILD**

_____ _____

Signature of parent/Guardian agreeing to participate Date

_____

Printed name of person above

☐ **I agree to be contacted for follow up or for future research studies**

_____

**Contact Information (email or phone)**

_____ _____

Signature of person who obtained consent Date

_____

Printed name of person above

☐ Online, virtual, verbal consent and assent obtained:

_____ _____

Printed name of person who obtained consent verbal consent Date

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