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AWARD NUMBER: W81XWH-16-1-0581

TITLE: Development, Reliability, and Equivalence of an Alternate Form for the CQ Duty Performance-based Measure

PRINCIPAL INVESTIGATOR: Mary Vining Radomski

CONTRACTING ORGANIZATION: Allina Health

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Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S)
Mary Vining Radomski

E-Mail: mary.radomski@allina.com

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Allina Health System
800 E. 28th Street
Minneapolis, MN 55407-3723

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Previous research demonstrated that the recently-developed Charge of Quarters Duty Test (CQDT), a performance-based assessment of executive function, can be reliably administered and distinguishes between known-groups of healthy control soldiers and those with traumatic brain injury. As such, the CQDT shows promise in helping to inform readiness to return to duty and need for rehabilitation. However, performance based assessments that involve multitasking such as the CQDT, cannot be repeated as a post-treatment outcome measure due to learning effects. Therefore, an equivalent alternate form is needed.

Research Question #1. Can an expert team of military, Veterans Administration, and civilian rehabilitation researchers and clinicians develop an equivalent alternate form of the CQD that is experienced as novel by SM with mTBI?

Research Question #2. To what extent can 2 independent raters achieve acceptable levels of inter-rater reliability in scoring subject performance of CQD-Original (CQD-O) and CQD-Alternate Form (CQD-AF)?

Research Question #3. To what extent is the CQD-AF equivalent to the CQD-O based on a) difference of paired scores for both forms of the CQD and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQD?

15. SUBJECT TERMS
mild traumatic brain injury; implementation intentions; executive function; metacognitive strategy instruction

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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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

Many Service Members (SM) experience concussion (also known as mild traumatic brain injury [mTBI]) as a result of military combat and training, motor vehicle crashes, and sports-recreational activities. After mTBI, SM may experience an array of sensorimotor and cognitive problems, including difficulty with executive functions. Executive functions refer to higher order thinking abilities that enable goal-directed behavior, particularly in novel situations where people lack well-learned behaviors to draw upon. Because there are evidence-based cognitive rehabilitation interventions that can improve executive functioning, it is important to identify SM with mTBI with executive dysfunction who should be referred to these services before resuming high-consequence activities such as military duty. Unfortunately, executive dysfunction often goes undetected because traditional neurocognitive measures are designed to evaluate single domains rather than integrated functioning and the high levels of structure inherent in these assessments fail to adequately challenge the impaired functions. Performance-based assessment requires the patient to perform tasks that simulate the demands of everyday activities while the examiner uses behaviorally-based metrics to quantify functioning. **Performance-based measures designed to incorporate multitasking appear to be particularly sensitive to detecting deficient executive functions**. Existing performance-based involving multitasking have demonstrated sensitivity to executive dysfunction but the nature of the task components may lack face validity for SM with mTBI and their superiors, especially as related to readiness for return to duty.

Previous research demonstrated that the recently-developed Charge of Quarters Duty Test (CQDT), a performance-based assessment of executive function, can be reliably administered and distinguishes between known-groups of healthy control soldiers and those with traumatic brain injury. As such, the CQDT shows promise in helping to inform readiness to return to duty and need for rehabilitation. However, performance based assessments that involve multitasking such as the CQDT, cannot be repeated as a post-treatment outcome measure due to learning effects. Therefore, an equivalent alternate form is needed.

Research Question #1. Can an expert team of military, Veterans Administration, and civilian rehabilitation researchers and clinicians develop an equivalent alternate form of the CQD that is experienced as novel by SM with mTBI?

Technical Objective #1: Develop an alternate form of the CQD.

Research Question #2. To what extent can 2 independent raters achieve acceptable levels of inter-rater reliability in scoring subject performance of CQD-Original (CQD-O) and CQD-Alternate Form (CQD-AF)?

Technical Objective #2: Assure rater agreement across 2 raters.

Research Question #3. To what extent is the CQD-AF equivalent to the CQD-O based on a) difference of paired scores for both forms of the CQD and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQD?

Technical Objective #3: Evaluate equivalence of CQD-AF.

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

Mild traumatic brain injury symptom complex
Executive function
Performance-based assessment
Multitasking
Alternate form

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.

Table 1. Goals, milestones, and status

Updated 12-2019	**Estimated, Updated Timeline**	**Status**	**% of Study Activities Completed**
Technical Objective 1: Develop a CQDT-AF			
Subtask 1: Establish contracts and critical documents for all participating institutions, contracts, and consultants	Oct. -Nov. 2016	Completed	100%
Subtask 2: Obtain Allina Health IRB and ORP/HRPO approval to conduct study	[Part 2 – October 2018]	Completed for Part 1 & 2	100%
Develop and submit research protocol to the Allina Health IRB for Part 1 (*CQDT-AF development*) **(formal data collection for all technical objectives to occur only at CKRC)**	Nov. – Dec. 2016	Completed	100%
Once approved by the Allina Health IRB, submit protocol to USAMRMC Office of Research Protections for Part 1, as needed.	May 2017	Completed	100%
Develop and submit research protocol to the Allina Health IRB for Part 2 (*CQDT-AF validation*) **(formal data collection for all technical objectives to occur only at CKRC)**	April 2018	Completed	100%
Once approved by the Allina Health IRB, submit protocol to USAMRMC Office of Research Protections for Part 2, as needed.	May-June 2018	Completed (submitted, waiting approval)	100%
Order supplies: CQDT test materials, camcorder	Nov. 2016	Completed	100%
Create study database for Part 1	Feb.-May. 2017	Completed	100%
Create study database for Part 2	Dec. 2018	Completed	100%
Subtask 3: Characterize CQDT			
Finalize CQDT task analysis methodology	Nov. 2016 – Jan. 2017	Completed	100%%
CQDT document review; administration of CQDT for experiential analyses	Nov. 2016 – Jan. 2017	Completed	100%
Recruit volunteers at CKRI; video-record performance of CQDT	July 2017	Completed	100%
Hierarchical and cognitive task analyses based on video-recorded performance of CQDT	August 2017	Completed	100%
Subtask 4: Develop an optimal CQD-AF			
Team work groups generate, develop options for CQD-AF	Oct. – Nov. 2017	Completed	100%

Identify 2 best CQD-AF options; reduce to practice and informally administer (no formal data collection)	December 2017	Completed	100%
Team consensus meeting to select optimal version of CQD-AF for subsequent evaluation and to finalize Phase 2 protocol	January 2018	Completed	100%
Further testing and refinement of CQD-AF in preparation for Phase 2	January – March 2018	Completed	100%
Technical Objective 2: Assure rater agreement across 2 raters			
Subtask 1: Recruit and consent up to 15 participants	October – December 2018	Completed	100%
Subtask 2: Administer CQDT and MODT to up to 15 participants to verify interrater reliability with 2 raters			
Technical Objective 3: Evaluate equivalence of CQD-AF			
Subtask 1: Recruit and consent participants	December 2018 – June 2019	Completed	100%
Subtask 2: Administer CQDT, MODT, and neurocognitive measures on 43 volunteers			
Subtask 3: Recruit and consent up to 20 participants, most of which have a history of acquired brain injury	November 2019 – Feb. 2020	Not started	0%
Subtask 4: Administer CQDT, MODT, and neurocognitive measures on up to 20 additional participants.	November 2019 – Feb. 2020	Not started	0%
Assure protocol fidelity and adherence to all IRB requirements	June 2018– Feb. 2020	Ongoing	
Enter data into study database.	Feb. 2019 – March 2020	Ongoing	
Major Task: Data Analysis & Dissemination			
Perform all analyses according to specifications, share output and finding with all investigators			
Subtask 1: Conduct analyses to evaluate reliability and equivalence of CQDT and MODT	July 2019 – October 2019	In-process	50%
Subtask 2: Develop a combined dataset that includes item scores from CQDT, MODT, and Front Desk Duty (civilian version of CQDT) to evaluate score and performance patterns.	September – October 2019	In-process	50%
Subtask 3: Conduct analyses on a dataset that includes item scores from CQDT, MODT, and Front Desk Duty (civilian version of CQDT) to evaluate score and performance patterns.	March 2020 – May 2020	Not started	0%
Subtask 4: Conduct a 1-day workshop with research team (via WebEx for consultants) and use findings develop a clinical guidance	May 2020 – June 2020	Not started	0%

document to be used by test administrators/end-users to interpret CQDT-MODT performance scores.			
Work with data core and dissemination of findings (abstracts, presentation, publications, DOD)	April 2018 – September 2020	In-process	15%

Table 2. Projected Quarterly Enrollment

	Year 1				Year 2				Year 3				Year 4			Total
Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Q11**	**Q12**	**Q13**	**Q14**	**Q15**	
Courage Kenny Research Center *(Target)*	-	-	**2**	-	-	**8**		**12**	**10**	**30**	**10**	**0**	**0**	**20**		**92***
Target Enrollment - Cumulative	-	-	**2**	-	-	**10**		**22**	**32**	**62**	**72**	**72**	**72**	**92**		
Courage Kenny Research Center *(Actual)*			**2**			**7**	**0**	**0**	**10**	**36**	**7**	**0**	**0**			
Actual Enrollment - Cumulative			**2**			**9**	**9**	**9**	**19**	**55**	**62**	**62**	**62**			

*We submitted an Amendment to the Allina Health IRB (approved 12-18-19) requesting to enroll up to 20 more participants with acquired brain injury for Part 2 of this study. A submission to USAMRMC HRPO for administrative review is in-process.

Annual Progress on Technical Objectives and Sub-tasks
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.

I. Technical Objective 2: Assure rater agreement between 2 raters
Achievement: *We determined that there was sufficient rater agreement between 2 raters.*
Summary:

An iterative process was used to achieve scoring agreement between the 2 raters who collected data in Part 2 of this study. Scoring by both raters established inter-rater reliability based on pre-established tolerances (Total Performance Times are within ± 1 minute of each other; Total Visits scores are within ± 1 of each other; Total Task Performance Accuracy scores are within ± 2 of each other).

Ten participants (3 with a history of acquired brain injury) performed either the CQDT or MODT twice, approximately 2 weeks apart. This resulted in 60 observations (20 test administrations x 3 test metrics); 58/60 observations were within a priori tolerances for rater agreement.

II. Technical Objective 3: Evaluate equivalence of CQD-AF

Achievements: *We collected data on 52 participants and conducted preliminary equivalence analyses. Preliminary findings informed our NCE request to increase the number of participants with ABI and to develop a preliminary score interpretation guide.*

Summary:

We attempted to evaluate the equivalence of the CQDT and MODT (the CQDT's alternate form) by comparing Time 1 and Time 2 scores when participants performed each test twice over a period of 2-3 weeks and Time 1 and Time 2 scores when participants performed both tests over the same time period (see tables below). Seven participants had a military background; 2 were active duty Service members. There were gender differences between participants relative to ABI (p=0.002).

Participants who performed CQDT or MODT twice (n=17)	Total number	Mean age in years	Gender	
			Male	Female
History of ABI	7	41.9	1	6
No history of ABI	10	36.7	3	7

Note: 10 of the 17 were incorporated into the rater agreement evaluation.

Participants who performed CQDT & MODT (n=35)	Total number	Mean age in years	Gender	
			Male	Female
History of ABI	11	37.6	8	3
No history of ABI	24	35.3	4	20

Time 1-Time 2 learning effects appear to depend upon ABI status.

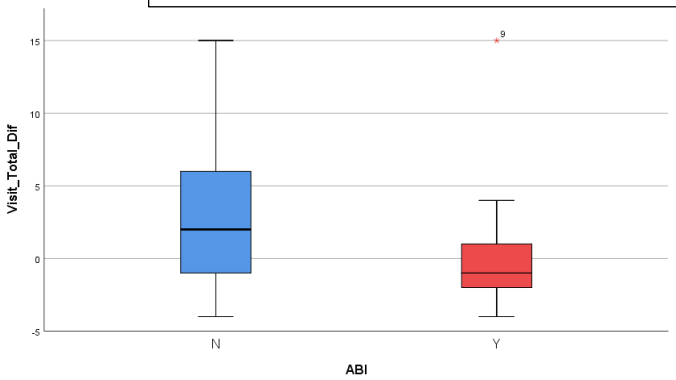
Whether or not participants had an ABI appears to influence the correlation between time 1 and Time 2 test scores when participants performed the same test twice over a period of 2-3 weeks. Note in the table below that there was strong correlation between mean scores for those with ABI but not for those with no history of brain injury. This suggest individuals with ABI may have relatively insignificant learning effects when performing the same test twice.

Condition	Outcome	Mean1	Mean2	ICC	Sig
ABI	Perf. Score	32.2	34.6	.805	0.151
ABI	Visit Count	13.2	13.4	.913	0.010
ABI	Perf. Time (sec)	1358.6	1105.0	.883	0.018
No ABI	Perf. Score	34.6	36.7	-.160	0.564
No ABI	Visit Count	14.6	9.6	.350	0.292
No ABI	Perf. Time (sec)	1255.1	972.1	.464	0.216

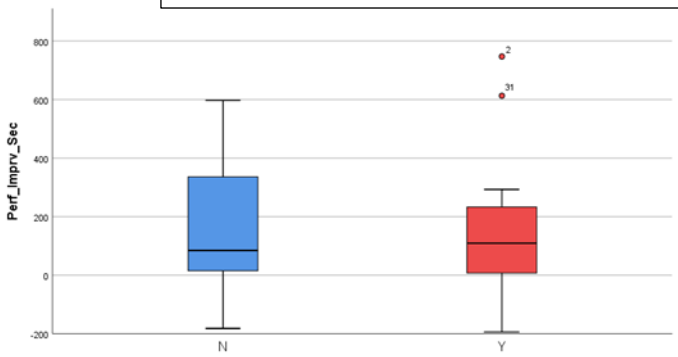
The same pattern continued when participants performed the MODT and CQDT over the same time period.

The following boxplots exemplify the changes in test score between Time 1 and Time 2. The red box plot denotes the performance of individuals with ABI. For # of visits and performance time, the amount of change in T1 and T2 performance is less for people with ABI than those without past ABI.

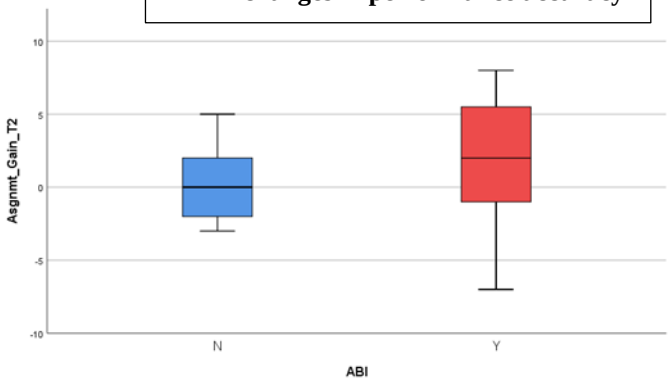
T1-T2 changes in # of visits between work areas



T1-T2 changes in performance time (seconds)



T1-T2 changes in performance accuracy



Overall, a larger number of participants with ABI are needed for a full equivalence evaluation, which informed NCE request.

III. Developed and submitted a NCE to accomplish the following in Year 4:

- Develop and submit an amendment to increase participant enrollment (up to 20 additional subjects with acquired brain injury)
- Collect study data on up to 20 more participants, including an additional measure to capture self-reported executive functioning in daily life
- Develop preliminary score interpretation guidance by examining score patterns and organizing a one-day workshop for research and clinical experts

Dissemination

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.

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 team did two research presentations related to this research:

- Military Health System Research Symposium August 2019 Orlando, FL
  Presentation: Development and equivalence of an alternative form of the Charge of Quarters Duty Test, a multitasking test to inform duty readiness after concussion
- Minnesota Occupational Therapy Association Annual Conference October 2019 St. Paul, MN
  Multitasking assessment of executive dysfunction after acquired brain injury: Emerging research and practice implications

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

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

Year 4, Q13	**Estimated, Timeline**
Develop and submit **amendment** for research protocol to the Allina Health IRB for Part 2 (*CQDT-AF validation*) **(formal data collection for all technical objectives to occur only at CKRC)**	November 2019
Once approved by the Allina Health IRB, submit protocol amendment to USAMRMC Office of Research Protections for Part 2, as needed.	December 2019
Begin to set up modified recruitment strategy pending Allina IRB and USAMRMC HRPO approval	December 2019
Begin to plan 1-day workshop with research team (via WebEx for consultants) and use findings develop a clinical guidance document to be used by test administrators/end-users to interpret CQDT-MODT performance scores.	December 2019

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).

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 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.

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.

Nothing to report.

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.

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

None.

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. **PRODUCTS:** 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.*

[See above]

- **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.

- **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.

Nothing 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.

- **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.

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."

Name:	Mary Vining Radomski
Project Role:	PD/PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-0600-4494
Nearest person month worked:	1
Contribution to Project:	Dr. Radomski contributed the following: -Developed and submitted the Part 2 IRB protocol to Allina Health and USAMRMC -Worked with study coordinator to set up team TCONs, facilitated meetings and distributed minutes -Oversaw data collection and analyses so far -Presented preliminary findings at 2 conferences
Funding Support:	This grant

There were no other individuals who contributed at least one person month over the past year.

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.*

Nothing to report.