

**Title of research study:** Neuroplastic Mechanisms Underlying Augmented Neuromuscular Training #2019-0245

**Key Information:**

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

**If you are 18 years and older:** This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

**Parents/Guardians:** You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

**COMBINED Parental Permission/Assent:** If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say “you” in this form, we mean you or your child; “we” means the study doctor and other staff.

We are asking you to be in a research study so that we can learn new information about how the brain works before and after a neuromuscular training program. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

***Reason for the study:***

The main reason for this research study is to learn more about how the brain works before and after an augmented neuromuscular training program. We are asking you and approximately 119 other people who are also participating in the study entitled “Real-time Biofeedback for Injury Prevention Assessed in Virtual Reality”, because we want to find out more about how the brain changes as a result of our training program intervention.

***Investigator:***

Gregory D. Myer,  
PhD

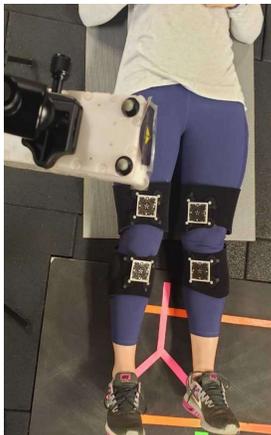
***Contact Info:***

(513) 636-0249

We have successfully developed tasks (see images below) that can help us do this. These tasks will have you move your legs while we use functional magnetic resonance imaging (fMRI) to look at changes in brain activity. We will ask you to flex and extend your knee (top picture) and flex and extend your knee *and* hip against light resistance (bottom two pictures).



We will also be collecting some biomechanics while in the scanner using some markers that are attached to Velcro straps around your thighs and calves (shown in picture below).



These visits will consist of collecting height, weight, and hand/leg dominance information, a series of questionnaires, computer based reaction time tasks, a training session of the tasks, and a brain MRI that will last approximately 3 hours. The MRI-specific portion will take no longer than 1 hour and 30 minutes.

**Procedures:**

The research staff will explain the visits to you and may give you a handout that explains the visit in more detail. You will be able to ask questions to make sure that you understand what will happen. If you qualify and decide to be in the study, you will come to CCHMC twice over approximately the next 6 weeks-4 months.

These are the things that will happen to you while you are in the study:

- Anthropometrics (height, weight, hand/leg dominance)
- Computer based reaction time tasks
- Questionnaires
- MRI Imaging

We expect that you will be in this research study for approximately 6 weeks-4 months.

More detailed information about the study procedures can be found under ***“(Detailed Procedures)”***

**Risks to Participate:**

There are no known negative effects from exposure to the magnet or radio waves used in the MRI at this time; however it is possible that harmful effects could be recognized in the future. The tight space of the MRI may make some people feel uncomfortable. One known risk is that the magnet can attract certain kinds of metal. Therefore, we will have all subjects complete a pre-MRI screening questionnaire. If there is any indication from this questionnaire that the MRI is not safe you will not have the MRI testing. The MRI testing will require you to lie on your back and remain still for the duration of the test, which could last about 90 minutes. Due to the nature of the test, there will be a loud knocking noise that you will hear while the test is being performed. You will be instructed that if at any point during the test you get too uncomfortable, you can signal to the research staff to stop the test immediately.

There is also a minimal risk that the data collected may be viewed by individuals outside the research team. The risk that confidential data may be viewed is relevant for both the written forms and the electronic databases.

*There may be other risks that we do not know about yet.*

<b>COMMON, SOME MAY BE SERIOUS</b>
• Tight space may be uncomfortable

More detailed information about the risks of this study can be found under ***“(Detailed Risks)”***

**Benefits to Participate:**

There are no benefits to you from your taking part in this research. However, possible benefits to others include learning more about neuromuscular training with MRI testing.

**Other Options:**

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive.

Your alternative to participating in this research study is to not participate.

**Cost to Participate:**

Participating in this study will not cost you anything other than time and effort. Your insurance will not be billed for any testing associated with this study.

**Payment:**

If you agree to take part in this research study, we will pay you \$150 (\$50 for completing the pre-training testing and \$100 for completing the post-training testing) for your time and effort. You (your child) will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you (your child) a handout that will explain how to use the card. Because you (your child) are being paid for your participation, Cincinnati Children’s is required by the Internal Revenue Service (IRS) to collect and use your (your child’s) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child’s Social Security number. This form will be given to the Cincinnati Children’s business office. It will not be kept as part of your child’s study chart. If you move, you will need to complete another W-9 with an updated address.

**Additional Study Information:**

The following is more detailed information about this study in addition to the Key Information.

***If I have Questions or would like to know about:***

 Who to talk to...	 You can call ...	 At ...
<ul style="list-style-type: none"> <li>• Emergencies</li> <li>• General study questions</li> <li>• Research-related injuries</li> <li>• Any research concerns or complaints</li> </ul>	<p><b>Principal Investigator:</b></p> <p>Greg Myer</p>	<p>Phone: 513-636-0249</p>
<ul style="list-style-type: none"> <li>• Emergencies</li> </ul>	<p><b>Lead Study Coordinator:</b></p>	

 <b>Who to talk to...</b>	 <b>You can call ...</b>	 <b>At ...</b>
<ul style="list-style-type: none"> <li>• General study questions</li> <li>• Research-related injuries</li> <li>• Any research concerns or complaints</li> </ul>	Kim Barber Foss	Phone: 513-636-5971
<ul style="list-style-type: none"> <li>• Your child's rights as a research participant</li> </ul>	<b>Institutional Review Board</b>  This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

**Total number of participants:**

We expect about 120 people will be in this research study.

**Detailed Procedures:**

Pre-Training Visit	Complete Anthropometrics, Computer reaction time task, and Questionnaires	Complete MRI Scan
Post-Training Visit	Complete Anthropometrics, Computer reaction time task, and Questionnaires	Complete MRI Scan

These are the things that will happen to you while you are in the study:

1. Anthropometrics: Your height and weight will be recorded. You will also be asked about your hand and leg dominance.
2. Computer reaction time task: You will be asked to look at a computer screen and respond as quickly and accurately as possible to the targets on the screen.
3. Questionnaires: You will be asked to complete a series of non-invasive questionnaires on a tablet/computer pertaining to demographics, general health history and any knee pain.
4. MRI Imaging: You will be asked to lie down in a machine that will take images of your brain. For most portions of MR acquisition, you will only be instructed to lie still. For other parts of the acquisition, you will be asked to complete various

lower extremity movements such as knee extension/flexion and a combined knee and hip flexion/extension movement. Prior to the imaging appointment, you will be asked to complete a screening questionnaire to ensure that it is safe for you to receive an MRI. For example, if you have any permanent metal dental/orthodontic work, cochlear implant, cardiac pacemakers, recent orthopedic pins/screws/plates, etc., you will not be able to complete this study. A practice session of the different tasks you will be doing while scanned will also be completed just prior to the 'real test scanning' to allow you to ask any questions and be familiar with what we will ask you to do.

***Change of Mind/Study Withdrawal:***

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the study coordinator or the investigator so that they can terminate your study participation.

If you stop being in the research, data already collected may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

***Detailed Risks:***

LESS COMMON, LESS SERIOUS
<ul style="list-style-type: none"><li>• Tight space may be uncomfortable</li></ul>

There are no known negative effects from exposure to the magnet or radio waves used in the MRI at this time; however it is possible that harmful effects could be recognized in the future. The tight space of the MRI may make some people feel uncomfortable. One known risk is that the magnet can attract certain kinds of metal. Therefore, we will have all subjects complete a pre-MRI screening questionnaire. If there is any indication from this questionnaire that the MRI is not safe you will not have the MRI testing. The MRI testing will require you to lie on your back and remain still for the duration of the test, which could last about 75 minutes. Due to the nature of the test, there will be a loud knocking noise that you will hear while the test is being performed. You will be instructed that if at any point during the test you get too uncomfortable, you can signal to the research staff to stop the test immediately.

There is also a minimal risk that the data collected may be viewed by individuals outside the research team. The risk that confidential data may be viewed is relevant for both the written forms and the electronic databases.

There may be other risks that we do not know about yet. In addition to these risks, this research may hurt you in ways that are unknown.

***Privacy:***

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and /or data may be shared with other collaborators at Cincinnati Children’s and possibly with outside collaborators, who may be at another institution or for-profit company.

If information that could identify you is removed from your information or samples collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 Website at any time.

***Return of results:***

Most tests done on samples or images obtained in research studies are only for research and have no clear meaning for healthcare. If the research with your information or samples gives results that do have meaning for your health, the researchers will contact you and ask you if you would like to know what they have found. You can say No to hearing about the results at that time if you desire. If an incidental finding is discovered during the MRI scan the neuroradiologist reviewing the scans may contact your primary care physician to convey this finding.

**AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH**

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your “protected health information” (called PHI for short).

### **What protected health information will be used and shared during this study?**

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children's medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

### **Who will share, receive and/or use your protected health information in this study?**

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

### **How will you know that your PHI is not misused?**

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

### **Can you change your mind?**

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

**Will this permission expire?**

Your permission will expire at the end of the study.

**Will your child's other medical care be impacted?**

By signing this document, you / your child agree to participate in this research study and give permission to Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

## SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

\_\_\_\_\_  
Printed Name of Research Participant

\_\_\_\_\_  
Signature of Research Participant  
Indicating Consent or Assent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent or Legally Authorized  
Representative\*

\_\_\_\_\_  
Date

\_\_\_\_\_  
\* If signed by a legally authorized representative, a description of such representative's  
authority must be provided

\_\_\_\_\_  
Signature of Individual Obtaining Consent

\_\_\_\_\_  
Date