Northeastern

NOTIFICATION OF IRB ACTION
FULL BOARD RENEWAL APPROVAL

Date: September 11, 2019	IRB #: 15-10-22
Principal Investigator(s):	Eugene Tunik
Department:	Physical Therapy, Movement and Rehabilitation Sciences Bouvé College of Health Sciences
Address:	120E BK Northeastern University
Title of Project:	Neural Substrates of Sensorimotor Integration
MODIFICATION:	**1. Increase in projected subject enrollment from 100 to 250; 2. For the neurological condition, patient subject population will now also include individuals with a) central or peripheral nerve injury and b) neuropathic pain. Recruitment and consent materials for neurological condition have been updated; 3. Remuneration for the study reduced from $20/session to $10/hour; 4. Addition of Madhur Manalgam and Nathaniel Pinkes to the project; and 5. PI's office address has been updated on various documentation.**
Participating Sites:	NJIT (#F123-12) – IRB renewal approval valid through 11/14/19
Original Protocol Approved:	October 14, 2015
Informed Consents:	One (1) signed consent form for healthy subjects One (1) signed consent form for subjects with neurological condition
DHHS Review Category:	Full Board
Monitoring Interval:	12 months

Human Subject Research Protection
Mail Stop 560-177
360 Huntington Avenue
Boston, MA 02115
617.373.7570
fax 617.373.4595
northeastern.edu/hsrp

The above-mentioned protocol received continuing review at the September 11, 2019 meeting and was approved without further requirements.

APPROVAL EXPIRATION DATE: SEPTEMBER 10, 2020

Investigator's Responsibilities:

1. The informed consent form bearing the IRB approval stamp must be used when recruiting participants into the study.
2. The investigator must notify IRB **immediately** of unexpected adverse reactions, or new information that may alter our perception of the benefit-risk ratio.
3. Study procedures and files are subject to audit any time.
4. Any modifications of the protocol or the informed consent as the study progresses must be reviewed and approved by this committee **prior to being instituted.**
5. Continuing Review Approval for the proposal should be requested at least one month prior to the expiration date above.
6. This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.

C. Randall Colvin

C. Randall Colvin, Ph.D., Chair
Northeastern University Institutional Review Board

MOVEMENT NEUROSCIENCE LAB

Motor Control Research Study

Participants needed for a research study investigating how the brain controls movements and how this is affected by neurological disease.

Requirements

Participation is voluntary. Participants should be 18-80 years old and have any of the following conditions: Stroke, Traumatic Brain Injury (TBI), concussion, amputation, Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis, Dystonia/Writer's cramp, Parkinson's Disease, Sensory Neuropathy, Central or peripheral nerve injury, neuropathic pain. Individuals should not have a history of psychiatric disease or seizures, and cannot be pregnant.

Study Timeline

Participants may be asked to attend one or more sessions.
Each session will last 90-180 min.

Compensation

$10/hour + travel expenses
reimbursed ($40 max, please provide receipts).

APPROVED
NU IRB# 15-10-22
VALID 9/11/19
THROUGH 9/10/20

Contact Information

E-mail: tuniklab@gmail.com

Movement Neuroscience Laboratory · Director: Eugene Tunik, PhD, PT
Northeastern University · Department of Physical Therapy, Movement, and Rehabilitation Science, 404 Robinson Hall

MOVEMENT NEUROSCIENCE LAB

Motor Control Research Study

Healthy individuals needed for a research study investigating how the brain controls movements.

Requirements

Participation is voluntary. Participants should be: 18-80 years old, right-handed, without a history of psychiatric or neurological disease, no seizures, and not pregnant.

Study Timeline

Participants may be asked to attend one or more sessions.
Each session will last 90-180 min.

Compensation

$10/hour + travel expenses
reimbursed ($40 max, please provide receipts).

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Contact Information

E-mail: tuniklab@gmail.com

Laboratory for Movement Neuroscience · Director: Eugene Tunik, PhD, PT
Northeastern University · Department of Physical Therapy, Movement, and Rehabilitation Science, 404 Robinson Hall

Experiments in the Laboratory for Movement Neuroscience are ongoing to study how neurological disease affects one's ability to coordinate movements of the hand and arm. We are recruiting individuals with: _____

Individuals must be between 18-80 years of age, without a history of psychiatric conditions or seizures, and cannot be pregnant. After providing consent to participate, individuals will be asked to perform a battery of simple movements to reach/grasp/point to objects and/or to play a simple video game in virtual reality. Hand/arm movements and muscle activity will be measured with special sensors. Participants may also be asked to get a magnetic resonance imaging (MRI) brain scan that measures brain activity at rest and/or during movements, and/or to receive a form of non-invasive brain stimulation that is used to measure brain activity.

An experimental session may take between 90-180 minutes including all paperwork, time to connect the sensors, and conduct the experiment. The experiment (including the brain scan and stimulation) will be free to the participant. In addition, participants will receive $10 / hour, and reimbursement for travel to/from the study (up to $40, please provide receipts).

If you are interested or know someone that is, please contact the Principal Investigator at:

Eugene Tunik, PhD, PT
Department of Physical Therapy, Movement, and Rehabilitation Science
120E BK
Northeastern University
Boston MA 02115
Tel: 617-373-2924
tuniklab@gmail.com

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THROUGH 9/10/20

APPROVED
NU IRB# 15-70-22
VALID 9/11/19
THROUGH 9/10/20

Northeastern University, Department of Physical Therapy, Movement, and Rehabilitation Science
Name of Investigator(s): PI: Eugene Tunik, PhD, PT
Title of Project: Neural substrates of sensorimotor integration

Informed Consent to Participate in a Research Study

We are inviting you to take part in a research study. This form will tell you about the study, but the researcher will explain it to you first. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the researcher if you want to participate or not. You do not have to participate if you do not want to. If you decide to participate, the researcher will ask you to sign this statement and will give you a copy to keep.

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

We are asking you participate because you are 18-80 years old, right-handed, and have no history of neurological disease, psychiatric conditions, or seizures.

Why is this research study being done?

The purpose of this research is to understand how the brain allows people to coordinate movements.

What will I be asked to do?

If you decide to take part in this study, we will ask you to

- Fill out a brief background questionnaire (age, gender, medical background, etc.).
- Sit and move your fingers / arms to press a button or grasp table-top objects, move a joystick that slightly resists your movement, or play a simple computer game.
- You may be asked to wear special glasses used to control visual feedback and/or track the movement of your eyes, or sensors on your hand / arm that let us measure your movement and muscle activity (EMG). EMG is similar to how a doctor measures heart rhythm. For this, we will clean your skin with an alcohol pad, shave a small part of it if it is hairy, and stick a sensor using double-sided tape. You will not feel any sensations or discomfort since this is a measuring device, and there are no known risks or adverse effects of this procedure.
- You may be asked to participate in a magnetic resonance imaging session (MRI), which are scans that measure brain structure and activity while you lie on your back and move your fingers/hand. The scans will be done at Northeastern University MRI Center, located at the Interdisciplinary Science and Engineering Complex. If we think the brain scan shows an abnormality, the investigator will tell you to follow up with your doctor. The investigator is not a radiologist and the scan is not meant for medical diagnosis. If you did an MRI before, we may ask you for the scan.
- You may receive peripheral nerve stimulation, a technique that applies brief electrical pulses to the hand / arm / leg. This may produce a brief twitch in your muscles.
- You may receive Transcranial Magnetic Stimulation (TMS). In this technique, we hold a coil that produces short magnetic pulses close to your head and activate a small area of the brain that will produce a small twitch in your finger / hand / arm muscles
- You may receive non-invasive electrical brain stimulation, a technique that applies small pulses to the head with an electrode (a moist sponge). People usually do not feel this at the level used in this study. The stimulation will remain on for less than 30 minutes, while you make hand-arm movements.

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

You may first be interviewed by email or phone to see if you can participate. This will take about 5-10 min. You will then come either to the Northeastern University MRI Center, located at the Interdisciplinary Science and Engineering Complex for the MRI experiment, or to the Laboratory for Movement Neuroscience (404 Robinson Hall) for all other experiments. One session will last between 90-180 minutes. The paperwork will take about 20 minutes, the set up time will be about 20 minutes, and the experiment will be about 60 minutes. We also expect that we may pause to let you rest, get water, and use the bathroom, as needed.

Will there be any risk or discomfort to me?

- Behavioral task: There are no risks with the behavioral task.
- Risks with MRI: There is a risk that metal objects can be drawn into the MRI. You will need to remove any metal (jewelry, hair pins, keys). If it is not made of MRI-safe materials and cannot be removed or is an electrically/magnetically/mechanically activated implant (cardiac pacemaker, cochlear implant), you may not be able to participate. Since the risk to an unborn baby is unknown, you cannot participate if you are pregnant; we have pregnancy tests that you can use. You may feel uncomfortable because the MRI table slides into a narrow cylinder during the scan. The MRI makes loud sounds; we will give you earplugs or headphones to reduce the noise. You may feel mild tingling or heating sensations during scanning. If you wear contacts, you will be asked to moisten your eyes or remove the contacts to prevent them from drying. MRI-safe prescription glasses are available if needed. You will be in contact with the research staff at all times through a microphone and told how to use an emergency handheld device to let the operator know if you wish to stop scanning.
- Risks with TMS: TMS can make your muscles twitch. This is not dangerous but can be annoying; we can lower the intensity or stop stimulation. Since the effect of TMS to an unborn baby is unknown, you cannot participate if you are pregnant; we have pregnancy tests that you can use. The TMS makes a clicking sound; we can provide earplugs if it is too loud. You may feel some mild scalp pain or a headache; this usually goes away within minutes and it responds well to mild analgesics (ibuprofen). In 30 years of use, there are about a dozen cases where TMS caused a seizure. This mainly occurred when people had a history of seizure or when TMS was done at higher intensities/frequencies than used in this study.
- Risks with non-invasive electrical brain stimulation. You may feel mild tingling or itching around the scalp, feel tired after the experiment, or have a mild headache. These feeling should go away as soon as stimulation is stopped, or shortly after.
- Risks with peripheral nerve stimulation. There are no known risks with this.
- Risks of eye-tracking: The risk of damaging infrared radiation from the eye-tracking equipment is extremely small. The potential amount of radiation that you could receive is less than what is received on a sunny day.

The risks with MRI, and non-invasive magnetic (TMS) and electrical brain stimulation are minor when conducted on individuals who have been carefully screened before participating. To protect against the above risks, you will be carefully screened for safe participation in all experiments. You may notify the research staff at any time if you feel uncomfortable, no matter the reason. We can stop all experiments at any time. You will be provided with rest and water / bathroom breaks as needed during the experiment. In the unlikely event that an adverse event occurs, we will help you get into a comfortable and safe position, and call for emergency medical help.

Will I benefit by being in this research?

There may be no direct benefit to you. However, information learned by this research may help our understanding of normal brain function and what happens in different diseases.

Who will see the information about me?

Your participation in the study will be confidential. Only researchers on this study will see the information about you. The data may be used for educational / scientific presentations or publications. We will not use information that can identify you. To protect your identity, we will code your files with a number ~~(subject 001xx) and store them a locked cabinet in the lab or office. Only research personnel will have~~ access to this file. Computer files will be password protected and accessible to the study researchers. Data will be kept for at least three years after it is published in a scientific journal. 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 the research is done properly. We would only permit people who are authorized by organizations such as the Northeastern University Institutional Review Board, or the sponsor agency such as the NIH, NSF, FDA, OHRP to see this information.

If I do not want to take part in the study, what choices do I have?
You have the option of not participating in this study.

What will happen if I suffer any harm from this research?
No special arrangements will be made for compensation or for payment for treatment solely because of your participation in this research.

Can I stop my participation in this study?
Yes, your participation is completely voluntary. You do not have to participate if you do not want to and you can refuse to answer any question. Please send a written request for withdrawal to the Principal Investigator responsible for the study. If you do not participate or decide to quit, you will not lose any rights, benefits, or services that you would otherwise have. However, the researcher can continue to use the health information collected about you prior to your withdrawing your authorization.

Who can I contact if I have questions or problems?
If you have questions about the study, please contact the principal investigator: Eugene Tunik, PhD, PT; 360 Huntington Ave, 120E BK, Boston, MA 02115. Tel: 617-373-2924. Email: e.tunik@neu.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, 560-177 Huntington Ave., 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?
You will be paid $10/hour. If you took public transportation (taxi, train/bus) or pay for parking, we will reimburse you up to $40 (please provide receipts). Payment will be made after a session.

Will it cost me anything to participate?
You may need to pay for transportation or parking. We will reimburse you for this based on receipts.

Is there anything else I need to know?
This research is supported in part by the National Institutes of Health.

If the study is HIPAA-covered, when will this authorization end?
N/A

May we contact you again to participate in further studies? (Please initial in YES, or NO space).
YES:_____ NO:_____

I agree to take part in this research and authorize the use and disclosure of my health information consistent with provisions above.

_____ _____
Signature of person agreeing to take part **Date**

_____
Printed name of person above

_____ _____
Signature of person who explained the study to the participant above and obtained consent **Date**

_____
Printed name of person above

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NU IRB# 15-70-22
VALID 9/11/19
THROUGH 9/10/20

Sensorimotor Integration - Patient Subjects
Ver. 9/3/2019

Northeastern University, Department of Physical Therapy, Movement, and Rehabilitation Science
Name of Investigator(s): PI: Eugene Tunik, PhD, PT
Title of Project: Neural substrates of sensorimotor integration

Informed Consent to Participate in a Research Study

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

We are asking you participate because you are 18-80 years old and have a neurological condition that makes it difficult for you to move your arm / hand. This can be because you have one of the following conditions: Stroke, Traumatic Brain Injury (TBI), concussion, amputation, Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis, Dystonia/Writers cramp, Parkinson's Disease, Sensory Neuropathy, central or peripheral nerve injury, neuropathic pain.

Why is this research study being done and for what purpose will my health information be used and disclosed?

The purpose of this research is to understand the link between brain disease and a person's ability to make movements. This research may help to detect disease sooner and find better treatments.

Who will be using and disclosing information about me?

The investigators involved on this study will use and disclose your health information pursuant to this authorization.

What will I be asked to do?

If you decide to take part in this study, we will ask you to

- Fill out a brief background questionnaire (age, gender, medical background, etc.).
- Sit and move your fingers / arms to press a button or grasp table-top objects, move a joystick that slightly resists your movement, or play a simple computer game.
- You may be asked to wear special glasses used to control visual feedback and/or track the movement of your eyes, or sensors on your hand / arm that let us measure your movement and muscle activity (EMG). EMG is similar to how a doctor measures heart rhythm. For this, we will clean your skin with an alcohol pad, shave a small part of it if it is hairy, and stick a sensor using double-sided tape. You will not feel any sensations or discomfort since this is a measuring device, and there are no known risks or adverse effects of this procedure.
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- Risks with non-Invasive electrical brain stimulation. You may feel mild tingling or itching around the scalp, feel tired after the experiment, or have a mild headache. These feeling should go away as soon as stimulation is stopped, or shortly after.
- Risks with peripheral nerve stimulation. There are no known risks with this.
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Will I benefit by being in this research?

There may be no direct benefit to you. However, information learned by this research may help our understanding of brain function and lead to development of better therapies.

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VALID 9/11/19
THROUGH 9/10/20

What health information will be used and disclosed?

We will ask you for your medical history. If you have any clinical tests that have been done that are relevant to this study, we may ask you or the collaborating physician to provide those as well.

Who will see the information about me?

Your participation in the study will be confidential. Only researchers on this study will see the information about you. The data may be used for educational / scientific presentations or publications. We will not use information that can identify you. To protect your identity, we will code your files with a number (subject 001xx) and store them a locked cabinet in the lab or office. Only research personnel will have access to this file. Computer files will be password protected and accessible to the study researchers. Data will be kept for at least three years after it is published in a scientific journal. 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 the research is done properly. We would only permit people who are authorized by organizations such as the Northeastern University Institutional Review Board, or the sponsor agency such as the NIH, NSF, FDA, OHRP to see this information.

Note: Some persons or organizations that receive your health information pursuant to this authorization may not be covered by the Health Insurance Portability and Accountability Act or other privacy laws.

If I do not want to take part in the study, what choices do I have?

You have the option of not participating in this study.

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

No special arrangements will be made for compensation or for payment for treatment solely because of your participation in this research.

Can I stop my participation in this study?

Yes, your participation is completely voluntary. You do not have to participate if you do not want to and you can refuse to answer any question. Please send a written request for withdrawal to the Principal Investigator responsible for the study. If you do not participate or decide to quit, you will not lose any rights, benefits, or services that you would otherwise have. However, the researcher can continue to use the health information collected about you prior to your withdrawing your authorization.

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Can I access the health information collected about me and request corrections where necessary?

If you wish, you can ask to review and request amendment of your health records throughout the study period. As the data analysis proceeds and results become available, we are happy to share and explain the results to you. Please feel free to contact the principal investigator at any time for this.

Will I be paid for my participation?

You will be paid $10/hour. If you took public transportation (taxi, train/bus) or pay for parking, we will reimburse you up to $40 (please provide receipts). Payment will be made after a session.

Will it cost me anything to participate?

You may need to pay for transportation or parking. We will reimburse you for this based on receipts.

Is there anything else I need to know?

This research is supported in part by the National Institutes of Health and National Science Foundation.

If the study is HIPAA-covered, when will this authorization end?

HIPAA will be active indefinitely.

May we contact you again to participate in further studies? (Please initial in YES, or NO space).

YES:_____ NO:_____

I agree to take part in this research and authorize the use and disclosure of my health information consistent with provisions above.

_____ _____

Signature of person [parent] agreeing to take part **Date**

_____

Printed name of person above

_____ _____

Signature of person who explained the study to the participant above and obtained consent **Date**

_____

Printed name of person above

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