

**AWARD NUMBER:** W81XWH-18-2-0041

**TITLE:** Randomized Controlled Trial of Precision Vestibular Rehabilitation in Military Personnel with mTBI

**PRINCIPAL INVESTIGATOR:** Anthony P. Kontos, PhD

**CONTRACTING ORGANIZATION:** University of Pittsburgh

**REPORT DATE:** SEP-2020

**TYPE OF REPORT:** Year 2 Annual Report

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

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# REPORT DOCUMENTATION PAGE

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<b>4. TITLE AND SUBTITLE</b>  Randomized Controlled Trial of Precision Vestibular Rehabilitation in Military Personnel with mTBI				<b>5a. CONTRACT NUMBER</b>	
				<b>5b. GRANT NUMBER</b> W81XWH-18-2-0041	
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<b>6. AUTHOR(S)</b>  Anthony P. Kontos, PhD; Patrick J. Sparto, PT, PhD; Hannah Bitzer, BS  Email: <a href="mailto:akontos@pitt.edu">akontos@pitt.edu</a> ; <a href="mailto:psparto@pitt.edu">psparto@pitt.edu</a>				<b>5d. PROJECT NUMBER</b>	
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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> During the past 17 years, US military personnel experienced 305,000 mTBI, with as many as 187,000 involving some type of vestibular impairment such as trouble walking and maintaining balance; or symptoms such as dizziness and vertigo. These vestibular impairments and symptoms can be actively treated using targeted vestibular rehabilitation exercises. Although vestibular exercises are being implemented by military medical personnel following mTBI, we do not know how frequently or intensely the exercises should be performed in order for injured personnel to have the best recovery. The objective of the proposed study is to conduct a 4-year randomized controlled trial to determine the effectiveness of different targeted vestibular rehabilitation exercise frequencies and intensities in military personnel and civilians with mTBI and vestibular symptoms, impairments, and functional limitations. Participants will be randomly assigned to receive varying levels of frequency (1x or 2x/day) and intensity (30% or 70%) of vestibular rehabilitation exercises. Weekly in-clinic treatment sessions will be complemented with a daily home exercise program lasting 4 weeks. To date, we completed site visits at Fort Carson and Camp Lejeune; received IRB approval for Fort Carson/Camp Lejeune; received HRPO approval; received a fully executed CRADA and DSA; hired new study staff at UPITT and Fort Carson; conducted FITBIR training with QuesGen Systems, Inc. and FITBIR; enrolled subjects at all sites; randomized first 5 participants at UPITT; submitted and received continuing review approval at UPITT and Camp Lejeune/Fort Carson; conducted 2 <sup>nd</sup> DSMB meeting; and submitted HRPO continuing review.					
<b>15. SUBJECT TERMS</b> Concussion, vestibular rehabilitation, dizziness					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b>
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>			<b>19b. TELEPHONE NUMBER</b> (include area code)
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**1. INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

During the past 17 years, US military personnel experienced 305,000 mTBI, with as many as 187,000 involving some type of vestibular impairment such as trouble walking and maintaining balance; or symptoms such as dizziness and vertigo. These vestibular impairments and symptoms can be actively treated using targeted vestibular rehabilitation exercises. Although vestibular exercises are being implemented by military medical personnel following mTBI, we do not know how frequently or intensely the exercises should be performed in order for injured personnel to have the best recovery. The objective of the proposed study is to conduct a 4-year randomized controlled trial to determine the effectiveness of different targeted vestibular rehabilitation exercise frequencies and intensities in military personnel and civilians with mTBI and vestibular symptoms, impairments, and functional limitations. Participants will be randomly assigned to receive varying levels of frequency (1x or 2x/day) and intensity (30% or 70%) of vestibular rehabilitation exercises. Weekly in-clinic treatment sessions will be complemented with a daily home exercise program lasting 4 weeks.

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

Concussion, vestibular rehabilitation, dizziness

**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.*

Major Task	Target Date	Completion (% or Date)
Obtain IRB Approval	July 2019	Completed 100% – 14-JUL-2020
Coordinate Study Staff for Clinical Trial	July 2019	Completed 100% – 25-SEP-2019
Participant recruitment, intervention and follow-up	December 2021	Completed 12/200 5% of overall enrollment and 12/25 or projected current enrollment
Data Analysis/Project Reports	September 2022	Completed 0%

**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 Task 1: Obtain IRB Approval

- Subtask 1 – Develop and submit proposal to local IRB at UPITT – 100%
  - **Milestone achieved: Local UPITT IRB modification approval – 19-DEC-2019**
  - **Milestone achieved: UPITT coordinating center approval – 04-MAR-2020**
  - **Milestone achieved: DSMB approved protocol – 26-SEP-2019**
- Subtask 2 – Submit and receive approval from HRPO – 100%
  - **Milestone achieved: Received HRPO Approval – 10-FEB-2020**
- Subtask 3 – Develop and submit proposal to local IRB/assurance for Camp Lejeune and Fort Carson – 100%
  - **Milestone achieved – IAIR agreement in place between UPITT and Camp Lejeune IRB – 16-DEC-2019**
  - **Milestone achieved – Camp Lejeune IRB amendment to include a HIPAA Authorization form approved on 11-JUN-2020**
  - **Milestone achieved – Evans Army Community Hospital (EACH) site-specific application for Fort Carson approved on 23-JAN-2020**
  - **Milestone achieved – Data Sharing Agreement between UPITT, Ft. Carson and Camp Lejeune approved 25-JUN-2020**
  - **Milestone achieved – Fully executed CRADA covering Camp Lejeune and Ft. Carson sites was received – 14-JUL**

## Major Task 2 – Coordinate Study Staff for Clinical Trial

- Subtask 1: Hiring of staff members – 100%
  - **Milestone achieved – hired new Research Assitant at UPITT (30-MAR-2020) and new Research Associate at Fort Carson (01-JUN-2020)**
- Subtask 2: Conduct “kick-off” meeting at Camp Lejeune (04-JUN-2019) and Fort Carson (23-SEP-2019) sites – 100%
- Subtask 3: Develop, coordinate, and schedule training (in person and teleconference sessions) – 100%
  - **Milestone achieved – Camp Lejeune: 04-JUN-2019; 22-JAN-2020 and Fort Carson: 23-SEP-2019**
- Subtask 4: Conduct training session at each site – 100%
  - **Milestone achieved: Data Entry and Management training for Quesgen completed at all sites on 10-JAN-2020**
  - **Milestone achieved: HiMAT training conducted with UPITT Staff on 14-FEB-2020**
  - **Milestone achieved: Intervention training with UPITT Physical Therapists on 17-FEB-2020**
  - **Milestone achieved: Intervention and assessment training at Camp Lejeune on 22-JAN-2020**
  - **Milestone achieved: Intervention and assessment training at Ft. Carson on 22-SEP-2019.**

## Major Task 3 – Participant recruitment, intervention and follow-up (Aims 1-2)

- Subtask 1 – Begin study recruitment – 100%
  - **Milestone achieved: Enrollment opened at UPITT on 24-FEB-2020**
  - **Milestone achieved: First 5 participants randomized at UPITT – 20-JUL-2020**
  - **Milestone achieved: Enrollment opened at Camp Lejeune and Fort Carson on 15-JUL-2020**
  - **Milestone achieved: First enrollment at Fort Carson (27-JUL-2020) and Camp Lejeune (08-SEP-2020)**
  - Milestone in progress: Enrolled 9 mTBIs at UPITT, 2 mTBIs at Fort Carson, and 1 at Camp Lejeune by 30-SEP-2020- current enrollment levels represent 12/25 or 48% of projected yearly enrollment levels.
- Subtask 2 – Participants complete 1- and 3-month evaluations – 1
  - Milestone in progress: UPITT 1-months completed: 5; UPITT 3-months completed: 1
  - Milestone in progress: Fort Carson 1-months completed: 1; Fort Carson 3-months completed: 0
  - Milestone in progress: Camp Lejeune 1-months completed: 0; Camp Lejeune 3-months completed: 0
- Subtask 3: Conduct on-site site visits/annual research meetings at each site – on going
  - Milestone in progress: No on-site site visits are currently scheduled due to travel restrictions at UPITT; virtual site visit scheduled for 30-OCT with Fort Carson

## Major Task 4 – Data Analysis/Project Reports

- Subtask 1 – Coordinate with sites and data center repository for monitoring data collection rates and data quality – bi-annually, on going
  - **Milestone achieved: Complete FITBIR Introduction Call with Pitt FITBIR POC (Heather Rodney) – 26-MAY-2020**
  - **Milestone achieved: All study staff completed FITBIR Deep Dives Training on 02-JUL-2020**
  - **Milestone achieved: All study staff completed FITBIR Training with Quesgen –16-JUL-2020**
  - **Milestone achieved: Convened second DSMB meeting – 26-AUG-2020**
  - Milestone in progress: Develop plan for quality management reviews

**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.*

UPITT PI Dr. Sparto conducted intervention, VOMS, and HiMAT training with physical therapists at all sites during site visits. UPITT staff were trained on FITBIR submissions. All study staff completed Quesgen training to ensure accuracy with data entry across all sites.

**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.*

Nothing to Report.

**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. If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

Major Task 3: Participant recruitment, intervention and follow-up

- Continue enrollment of subjects at all sites
- Participants complete 1- and 3-month evaluations: Data collection by research staff
- Conduct annual data collection research meetings at each site: Site visits (virtual or in-person depending on COVID-19 restrictions) to Camp Lejeune and Fort Carson will occur 4-6 months after first participants are enrolled

**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?**

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).*

Our focus in Year 2 was obtaining UPITT, site-specific, and HRPO IRB approvals; obtaining a fully executed CRADA and DSA; hiring study personnel; conducting site visits and training at Fort Carson and Camp Lejeune; conducting trainings at UPitt; convening the 2<sup>nd</sup> DSMB meeting in Pittsburgh and via Zoom; opening enrollment at all sites; starting follow-up data collection at all sites; receiving FITBIR training with Quesgen Systems, Inc.; submitting and receiving approval for Continuing Reviews at UPITT and Camp Lejeune/Fort Carson; and submitting HRPO Continuing Review. The TREV training at Camp Lejeune and Fort Carson has enhanced clinical practice by standardizing the way in which medical personnel assess and monitor vestibular, oculomotor, gait, and balance impairment. Moving forward, findings from the current study may inform better clinical practice guidelines for treating military personnel with vestibular impairment and symptoms following complex mTBI.

**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:*

**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.*

A COVID-19 screening is performed prior to approaching any eligible recruits and within 24 hours of any research activities or follow-up visits. If an eligible recruit fails the screening, we cannot enroll them in the study and if a enrolled subject fails the screening, we will reschedule the visit or collect data remotely. Study staff at all sites wear appropriate PPE when interacting with potential or enrolled subjects. Changes were made to the HiMAT procedures to remove all components except for the “WALK” portion and the FGA will be added with DSMB & IRB approvals.

**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.*

**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.*

The travel restrictions in place at UPITT have prevented in-person site visits from occurring which has resulted in a decrease use of travel funds for this reporting period.

**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**

There was one unexpected Adverse Event that occurred at the UPITT site. During the HiMAT procedure, which is an assessment that measures physical activity, a participant was completing the “SKIP” portion and experienced a mild strain in her calf muscle. All data collection ceased and the participant was evaluated within 15 minutes of the injury by UPMC Sports Medicine physician. The participant continues to undergo physical therapy for this injury. The UPITT IRB determined that this incident did not meet the criteria for an unanticipated problem and requested that modify the study consent and protocol to state “musculoskeletal strain/injury” as a potential risk of the HiMAT. However, in light of this AE, and additional logistic/safety issues in performing the HiMAT- particularly at the military sites where space is limited- the research team decided to eliminate all portions of the HiMAT with the exception of the “WALK” portion which has participants walk as quickly as possible without running or jogging.

**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.*

An abstract was accepted to present at Military Health System Research Symposium (MHSRS) in August 2020 but the conference was cancelled due to COVID-19. In lieu of the conference, MHSRS is posting all of the accepted abstracts on their website.

- **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.*

Nothing 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”.*

<i>Name:</i>	<i>Anthony P. Kontos, PhD – no change</i>
<i>Name:</i>	<i>Patrick Sparto, PT, PhD – no change</i>
<i>Name:</i>	<i>Michael Collins, PhD – no change</i>
<i>Name:</i>	<i>Susan Whitney, DPT, PhD – no change</i>
<i>Name:</i>	<i>Joseph Furman, MD, PhD – no change</i>
<i>Name:</i>	<i>Charity Patterson, PhD – no change</i>
<i>Name:</i>	<i>Anne Mucha, DPT, MS – no change</i>
<i>Name:</i>	<i>Kara Viggiano, MPH</i>
<i>Project Role:</i>	<i>Research Coordinator, UPITT site</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>1</i>
<i>Contribution to Project:</i>	<i>Ms. Viggiano has performed work in the area coordination and implementation of the grant at University of Pittsburgh site.</i>

<i>Name:</i>	<i>Clair Smith, MS – no change</i>
<i>Name:</i>	<i>Christina Fitzpatrick, PT – no change</i>
<i>Name:</i>	<i>Kelly Glazier,</i>
<i>Project Role:</i>	<i>Research Coordinator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>10.75</i>
<i>Contribution to Project:</i>	<i>Ms. Glazier has performed work in the area coordination and implementation of the grant at the Camp Lejeune site.</i>
<i>Name:</i>	<i>Alicia Souvignier, DPT, CGD</i>
<i>Project Role:</i>	<i>Co-Investigator, Fort Carson Site PI</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>1</i>
<i>Contribution to Project:</i>	<i>Dr. Souvignier has overseen all study activities at the Fort Carson site.</i>
<i>Name:</i>	<i>Hannah Bitzer, BS</i>
<i>Project Role:</i>	<i>Research Project Coordinator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>3</i>
<i>Contribution to Project:</i>	<i>Ms. Bitzer has performed work in the area of coordination and implementation of the grant at University of Pittsburgh site.</i>
<i>Name:</i>	<i>Nick Blaney, BS</i>
<i>Project Role:</i>	<i>Research Project Coordinator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>2</i>
<i>Contribution to Project:</i>	<i>Mr. Blaney has performed work in the area of recruitment and data collection at University of Pittsburgh site.</i>
<i>Name:</i>	<i>Adam Colorito, MA</i>
<i>Project Role:</i>	<i>Research Project Coordinator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>1</i>
<i>Contribution to Project:</i>	<i>Mr. Colorito has performed work in the area of recruitment and data collection at University of Pittsburgh site.</i>

*Name:* Chris Santucci, BA  
*Project Role:* Research Assistant  
*Researcher Identifier (e.g. ORCID ID):*  
*Nearest person month worked:* 1  
*Contribution to Project:* Mr. Santucci has performed work in the area of recruitment and data collection at University of Pittsburgh site.

*Name:* Shawn Eagle, PhD  
*Project Role:* Post-Doc  
*Researcher Identifier (e.g. ORCID ID):*  
*Nearest person month worked:* 7  
*Contribution to Project:* Mr. Eagle has performed work in the area of published works including but not limited to manuscripts and presentations

*Name:* Candace Pearson, RN, BSN, CCRC  
*Project Role:* Research Nurse Coordinator, Co-Investigator  
*Researcher Identifier(e.g. ORCID ID):*  
*Nearest person month worked:* 5  
*Contribution to Project:* Ms. Pearson has been responsible for site specific study development and has supervised all study activities at the Fort Carson site.

*Name:* Nicholas Wood  
*Project Role:* Research Assistant  
*Researcher Identifier(e.g. ORCID ID):*  
*Nearest person month worked:* 11  
*Contribution to Project:* Mr. Wood has helped with study initiation and was primarily responsible for performing study activities at the Fort Carson site.

*Name:* Megan Loftin  
*Project Role:* Research Assistant  
*Researcher Identifier(e.g. ORCID ID):*  
*Nearest person month worked:* 6  
*Contribution to Project:* Ms. Loftin has helped with study initiation at the Fort Carson site

**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.*

The previous research coordinator, Kara Viggiano, MPH, left the UPITT staff in DEC 2019. An Associate Investigator, Joshua Gatson, PhD, left the Camp Lejeune staff in SEP-2020. A research assistant, Megan Loftin, MS, left the Fort Carson staff in JUL-2020. All departed staff no longer perform any activities related to this grant. A research assistant (Chris Santucci) was hired at UPITT in MAR-2020 and a research associate (Dawn Collins) was hired at Fort Carson in JUN-2020. New research staff have been trained on all research/study procedures.

**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: Quesgen Systems, Inc.

Location of Organization: Burlingame, California

Partner’s contribution to the project: Creation of database; data management and storage

## 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.

*Appendix A: Camp Lejeune Site Visit Agenda*

*Appendix B: UPITT IRB Coordinating Center IRB Approval Letter*

*Appendix C: NMCCL Approval Letter*

*Appendix D: HRPO Approval Letter*

*Appendix E: UPITT IRB Modification Approved (Remote Data Collection)*

*Appendix F: Fully executed DSA and DSA renewal*

*Appendix G: Fully executed CRADA*

*Appendix H: MHSRS Abstract*

*Appendix I: UPITT Research Shutdown*

*Appendix J: UPITT Restart Documents*

*Appendix K: UPITT Continuing Review Approval Letter*

*Appendix L: Camp Lejeune Continuing Review Outcome Letter*

*Appendix M: Fort Carson/Camp Lejeune Informed Consent Form (ICF)*

*Appendix N: Fort Carson/Camp Lejeune HIPAA Form*

*Appendix O: UPITT Informed Consent Form*