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TITLE: Improved Training Program for Fall Prevention of Warfighters w ith Low er Extremity Trauma

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14. ABSTRACT
In the current military and healthcare environment, it is essential to focus on rapid but safe development of functional skills with a goal of early discharge from rehabilitation to return to active duty or civilian life. Although the U.S. military has access to state-of-the-art treatment and devices, warfighters with lower extremity trauma still struggle to regain full functional capabilities. A key factor that limits the ability of these individuals to achieve maximum functional capabilities is falls. Falls have serious consequences including loss of confidence, fear of falling, and injury. Warfighters with lower extremity trauma need to face the risk of falling and overcome that fear. After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay healing. When individuals trip or slip, they are likely to fall and injure themselves, in spite of advances in rehabilitation care. This project develops a secondary rehabilitation program, implemented after traditional therapy, and designed to reduce falls in warfighters with amputations or limb preservation procedures. The goals of this research effort are to augment existing rehabilitation with a novel, demonstrably successful fall-prevention training method to help warfighters return to full high-level functional capabilities and emotional wellness, and to decrease the time required to either return to active duty or to a productive, active civilian life. The training program utilizes a microprocessor-controlled treadmill designed to deliver task-specific training perturbations. The training consists of six, 30 minute sessions delivered over a 4-week period. In the current year, we have developed and operationalized perturbation protocols for all sites. Enrollment is underway.

15. SUBJECT TERMS
Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy

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1. INTRODUCTION

After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay return to active duty or to a productive, active civilian life. Following a trip or slip, many warfighters are still likely to fall and injure themselves, in spite of advances in rehabilitation care. Adaptations due to the loss of function, while necessary, may also limit physical performance and reduce quality of life. This research project is a secondary rehabilitation program, implemented after and as augmentation to existing rehabilitation by providing advanced fall-prevention training, to help warfighters return to as close to full high-level functional capabilities and emotional wellness as possible, and to decrease the time required to either return to active duty or to a productive, active civilian life. The proposed novel training method has the potential to change the standard of care for lower extremity limb trauma.

2. **KEYWORDS:** Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy,

3. ACCOMPLISHMENTS

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

  This project has three main goals.
  (1) Implement a novel postural perturbation training program in the three DOD Medical Treatment facilities. This rehabilitation protocol will be provided to active-duty service members who have suffered combat-related lower limb trauma, specifically amputations or salvaged limbs.
  (2) Assess whether the benefits of improved motor skills induced by the rehabilitation protocols can be retained following training.
  (3) Identify, evaluate, and implement existing low cost methods for measuring trunk control that can be used in lieu of substantially more expensive fixed motion capture systems. This will ensure that the rehabilitation program can be transitioned to clinical settings.

- **What was accomplished under these goals?**

  The primary goals in the third year of the study were to create the perturbation protocols for all treadmills and begin subject enrollment.

  Major activities:

  - The fall prevention training program utilizes a microprocessor-controlled treadmill to deliver task specific training perturbations. The software to operate these treadmills has been installed at all sites.

  - Trunk kinematics, at recovery step, are key outcome measures. Motion capture systems, which are expensive, require dedicated space and well-trained staff, have been used to measure trunk kinematics. However, in order to translate this research into a clinical setting, we plan to use small, inexpensive inertial measurement units (IMU). Thus, we needed to validate the IMU measurement of trunk kinematics at recovery step against the gold-standard motion capture system during treadmill induced forward and backward disturbances. Ten healthy young adults participated in the study. The subjects had an IMU on their sternum and retro-reflective triad of markers on the IMU to measure trunk kinematics at recovery step. The participants experienced forward and backward disturbances, which incrementally increased in intensity until the harness supported at least 50% of the subject's body weight. Equivalence testing (α=0.05) demonstrated that both the trunk angle (TA) and angular velocity (TAV) measured by the IMU and motion capture were equivalent. The 95% Confidence Intervals (TA: [-1, 1], TAV:

[0, 17]) were within the equivalence interval (TA: [-2, 2], TAV: [-20, 20]) and the p-values (TA: 0.005, TAV: 0.011) were less than alpha (p=0.05). A comparison of the mean trunk angle and mean trunk angular velocity for both the IMU and motion capture measurements across all 10 subjects demonstrates the measurement equivalence (Figure 1). As a result of this study, we can state that IMUs provide a valid method for measuring trunk kinematics on a treadmill during clinical fall prevention rehabilitation.

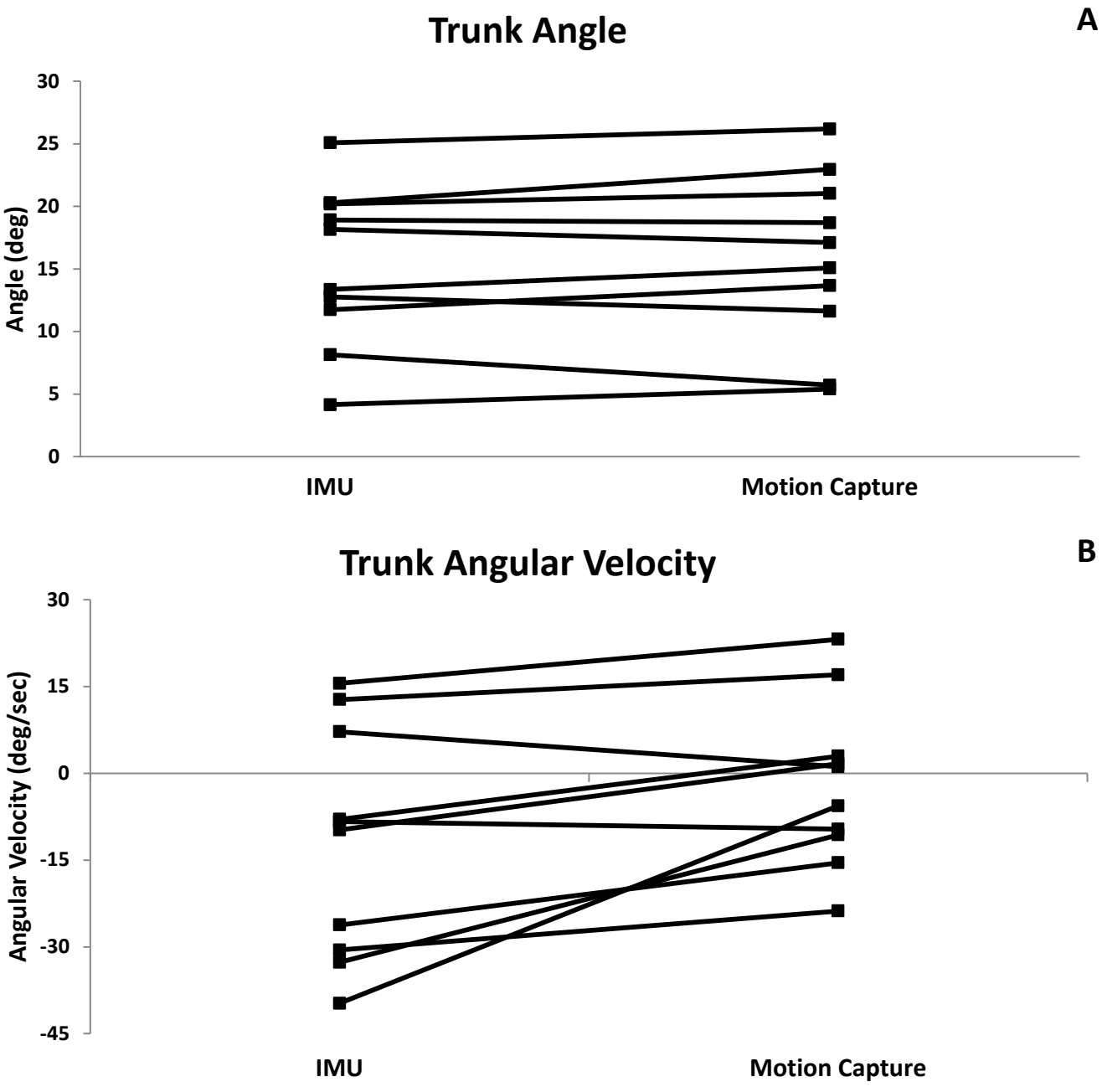

Figure 1: Mean trunk angle (A) and trunk angular velocity (B) for IMU and motion capture measurements across all 10 subjects. Each line represents a single subject. Positive angles are flexion.

- Data collection has begun. 108 subjects have been screened, 16 subjects were eligible, 5 subjects have been enrolled, 4 are currently being trained, and 1 subject has completed the training. The goal for the project is to enroll, train, and test 30 subjects.

- **What opportunities for training and professional development has the project provided?**
  Nothing to report.

- **How were the results disseminated to communities of interest?**
  The IMU validity study was presented at the 2018 annual meeting of the American Society of Biomechanics held in Rochester, MN.

- **What do you plan to do during the next reporting period to accomplish the goals?**
  - Continue, and hopefully complete, data collection.
  - Analyze results.
  - Submit a paper describing the findings of the study.

4. IMPACT

- **What was the impact of 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**
  No changes to report.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  There were significant delays in the receipt and installation of the microprocessor-controlled treadmills for two sites. Once the treadmills were received, software needed to be developed to provide the perturbations required for the performance of the testing and training. This resulted in further delays. Fortunately, all of these matters have been resolved and recruitment is now underway.

- **Changes that had a significant impact on expenditures**
  Nothing to report.

- **Significant changes in use or care of human subjects**
  None.

6. PRODUCTS

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

Journal Publication: Taylor L, Miller E, Kaufman KR. Static and dynamic validation of inertial measurement units. Gait & Posture, 57:80-84, 2017.

Abstract Presented: Miller E, Kaufman KR. Validation of IMUs for Trunk Kinematics during Treadmill Disturbances. 42nd Annual Meeting of the American Society of Biomechanics, Rochester, MN, August 8-11, 2018.

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

Nothing to report.

- **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?**

Name:	Kenton Kaufman, PhD, PE
Project Role:	Principal Investigator, Mayo Clinic
Nearest person month worked:	2
Contribution to Project:	Dr. Kaufman held regular meetings with the Co-Investigators. He has prepared materials for the Mayo IRB and HRPO. He has developed the standard operating procedures for the research protocols. He has served as the liaison with the Grants Officer's Representative and has provided the required quarterly and annual reports.
Funding Support:	

Name:	Emily Miller, MS
Project Role:	Research Engineer, Mayo Clinic
Nearest person month worked:	5
Contribution to Project:	Emily Miller attended regular meetings with the Co-Investigators. She conducted tests to validate the trunk kinematics from the IMUs vs motion capture. She developed custom software to implement the controlled disturbances on the AMTI and Treadmetrix treadmills utilized in the training program and wrote a user's manual for both treadmills. She has prepared and submitted two manuscripts. She presented these findings from one of the manuscripts at the 2018 Annual Meeting of the American Society of Biomechanics.
Funding Support:	

Name:	Christine Huyber, CCRP
Project Role:	Kinesiologist, Mayo Clinic
Nearest person month worked:	1
Contribution to Project:	Christine Huyber attended regular meetings with the Co-Investigators. She developed surveys for subjects in the study and REDCap data collections tools for use across institutions.
Funding Support:	

Name:	Marilynn Wyatt, MA, PT
Project Role:	Site Principal Investigator, NMCSD
Nearest person month worked:	2
Contribution to Project:	Ms. Wyatt is the NMCSD site principal investigator for the project. She has attended all study meetings with the other Co-Investigators and coordinates the work being accomplished at Naval Medical Center San Diego (NMCSD). The focus this year continued to be on the multi-site regulatory review including IRB approvals and secondary approval of HRPO. NMCSD is the IRB of record for the three DoD study sites. Other areas of focus have been on finalizing all the SOPs and documentation, coordinating NMCSD staff to travel to the other sites to train their staff, working with engineering support to sort out the treadmill issues and recruiting/hiring/training a new clinical research coordinator. She has worked with Geneva Foundation to coordinate the sub-award requirements and hiring.
Funding Support:	Federal Employee (11 months)/transitioned to Grant/Geneva Foundation sub award 1 September 2018.

Name:	Tatiana Djafar, MA
Project Role:	Engineer, NMCSD
Nearest person month worked:	6
Contribution to Project:	Ms. Djafar was the NMCSD site engineer for the project. Her role was to oversee the technical aspects of the project for NMCSD and support the other sites as required. She has attended regular meetings with the other Co-Investigators. She worked closely with the Mayo engineer (Miller) to troubleshoot, fine-tune, and finalize the custom software for the AMTI treadmill. She began the process to adapt the software's architecture to more closely mimic that of the custom Treadmetrix software being used at the other sites. She helped write and finalize the general SOP that was shared with the other Co-Investigators for guidance and helped develop a training plan for the other sites, which was used when she travelled to CFI and WR to help train site staff. She has been troubleshooting issues with the AMTI treadmill belt slipping laterally and the back belt stopping upon recovery landings. She has been involved in all enrollment, data collection, and training to date and has begun training new site staff in related procedures.

Funding Support:	Grant/Geneva Foundation sub award

Name:	John-David Collins, MA, ATC
Project Role:	Biomechanist/AI, NMCSD
Nearest person month worked:	11
Contribution to Project:	Mr. Collins was the NMCSD Biomechanist for the project. His role was to oversee the recruitment, data collection and initiation of training for the project. Additionally he has contributed to any troubleshooting efforts and any administrative duties needed. He regularly attended telcon and other meetings with the other investigators and helped write and finalize the general SOP that was shared with the other sites for guidance. Along with the other NMCSD Co-I's, Mr. Collins develop a training plan which was used when he traveled to WRNMMC with 2 other NMCSD investigators for on-site familiarization and training utilizing the general SOP and training plan. He also assisted in all recruitment, data collection and general implementation of the protocol. Additionally, he assisted with troubleshooting of AMTI treadmill belt issues and the training of new staff.
Funding Support:	Grant/Geneva Foundation sub award

Name:	Claire Zai, MS
Project Role:	Clinical Research Coordinator/ Researcher, NMCSD
Nearest person month worked:	2
Contribution to Project:	Claire Zai replaced Amanda Wingate on this project. Claire has attended all meetings and teleconferences since her arrival in June 2018. Since that point she has organized and maintained all regulatory documents (IRB, CRADA, HRPO) for the study. She has submitted both the continuing review and several amendments to ensure smooth continuation of the project. Claire has also been training to take over some of the responsibilities previously held by Tanya Djafar. These new responsibilities include, but are not limited to, scheduling subjects, running the treadmill and data collection of IMU sensors, reviewing and checking all collected data after the session has concluded and REDCap entry.
Funding Support:	Grant/Geneva Foundation sub awards

Name:	Julianne Stewart, PT, DPT
Project Role:	Research Physical Therapist, NMCSD
Nearest person month worked:	3
Contribution to Project:	Dr. Stewart has attended all in-person meetings and teleconferences with co-investigators. She traveled to WRNMMC and CFI to perform training for investigators at those sites. She has contributed to writing and finalizing the SOPs for training and assessment sessions. She has also tested and given feedback on digital data collection using REDCap. She assists with subject screening and scheduling. During subject assessments at NMCSD she is responsible for the subject consent process as well as questionnaire

	administration, PT Evaluation completion, and providing clinical supervision of the patient's status during treadmill assessments. Additionally, she made changes to data collection forms to ensure regulatory compliance and data uniformity across paper and digital versions of these forms and prepared these forms for submission to the IRB at NMCSD.
Funding Support:	Grant/Geneva Foundation sub awards

Name:	Trevor Kingsbury, MS
Project Role:	Biomechanist/AI, NMCSD
Nearest person month worked:	1
Contribution to Project:	Mr. Kingsbury, a DoD civilian employee, has been involved in the project since inception but on a more limited basis. He has provided project support as a biomechanist and traveled to BAMC to perform training for investigators at that site in June 2018. He has also assisted during subject data collection as needed. In September, Mr. Kingsbury assumed the lead role for all NMCSD IRB matters since Ms. Wyatt transitioned from government service. This included the year-end continuing review and other IRB related documents. Additionally he is responsible for coordinating tasks and patient scheduling with other staff members at NMCSD.
Funding Support:	Federal Employee

Name:	Pinata Sessoms, PhD
Project Role:	Site Principal Investigator, Naval Health Research Center
Nearest person month worked:	1
Contribution to Project:	Dr. Sessoms is the NHRC site lead for the project. During the current reporting period, Dr. Sessoms has participated in the regularly scheduled meetings with Co-Investigators and has served as liaison to key personnel at NHRC, helping to obtain the needed approvals from NHRC personnel for the multi-site IRB protocol.
Funding Support:	BUMED

Name:	John Fergason, CPO
Project Role:	Site Principal Investigator, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	2
Contribution to Project:	John Fergason was the Site PI prior to transferring the responsibilities to Riley Sheehan in July. He has participated in regular teleconferences with C0-Investigators.
Funding Support:	Federal Employee

Name:	Riley C. Sheehan, PhD
Project Role:	Site Principal Investigator, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	4
Contribution to Project:	Riley Sheehan assumed the role of Site PI in July. He has

	participated in regular teleconferences with C0-Investigators as well as attended the project meeting held at the American Society of Biomechanics annual meeting. He has also worked on purchasing, setting up, and troubleshooting study equipment in preparation for data collection. He has also coordinated the administration of the Henry Jackson Foundation sub-award to the CFI
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Noel Guerrero, BS
Project Role:	Research Assistant, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	3
Contribution to Project:	Noel Guerrero has participated in regular teleconferences with C0-Investigators. He has also worked to prepare equipment for data collection including creating SOPs.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Mark D. Grabiner, PhD
Project Role:	Site Principal Investigator, University of Illinois-Chicago
Nearest person month worked:	2
Contribution to Project:	Dr. Grabiner attended the regularly scheduled meetings with the research team. He directs and oversees the effort of a 0.25 FTE doctoral student on this project. The project-based work at UIC is focused on post-collection analysis of biomechanical data collected at and transferred from Mayo, NMCSD, CFI, and WRNMMC.
Funding Support:	

Name:	Christopher L. Dearth, PhD
Project Role:	Site Principal Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Dr. Dearth serves as the WRNMMC site lead for the project. During the current reporting period, Dr. Dearth has participated in all study meetings, coordinated equipment orders/deliveries/install, and engaged in discussions with WRNMMC clinical and research staff to ensure a smooth start to subject enrollment and data collection in the upcoming year and participated in training with NMCSD study team.
Funding Support:	Federal Employee

Name:	Bradford D. Hendershot, PhD
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Dr. Hendershot serves as an Associate Investigator for the project. During the current reporting period, Dr. Hendershot has participated in all study meetings, assisted with the coordination of equipment orders/deliveries/install, and

	engaged in discussions with WRNMMC clinical and research staff to ensure a smooth start to subject enrollment and data collection in the upcoming year. He has also led the development and validation of a trunk postural control assessment device and testing protocol with corresponding SOP to be used at all sites.
Funding Support:	Federal Employee

Name:	Elizabeth Husson, CCRC
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Ms. Husson serves as an Associate Investigator for the project working as the research coordinator for WRNMMC. During the current reporting period Ms. Husson has participated in all study meetings, assisted with the coordination of equipment orders / deliveries / install and assisted with the creation of documentation for the clinical research protocol that was submitted to the NMCSD IRB and HRPO and subsequent modifications to the IRB protocol.
Funding Support:	Federal Employee

Name:	Meghan Tullos, PTA
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	11 (started employment on 10/03/2017)
Contribution to Project:	Ms. Tullos serves as an Associate Investigator for the project. During the current reporting period Ms. Tullos has participated in all study meetings, coordinated and assisted with Treadmetrix treadmill troubleshooting to ensure it is working properly for training, which included facilitating a visit from Treadmetrix to WRNMMC in person as well as participating in teleconferencing to trouble shoot various areas of the treadmill (load cell, gantry upright, e-stop on front rail, tuning of treadmill belt). Additionally, Ms. Tullos facilitated a site visit from Emily Miller on 6/13-6/14 to install computer software and provide instruction to operate the perturbation protocol on the treadmill, updated treadmill software, and set up the laptop for this project with the required software. The NMCSD team visited WRNMMC on 6/19-6/20 to provide instruction on running the research protocol in order to commence recruitment and data collection in the next reporting period. Ms. Tullos provided in-service training to clinical staff at WRNMMC to facilitate referral to this research study as well as provided training for use of the treadmill for clinical patients. Ms. Tullos has worked with Emily Miller to trouble shoot coding for the e-trip profile and perturbation assessment profile. That task has been completed. Ms. Tullos has set up and facilitated pilot trials with RAs to ensure all staff are able to assist with data collection as needed.

Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Jason Wilken, PT, PhD
Project Role:	Collaborator, University of Iowa
Nearest person month worked:	1
Contribution to Project:	Dr. Wilken previously was the Site Principal Investigator at CFI. He participated in all regularly scheduled meetings. He supervised treadmill acquisition and worked on obtaining regulatory approval. He is now at the University of Iowa. He will continue to participate in regularly scheduled meetings. He will also participate in data analysis and reporting results from the study.
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  No.

- **What other organizations were involved as partners?**
  Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

- **Collaborative Awards**

- **Quad Chart**

9. APPENDICES: n/a