

AWARD NUMBER: W81XWH-17-2-0070

TITLE: Characterization of Psychological Resilience and Readiness: Cross-Validation of Cognitive Behavioral Metrics During Acute Military Operational Stress

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REPORT DATE: October 2020

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE Oct 2020		2. REPORT TYPE Annual		3. DATES COVERED 30 Sept 2019 -- 29 Sept 2020	
4. TITLE AND SUBTITLE Characterization of Psychological Resilience and Readiness: Cross-Validation of Cognitive Behavioral Metrics During Acute Military Operational Stress				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-17-2-0070	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Bradley C. Nindl, PhD E-Mail:				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The University of Pittsburgh Pittsburgh, PA 15203				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT: Military operational stress can come in many forms via physical exertion, cognitive overload, sleep restriction, energy insufficiency, and emotional or psychological stress. In 2013, a DoD Human Performance Optimization Metrics Conference was held and identified the lack of a consensus for operationally relevant and standardized metrics that meet military requirements as the single most important issue related to the translation of cognitive readiness to operational and military leader utility. For metrics to be of benefit to the military, their relationship to Service member health and performance must be established under acute and chronic military operational stress scenarios. Our objective is to validate a comprehensive series of neurocognitive, psychological, psychomotor, sensorimotor, physiological, and sleep metrics within military operational stress paradigms to assess military-relevant and tactical cognitive readiness and resiliency. Our study proposes to use an ecologically valid model of simulated military operational stress (sleep restriction, caloric deficit, and physical work). This model will provide a biomedical framework to quantify temporal changes in metrics across the neurocognitive, psychological, psychomotor, sensorimotor, physiological, and sleep domains. Machine learning will be used to provide a dashboard and predictive algorithm for dependent variables centered on military-relevant and tactical cognitive readiness and resiliency					
15. SUBJECT TERMS None Listed					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
Unclassified	Unclassified	Unclassified	Unclassified	21	

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	5
4. Impact	9
5. Changes/Problems	11
6. Products	13
7. Participants & Other Collaborating Organizations	16
8. Special Reporting Requirements	20
9. Appendices	20

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

Military operational stress can come in many forms via physical exertion, cognitive overload, sleep restriction, energy insufficiency, and emotional or psychological stress. In 2013, a DoD Human Performance Optimization Metrics Conference was held and identified the lack of a consensus for operationally relevant and standardized metrics that meet military requirements as the single most important issue related to the translation of cognitive readiness to operational and military leader utility. For metrics to be of benefit to the military, their relationship to Service member health and performance must be established under acute and chronic military operational stress scenarios. Our objective is to validate a comprehensive series of neurocognitive, psychological, psychomotor, sensorimotor, physiological, and sleep metrics within military operational stress paradigms to assess military-relevant and tactical cognitive readiness and resiliency. Our study proposes to use an ecologically valid model of simulated military operational stress (sleep restriction, caloric deficit, and physical work). This model will provide a biomedical framework to quantify temporal changes in metrics across the neurocognitive, psychological, psychomotor, sensorimotor, physiological, and sleep domains. Machine learning will be used to provide a dashboard and predictive algorithm for dependent variables centered on military-relevant and tactical cognitive readiness and resiliency.

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

Resilience, readiness, sleep, health, performance

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 1: Secure Human Research Approvals - completed
 - o University of Pittsburgh IRB approval 2/2/18
 - o HRPO Approval 6/1/18
- Major Task 2: Hire/Train Study personnel – completed
- Major Task 3: Prepare/finalize materials for participant recruitment – completed/ongoing
 - o Recruitment materials have been finalized, IRB approved, and disseminated
 - o Recruitment briefs ongoing. Plan to reach out to local ROTC recruiting offices.
- Major Task 4: Launch Study, initiation of enrollment – completed 6/5/18 (2 pilot subjects)
- Major Task 5: Completion of experimental study procedures – completed
- Major Task 6: Data and Safety Monitoring – ongoing
 - o Biweekly data centric meetings held to monitor active manuscript progress. Biannual meeting including the independent medical monitor as outlined in the DoD grant was held on 1/23/20.
 - o IRB approval attained on 4/20/20 regarding slight study personnel changes. Pitt IRB confirmed no further changes were necessary regarding this alteration.
 - o IRB approval attained on 10/5/20 of addendum consent for future blood analysis that may be conducted at an external lab
- Major Task 7: Preliminary and confirmatory data analysis – ongoing
 - o Seven abstracts on preliminary data presented at the International Congress on Soldier’s Physical Performance (ICSPP) February 11-14, 2020.
 - o One abstract on preliminary data presented to the Military Health System Research Symposium (MHSRS) on August 19-22, 2019.
 - o Six abstracts on preliminary data presented by doctoral students at MARC ACSM November 1-2, 2019.
 - o One Freddie H. Fu, MD Graduate Research Award awarded on 10/15/19. Another Freddie H. Fu MD Graduate Research Award awarded on 10/31/19.
 - o 3 abstracts presented by doctoral students at ACSM June 17, 2020 virtually.
 - o Two abstracts to be presented at MARC ACSM virtually November 6, 2020.
 - One doctoral student under consideration for MARC-ACSM Doctoral Student Investigator Award
 - o One manuscript in review, one manuscript submitted, two in preparation

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.

Initial Pitt IRB approval was obtained 2/2/18 and subsequent HRPO approval was obtained 6/1/18. Two pilot subjects were enrolled on 6/5/18 and completed testing on 6/10/18. As of **10/21/20**, 243 subjects have been screened, 78 subjects have been enrolled, and 69 subjects have completed the study. Due to the COVID-19 pandemic, data collection was ceased at 69 participants instead of the original planned 80. Now, the study team has moved into the data synthesis phase with goals of data reduction, statistically analyzing results, and writing manuscripts. The study team takes part in biweekly study meetings to discuss findings and ensure data quality. Phase 2 is ready to take place at Tufts University but has not been able to start data collection due to COVID-19 restrictions. The spit collection protocol had had to be altered to adhere to COVID-19 safety measures.

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.

This project has provided the opportunity for many Pitt undergraduate and graduate students to gain experience in research and internship credit hours as part of their course curriculum. Preliminary data was presented at the Military Health System Research Symposium (MHSRS) on August 19-22, 2019, Mid-Atlantic American College of Sports Medicine Regional Meeting on November 1-2, 2019, and the International Congress on Soldier's Physical Performance (ICSPP) on February 11-14, 2020. Current doctoral student, William Conkright, was awarded the Freddie H. Fu, MD Graduate Research Award on 10/15/19 in the amount of \$5,000 for his presentation entitled, "Dynamic Variation of Extracellular Vesicles as Resilience Biomarkers During Simulated Military Operational Stress". Fellow doctoral student Meaghan Beckner, presented on 10/31/19, was also awarded this award for her work entitled, "Biological Variances in Extracellular Vesicle Profiles Related to Neurocognitive Resilience During Simulated Military Operational Stress." Both projects will provide students an opportunity to enhance technical expertise and perform cutting edge biological analyses.

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.

Doctoral students presented preliminary data in the form of thematic posters and podium presentations at the following conferences:

The Mid-Atlantic American College of Sports Medicine Regional Meeting on November 1-2, 2019:

- Lagoy, Alice. Increased deep sleep may relate to compromised perception-action coupling performance in military personnel
- Sinnott, Aaron. Association between Affordance-Detection Accuracy and Marksmanship Performance during Sleep and Caloric Restriction among Active Duty Soldiers
- Conkright, Will. Implications on Estimated Susceptibility to Enemy Fire Following 5-Days of Simulated Military Operational Stress
- Beckner, Meaghan. Simulated Military Operational Stress Negatively Impacts Psychomotor Vigilance and Neurocognitive Biomarkers in Men and Women
- Proessl, Felix. Normalization Removes Differences in Contractile Properties and Corticospinal Excitability Between Single- and Multi-Joint Exercises
- Agostinelli, Philip. Differences in Performance Decline Between Sex Under Simulated Military Operational Stress

The Military Health System Research Symposium (MHSRS) on August 19-22, 2019:

- Lagoy, Alice. Changes in affordance perception behaviors during exposure to acute military operational stress

The International Congress on Soldier's Physical Performance (ICSPP) on February 11-14, 2020:

- Lagoy, Alice. Visuomotor performance is maintained under conditions of military operational stress
- Conkright, Will. Implications on Estimated Susceptibility to Enemy Fire Following 5-Days of Simulated Military Operational Stress
- Beckner, Meaghan. Emotion Recognition and Vigilance is Compromised During Military Operational Stress
 - Second Abstract: High Grit Scores Associated with Elevated BDNF During Military Operational Stress
- Canino, Maria. Impact of Operational Stress on Motor Evoked Potentials in Military Personnel
- Eagle, Shawn. Simulated Military Operational Stress Impairs Action Boundary Perception
- Haufler, Amy. Adaptability, Emotion, Perception and Attention: Tactical Cognitive Resilience in Response to Operational Stress

American College of Sports Medicine Virtual Meeting on June 17, 2020

- Canino, Maria. Impact of operational stress on motor evoked potentials in military personnel.
- Beckner, Meaghan. Simulated Military Operational Stress Negatively Impacts Psychomotor Vigilance and Neurocognitive Biomarkers in Men and Women
- Conkright WR, Beckner ME, Martin BJ, Sinnott AM, LaGoy AD, Proessl F, Eagle SE, Flanagan SD, Connaboy C, Germain A, Nindl BC, FACSM. Differential Responses of Resting Vs. Post-exertion Hormone Concentrations During Simulated Military Operational Stress.

The Military Health System Research Symposium (MHSRS) 2020 (cancelled due to COVID-19)

- Nindl BC, Beckner ME, Conkright WR, Martin BJ, Eagle SR, Sinnott AM, Proessl F, LaGoy AD, Canino M, Flanagan S, Sekel N, Ferrarelli F, Roma P, Dretsch P, Haufler A, Germain A, Connaboy C. Physiological, Behavioral, Neurocognitive and Tactical Performance Response Trajectories in Male and Female Soldiers During Military Operational Stress.

- Sinnott AM, Eagle SR, LaGoy AD, Beckner ME, Conkright WR, Germain A, Rivetti DA, Flanagan SD, Roma PG, Dretsch MN, Nindl BC, Connaboy C. Association between Affordance-Detection Accuracy and Marksmanship Performance during Sleep and Caloric Restriction among Active Duty Soldiers

The Mid-Atlantic American College of Sports Medicine Regional Meeting on November 6, 2020

- Beck, Alaska. Similar Corticospinal Excitability in Military Men and Women During Simulated Operational Stress.
- Conkright WR, Beckner ME, Sahu A, Clemens ZJ, Lovalekar M, Mi Q, Martin BJ, Flanagan SD, Ambrosio F, Nindl BC, FACSM. Extracellular Vesicle Concentration but Not Size Differs Between Men and Women During Military Operational Stress.

Center for Sleep and Circadian Science Research Day on November 19, 2019

- Ambarian MK, LaGoy AD, Conkright WR, Eagle SR, Sinnott AM, Beckner ME, Flanagan SD, Martin BJ, Ferrarelli F, Nindl BC, Germain A, Connaboy C. Impact of sleep quality and deployment history on resilience in a military population.

Associated Professional Sleep Societies (Sleep) Meeting, August 27-30, 2020 (Virtual due to COVID-19)

- LaGoy AD, Beckner ME, Eagle SR, Sinnott AM, Beckner ME, Conkright WR, Flanagan SD, Martin BJ, Nindl BC, Germain A, Ferrarelli F, Connaboy C. Efficient perception-action coupling relates to more slow wave sleep in military personnel.

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.

For Specific Aim #1, the study team plans to continue to conduct biweekly data-centric meetings to discuss their findings and future manuscripts as data reduction is completed. Our objectives for the next reporting period revolve around data reduction/analysis, statistical analyses of the data, and disseminating the data to the public through manuscripts and abstracts.

For Specific Aim #2, data collection was set to begin on 10/26/20, however, there were additional delays due to COVID-19. Planned to use local human research volunteer Soldier population, but the program is currently on hold for data collection. The research team has finalized and completed walkthroughs of all SOPs for running the SA2 tasks and questionnaires at CABCS, as well as the virtual reality scenario and accompanying physiological monitoring devices (heart rate, respiration, eye tracking, weapon tracking, and EEG) and saliva oral swabs for measuring arousal-associated biomarkers. The team has also sourced and organized all PPE, cleaning supplies, and lab markings that we stipulated in the return to research plan to mitigate the risk of COVID transmission.

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.

What was the impact to 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:*

Due to the COVID-19 pandemic circumstances and the University of Pittsburgh and Neuromuscular Research Lab policies in order to maintain the health and well-being of all employees and subjects, all research activities were temporarily paused and work was moved remotely. The study team terminated data collection as of 27 May 2020 with written correspondence from Claudio Ortiz approving to cease data collection at 69 participants instead of the originally planned 80 due to the COVID-19 pandemic. The study team for Specific Aim 2 has also been impacted by the COVID-19 pandemic as they have not been able to begin data collection and were required to modify their salivary collection protocol to accommodate COVID-19 safety measures.

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.

The study team received written correspondence from Claudio Ortiz on 27 May 2020 confirming that it was appropriate to cease data collection at 69 participants instead of completing the originally planned 80 participants due to the COVID-19 pandemic. The study team for Specific Aim 2 has so far been unable to proceed with data collection due to the COVID-19 pandemic.

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.

As we had expanded recruitment efforts, the subsequent compensation for travel was not budgeted in the original proposal. We have therefore used laboratory discretionary funds to cover participant travel funds.

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

Due to the COVID-19 pandemic, data collection was ceased in March 2020 to ensure the safety of all study personnel and participants. It was determined in May 2020 that data collection would be terminated as the ongoing COVID-19 risk to participants outweighed the benefit of collecting data on the remaining 12 subjects to meet our target goal of 80.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

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

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

Report only the major publication(s) resulting from the work under this award.

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

Conkright WR, Beckner ME, Sinnott AM, Eagle SE, Martin BJ, LaGoy AD, Proessl F, Lovalekar M, Doyle T, Agostinelli P, Sekel NM, Flanagan SD, Germain A, Connaboy C, Nindl BC. “Neuromuscular Performance and Hormonal Responses To Military Operational Stress In Men and Women” *Medicine & Science in Sports & Exercise*; Under Review; Yes

Proessl F, Canino MC, Beckner ME, Sinnott AM, Eagle SR, LaGoy AD, Conkright WR, Sterczala AJ, Connaboy C, Ferrarelli F, Germain A, Nindl BC, Flanagan SD. “Characterizing the spatial extent of off-target corticospinal responses to double-cone transcranial magnetic stimulation.” *Experimental Brain Research*; Submitted; Yes

Manuscripts in Preparation:

Beckner ME, Conkright WR, Eagle SR, Martin BJ, Sinnott AM, Lagoy AD, Proessl F, Lovalekar M, Jabloner LR, Roma PG, Basner M, Ferrarelli F, Germain A, Flanagan SD, Connaboy C, Nindl BC. “Impact of Simulated Military Operational Stress on Executive Function Relative to Trait Resilience, Aerobic Fitness, Sustained Vigilance, and Neuroendocrine Biomarkers”

Proessl F, Beckner ME, Conkright WR, LaGoy AD, Canino MC, Sinnott AM, Eagle SR, Sterczala AJ, Connaboy C, Ferrarelli F, Germain A, Nindl BC, Flanagan SD. “Corticospinal excitability moderates exercise-induced neuroplasticity during military operational stress.”

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.

Nothing 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.

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.*

See Section 3: Accomplishments.

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: Bradley C. Nindl

Project Role: co-PI

Nearest person month worked: 1

Contribution to project: Dr. Nindl has provided oversight of NMRL study preparations, coordinated collaborator efforts and recruitment procedures.

Name: Fabio Ferrarelli

Project Role: co-PI

Nearest person month worked: 1

Contribution to project: Dr. Ferrarelli has provided oversight of M-STARRT study preparations, coordinated collaborator efforts and recruitment procedures.

Name: Chris Connaboy

Project Role: PhD

Nearest person month worked: 1

Contribution to project: Dr. Connaboy has provided oversight over the sensorimotor and psychomotor task batteries, including study procedures, relevant metrics, and training of necessary personnel.

Name: Shawn Flanagan

Project Role: PhD

Nearest person month worked: 1

Contribution to project: Dr. Flanagan has provided oversight over neurophysiological task batteries, including study procedures, relevant metrics, and training of necessary personnel.

Name: Qi Mi

Project Role: PhD

Nearest person month worked: 1

Contribution to project: Dr. Mi has provided oversight over statistical modeling, as well as database management.

Name: Mita Lovalekar

Project Role: PhD

Nearest person month worked: 1

Contribution to project: Dr. Lovalekar has provided oversight over statistical analysis as it relates to changes in study design and protocol management.

Name: Hassen Khan

Project Role: Database Manager

Nearest person month worked: 1

Contribution to project: Mr. Khan has provided oversight over database development and management procedures.

Name: Mackenzie Osborn

Project Role: Lab technician

Nearest person month worked: 1

Contribution to project: Recruitment, phone screening, and scheduling participants

Name: Maggie Sphar
Project Role: Lab technician
Nearest person month worked: 1
Contribution to project: Recruitment, phone screening, and scheduling participants

Name: Alice Lagoy
Project Role: Graduate student
Nearest person month worked: 1
Contribution to project: Lab procedures for heart rate variability, psychological measures and sleep

Name: Jenna Parrish
Project Role: PhD
Nearest person month worked: 1
Contribution to project: Dr. Parrish has provided oversight over M-STARRT sleep study procedures, relevant metrics, and training of necessary personnel.

Name: Brian Martin
Project Role: PhD
Nearest person month worked: 1
Contribution to project: Dr. Martin has provided oversight over blood analysis, including study procedures, relevant metrics, and training of necessary personnel.

Name: Amy Haufler
Project Role: PhD
Nearest person month worked: 1
Contribution to project: Dr. Haufler has provided oversight over SPEAR test, including study procedures, relevant metrics, and training of necessary personnel.

Name: Peter Roma
Project Role: PhD
Nearest person month worked: 1
Contribution to project: Dr. Roma has provided oversight over Cognition test battery, including study procedures, relevant metrics, and training of necessary personnel.

Name: Nicole Sekel
Project Role: Research Assistant and Project Manager
Nearest person month worked: 0.5
Contribution to project: Ms. Sekel joined the project in August as a Research Assistant and Project Manager assisting primarily in data collection as well as regulatory processes.

Name: Meaghan Beckner
Project Role: Graduate Student
Nearest person month worked: 1
Contribution to project: Ms. Beckner has provided oversight over NMRL study procedures, relevant metrics, and training of necessary personnel. She also submitted the local IRB protocol to HRPO.

Name: Aaron Sinnott
Project Role: Graduate Student
Nearest person month worked: 1
Contribution to project: Mr. Sinnott has provided oversight over NMRL study procedures, primarily EST 3000, and training of necessary personnel.

Name: William Conkright
Project Role: Graduate student
Nearest person month worked: 1
Contribution to project: Recruitment, phone screening, and scheduling participants

Name: Felix Proessl
Project Role: Graduate Student
Nearest person month worked: 1
Contribution to project: Felix will be involved with data collection, analysis and interpretation of TMS.

Name: Maria Canino
Project Role: Graduate Student
Nearest person month worked: 1
Contribution to project: Maria will be involved with data collection, analysis and interpretation of TMS.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

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

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

Nothing to Report.

What other organizations were involved as partners?

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

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

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

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

Organization Name: The McGowan Institute for Regenerative Medicine

Location of Organization: Pittsburgh, PA

Partner’s Contribution to the project: Dr. Fabrisia Ambrosio at The McGowan Institute for Regenerative Medicine has provided in-kind support, allowing PhD students William Conkright and Meaghan Beckner to use their facilities and train them on techniques to isolate and characterize extracellular vesicles as part their respective Freddie Fu student grant projects.

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.*

