**AWARD NUMBER:** W81XWH-18-1-0321

**TITLE:** Natural Sensation of Foot-Floor Interactions for Trans-femoral Amputees via Neural Stimulation

**PRINCIPAL INVESTIGATOR:** Ronald Triolo, PhD

**CONTRACTING ORGANIZATION:** Louis Stokes Cleveland VA Medical Research & Education Foundation

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**PREPARED FOR:** U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Natural Sensation of Foot-Floor Interactions for Trans-femoral Amputees via Neural Stimulation

**5a. CONTRACT NUMBER**

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**6. AUTHOR(S):** Ronald Triolo, PhD

E-Mail: Ronad.Triolo@case.edu

**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

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

CLEVELAND VA MEDICAL
RESEARCH & EDUCATION
10701 EAST BOULEVARD
CLEVELAND OH 44106-1702

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Development Command
Fort Detrick. Marvland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

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N/A

**14. ABSTRACT**

The objective of this project is to provide useful sensation of prosthetic foot-floor interactions to trans-femoral amputees by directly interfacing with the nervous system in the intact residuum. Amputees are extremely slow to adapt to loss of lower limb sensation, and fall-related fear and anxiety are all life-long consequences of amputation. Our technical and clinical have worked to develop a surgical plan in which the ideal incision locations for the internal connectors and percutaneous exit sites are determined. Additionally, the study team has increased recruitment efforts to target a new potential source of participant referrals from physical and occupational therapists. We have designed informative flyers and promotional videos. Furthermore, we have added two new members to our team to accelerate the progression of this project, a biomedical engineer and a graduate student. We have established contact with the technical team at Ottobock for assistance with accessing internal sensor data of the Genium device. A non-disclosure agreement is in place. Finally, we have procured two Genium devices, ready to be utilized in the project as well as all the components required for the 1st implant surgery.

**15. SUBJECT TERMS**

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
|---|---|---|---|---|---|
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | | 19b. TELEPHONE NUMBER *(include area code)* |
| Unclassified | Unclassified | Unclassified | Unclassified | | |

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The objective of this project is to provide useful sensation of prosthetic foot-floor interactions to trans-femoral amputees by directly interfacing with the nervous system in the intact residuum. Amputees are extremely slow to adapt to loss of lower limb sensation, and fall-related fear and anxiety are all life-long consequences of amputation. These issues are particularly important for trans-femoral amputees who constitute approximately 40% of the entire amputee population. Despite noteworthy advances in robotic prostheses for lower limb amputees, natural sensory feedback from the lost limb has not yet been incorporated into current prosthetic technologies. This project focuses on restoring useful and natural sensation of prosthetic foot-floor interactions that can be provided to trans-femoral amputees by directly exciting the upper sciatic nerves remaining in the residual limb with a new, non-penetrating, high contact density Composite Flat Nerve Interface Nerve Electrode (C-FINE). We hypothesize that the electrically evoked sensations from C-FINEs implanted on the proximal sciatic nerve in the residuum will be perceived as naturally arising from the missing limb, that their psychometric properties (quality, location, modality and intensity) will be stable, and will improve standing balance, gait mechanics and symmetry, and the ability to negotiate unstructured terrain and uneven surfaces. Positive effects on the cognitive attention required for walking in unfamiliar or distracting environments, incidence and fear of falling, balance confidence, and phantom pain are also anticipated and will be reflected in patterns of home and community use.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Sensory restoration, trans-femoral amputee, C-FINEs, sciatic nerve, gait, balance, neuroprosthesis, microprocessor controlled knee, prosthesis

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

**What were the major goals of the project?**

*List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

During this project we aim to:
1) Design, prototype, verify and produce new hardware and software to extract sensor signals from an advanced microprocessor controlled knee and utilize them to control neural stimulation. (55% Completed). Expected end date 9/15/2020
2) Identify five trans-femoral amputees and install high contact density C-FINEs on their proximal femoral nerves. (21% Completed). Expected end date 12/15/2021
3) Characterize psychometric properties and explore interactions between perceived sensation and all system inputs. (Not started yet). End date 5/13/2022
4) Determine effects of natural sensation on standing balance, gait mechanics, stair/ramp ascent and negotiating difficult terrain under various conditions. (Not started yet). End date 5/11/22
5) Explore subjective perceptions of balance confidence, utility, comfort, satisfaction and ease of use of the sensory neuroprosthesis and measure effects on cognitive/attentional burden and incidence/severity of falls and phantom pain episodes. (Not started yet). End date 5/11/22
6) Evaluate patterns of usage in the home and community and other objective or subjective outcome measures including any carryover effects. (Not started yet). End date 5/11/22

**What was accomplished under these goals?**

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

We identified a potential candidate who was invited to meet the research team, including technical staff and clinicians, on August 21, 2019. The candidate was given an overview of the project aims and any questions she had about the study and procedures were answered. She is a 49-year-old Air Force Veteran who elected to have her leg amputated above the knee due to complications from a lower leg fracture. She is an accomplished ambulator using an Ottobock X3 Microprocessor knee. Screening Consent was given to access the candidate's medical records. Additionally, clinical assessments of her balance during standing and walking tasks were performed as part of the screening protocol. A physical exam was conducted to determine the size, anatomy, and degree of sensation of her residual limb. The candidate ranked exceptionally well on all of the physical and written screening tests, appeared highly motivated and interested in the study, and expressed her desire to sign the implant surgery consent form. Based on the suggestions from the surgeon on the team, we scheduled an appointment for the candidate to undergo a CT Scan and ultrasound imaging of her residual limb in order to determine the location of the remaining sciatic nerve.

Our technical and clinical teams have worked to develop a surgical plan in which the ideal incision locations for the internal connectors and percutaneous exit sites will be determined. To accomplish this goal, we considered factors such as avoiding potential discomfort to the participant and minimizing mechanical stress to connectors and leads. As part of this process, we are working with the prosthetics service at the Louis Stokes Cleveland VA Medical Center (LSCVAMC) to measure the pressure distribution within the prosthetic socket and identify suitable locations with least pressure on the incisions and internal connectors.

Additionally, the study team has increased recruitment efforts to target a new potential source of participant referrals from physical and occupational therapists. To broaden our recruiting efforts, we have worked with the medical illustrator in the Advanced Platform Technology (APT) Center at the LSCVAMC to design informative flyers and a promotional video. The research team has also expanded its recruiting efforts to area Physical and Occupational Therapy Departments in hospitals and private practices. Area therapists were sent the recruitment letter.

We showcased our sensory restoration project at the Research Day on the Hill event at the Rayburn House Office Building in Washington DC on June 20, 2019. During this event, a participant with a trans-tibial amputation enrolled in a parallel DARPA sponsored study shared his experience in our research project. This event was organized as an opportunity to increase the public awareness of our project and highlight the significance of our research to Members of Congress and their Staffers.

Moreover, we have continued to make progress in redesigning our external stimulator, with the aim of improving its functionality by increasing the number of I/O channels and by adding Bluetooth capability. The new features provide easier and more reliable communication between the stimulator and the instrumented prosthesis.

We have added three new members to our team to accelerate the progression of this project. Ms. Diana Suciu (biomedical engineer) will design and implement computer code for experiments as well as develop the necessary hardware tools to interface with the Genium microprocessor knee to extract the sensor data to be utilized to control sensory stimulation. Mr. Suzhou Li (doctoral student) will be responsible for conducting threshold/mapping experiments, functional assessments, and data processing for this project. Ms. Aarika Sheehan (physical therapist) is leading recruitment, functional training, and outcome assessment efforts.

Furthermore, we have established contact with the technical team at Ottobock for assistance with accessing internal sensor data of the Genium device. In addition, a non-disclosure agreement in now in place to facilitate communication between our team and Ottobock's. Finally, we have procured two Genium devices, ready to be utilized in the project as well as all the components required for the 1st implant surgery.

**What opportunities for training and professional development has the project provided?**
*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

All team members completed DoN Human Research training and VA Human Subjects Protection and Good Clinical Practices through Collaborative Institutional Training Initiative. Additionally, Ms. Diana Suciu (biomedical engineer) has learned how to develop the necessary hardware tools to interface with the Genium microprocessor knee. Mr. Suzhou Li (graduate student) has been trained on how to conduct threshold/mapping experiments, functional assessments, and data processing for this project.

**How were the results disseminated to communities of interest?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

We will publish all our scientific findings in lay and professional clinical/scientific venues that are Open Access to disseminate results and progress free of charge to the public.

To increase our outreach, we have worked with the medical illustrator in the Advanced Platform Technology (APT) Center at the Louis Stokes Cleveland VA Medical Center to design a more informative flyer and a promotional video. Additionally, we presented our work in different events and conferences to engage the public and increase awareness about our project. In the latest example, we showcased our sensory restoration project at the Research Day on the Hill event at the Rayburn House Office building in Washington DC on June 20$^{th}$, 2019.

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

- Finalizing the screening of our first trans-femoral amputee participant and scheduling the implant surgery should the participant's sciatic nerve be characterized as viable.
- Continuing our efforts in identifying, recruiting, screening, and enrolling subsequent trans-femoral amputee candidates into the study.
- Working with engineers at Ottobock to access internal sensor data of the Genium prosthesis. This prosthesis already contains multiple sensors that will provide information about limb position and the loads on the device, which we will utilize to control neural stimulation and generate corresponding sensations.
- Complete development of our newly modified stimulator. The wireless capability and additional I/O channels will be fully tested in the laboratory to ensure reliable performance prior to application to a research subject.
-Procure all the components necessary for the 2$^{nd}$ and 3$^{rd}$ implant surgeries.

***4.*** **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

**What was the impact on the development of the principal discipline(s) of the project?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to Report.

**What was the impact on other disciplines?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to Report.

**What was the impact on technology transfer?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

**What was the impact on society beyond science and technology?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

| |
|---|
| Nothing to Report. |

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

| |
|---|
| Nothing to Report. |

**Actual or anticipated problems or delays and actions or plans to resolve them**
*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

| |
|---|
| We anticipate some delays in proceeding with the implant surgery with our first participant. Our team must determine the suitability of the identified candidate by conducting medical imaging of the residual limb to ensure the suitability of the sciatic nerve for multiple cuff electrode deployment. In addition, our team is actively working to prevent delays by working closely with the first potential participant as well as the medical staff at Cleveland VA Medical Center. We are also working with the surgeon to secure OR time. To expedite the progress in identifying subsequent participants, we continue our recruitment efforts by engaging with clinical and patient advocacy groups locally and nationally. Furthermore, we are engaging the trans-tibial amputees already actively participating in our other DARPA sponsored sensory neuroprosthesis research in these recruiting efforts. Our study coordinator and the physical therapist on the team continue to attend Amputee Clinic weekly at the Cleveland VA Medical Center to pre-screen the scheduled patients and identify potential participants. We have also continued to cultivate our relationship with members of the PM&R department at Walter Reed National Military Medical Center to actively augment and enhance our recruiting efforts. |

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

Nothing to report

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

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

Nothing to Report.

**Significant changes in use or care of vertebrate animals**

Nothing to Report.

**Significant changes in use of biohazards and/or select agents**

Nothing to Report.

**6. PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  *Report only the major publication(s) resulting from the work under this award.*

**Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

| |
|---|
| Nothing to Report. |

**Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

| |
|---|
| Nothing to Report. |

**Other publications, conference papers and presentations**. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

| |
|---|
| We showcased our sensory restoration project at the Research Day on the Hill event at the Rayburn House Office building in Washington DC on June 20th. During this event, a participant with a trans-tibial amputation shared his experience in our research project. This event was organized as an opportunity to increase the public awareness to our project and highlight the significance of our research project to Congress Members and their Staffers. |

- **Website(s) or other Internet site(s)**
  *List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

| |
|---|
| Nothing to Report. |

- **Technologies or techniques**
  *Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.*

| |
|---|
| Nothing to Report. |

- **Inventions, patent applications, and/or licenses**
  *Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

| |
|---|
| Nothing to Report. |

- **Other Products**

  *Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*

  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

| |
|---|
| The link to the promotional video: https://www.youtube.com/watch?v=KPZSuFoND48 |

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

*Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".*

*Example:*

| | |
|---|---|
| *Name:* | *Mary Smith* |
| *Project Role:* | *Graduate Student* |
| *Researcher Identifier (e.g. ORCID ID):* | *1234567* |
| *Nearest person month worked:* | *5* |
| *Contribution to Project:* | *Ms. Smith has performed work in the area of combined error-control and constrained coding.* |

*Funding Support:* *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name: Ronald Triolo
Project Role: PI
Researcher Identifier (e.g. ORCID ID): 0000-0003-0984-5803
Nearest person month worked: 1
Contribution to Project: Programmatic, administrative and scientific oversight of all aspects of the project

Name: Hamid Charkhkar
Project Role: Senior Research Associate (Technical)
Researcher Identifier (e.g. ORCID ID): 0000-0001-5485-5969
Nearest person month worked: 2
Contribution to Project: Conducting sensory stimulation tests, including stimulus calibration and parameter setting, psychometric testing, system integration and outcome measurement

Name: Breanne Christie
Project Role: PhD Student
Researcher Identifier (e.g. ORCID ID): 0000-0003-3764-6836
Nearest person month worked: 1
Contribution to Project: Designing and performing psychometric evaluations and biomechanical tests

Name: Courtney Shell
Project Role: Postdoctoral Fellow (Technical)
Researcher Identifier (e.g. ORCID ID): 0000-0003-3764-6836
Nearest person month worked: 1
Contribution to Project: Designing and conducting psychometric evaluations and biomechanical tests

Name: Melissa Schmitt
Project Role: Nurse Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Regulatory reporting and compliance, medical monitoring and clinical services

Name: Aarika Sheehan
Project Role: Physical Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Subject recruiting, candidate screening, functional training and outcome assessment

Name: John Schnellenberger
Project Role: Biomedical Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Circuit design and software development for home-going system

Name: Jeremy Dunning
Project Role: Electrical Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Circuit design and software development for home-going system

Name: James Huang
Project Role: Electrical Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2
Contribution to Project: Circuit design and software development for home-going system

Name: Diana Suciu
Project Role: Biomedical Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Develop the necessary hardware tools to interface with the Genium microprocessor knee

Name: Suzhou Li
Project Role: PhD Student
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Develop computer code for upcoming experiments. Assist in conducting experiments to assess effects of sensory feedback in trans-femoral amputees

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

*Nothing to Report.*

**What other organizations were involved as partners?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*
*Organization Name:*

*Location of Organization: (if foreign location list country)*
*Partner's contribution to the project (identify one or more)*

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: Ottobock
Location of Organization: Vienna, Austria
Partner's contribution to the project: Industrial partner and collaborator. Ottobock provided us with a Genium Knee prosthesis on load without charge, and will lend technical assistance with accessing internal sensor data of the Genium device.

Organization Name: Case Western Reserve University
Location of Organization: Cleveland, OH
Partner's contribution to the project: Access to microfabrication, electronic design and circuit testing facilities, and technical support required for external stimulator design modifications and fabrication.

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

**QUAD CHARTS:** *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

**9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*