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TITLE: Restoring Multidimensional Coordinated Reaching and Dexterous Grasping to Persons with Chronic Tetraplegia Through Functional Electrical Stimulation

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5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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14. ABSTRACT
The purpose of the project is to develop an implanted system for restoring movement and sensation to persons with chronic tetraplegia resulting from spinal cord injury. The project aims to combine two technologies: Functional Electrical Stimulation (FES) that reanimates paralyzed limbs using electrical stimulation of the nerves, and Brain-Computer Interfaces (BCIs) that record electrical activity from the brain and converts the activity to movement command signals for the FES system. In doing so, study participants potentially have the capability of bypassing their spinal injury and can move their limbs simply by thinking about the movements. In the current reporting year, the project has achieved all federal (FDA IDE, HRPO) and local (IRB) regulatory approvals necessary, screened a number of participants, begun to plan the necessary surgical interventions, and develop the necessary engineering (hardware and software) capabilities to achieve the project aims. Despite challenges due to the COVID pandemic in the past year, the project is making steady progress towards achieving the milestones in a timely manner.

15. SUBJECT TERMS
Spinal cord injury; Tetraplegia; Intracortical; Brain-computer interfaces; iBCI; Functional electrical stimulation; FES; Reach; Grasp;

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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TABLE OF CONTENTS

1. **INTRODUCTION:** Spinal Cord Injury (SCI) resulting in chronic tetraplegia represents a severe condition in which affected individuals are unable to move their limbs to perform functional activities. Surveys of people with chronic tetraplegia have shown that regaining reach and grasp abilities is their top functional priority by a wide margin. While robotic devices to restore assistive arm and hand function have been developed, such devices are cumbersome and have not been widely accepted for daily use. Functional Electrical Stimulation (FES) uses electrical stimulation of the peripheral nerves and muscles to restore movement of the actual paralyzed limb. FES has a long history of research and clinical translation, with high acceptance rates among persons with *mid- and low-cervical* SCI. FES users often report a psychological benefit of seeing their own limbs move and a preference for FES over robotic arm assistance. Intracortical brain-computer interfaces (iBCIs) involving multiple electrodes implanted into the brain are able to extract multi-dimensional movement signals from intact cortical networks to allow people with *high cervical SCI* to command external devices naturally and effortlessly. Our preliminary studies have shown that iBCIs can sense neural signals from the brain and translate them into highly accurate signals for control of movement. The combination of FES and an iBCI to restore function in persons with high cervical SCI is an appealing solution that "bypasses" spinal injury to allow functional restoration using the most intuitive command source and output system conceivable: the individual's own brain and own limbs

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).* Spinal cord injury; Tetraplegia; Intracortical; Brain-computer interfaces; iBCI; Functional electrical stimulation; FES; Reach; Grasp;

3. **ACCOMPLISHMENTS:**

What were the major goals of the project?

Study Specific Aims: To conduct a first-in-human pilot clinical trial (N=4) to (1) implement an FES+iBCI arm system using direct nerve stimulation through permanently implanted nerve-cuff electrodes to restore coordinated multi-joint arm reaching to functionally meaningful targets. (2) Implement an FES+iBCI hand system that allows for coordinated movement of individual fingers for grasping and manipulating a wide variety of objects. (3) Assess performance of a combined implanted FES+iBCI neuroprosthesis using standard clinical functional assessment tasks and ADLs.

	Timeline	Progress
Major Task 1: Regulatory Approval	Months	
Subtask 1: Prepare Regulatory Documents and Research Protocol		
Finalize consent form & human subjects protocol	1-3	Completed 9/1/2019
IRB protocol submission and approval	1-3	Completed 9/1/2019
Submission to HRPO – Federal IRB Review	3-6	HRPO approval 11/8/2019
Annual IRB report for continuing review	Annually	Completed 4/9/2020
Expected Milestone: Local IRB approval at CWRU	3	Achieved
Expected Milestone: HRPO approval	6	Achieved
Major Task 2: Participant Recruitment, Therapy, Participant Evaluation		
Subtask 1: Subject Recruitment		
Begin subject recruitment	6	Recruitment initiated on 11/8/2019
Initial meeting w/ potential subjects	6-8	5 people contacted
Screening potential subjects	8-10	5 people screened
Subject consented	10-12	Expected 11/12/2020
Expected Milestone: 1st participant consented, screened and enrolled	10-12	Expected 11/12/2020
Major Task 3: Implantation of Cortical Electrodes for iBCI		
Subtask 1: Prepare for surgery		
Schedule Operating Room Time for Implantation	12-14	Not yet scheduled
Order and receive brain implant hardware	10-12	All items ordered & received
Implant brain recording hardware	12-14	Not yet scheduled
Participant recovery period	13-15	Not yet scheduled
Expected Milestone: 1st participant implanted with iBCI	12-15	Expected Feb 2021
Major Task 4: Participant Training to use iBCI		
Subtask 1: Research Sessions		
Initial Test of iBCI	15-16	Not yet started
Training on simple control of computer cursors	15-17	Not yet started
Training of brain control of virtual arm	15-17	Not yet started
Development of advanced BCI decoders for multifunctional limb control	Continually	In progress
Participant BCI performance is assessed by controlling virtual arm and hand in Center Out Center and Hand Shaping Tasks; Performance is assessed using metrics of accuracy (% of targets acquired), efficiency (time to acquire targets, and efficiency of trajectory), and overall learning rate (increase in accuracy and efficiency over time)	15-17	Not yet started
Expected Milestone: Participant shows efficacy of using BCI to control virtual arm	15-17	Expected Mar 2021
Major Task 5: Implantation of FES Electrodes		
Subtask 1: Prepare for surgery		
Schedule Operating Room Time for Implantation	17-18	Scheduled Dec 7, 2020
Order and receive FES implant hardware	17-18	All items ordered & received
Implant FES hardware	17-18	Scheduled Dec 7, 2020
Participant recovery period	17-19	Not yet scheduled
Expected Milestone: 1st participant implanted with FES	17-19	Expected Dec 7, 2020
Major Task 6: Aim 1: Development of FES+iBCI Arm Neuroprosthesis		

Training of FES+BCI Arm Movements	19-22	Not yet started
Implementation of novel decoders for enhancing multiDOF arm function	19-22	Not yet started
Performance Evaluation using Center out Center Task: this is the primary metric of performance. Users will perform the Center Out Center Task using their own limb, similar to what they performed in virtual space in Major Task 4. FES+BCI performance will be compared to other standard means of neuroprosthetic control, including standard EMG control.	19-22	Not yet started
Expected Milestone: 1st participant demonstrates multifunctional arm reaching	19-22	Expected May 2021
Major Task 7: Aim 2: Development of FES+iBCI Dexterous Hand Neuroprosthesis		
Training of FES+BCI Hand Movements	22-25	Not yet started
Implementation of novel decoders for enhancing multiDOF hand	22-25	Not yet started
Performance Evaluation using Hand Formation Task: Quantified metrics of success include the number of correct hand movements made, the time take to make the hand movements, and the total number of possible hand grasps that the user can formulate. Metrics using BCI control will be compared to standard control approaches, with each subject acting as his/her own comparison	22-25	Not yet started
Expected Milestone: 1st participant demonstrates multifunctional hand grasping	22-25	Expected Aug 2021
Major Task 8: Aim 3: Clinical and Functional Evaluations		
Long term assessments of performance benefit on NINDS CDE tasks and patient satisfaction	19-29	Not yet started
Assess clinical performance through Grasp Release Test *Track performance improvements over time to quantify learning rate* *Compare GRT performance of BCI controlled system to other control*	19-29	Not yet started
Assess clinical performance through Spinal Cord Independence Measure Test *Track performance improvements over time to quantify learning rate* *Compare GRT performance of BCI controlled system to other control methods*	19-29	Not yet started
Administer Neuroprosthesis User Satisfaction Survey to assess additional performance desires from study participants	19-29	Not yet started
Expected Milestone: Report findings from overall studies	19-29	
Major Task 9: Preliminary Investigation of Cortical Stimulation to Provide Sensory Feedback		
Explore possible space of electrical stimulation parameters and what sensory perceptions are elicited in study participants	1-13	Sensory stimulation evaluation protocols being developed
Quantify results of sensory stimulation through study participant surveys and psychometrics(e.g. 2-point discrimination, Just-Noticeable-Difference)	1-13	Baseline data to be obtained 11/12/2020
Expected Milestone: Report findings from overall studies		
Major Task 10: Additional Study Participants		
Recruit and assess additional participants	20-48	Not yet started
Major Task 11: Data Analysis and Manuscript Preparation		
Recruit and assess additional participants	15-48	Not yet started

What was accomplished under these goals?

Executive Summary

In this first reporting year, our major efforts have focused on obtaining regulatory approvals, which we have fully done, and recruiting and evaluating potential study participants. Regarding regulatory approvals, we have obtained full FDA IDE and local IRB approvals, including minor protocol changes (described below). Regarding participant recruitment, we have had a number of inquiries and evaluated a number of potential participants. One participant was slated to be enrolled in December 2019, but due to the COVID-19 pandemic, his enrollment has been delayed. We have reengaged with this participant, and anticipate enrolling him, with the first surgeries slated for December 2020.

In preparation for the upcoming surgeries, we have made significant efforts to optimize surgical procedures for ensuring that the electrodes get implanted in the optimal parts of the peripheral nerve and the brain, to ensure optimal brain recordings and restored motor and sensory performance. Additionally, we have developed hardware and software platforms that will be used for restoring movement and sensation once the participant receives the FES and brain electrode implants.

Details pertaining to each major task of the SOW are described below.

Major Task 1: Regulatory Approval

Between the time when the proposal was submitted for this grant and when the grant was awarded, we were able to successfully obtain an Investigational Device Exemption (IDE) from the FDA. We were also able to successfully obtain local IRB approval for this study.

The protocol was submitted to the Human Research Protection Office (HRPO) of the Office of Research Protections (ORP) on May 14, 2019. Final approval of the protocol from HRPO was received on November 8, 2019.

The IDE annual report was submitted to the FDA on February 5, 2020, and was subsequently approved. A Continuing Review (annual report) was approved by our local IRB on January 12, 2020. The HRPO Continuing Review was submitted on April 9, 2020 and approved on May 29, 2020.

A series of minor protocol changes were submitted to the FDA and our local IRB, and were approved. These changes included:

- An option to have the FES electrode implant surgery occur before the cortical array implant surgery, and to allow the trimming of unused percutaneous leads.
- Surface EMG recording during sessions, and surface or needle EMG recording during surgery.
- Additional cortical array targeting techniques before or during surgery, including nerve ultrasound, somatosensory evoked potentials, intraoperative cortical stimulation, a temporary intraoperative micro-electrocortigram recording array, and vibrotactile stimulators.
- The addition of some qualitative interviews at different timepoints during the study.
- Several administrative changes, including staff changes and virtual medical followup visits.

Major Task 2: Participant Recruitment, Therapy, Participant Evaluation

Upon receiving FDA IDE approval, local IRB approval, and HRPO approval, we began to recruit participants for the study. Recruitment information was posted on the ClinicalTrial.gov site (study# NCT03898804). Presentations were made to spinal cord injury physicians at two local hospitals with significant numbers of spinal cord injury patients – the VA Medical Center and MetroHealth Medical Center.

Thirteen inquiries about participation in the study were received from individuals with spinal cord injuries, either because of a referral from their physician, or because of their own review of studies on the ClinicalTrials.gov site. Five individuals were identified as meeting the inclusion criteria for the study, and screening appointments were scheduled for them. During screening, it was discovered that two of the individuals had denervated deltoids and biceps muscles (the muscles could not be electrically activated), so they were excluded from the study. One individual who initially appeared to be a good candidate subsequently developed a medical issue that excluded him from the study. The remaining two individuals meet all the inclusion criteria and are interested in participating in the study. One of them has stated a preference to not be the first participant.

Our first participant was slated to be enrolled in December 2019, but developed a temporary medical issue. While that was getting resolved, the COVID pandemic occurred, which shut down our clinical research program for several months. We developed a set of COVID-related safety procedures for recruitment, surgeries, and experimental sessions. Our study is now permitted to enroll participants, and our first participant has expressed an interest in enrolling, which we expect will happen in the next few weeks. We anticipate that the initial surgery (for implantation of the FES electrodes) will occur in December.

Major Task 3: Implantation of Cortical Electrodes for iBCI

In preparation of implantation of the cortical electrodes, we are developing a surgical plan for targeting specific areas of cortex for implantation. We identified new surgical targets by leveraging information from non-human primate data (Davare et. al. 2011) on the theory of a grasp network that connects the visual cortex to anterior intraparietal area (AIP), F5, and primary motor cortex. Based on the strong evidence of hand grasp and individuated finger movement information in AIP and F5, our lab decided to pursue targeting the homologous structures in the human cortex. An extensive literature review was conducted about how to best target these two areas and determine what the closest human homologue would be. It was determined that the inferior frontal gyrus (IFG) and the anterior intraparietal area (AIP) were the strongest surgical targets. AIP was determined to be identified by anatomical landmarks while more extensive protocols were needed for identification of the exact location of IFG. Therefore, we will implement high gamma micro-electrocorticography (ECoG) to be executed during the surgery, and diffusor tensor imaging (DTI) to be executed pre-operatively in order to solidify the locations of the IFG target. Currently, we are also pursuing first steps in creating DTI images that will allow us to isolate areas of interest, such as AIP, and highlight the interconnectivity between AIP and IFG. This will give us an idea of where our IFG target will be. While DTI will give us a first good pass, the resolution is low and we will need a more targeted method of identifying the IFG target. Thus we are also developing a system that takes real time recordings from micro-electrocorticography grids placed on the surface of the participant's brain and gives a visual representation of the excitable areas during a specific motor paradigm. We are currently in the process of refining the paradigm to be used during the surgery. The developed paradigm currently involves cuing the participant to either attempt or imagine creating different grasp states or reaching motions. This information will be recorded by the micro-electrocorticography grids, filtered for high gamma information, and sent to our software system to display the areas of high excitability, indicating our surgical target. Overall, we have made significant progress on developing a surgical plan for targeting the cortical areas of interest.

Major Task 4: Participant Training to use iBCI

We are working with collaborators at Brown University and Massachusetts General Hospital to develop advanced algorithms for use with the FES+BCI system for multifunctional limb control. Specifically, our collaborators are working on investigating the motor cortical ensemble encoding of multiple hand gestures and real-time multi-state gesture decoding methods. Investigations began into the spiking and field potential neural activity related to rapid, discrete gestures compared to the neural execution of sustained gesturing (i.e., grasp-and-hold). These investigations are informing potential decoding methods for the neuroprosthetic control of hand movement and sustained grasps of different hand shapes. Once a participant receives the brain implant technology, s/he will attempt to use the developing algorithms to perform both control of a virtual arm/hand and actual control of their own arm/hand that is reanimated through functional electrical stimulation.

Major Task 5: Implantation of FES Electrodes

All hardware required for performing the FES surgical implantation have been ordered, sterilized, and received. The FES surgery has been tentatively scheduled for December 7, 2020, pending final screening and consent results of a currently interested potential participant. One minor change in the previously proposed order of surgeries is that the implantation of the FES nerve electrodes (for restoring arm and hand function) will occur prior to implantation of the brain recording electrodes (previously we intended to implant the brain electrodes first). The reason for this change in strategy is that our previous experience suggests that after receiving FES electrodes, participants will need time to strengthen their muscles through electrical stimulation. Thus by implanted the FES electrodes sooner, we can give a potential participant the opportunity to be better prepared for performing movement tasks using his/her own arm and hand.

Major Task 6: Aim 1: Development of FES+iBCI Arm Neuroprosthesis

Not yet started

Major Task 7: Aim 2: Development of FES+iBCI Dexterous Hand Neuroprosthesis

Not yet started

Major Task 8: Aim 3: Clinical and Functional Evaluations

Not yet started

Major Task 9: Preliminary Investigation of Cortical Stimulation to Provide Sensory Feedback

Much of our efforts have focused on developing intra-surgical and post-surgical approaches for ensuring that the microelectrode arrays will be accurately and precisely implanted in the correct part of the brain to achieve sensory feedback of the hand through cortical stimulation. We have developed surgical mapping techniques to precisely locate the part of the sensory cortex that relates to hand and fingertip sensations, using a technique known as high gamma micro-electrocorticography mapping. We have obtained all the necessary hardware to perform this novel surgical mapping procedure, and are presently developing the necessary software for visualization of the brain activity and co-registration of brain images with electrode location.

For post-surgical analysis, we have purchased and integrated hardware from Blackrock Microsystems, called the Cerestim, to allow for direct intracortical micro-stimulation (ICMS) for sensory feedback. Using this hardware, we can change the electrical stimulation parameters (within the safety limits described by our IDE) to change the sensation that is perceived by study participants. While we have fully integrated the hardware, we are presently developing the necessary software to help rigorously run these sensory feedback experiments.

Major Task 10: Additional Study Participants

Not yet started

Major Task 11: Data Analysis and Manuscript Preparation

Not yet started

REGULATORY PROTCOL AND ACTIVITY STAUS

			Enter information regarding number of subjects					
HRPO Protocol Number	**Protocol PI Name**	**Organization (Site)**	**# Target**	**# Enrolled**	**# Completed**	**# Screened**	**# Recruited**	**Other**
E00732.1a	Ajiboye	Case Western	4	0	0	5	5	

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

Y2, Q1

The primary goal of Y2, Q1 (Sept 2020 – Nov 2020) is to fully consent a participant (Major Task 2) and implant the participant (Major Task 5) with the full complement of FES nerve cuff electrodes. We are well on our way towards reaching this goal, as the implant surgery is already scheduled for December 7, 2020, pending a final medical consult and consent of the potential participant. Our current efforts towards making the surgery successful include developing intra-operative software for characterizing the efficacy of the electrodes to optimize their in-surgery placement and future neuroprosthetic function.

Y2, Q2

The primary goal of Y2, Q2 (Dec 2021 – Feb 2021) is to plan and perform the surgery to implant the brain recording electrodes (Major Task 3) in the potential participant. After the participant fully recovers (usually 3-4 weeks full recovery time), we will begin training the participant to use the BCI system. Additionally during this

time, the participant will undergo an exercise regime consisting of electrical stimulation of his paralyzed muscles to increase their strength and resistance to fatigue.

Y2, Q3

The primary goal of Y2, Q3 (Mar 2021 – May 2021) is to train the participant in use of the BCI system. We are continually developing hardware, software, and algorithmic platforms to train participants to to perform control of a computer cursor and then virtual arm and hand (Major Task 4). Our previous experience has established a training paradigm that slowly ramps up the difficulty of required brain control tasks, and quantifies performance using standard human movement metrics. By the end of this quarter, the participant will demonstrate consistent control over simple 1 and 2-dimensional cursor movements, as well as multi-dimensional and coordinated movements of a virtual hand and arm system.

Y2, Q4

The primary goal of Y2, Q4 (June 2021 – Aug 2021) will be to connect the implanted BCI system to the implanted FES nerve cuff electrodes, such that this first participant will be able to command basic reaching and grasping movements of the arm and hand through direct brain control. The participant will perform first simple one-dimensional movements of the shoulder, elbow, wrist, and hand individually. The participant will train to perform multi-dimensional coordinated movements to reach out to various physical targets. We will assess performance of control using standard human performance metrics and tasks, including our previously described Center-Out-Center tasks, and more natural tasks such as reaching to various parts of the body and face.

Additionally, through Y2, we will continue recruitment for a second study participant, with a goal of consent by Y2, Q4.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Study participants will undergo two surgeries as part of this protocol: an FES surgery to implant electrodes to reanimate the paralyzed limbs, and a brain surgery to implant the brain recording electrodes. The initial plan was to perform the brain surgery first, allow recovery for 3-4 weeks, and then perform the FES surgery. We are now planning on performing the FES surgery first, followed by the brain surgery. The reason for this change primarily to give the participant more time to exercise his muscles using the FES system to enhance muscle strength and resistance to fatigue. This change was primarily a result of the surgeon's and clinical caregiver's expert opinions, and no material changes in risk or procedures will result because of this change.

Actual or anticipated problems or delays and actions or plans to resolve them

The primary significant delay over the reporting period has been research and recruitment shutdowns due to the coronavirus pandemic. Since March 2020, all participant recruitment activities had to be halted, and were only resumed per local institutional guidelines in August 2020. We have been working on implementing COVID-related safety precautions to ensure the safety of study participants and staff, consistent with our hospital guidelines. As these recruitment shutdowns has been lifted, we were able to reengage with potential study participants. While this delay has had tangible effects on our timeline, with potential financial ramifications, we are working diligently to achieve the milestones originally stated.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

No significant changes occurred.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Nothing to report.

Journal publications.

Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

- **Website(s) or other Internet site(s)**

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Investigators

Name: A. Bolu Ajiboye, PhD
Project Role: PI
Nearest person month worked: 4
Contribution to Project: Project planning, participant recruitment, experiment session planning

Name: Jonathan Miller, MD
Project Role: Co-PI
Nearest person month worked: 2
Contribution to Project: Project planning, participant recruitment, regulatory support, surgical planning
Funding Support: Other (Hospital)

Name: Robert Kirsch, PhD
Project Role: Co-PI
Nearest person month worked: 2
Contribution to Project: Project planning, participant recruitment, experiment session planning

Name: Emily Graczyk, PhD
Project Role: Investigator
Nearest person month worked: 2
Contribution to Project: Project planning, experiment session planning

Name: John Simeral, PhD
Project Role: Investigator (Brown University)
Nearest person month worked: 2
Contribution to Project: Decoding algorithm development

Staff & Students

Name: William Memberg, MS
Project Role: Project Manager and Study Coordinator
Nearest person month worked: 4
Contribution to Project: Project planning, participant recruitment, regulatory support, device acquisition, hardware preparation

Name: D. Cale Crowder
Project Role: Graduate Research Assistant
Nearest person month worked: 3
Contribution to Project: Project planning, hardware preparation, software development, experiment session planning
Funding Support: Other (Graduate Fellowship)

Name: Jessica de Abreu
Project Role: Graduate Research Assistant

Nearest person month worked: 3
Contribution to Project: Project planning, hardware preparation, software development, experiment session planning
Funding Support: Other (Graduate Fellowship)

Name: Kenya Alfaro
Project Role: Graduate Research Assistant
Nearest person month worked: 6
Contribution to Project: Project planning, experiment session planning
Funding Support: Other (Graduate Fellowship)

Name: Brianna Hutchison
Project Role: Graduate Research Assistant
Nearest person month worked: 6
Contribution to Project: Project planning, experiment session planning

Name: John Krall
Project Role: Graduate Research Assistant
Nearest person month worked: 6
Contribution to Project: Project planning, experiment session planning
Funding Support: Other (External Grant)

Name: Anisha Rastogi
Project Role: Graduate Research Assistant
Nearest person month worked: 6
Contribution to Project: Project planning, experiment session planning

Name: Emily Conlan
Project Role: Graduate Research Assistant
Nearest person month worked: 4
Contribution to Project: Project planning, experiment session planning
Funding Support: Other (External Grant)

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Ajiboye (PI) received a notice of award for an R01 grant through the National Institutes of Health National Institute for Neurological Disorders and Stroke (NIH/NINDS). The grant started in June 2020, and Dr. Ajiboye's effort on this new grant is 10%. The scientific aims of this new grant have no overlap with the aims of the present SCIRP award.

What other organizations were involved as partners?

Organization Name: **Brown University**
Location of Organization: **Providence, RI**
Partner's contribution to the project **In-kind support (partner assists in developing algorithms for future use in scientific aims)**

Organization Name: **Massachusetts General Hospital**
Location of Organization: **Boston, MA**
Partner's contribution to the project **In-kind support (partner assists in developing algorithms for future use in scientific aims)**

SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

N/A

QUAD CHARTS:

Quad chart submitted.

8. APPENDICES:

None