Project Title

Restoring High Dimensional Hand Function to Persons With Chronic High Tetraplegia

NCT Number

NCT03482310

Document Date

Approved March 23, 2018

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM

Subject Name: _____ Date: _____

Title of Study: Restoring Control of Multi-Dimensional Upper Limb Function in People with High Tetraplegia

Principal Investigator: A. Bolu Ajiboye, Ph.D. VAMC: Cleveland (541)

Consent Version Date: 03/19/2018

DESCRIPTION OF RESEARCH BY INVESTIGATOR

NOTE: The consent form must include the following section headings:

I. Purpose of the Study
II. Description of the Study
III. Inconveniences
IV. Discomforts/Risks/Side Effects
V. Benefits
VI. Alternative Procedure(s)/Treatment(s)
VII. Privacy, Confidentiality, and Use of Research Results
VIII. Special Circumstances
IX. Contact Information

TO POTENTIAL PARTICIPANTS: Federal regulations require written informed consent before participation in a research study. This is to be certain that research volunteers know the nature and risks of the study, so they can make an informed decision about participation. You are asked to read the following information and discuss it with the investigator, so that you understand this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate. It is also important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part in the research is entirely voluntary.

2. You may not personally benefit from taking part in the research but the knowledge obtained may help the health care professionals caring for you to better understand the disease/condition and how to treat it.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies, which may affect your willingness to continue in the research project, your doctor will discuss the new information with you and will help you make a decision about continuing in the research.

Cleveland VAMC IRB approved
the use of this version on 3/23/18

5. The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information, which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions, concerns, or complaints you have about this research with the research staff members.

I. PURPOSE OF THE STUDY:

You are being asked to participate in a research study of how well a brain-computer-interface (BCI) can control the movements of several joints in the hand and arm. For example, to control your hand to grasp an item, you need to control the position of your thumb and finger joints to hold the item. You are being asked to participate because you have a spinal cord injury and have received a brain-computer-interface, and may have also received a functional electrical stimulation (FES) system.

This study is sponsored by the Department of Veteran Affairs. We expect to enroll up to 4 subjects with spinal cord injuries for this study, who are participants in the BrainGate2 study.

II. DESCRIPTION OF STUDY:

In this study, you will be asked to come to the FES laboratory in the Louis Stokes Cleveland Department of Veteran Affairs Medical Center (LSCDVAMC). These tests will occur outside of your normal standard of care from your doctors. You will be asked to participate in 1-3 separate experimental sessions per week, each 1-3 hours long, for a maximum of 30 sessions. These sessions may be spread out over a one-year period.

Virtual Hand and Arm Sessions

In these sessions, cables will be connected to the pedestal(s) on your head to record the neural signals from the sensor(s) in your brain. You will be asked to imagine and attempt to perform various virtual finger, hand, and arm movements that are shown on a computer screen. Since some of the virtual movements are intended to be three-dimensional, you may be asked to wear 3D glasses while watching the virtual movements on the screen. The computer will calculate the relationship between the recorded neural signals and the movements on the screen (also known

as the 'filter'). You will then be shown targets on the screen and asked to attempt to move the virtual arm and hand to the target and match the orientation of the target. The 'filter' will convert your neural signals to move the virtual hand and arm. When your brain-controlled movements match the target movements, you will receive a cue indicating success (for example, a noise will sound and/or the target will change colors). Several trials like this will be performed, with the 'filter' being refined after each trial. The trials will last around 3-5 minutes each.

FES Control Sessions

In these sessions, cables will be connected to the pedestal(s) on your head to record the neural signals from the sensor(s) in your brain. Your FES system will also be connected. You will be asked to imagine and attempt to move your hand and arm when instructed by the computer (for example, 'Open', 'Close', 'Extend', 'Flex'). The computer will then send commands to your FES system to stimulate the appropriate muscles and move your hand and arm to match the instructed movement. The computer will calculate the relationship between the recorded neural signals and the instructed movements (also known as the 'filter'). The computer will then give you movement instructions and you will be asked to attempt to move your hand and arm to match the instructions. The 'filter' will convert your neural signals to FES system commands to stimulate the appropriate muscles and move your hand and arm. When your brain-controlled movements match the instructed movements, you will receive a cue indicating success (for example, a noise will sound). Several trials like this will be performed, with the 'filter' being refined after each trial. The trials will last around 3-5 minutes each.
Once you are able to achieve an acceptable success rate in matching the instructed movements, you will be asked to perform trials in which you use your brain-controlled movements to pick up and move an object from one location to another.

EMG Comparison Sessions

In these sessions, electromyographic (EMG) recording electrodes will be placed over muscles that you still can voluntarily control (usually in your neck or head). These electrodes will record the electrical signals produced by your muscles when you contract them. Either tape or adhesive gel will be used to keep the EMG electrodes in place. You will be asked to move the various muscles that are under the EMG electrodes, and each muscle will be assigned one of the instructed movements (for example, 'Open', 'Close'). The computer will use the EMG signals to measure how hard you are contracting those muscles, and will send the FES system commands to stimulate the appropriate muscles and move your hand and arm. Several trials like this will be performed, with the trials lasting around 3-5 minutes each.

Once you are able to achieve an acceptable success rate in matching the instructed movements, you will be asked to perform trials in which you use your EMG-controlled movements to pick up and move an object from one location to another.

During these tests, if we see something that needs to be checked by a physician, we will refer you to your primary physician, or a physician within the VA system. Please note that we are not specifically looking for any medical problems so it is very unlikely that we will find any underlying issues.

Discontinuation of Testing

You are free to participate in this study for as long as you like unless we think it would be best for you to stop. We might stop testing, even if you don't want to, if you are having too much discomfort, fatigue or other undesired symptoms.

You may withdraw from the study at any time. You can call us to finish testing if you change your mind later. If you withdraw we will keep any of your information that has already been collected.

III. INCONVENIENCES:

Participation in this study requires 1 to 3 visits per week to the medical center for up to 30 sessions. Each visit will last 1 to 3 hours. These sessions may be spread out over a one-year period.

IV. DISCOMFORTS / RISKS / SIDE EFFECTS:

Your participation in this study may involve the following risks:

Connecting to the BrainGate Pedestals

When connecting the cable(s) to the BrainGate pedestal(s), a pedestal could be damaged, or the tissue surrounded a pedestal could become infected. The same strict connection protocol that is used in the other BrainGate sessions will be used for this study. This includes the use of sterile gloves, antiseptic wipes, and careful alignment and screwing on of the cable.

Skin irritations

When we measure the muscle activity with surface electrodes, the adhesive of the electrode or tape can sometimes cause irritation. Usually this irritation goes away within an hour. If your skin becomes extremely irritated, we might change the type of electrode or stop the test.

Burns and electrical hazards

The EMG electrodes, BrainGate recording cable, and the FES system can provide an electrical path across the skin into the body. Commercial, medical-grade amplifiers with electrical isolation circuitry will be used for all connections that contact you to prevent electrical shock and injury.

Unknown Risks

There may be other risks as yet unknown. The investigators will inform you of any new findings that may influence your willingness to continue your participation in this study.

Video/Digital Photograph Recording

We may make a recording of one or more of the tests above to document your performance. We may take digital pictures or videos during the test. These recordings may show your face. You will have the option to review the pictures or videos and decide if you wish to allow them to be used for research purposes. These pictures and videos will only be used for internal analysis of the data, unless you sign an FES Center release for videos and/or photos as well as a VA audiotape/videotape consent form (VA Form 10-3203).

V. BENEFITS:

You will not directly benefit from participating in this study. We hope the information learned from this study will benefit people with cervical-level spinal cord injuries in the future.

VI. ALTERNATIVE PROCEDURE(S) / TREATMENT(S):

Because this study offers no direct benefits to participants, your only alternative is to not participate.

Subject Name: _____ Date:

Title of Study: Restoring Control of Multi-Dimensional Upper Limb Function in People with High Tetraplegia

Principal Investigator: A. Bolu Ajiboye, Ph.D. VAMC: Cleveland (541)

Consent Version Date: 03/19/2018

VII. PRIVACY, CONFIDENTIALITY, AND USE OF RESEARCH RESULTS:

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974.

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. The research records will be kept in a password-protected computer file that only the study team has access to. However, due to the small number of participants in the study, and since all participants are also enrolled in the BrainGate2 study, members of the local research team, local Institutional Review Board, and BrainGate2 research team may be able to identify your research records. Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any presentations or publications from this information will not identify you.

VA policy requires us to keep study records indefinitely. However, protections will be put in place to be sure that this information is kept confidential.

In order to comply with federal regulations, research records identifying you may be reviewed by the following:

- Representatives of the sponsor of this study - the Department of Veteran Affairs
- Authorized representatives of the LSCDVAMC Institutional Review Board and VA
- Federal Agencies such as the Government Accounting Office (GAO, the Office for Human Research Protections (OHRP)

VIII. SPECIAL CIRCUMSTANCES:

New Findings:

You will be told by the study doctor of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

Financial Considerations

Your participation in this research study will be done at no cost to you, nor will you receive any payment for your participation. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Ending Participation

The investigators may stop your participation in this study without your consent, for example, if they think that it will be in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason.

Compensation for Research-Related Injury

If you sustain injury as a direct result of your study participation, medical care will be provided by the LSCDVAMC at no cost to you. Financial compensation for such things as lost wages, disability, or discomfort due to an injury may not be available.

Subject Name: _____ Date:

Title of Study: Restoring Control of Multi-Dimensional Upper Limb Function in People with High Tetraplegia

Principal Investigator: A. Bolu Ajiboye, Ph.D. VAMC: Cleveland (541)

Consent Version Date: 03/19/2018

VIII. CONTACT INFORMATION

To answer questions about the research or if you sustain a research related injury contact the following:

- During the Day: Dr. Ajiboye at 216-368-6814
- After Hours: Dr. Ajiboye at 856-254-2693

For answers to questions about rights as a research participant or to voice a concern or complaint contact the following:

- The Research Administrative Officer at (216) 791-3800 ext. 4657
- The LSCDVAMC Patient Representative at (216) 791-3800 ext. 4026

If you wish to speak with someone other than study staff to provide input concerning the research process, check whether a study is being conducted at the LSCDVAMC ,and if study staff are permitted to represent the study contact :

- The LSCDVAMC Institutional Review Board Office at (216) 791-3800 ext. 4658

Subject Name: _____ Date:

Title of Study: Restoring Control of Multi-Dimensional Upper Limb Function in People with High Tetraplegia

Principal Investigator: A. Bolu Ajiboye, Ph.D. VAMC: Cleveland (541)

Consent Version Date: 03/19/2018

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the preceding information.

Dr./Mr./Ms. _____has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalt or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss c VA or other benefits to which I am entitled.

The results of this study may be published, but I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state and federal agencies.

I understand my rights as a subject, and I voluntarily consent to participate in this study. I understand what the study about and how and why it is being done. I will receive a signed consent form or a photocopy of it. I understand that in signing this consent form I do not waive my legal rights nor release the LSCDVAMC from liability for negligence.

Subject's Signature_____ Date __ /__/__

Signature of Subject's Representative _____ Date __ /__/__
(if subject not competent)

Printed name_____

Signature of Person Obtaining Consent_____ Date __ /__/__

Department of Veterans Affairs

CONSENT FOR PRODUCTION AND USE OF VERBAL OR WRITTEN STATEMENTS, PHOTOGRAPHS, DIGITAL IMAGES, AND/OR VIDEO OR AUDIO RECORDINGS BY VA

Name of individual whose statement, likeness, or voice is requested

NOTE: The execution of this form does not authorize production or use of materials except as specified below. The specified material may be produced and used by VA for authorized purposes identified below, such as education of VA personnel, research activities, or promotional efforts. It may also be disclosed outside VA as permitted by law and as noted below. If the material is part of a VA system of records, it may be disclosed outside VA as stated in the "Routine Uses" in the "VA Privacy Act Systems of Records" published in the Federal Register.

The purpose of this form is to document your consent to the Department of Veterans Affairs' (VA) request to obtain, produce, and/or use a verbal or written statement or a photograph, digital image, and/or video or audio recording containing your likeness or voice. By signing this form, you are authorizing the production or use only as specified below.

You are NOT REQUIRED TO CONSENT TO VA's REQUEST to obtain, produce, and/or use your statement, likeness, or voice. Your decision to consent or refuse will not affect your access to any present or future VA benefits for which you are eligible.

You may rescind your consent at any time prior to or during production of a photograph, digital image, or video or audio recording, or before or during your provision of a verbal or written statement. You may rescind your consent after production is complete if the burden on VA of complying with that request is not unreasonable considering the financial and administrative costs, the ease of compliance, and the number of parties involved.

The photograph, digital image, and/or video or audio recording will be produced while I am (describe the activity or situation) (***To Be Completed by the Department of Veteran Affairs, if applicable)***

performing arm and hand movement activities, or controlling a virtual arm and hand, in the laboratory.

Check at least one of the following (to be completed by VA)

☒ I hereby voluntarily and without compensation authorize Louis Stokes VA Medical Center
Name of Facility

to produce a photograph, digital image, and/or video or audio recording of me (or of the above named individual if the individual is legally unable to give consent).

☐ I hereby voluntarily and without compensation authorize _____
Name of Facility

to obtain or use a verbal or written statement from me (or the of the above named individual if the individual is legally unable to give consent).

VA FORM 10-3203
NOV 2014

TOMICA JEFFERSON 191145

Digitally signed by TOMICA JEFFERSON 191145
Date: 2018.02.22 07:27:30 -05'00'

I consent to allowing VA to record and use a verbal or written statement, or produce and use photographs, digital images, and video or audio recording for the purpose(s) identified below:

This product will be used: (NOTE: At least one of these boxes must be checked as well as a purpose described below) (to be completed by VA)

☒ Internally (stay within VA) ☒ Externally (shared outside VA)

Please check the applicable purpose(s) (to be completed by VA)

Promotional Efforts:

☐ Internal Publication (only VA) ☐ External publication (publicly available)

☐ Other (Specify): _____

Research Activities: ☒ Study

Education Purposes:

☒ Presentation ☒ Conference ☒ Publication in a Journal ☐ Training

☐ Other (Specify): _____

VA ONLY Use:

☐ Performance Improvement ☐ Quality Improvement ☐ Health Care Operations

☐ Other (Specify): _____

☐ All of the Above

NOTE: Do not sign this form unless one or more of the boxes above has been checked.

I have read and understand the foregoing, and I consent to the use of a verbal or written statement from me, and/or of my likeness and/or voice as specified for the above-described purpose(s). I understand that no royalty, fee, or other compensation of any kind will be made to me by the United States for such use. I understand that consent to obtain, produce, and/or use a verbal or written statement, photograph, digital image, and video or audio recording containing my likeness or voice is voluntary, and my refusal will not adversely affect my access to any present or future VA benefits for which I am eligible. I further understand that I may, at any time, rescind my consent prior to or during production of a photograph, digital image, or video or audio recording. I also understand that I may rescind my consent after production is complete if the burden on VA of complying with that request is not unreasonable considering the financial and administrative costs, the ease of compliance, and the number of parties involved.

Print Full Name (First and Last Name)	Signature	Date

Consent Obtained By (TO BE COMPLETED BY VA)

Print Employee Full Name	Title	Date

Signature of Person Obtaining Consent (TO BE COMPLETED BY VA)

Signature

IMPORTANT: If VA is providing or releasing any patient health or demographic information with the verbal or written statement, photograph, digital image, or video or audio recording, VA Form 10-5345, Request for and Authorization to Release Medical Records or Health Information, is required prior to the release of such data to any source outside VA.

Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
Louis Stokes Cleveland Department of Veterans Affairs Medical Center
Medical Research Service 151(W)
10701 East Boulevard
Cleveland, OH 44106

VA Principal Investigator (PI):	**PI Contact Information:**
	216-368-6814

Study Title:
Restoring Control of Multi-Dimensional Upper Limb Function in People with High Tetraplegia

Purpose of Study:
The purpose of this study is to research whether participants with high tetraplegia who have an intracortical brain-computer-interface (iBCI) and a functional electrical stimulation (FES) system, are able to control multi-dimensional hand and arm stimulation patterns.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☐ Specific information concerning:

☐ alcohol abuse ☐ drug abuse ☐ sickle cell anemia ☐ HIV

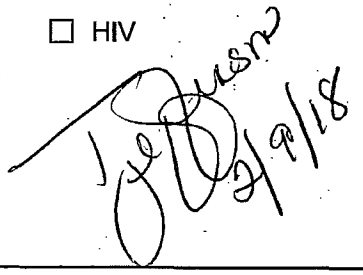
☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☐ Questionnaire, Survey, and/or Subject Diary

☐ Other as described:



Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☐ Non-VA Institutional Review Board (IRB) at _____
who will monitor the study

☒ Study Sponsor/Funding Source: VA-ORD
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☐ Academic Affiliate (institution/name/employee/department):
A relationship with VA in the performance of this study

☐ Compliance and Safety Monitors: _____
Advises the Sponsor or PI regarding the continuing safety of this study

☒ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):
FDA

☐ A Non-Profit Corporation (name and specific purpose):

☐ Other (e.g. name of contractor and specific purpose):

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research		
Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

A. Bolu Ajiboye, PhD
Department of Biomedical Engineering
2071 Martin Luther King Jr. Dr.
Cleveland, OH 44106

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☒ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research		
Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

Name of Legal Representative (please print) _____