Principal Investigator: Wesley Thayer, MD, PhDRevision Date: June 20, 2018
Study Title: MRI Diffusion Tensor Tractography to Track and Monitor Peripheral Nerve Recovery after Severe Crush or Cut/Repair Nerve Injury (Department of Defense)
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to Adults with traumatic peripheral nerve injuries of the upper extremities

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have suffered a traumatic nerve injury to the upper extremity (hand, mid-forearm) that requires surgical repair. The purpose of this study is to determine if advanced imaging tools using Magnetic Resonance Imaging (MRI) can be used to non-invasively study peripheral nerves after repair and to use these findings to help track and predict outcomes of nerve regrowth much earlier than current techniques. You will be in the study for 12 months after injury and surgical repair.

2. What will happen and how long will you be in the study?

There will be 24 subjects enrolled in this study at Vanderbilt over three years with peripheral nerve injuries undergoing surgical repair. If you are a woman of child-bearing potential, you will undergo a pregnancy test. If you are pregnant, you cannot participate in this study. You will undergo a standard of care anesthesia evaluation before your surgery and the current standard of operative procedures will be performed. During your clinic visits after surgery, various tests will be performed to assess your grip and sensation including grip strength and the ability to feel two points on your fingertip compared to only feeling one. How well your nerves are healing will be assessed using the Medical Research Council Classification. Your pain assessment will be performed using a numeric scale, 1/10. You will also be asked to complete surveys such as the Michigan Hand questionnaire and the Short Form 12 survey, on how well you are able to function and perform your activities of daily living. A physical examination of your affected limb will be performed as well as collecting information from your medical record. You will go to the Vanderbilt Institute of Imaging for an MRI of both the injured and non-injured arm for comparison at 1, 3, 6, and 12 months after surgery. The MRI scan will take about 30 minutes per arm. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio, to make pictures of your body.

You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear implants. Also, you may not be able to have the scan if you have an iron-based tattoo, pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

You will hear “hammering”, clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them.

During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. You may be asked to lie very still throughout the scan.

In this study, the MRI scan is for research only. But, if we see something that is not normal, you will be told and asked to consult your doctor.

A table of all research activities and frequencies are listed below:

MRI	1,3,6 and 12 months after your operation
Rehabilitation Regimen	1,3,6 and 12 months after your operation
Affected limb evaluation	Study entry, day one, 1 3, 6 and 12 months
Normal limb evaluation	Study entry, 1, 3, 6 and 12 months
Pain assessment	Study entry, day one, 1, 3, 6, and 12 months
Static 2-point discrimination	Study entry, day 1,14, 1,3,and 6 months
Moving 2-point discrimination	Study entry, day 1,14, 1,3,and 6 months
Michigan Hand questionnaire	Study entry, day 1,14, 1,3,and 6 months
Grip Strength (if indicated)	Study entry, day 1,14, 1,3,and 6 months
Nine Hole Peg Test (if indicated)	Study entry, day 1,14, 1,3,and 6 months
Short Form 12 survey	Study entry, day 1,14, 1,3,and 6 months
Medical Research Council Classification	Study entry, day one, 1, 3, 6, and 12 months
Demographic	Study entry
Dash questionnaire	Study entry, day 1, 14, 1, 3, and 6 months

3. Costs to you if you take part in this study:

If you agree to take part in this research study you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

MRI: There are no known major risks with an MRI scan but it is possible that harmful effects could be found out in the future. It may bother you to be placed in a tight space (claustrophobia), or to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. If you have any metal pieces in your body, they could move or heat up during the scan and damage the nearby tissue.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of

these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your study doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch. You should so this when you come for your appointment for the MRI scan and during the health history questions you are asked.

The MRI scanners used in this study have been used in human research for several years and no risks have been identified. However, some people may experience discomforts such as nausea, dizziness, flashing lights in the eyes, and a metal taste in the mouth. These discomforts are most likely to occur as a result of rapid head movement in or near the MRI machine. For this reason, you should try not to move, especially your head, while you are inside the MRI.

There are no known risks of having an MRI scan while pregnant. However, there may be risks that are unknown and therefore if you are pregnant you will be excluded.

5. Risks that are not known:

There are no known side effects of having an MRI. However, there may be risks that are unknown at this time.

6. Payment in case you are injured because of this research study:

If you are hurt or get sick because of this study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic.

7. Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. The study could benefit others finding a better instrument for monitoring nerve regeneration following surgical repair and in some cases determine if surgical repair is even indicated.
b) The benefits you might get from being in this study. There may be no direct benefit to you for being in this study.

8. Other treatments you could get if you decide not to be in this study:

You do not have to participate in this study to receive treatment for your condition. Alternatives include standard of care for monitoring your nerve regeneration and progress after your surgery.

9. Payments for your time spent taking part in this study or expenses:

The investigator will provide payments that may assist you with the costs incurred (e.g. time and travel), including the costs of standard visits as a result of your participation in this study. These payments will be provided to you by debit card mailed to the address provided. As you complete each study visit, surveys and MRIs at 1, 3, 6 and 12 months after your surgery, you will be reimbursed $100.00. At the completion of the study if all followup visits, surveys and MRIs have been completed, you will receive an additional $250.00. You will not be paid if you miss a visit. If you do not complete all of the study visits you will not receive payments for the uncompleted visits.

Followup, MRI and Surveys	
One month	$100.00
Three months	100.00

Six months	100.00
Twelve months	100.00
Completion of all study visits and MRIs	250.00
Total reimbursement	$650.00

10. Reasons why the study doctor may take you out of this study:

Your study doctor may decide to take you out of the study early. If you are taken out of the study, you will be told the reason why.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Wesley Thayer, MD, PhD

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

14. Confidentiality:

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Thayer and *his* staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information. Information will be stored in a password protected database and only Dr. Thayer and his staff will have access to this information. Codes will be used in place of names whenever possible and stored in a locked cabinet and only study staff will have access.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. *Thayer* and *his* study team may share the results of your study and/or non-study linked such as laboratory tests and x-rays as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government, Office for Human Research Protections, and the Vanderbilt University Institutional Review Board, Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Thayer in writing and let *him* know that you withdraw your consent. *His* mailing address *is D-4207 Medical Center North, Nashville, TN 37232.* At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

Time