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TITLE: Ambulatory and Non-Ambulatory Benefits of Lower Limb Exoskeleton Use, with and without FES, in Clinical and Community Settings

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14. ABSTRACT

This research investigates the extent to which regular walking in an exoskeleton will provide mobility, health, and recovery benefits to individuals with spinal cord injury. The research is comprised of three sub-studies. The first investigates prospective benefits while walking in an exoskeleton; the second investigates prospective additional benefits when the exoskeleton is supplement with lower limb functional electrical stimulation; and the third investigates prospective benefits during home and community use. As of this annual report, the first study is essentially complete, with a final enrollment of 22 subjects. Results from study 1 appear promising. The second study, which essentially repeats the first with supplemental FES, is ongoing, with 15 subjects either completed or under treatment (and 7 more to be enrolled). The third study is under IRB review at Johns Hopkins University, the IRB of record for the lead institution. The period of performance has been extended via a one-year no-cost extension to complete the three sub-studies.

15. SUBJECT TERMS
spinal cord injury, paraplegia, exoskeleton, physical medicine and rehabilitation, rehabilitation research, legged mobility, neuromuscular impairment, neural and functional recovery

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1. INTRODUCTION:

This research investigates the extent to which regular walking in an exoskeleton will provide mobility, health, and recovery benefits to individuals with spinal cord injury. The research is comprised of three sub-studies. The first investigates prospective benefits while walking in an exoskeleton; the second investigates prospective additional benefits when the exoskeleton is supplemented with lower limb functional electrical stimulation; and the third investigates prospective benefits during home and community use. The respective studies will characterize effects of exoskeleton walking on pain, spasticity, bowel and bladder function, body-mass index (BMI), bone mineral density (BMD), cardiovascular health, well-being, potential neurological recovery, and level of mobility. The research is being conducted at three sites – Vanderbilt Medical Center, Mayo Clinic, and the Tampa VA – each of which is conducting the same study protocol. The first two studies, each of which are conducted in a clinical setting, will enroll 22 subjects total, while the third, which is a take-home study, will enroll 3 subjects total (1 per study site). Due to approval delays, the research is approximately one year behind the original schedule, but all studies are expected to be completed following a one-year no-cost extension. At this point, the first study is essentially complete; the second has 15/22 subjects under treatment or completed; and the third is awaiting IRB approval at Vanderbilt.

2. KEYWORDS:

spinal cord injury; paraplegia; exoskeleton; physical medicine and rehabilitation; rehabilitation research; legged mobility; neuromuscular impairment; neural and functional recovery

3. ACCOMPLISHMENTS:

The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

The following narrative provides a description of progress:

This research entails three sub-studies. Studies 1 and 2 are the core investigations of the research. Study 1 investigates the potential health benefits of regular walking in an exoskeleton, while Study 2 investigates the potential added benefits of regular exoskeleton walking with supplement functional electrical stimulation (FES). Each of Studies 1 and 2 enrolls 22 subjects, each of which walks for 24 walking sessions over an 8-week treatment period. Study 3 is a follow-on exploratory pilot study involving 3 subjects, intended to inform the potential utility of an exoskeleton in the home and community, and to examine the potential health and mobility benefits associated with exoskeleton use in the home and community over a two-month usage period. At this point in the project, Study 1 is essentially complete (awaiting the follow-up visit of the last subject). Study 2 has 15/22 subjects either undergoing or completed treatment. Specifically, Vanderbilt is treating its fifth of seven Study 2 subjects; Mayo is treating is eighth of eight Study 2 subjects; and Tampa is treating its second of seven Study 2 subjects. Note that Tampa was substantially delayed in the start of Study 2 by unanticipated approval delays. Assuming no inordinate delays in the approval of Study 3, both Vanderbilt and Mayo will complete all three studies within the one-year NCE. Tampa will likely complete all three studies within the one-year NCE, but does not have much margin for delay. The table below outlines progress with respect to the SOW milestones.

The following table outlines the major tasks there were scheduled to start and be in progress during previous reporting periods:

Task/Milestone	Description	Target Completion Date/Quarter	Status
Major Task 1	Finalize Protocol and Obtain IRB/HRPO Approval for Study 1	Apr 2016 or Y1Q3	COMPLETED
Major Task 2	Conduct Study 1	Jan 2018 or Y3Q2	COMPLETED (final enrollment of 22, relative to originally planned enrollment of 24)
Major Task 3	Finalize Protocol and Obtain IRB/HRPO Approval for Study 2	Jan 2018 or Y3Q2	COMPLETED
Major Task 4	Conduct Study 2	Jan 2019 or Y4Q2	IN PROGRESS (15/22 subjects under treatment or completed)
Major Task 5	Finalize Protocol and Obtain IRB/HRPO Approval for Study 3	Jan 2019 or Y4Q2	IN PROGRESS
Major Task 6	Conduct Study 3	Sept 2019 or Y4Q4	NOT YET STARTED

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.

- Major activities during Y4:
  - Study 1 completed (except one subject at Tampa who needs 2-month follow-up).
  - Study 1 data analysis conducted.
  - Study 1 results drafted into a journal paper currently in preparation.
  - Study 2 IRB and HRPO approval completed at all sites (Vanderbilt and Mayo had IRB/HRPO approval for Study 2 in Y3, but Tampa did not receive HRPO approval for Study 2 until 9/25/2019).
  - 10 additional subjects for Study 2 were enrolled or completed during Y4, for a total of 15/22 Study 2 subjects.
  - Study 3 protocol was drafted and submitted for IRB approval at the lead institution.

- Specific objectives (for Y5):
  - Publish results for Study 1
  - Complete Study 2.
  - Analyze and publish results from Study 2.
  - Receive IRB/HRPO approval for Study 3.
  - Conduct and complete Study 3.

- Significant results or key outcomes (from Y4):
  - Study 1 has been completed. Facilitation of functional recovery for the n=7 poorly-ambulatory (PA) participants, in aggregate, between the baseline and treatment-end time points, participants improved mobility in all five mobility measures. The changes included a 17% median improvement in the 10MWT, corresponding to an increase in walking speed from 0.22 m/s at baseline to 0.26 m/s at treatment-end; a 19% improvement in TUG test time; 14% improvement in 6MWT; 20% improvement in FIM-G score; and 30% improvement in WISCI-II score. Further, these improvements generally persisted two months following the walking intervention. The average time-since-injury for the n=7 PA participants was 5.0 years and median was 6.1 years, so in aggregate participants were well within a chronic classification. As such, the treatment of exoskeletal walking appears to have had a consistent effect in improving mobility among PA participants, with a number of limitations as follows.
  - Study 2 is underway at all sites. Mayo is treating 8/8 subjects; Vanderbilt is treating 5/7 subjects; and Tampa is treating 2/7 subjects.

- Other achievements: None yet.

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.

Clinical staff at all study sites attended an initial 3-day course, and subsequently attend another 2-day course, and obtained training and certification to use exoskeletons with FES in clinical practice.

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.

The results of Study 1 have been analyzed and drafted into a paper for publication. The paper is co-authored between the three institutions, and is currently undergoing inter-institutional review prior to submission for publication.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

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

The investigators plan to complete all three studies within the one-year NCE, which will entail:
1) Publish results from Study 1.
2) Complete and analyze results from Study 2.
3) Obtain IRB/HRPO approval for Study 3.
4) Complete and analyze results from Study 3.

4. **IMPACT:** Describe 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).

Facilitation of functional recovery
For the n=7 poorly-ambulatory (PA) participants, in aggregate, between the baseline and treatment-end time points, participants improved mobility in all five mobility measures. The changes included a 17% median improvement in the 10MWT, corresponding to an increase in walking speed from 0.22 m/s at baseline to 0.26 m/s at treatment-end; a 19% improvement in TUG test time; 14% improvement in 6MWT; 20% improvement in FIM-G score; and 30% improvement in WISCI-II score. Further, these improvements generally persisted two months following the walking intervention. The average time-since-injury for the n=7 PA participants was 5.0 years and median was 6.1 years, so in aggregate participants were well within a chronic classification. As such, the treatment of exoskeletal walking appears to have had a consistent effect in improving mobility among PA participants, with a number of limitations as follows.

Effects on secondary health issues
Of the five secondary health issues examined in the study, 24% of participants indicated changes in pain during the study; 29% indicated changes in spasticity; 33% indicated changes in bowel habits; 33% changes in bladder habits; and 52% changes in mood. In aggregate, the median rating of all five secondary health issues for these participants at baseline was zero; namely, they indicated "no change" over the preceding month in the respective secondary health issue at the baseline measurement (i.e., at the study start). In aggregate, the median rating of all five secondary health issues for these participants at treatment-end changed by 1.2 points in a direction of improvement, where 3 is the maximum possible change. Namely, for pain and spasticity, participants indicated a decrease of one point (i.e., 1/3 of the maximum rating) over the preceding month; for bowel habits, participants indicated an increase in two points (i.e., 2/3 of the maximum rating); and in bladder habits and mood, participants indicated an increase of one point (i.e., 1/3 of the maximum rating). Thus, for individuals who indicated some change in a second health issue, the treatment of exoskeletal walking in aggregate had a uniformly beneficial effect on all respective secondary healthy issues. On average, 34% of participants responded to any given secondary health issue, and in aggregate, each issue was improved by 40% of the maximum possible improvement. The results for effects on bowel and bladder habits exceed a 5% confidence level, while p-values for other measures provide lower confidence of the differences in medians. These improvements washed out at the two-month follow-up measurement, indicating the putative benefits are associated with continuing use of the exoskeleton.

Subjective comments
In the questionnaire, participants were asked to elaborate on changes observed for each secondary health issue, if changes had occurred. Specifically, participants were asked "If your overall level of [pain/spasticity] over the past month has changed, please elaborate," or "If you have noticed changes in your [bowel habits/bladder habits/mood] over the past month, please elaborate." Subjective comments from participants in answer to these questions support the quantitative measures presented above. Specifically, with respect to pain, all comments indicated a decrease in pain, while no comments indicated an increase. Representative comments, each from a different participant, include: "Pain has stopped due to standing more and straight up"; "My lower back feels like it has loosened up since walking in the exoskeleton"; "My overall level of pain has decreased extremely due to exoskeleton use"; and "In the past month my pain has not been as intense as usual." With regard to spasticity, as the low statistical confidence indicates, subjective comments were less uniform, with 4/6 comments indicating a decrease in spasticity and 2/6 indicating an increase. Representative comments reporting a decrease in spasticity include "My tone has decrease noticeably in both knees"; "It has decreased extremely due to daily use of the exoskeleton"; "Sessions have decreased spasticity"; and "Not as much as before." Comments reporting an increase in spasticity include "In the past month my right leg has had a little more spasticity than usual" and "The more I do the more spastic the legs can be." Subjective comments regarding bowel habits, bladder habits, and mood were uniformly positive (i.e., no negative comments were recorded by participants). Representative comments regarding changes in bowel habits, each from a different participant, include: "Going BM everyday where before it was 3-4 days"; "I have been going more easily and more frequently"; "It seems that the increased movement has helped me have a more consistent bowel movement"; and "I am now having sensations prior to bowel movement. These sensations are providing me adequate time to use the restroom." Representative comments regarding changes in bladder habits, each from a different participant, include: "Less bladder accidents"; "I don't have any accidents. My bladder is holding longer and throughout the night"; "I have been able to feel more often when I need to empty my bladder"; " I now have sensations that provide a warning for urination"; and "Better, feel like it's really trying to come back." Finally, representative comments regarding changes in mood, each from a different participant, include: "I have been in a better mood overall physically and mentally"; "While i have been able to do [walking] therapy, it just makes me feel better and be happy"; "I have felt physically and mentally stronger, more motivated"; "Love walking"; and "My emotional and mental health in general has significantly improved. I looked forward to being in exoskeleton. Self-esteem and confidence went up. Felt better about being in social situations."

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 at this point.

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 at this point.

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 Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

No changes in objectives or scope.

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.

Study 1 and 2 approval took longer than expected, and as result our study is behind the original schedule. Once approvals have been obtained, the studies have proceeded well, with few problems relative to expectations (i.e., we have had some occasional minor equipment problems, but those issues appear largely resolved, and we have had some subjects who had to withdraw due to non-study-related issues). In consideration of these delays and withdrawals, we requested and were granted a one-year NCE. Additionally, in order to complete the three studies given the time and resources remaining, we revised target enrollment to 22 for Studies 1 and 2 (relative to the originally planned 24), and to 3 for Study 3 (relative to the originally planned 6).

Changes that had a significant impact on expenditures

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.

None significant. We have relatively little funds remaining, but a sufficient amount to complete the research.

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

None to report.

Significant changes in use or care of vertebrate animals.

None to report.

Significant changes in use of biohazards and/or select agents

None 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).*

None yet to report, but first paper describing results of Study 1 has been drafted and is in internal review.

  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).*

None yet 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.*

None yet to report.

- **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.

None yet to report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

None yet to report.

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. 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.

None yet 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;*
- *biospecimen 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.*

None yet to report.

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: Dr. Michael Goldfarb
Project Role: PI, Vanderbilt lead researcher
Researcher Identifier: ORCID ID 0000-0002-6622-095X
Nearest person month worked: 3
Contribution to Project: Dr. Goldfarb is coordinating the research effort.

Name: Ms. Sheri Dixon
Project Role: Vanderbilt study coordinator
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Ms. Dixon is the Vanderbilt study coordinator, has been assembling IRB and HRPO applications for Vanderbilt and all sites, has set up the REDCap database, and the overall project (i.e., multi-site) study coordinator.

Name: Ms. Christina Durrough
Project Role: Vanderbilt lead physical therapist
Researcher Identifier: n/a
Nearest person month worked: 3
Contribution to Project: Ms. Durrough has been assisting with design and assembly of the protocol and data recording notebooks, and is responsible for exoskeleton use and oversight.

Name: Dr. Kristin Zhao
Project Role: Mayo lead researcher
Researcher Identifier: ORCID ID 0000-0001-7598-8197
Nearest person month worked: 2
Contribution to Project: Dr. Zhao is leading the research effort at the Mayo Clinic.

Name: Ms. Megan Gill
Project Role: Mayo Clinic lead physical therapist
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Ms. Gill has been administering the study protocol on the two subject currently enrolled at Mayo.

Name: Mr. Tyson Scrabeck
Project Role: Mayo study coordinator
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Mr. Scrabeck has authored and assembled IRB and HRPO applications for the Mayo site.

Name: Mr. Daniel Veith
Project Role: PT
Researcher Identifier: n/a
Nearest person month worked: 1
Contribution to Project: Mr. Veith oversees treatment for some subjects.

Name: Mr. Michael Boyd
Project Role: PT assistant
Researcher Identifier: n/a
Nearest person month worked: 1
Contribution to Project: Mr. Boyd oversees treatment for some subjects.

Name: Dr. Walter Kremers
Project Role: Statistician
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Dr. Kremers is the study statistician.

Name: Mr. Zachary Pohlkamp
Project Role: PT assistant
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Mr. Pohlkamp oversees treatment for some subjects.

Name: Dr. Sam Phillips
Project Role: Tampa VA lead researcher
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Dr. Phillips leading the research effort at the Tampa VA.

Name: Mrs. Padmaja Ramaiah
Project Role: Tampa VA study coordinator
Researcher Identifier: n/a
Nearest person month worked: 1
Contribution to Project: Mrs. Ramaiah has authored and assembled IRB and HRPO applications for the Tampa site.

Name: Mrs. Anita Ramrattan
Project Role: PT
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Mrs. Ramrattan is the lead PT at Tampa.

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.

There has been no significant net change in active support for the study PI or co-PIs.

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: Mayo Clinic
Location of Organization: Rochester MN
Partner's contribution to the project (identify one or more)

- Collaboration: Mayo is one of the three study sites conducting the study protocol.

Organization Name: Tampa VA
Location of Organization: Tampa Bay FL
Partner's contribution to the project (identify one or more)

- Collaboration: Tampa is one of the three study sites conducting the study protocol.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating 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.