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TITLE: Automated Neuropsychological Assessment Metrics, Version 4 (ANAM4): Examination of Select Psychometric Properties and Administration Procedures

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<b>14. ABSTRACT</b>  The ability to accurately and efficiently evaluate neurocognitive status of US Warfighters exposed to diverse operational and experimental conditions is of critical importance to the ongoing mission and Force 2025 objectives of the United States military. The Automated Neuropsychological Assessment Metrics (ANAM) is a computer assisted tool for evaluating neurocognitive performance with demonstrated effectiveness for application in a wide range of military operational and research testing scenarios. The primary objective of this project is to examine select psychometric and administration properties of the ANAM4. Four studies were proposed as part of the original effort: 1) examine common use practices and determine the effect of specific administration procedures on ANAM4 performance; 2) assess the test-retest reliability and practice effects of individual ANAM4 test modules; 3) examine the validity of the ANAM4 Mood Scale, and 4) establish a representative normative dataset of ANAM4 performance outcomes specifically for use with Army National Guard service members. Data collection for Studies 1-3 is complete; data collection for Study 4 was completed in 6 states (Minnesota, Maine, Arizona, Montana, Texas, and Kentucky). Reports summarizing data from Studies 1-3 are being finalized. Data management procedures for Study 4 are nearing completion and preliminary analyses have been coordinated. In August 2016, a supplemental project was approved, extending the project period of performance through 31 December 2017. The primary aim of the supplemental project is to leverage work carried out as part of the initial project funding and extend this to include review and analysis of assessment tools and approaches for evaluation of Warfighter cognitive performance and readiness in military operational settings. Specifically, this supplemental effort will provide recommendations and future roadmap for a synchronized, validated approach to assessment of cognitive performance and readiness in military operational environments. This work is currently underway with preparation of an initial report scheduled for delivery in March 2017.					
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## INTRODUCTION

The availability of easy-to-use, field-ready tools that can provide rapid, accurate, and reliable input regarding Warfighter cognitive readiness and performance is critical for establishing an accurate link between operational/environmental exposures and Warfighter cognitive status, predicting adverse health and performance outcomes, and providing guidance to leaders for mission preparations and risk mitigation. While a number of approaches have been advanced to evaluate Warfighter cognitive status and performance, most have not been suitable for implementation in rugged operational or training environments due to the sensitive nature of the equipment involved, the requirement for trained examiners to administer and interpret test results, or lengthy time requirements for task completion. A coordinated approach is needed to identify and validate accurate, sensitive, field-ready tools and models to evaluate and predict Warfighter cognitive readiness and performance under complex operational exposure scenarios.

Among the many assessment tools used to evaluate Warfighter cognitive performance, the Automated Neuropsychological Assessment Metrics Version 4 (ANAM4) is among the most frequently used and cited. The ANAM is a computer-assisted tool for evaluating neurocognitive performance with demonstrated efficacy for application in a broad range of military operational and research testing scenarios. The primary objective of this multi-study project is to examine select psychometric and common administration properties of the ANAM4. This project includes four studies that address different psychometric and administrative elements of the ANAM4, each critical to the understanding and utilization of this computer-assisted cognitive assessment system. Study 1 examines common use practices and their impact on ANAM4 performance. Study 2 assesses the test-retest reliability and practice effects of individual ANAM4 test modules. Study 3 examines the validity of the ANAM4 Mood Scale. Study 4 aims to establish a nationally-representative normative dataset of ANAM4 performance outcomes specifically reflecting Army National Guard Service members. A supplemental study was added in August 2016, extending examination and analysis of cognitive assessment metrics beyond ANAM4 to include other tools and approaches used to evaluate Warfighter cognitive performance and readiness in diverse military operational environments.

## BODY

The original project (which includes four studies specifically focused on ANAM4) was funded 01 December 2007. The originally approved study timeline/SOW is presented in **Table 1**.

**Table 1: Statement of Work/Study Timeline (Original, 2007)**

<b>Year 1</b>	<b>Months 1-2</b>	<b>Task 1</b>	Plan and finalize logistics for Phase I (Studies 1-3)
	<b>Months 3-12 (Dec 2008)</b>	<b>Task 2</b>	Subject recruitment, data collection and data management for Studies 1-3
<b>Year 2</b>	<b>Month 13-14</b>	<b>Task 3</b>	Perform preliminary data analyses for Study 3
	<b>Month 15-24 (Dec 2009)</b>	<b>Task 4</b>	Complete data collection for Study 1
		<b>Task 5</b>	Perform preliminary data analyses for Study 1
		<b>Task 6</b>	Continue recruitment, data collection and data management for Study 2 & 3
		<b>Task 7</b>	Complete data collection for Study 3
<b>Year 3</b>	<b>Month 25-36 (Dec 2010)</b>	<b>Task 8</b>	Complete data collection for Study 2
		<b>Task 9</b>	Plan and finalize logistics for Phase II (modified Study 4)
		<b>Task 10</b>	Complete data analyses for Studies 1, 2, 3
		<b>Task 11</b>	Preparation of journal manuscript(s) for Studies 1, 2, 3
		<b>Task 12</b>	Preparation of Project report for Studies 1, 2, 3
		<b>Task 13</b>	Set-up data management procedures for Study 4

**Table 1: Statement of Work/Study Timeline (Original, 2007) (continued)**

<b>Year 4</b>	<b>Month 37-48 (Dec 2011)</b>	<b>Task 14</b>	Initiate data collection procedures for Study 4
		<b>Task 15</b>	Carry out data collection procedures for Study 4
		<b>Task 16</b>	Initiate integrative data management structure set up for Study 4
		<b>Task 17</b>	Operationalize database for Study 4 analysis scheme
		<b>Task 18</b>	Perform preliminary data analyses for Study 4
		<b>Task 19</b>	Complete data collection procedures for Study 4
<b>Year 5</b>	<b>Month 49-60 (Dec 2012)</b>	<b>Task 20</b>	Complete data analyses for Study 4
		<b>Task 21</b>	Prepare Study 4 manuscript(s) for peer review
		<b>Task 22</b>	Preparation of Project Final Report

A request for a 12 month no-cost extension for this study was approved on 7 November 2012, extending study activities through December 2013. A modified statement of work, approved as part of the no-cost extension, is presented in **Table 2**.

**Table 2: MODIFIED SOW for remaining PROJECT Tasks and STUDY TIMETABLE (Nov 2012)**

<b>Year 4</b>	<b>Month 37-48 (Dec 2011)</b>	<b>Task 14</b>	Initiate data collection procedures for Study 4
		<b>Task 15</b>	Carry out data collection procedures for Study 4
		<b>Task 16</b>	Initiate integrative data management structure set up for Study 4
		<b>Task 17</b>	Operationalize database for Study 4 analysis scheme
<b>Year 5</b>	<b>Month 49-60 (ending Dec 2012)</b>	<b>Task 18</b>	Conduct data collection procedures for Study 4 (cont'd)
		<b>Task 19</b>	Complete manuscript preparations/submissions for Studies 1-3
		<b>Task 20</b>	Set up/operationalize data analyses plan for Study 4
<b>Year 6</b>	<b>Month 61-72 (ending Dec 2013)</b>	<b>Task 21</b>	Complete data collection for Study 4
		<b>Task 22</b>	Complete data analyses for Study 4
		<b>Task 23</b>	Prepare Study 4 manuscript(s) for peer review
		<b>Task 24</b>	Preparation of Project Final Report

A request for a second 12 month no-cost extension for this study was approved on 25 September 2013, extending study activities through December 2014. The modified statement of work is presented in **Table 3**.

**Table 3. MODIFIED SOW for remaining PROJECT Tasks and STUDY TIMETABLE (Nov 2013)**

<b>Year 6</b>	<b>Month 61-72 (ending Dec 2013)</b>	<b>Task 21</b>	Conduct data collection procedures for Study 4 (cont'd)
		<b>Task 22</b>	Initiate data quality control checks and preliminary analyses for Study 4.
<b>Year 7</b>	<b>Month 73-84 (ending Dec 2014)</b>	<b>Task 23</b>	Complete data collection for Study 4
		<b>Task 24</b>	Complete data analyses for Study 4
		<b>Task 25</b>	Prepare Study 4 manuscript(s) for peer review
		<b>Task 26</b>	Preparation of Project Final Report

A request for an additional 12 month no-cost extension for this study was approved on 28 October 2014, extending study activities through November 2015. The modified statement of work is presented in **Table 4**.

**Table 4. MODIFIED SOW for remaining PROJECT Tasks and STUDY TIMETABLE (Oct 2014)**

<b>Year 7</b>	<b>Month 73-84 (ending Dec 2014)</b>	<b>Task 23</b>	Initiate external data request procedures for Study 4
		<b>Task 24</b>	Conduct data collection procedures for Study 4 (cont'd)
		<b>Task 25</b>	Continue data quality control checks and preliminary analyses for Study 4 <ul style="list-style-type: none"> <li>Following each data collection trip, the newly collected data are entered into database and cleaned and preliminary data checks conducted</li> </ul>
<b>Year 8</b>	<b>Month 85-96 (ending Dec 2015)</b>	<b>Task 26</b>	Complete 100% data collection goal for Study 4 (with ARNG national sample from at least 8 geographically representative US states)
		<b>Task 27</b>	Complete data analyses for Study 4 <ul style="list-style-type: none"> <li>With 100% data collected, complete data analyses to address Study 4 research hypotheses</li> </ul>
		<b>Task 28</b>	Prepare Study 4 manuscript(s) for peer review <ul style="list-style-type: none"> <li>With completion of Study 4 analyses and manuscript preparation, travel to present findings at national conference forum is planned</li> </ul>
		<b>Task 29</b>	Preparation of Project Final Report

A request for no-cost extension, extending study activities through 31 August 2016, was approved on 30 October 2015. The complete statement of work with modified tasks for Years 7-9 (shaded) is presented in **Table 5**.

**Table 5. MODIFIED SOW for remaining PROJECT Tasks and STUDY TIMETABLE (Oct 2015)**

<b>Year 1</b>	<b>Months 1-2</b>	<b>Task 1</b>	Plan and finalize logistics for Phase I (Studies 1-3)
	<b>Months 3-12 (Dec 2008)</b>	<b>Task 2</b>	Subject recruitment, data collection and data management for Studies 1-3
<b>Year 2</b>	<b>Month 13-14</b>	<b>Task 3</b>	Perform preliminary data analyses for Study 3
	<b>Month 15-24 (Dec 2009)</b>	<b>Task 4</b>	Complete data collection for Study 1
		<b>Task 5</b>	Perform preliminary data analyses for Study 1
		<b>Task 6</b>	Continue recruitment, data collection and data management for Study 2 & 3
		<b>Task 7</b>	Complete data collection for Study 3
<b>Year 3</b>	<b>Month 25-36 (Dec 2010)</b>	<b>Task 8</b>	Complete data collection for Study 2
		<b>Task 9</b>	Plan and finalize logistics for Phase II (modified Study 4)
		<b>Task 10</b>	Complete data analyses for Studies 1, 2, 3
		<b>Task 11</b>	Preparation of journal manuscript(s) for Studies 1, 2, 3
		<b>Task 12</b>	Preparation of Project report for Studies 1, 2, 3
		<b>Task 13</b>	Set-up data management procedures for Study 4
<b>Year 4</b>	<b>Month 37-48 (Dec 2011)</b>	<b>Task 14</b>	Initiate data collection procedures for Study 4
		<b>Task 15</b>	Carry out data collection procedures for Study 4
		<b>Task 16</b>	Initiate integrative data management structure set up for Study 4
		<b>Task 17</b>	Operationalize database for Study 4 analysis scheme



<b>Year 5</b>	<b>Month 49-60 (ending Dec 2012)</b>	<b>Task 18</b>	Conduct data collection procedures for Study 4 (cont'd)
		<b>Task 19</b>	Complete manuscript preparations/submissions for Studies 1-3
		<b>Task 20</b>	Set up/operationalize data analyses plan for Study 4
<b>Year 6</b>	<b>Month 61-72 (ending Dec 2013)</b>	<b>Task 21</b>	Conduct data collection procedures for Study 4 (cont'd)
		<b>Task 22</b>	Initiate data quality control checks and preliminary analyses for Study 4
<b>Year 7</b>	<b>Month 73-84 (ending Dec 2014)</b>	<b>Task 23</b>	Initiate external data request procedures for Study 4
		<b>Task 24</b>	Conduct data collection procedures for Study 4 (cont'd)
		<b>Task 25</b>	Continue data quality control checks and preliminary analyses for Study 4 <ul style="list-style-type: none"> <li>Following each data collection trip, the newly collected data are entered into database and cleaned and preliminary data checks conducted</li> </ul>
<b>Year 8</b>	<b>Month 85-96 (ending Dec 2015)</b>	<b>Task 26</b>	Conduct data collection procedures for Study 4 (cont'd)
		<b>Task 27</b>	Continue data quality control checks and preliminary analyses for Study 4 <ul style="list-style-type: none"> <li>Following each data collection trip, the newly collected data are entered into database and cleaned and preliminary data checks conducted</li> </ul>
<b>Year 9</b>	<b>Month 97-104 (ending Aug 2016)</b>	<b>Task 28</b>	Complete 100% data collection goal for Study 4 (with ARNG national sample from at least 8 geographically representative US states)
		<b>Task 29</b>	Complete data analyses for Study 4 <ul style="list-style-type: none"> <li>With 100% data collected, complete data analyses to address Study 4 research hypotheses</li> </ul>
		<b>Task 30</b>	Prepare Study 4 manuscript(s) for peer review <ul style="list-style-type: none"> <li>With completion of Study 4 analyses and manuscript preparation, travel to present findings at national conference forum is planned</li> </ul>
		<b>Task 31</b>	Preparation of Project Final Report

**Task 1 (Month 1-2)****Plan and finalize logistics for Phase I (Studies 1-3) – COMPLETED**

All logistical aspects for USARIEM IRB approved studies (Studies 1-3) have been confirmed. Recruitment procedures, equipment, testing facilities, and other data collection elements have been finalized and are now complete

**Task 2 (Month 3-12) Subject recruitment, data collection and data management for Studies 1-3 – COMPLETED**

Subject recruitment, data collection and data management efforts have been completed for Studies 1-3. Recruitment of both Human Research Volunteers and civilians participants was effective and efficient.

**Task 3 (Month 13-14) Perform preliminary data analyses for Study 3– COMPLETED**

All preliminary data analyses for Study 3 have been completed. Initial analyses suggested that additional participants would be necessary to explore noted differences between military and civilian participants on discrete mood measures. Thus an amendment (14 July 2009) to increase enrollment from 50 to 80 participants was submitted and approved. Data analyses have been completed on this expanded sample.

**Task 4 (Month 15-24) Complete data collection for Study 1– COMPLETED**

Study 1 involves the examination of common use practices and specific administration procedures (individual or group administration, practice or no practice, single session or two sessions) on ANAM4 task performances. Our recruitment goal for Study 1 was 90 participants, 30 participants per condition. Enrollment data are presented in **Table 6**.

**Table 6. Study 1 Enrollment**

# Participants Enrolled	90
# Participants Completed	86*

*\*NOTE: 15 participants completed the ANAM4 without practice test modules; 15 participants completed the ANAM4 in a group setting and 15 participants completed the ANAM4 in two administration sessions. The remaining 41 participants served as controls for these discrete administration scenarios (individual administration using practice test modules and completed in a single testing session). Thus each condition had at least 30 participants, as required.*

**Task 5 (Month 15-24) Perform preliminary data analyses for Study 1 – COMPLETED**

Preliminary analyses (sample characterization, demographic analyses, and preliminary group analyses) on the Study 1 data set have been completed.

**Task 6 (Months 15-24) Continue recruitment, data collection and data management for Study 2 & 3 – COMPLETED**

Our recruitment goal for Study 2 was 90 participants, 30 participants per condition (days 1 & 7 / days 1 & 30 / 7 consecutive day retest). Recruitment goal for Study 3 was 80 participants. Recruitment goals were reached for Studies 2 and 3 and data collection has been completed for these studies.

**Task 7 (Months 15-24) Complete data collection for Study 3 – COMPLETED**

Data collection for Study 3 is complete. Enrollment data are presented in **Table 7**.

**Table 7. Study 3 Enrollment**

# Participants Enrolled	113
# Participants Completed	77

**Task 8 (Months 25-36) Complete data collection for Study 2- COMPLETED**

Data collection for Study 2 has been completed. Enrollment data are presented in **Table 8**.

**Table 8. Study 2 Enrollment**

# Participants Enrolled	99
# Participants Completed	92

**Task 9 (Months 25-36) Plan and finalize logistics for Phase II (modified Study 4) – COMPLETED**

The Study 4 protocol has been reviewed and approved by USARIEM IRB and Army Human Research Protections Office (HRPO) (final approval to initiate received June 2011). Endorsement of the approved Study 4 protocol was received 20 October 2011 by National Guard Bureau (NGB) and all 8 states (Arizona, Kentucky, Maine, Minnesota, Mississippi, Montana, Oklahoma, Pennsylvania) were contacted by both NGB and USARIEM study staff. Oklahoma declined participation in September 2012. We identified Texas as a suitable replacement for Oklahoma and secured NGB endorsement for the state in October 2012.

**Task 10 (Months 25-36) Complete data analyses for Studies 1, 2, 3 - COMPLETED**

Preliminary data analyses have been completed for Studies 1, 2, and 3. Higher-level analyses of these data, including new ANAM Composite Score and Effort Measure analyses, have also been conducted.

**Task 11 (Months 25-36) Preparation of journal manuscript(s) for Studies 1, 2, 3 – COMPLETED**

Manuscripts for these studies have been prepared. Data were presented at a professional meeting (Force Health Protection, 2010).

**Task 12 (Months 25-36) Preparation of project report for Studies 1, 2, 3 – COMPLETED**

Project summaries and completion of Studies 1-3 were included in previous continuing review reports. Manuscripts for these studies were prepared and data were reported at a professional meeting (Force Health Protection, 2010).

**Task 13 (Months 25-36) Set-up data management procedures for Study 4 - COMPLETED**

Study 4 data management procedures have been established. Study 4 datasets have been created and are being populated as data are obtained from field sites. Data entry and data quality and control checks have been successfully coordinated and are ongoing with data entry procedures.

**Task 14 (Months 25-36) Initiate data collection procedures for Study 4 – COMPLETED**

Data collection procedures were coordinated for Arizona, Montana and Maine in 2010-2011, with data collection commencing in these three states in 2011-2012.

**Task 15 (Months 37-48) Carry out data collection procedures for Study 4 – COMPLETED (See Task 18, 21, 24, & 26 for further updates)**

Data collection was completed in Arizona, Maine, and Montana.

**Task 16 (Months 37-48) Initiate integrative data management structure set up for Study 4 - COMPLETED**

Databases associated with Study 4 have been created and are being populated as data are obtained and subjected to data quality and control procedures.

**Task 17 (Months 37-48) Operationalize database for Study 4 analysis scheme – COMPLETED**

Data entry has commenced and databases have been refined for analytic schemes.

**Task 18 (Months 49-60) Conduct data collection procedures for Study 4 (cont'd) – CARRIED OUT (See Task 21, 24, & 26 for further updates)**

Data collection procedures were completed previously in four states (AZ, ME, MT, MN) and completed in two states (KY, TX) during the current reporting period.

**Task 19 (Months 49-60) Complete manuscript preparations/submissions for Studies 1-3 – COMPLETED**

Primary data analyses for Studies 1-3 have been completed and reported at professional meetings (Force Health Protection, 2010) during an earlier reporting period. Manuscripts were prepared but not submitted in order to include additional data being generated within the laboratory.

**Task 20 (Months 49-60) Set up/operationalize data analyses plan for Study 4 – COMPLETED**

Primary data analytic plan for Study 4 has been established and completed. Data have been populated in the Study 4 dataset as they were collected and checked for accuracy/quality.

**Tasks 21 (Months 61-72) Conduct data collection for Study 4 (cont'd) – CARRIED OUT**

Data collection continued in two states (KY, TX) in 2015-2016. ARNG Adjutant General-level approval to initiate data collection in New Hampshire was received and coordination of data collection activities were ongoing during this period. Efforts to coordinate Adjutant General-level approval to initiate data collection in Pennsylvania and Florida were continued. *(See Task 26 for current update)*

**Task 22 (Months 61-72) Initiate data quality control checks and preliminary analyses for Study 4 - COMPLETED**

Data quality control checks and preliminary analyses were carried out as planned. *(See Task 27 & 29 for current updates)*

**Task 23 (Months 73-84) Initiate external data request procedures for Study 4 – CARRIED OUT**

An external data request (with DMDC for military service history, AFQT, and additional demographic data) was initiated and completed (October 2014) for those participants from the three states in which data collection activities were completed (AZ, MT, ME). External data request is in progress for the remaining states (MN, KY, TX).

**Task 24 (Months 73-84) Conduct data collection procedures for Study 4 (cont'd) – CARRIED OUT**

Coordination of data collection activities continued in Kentucky, Texas and New Hampshire  
Coordination of ARNG Adjutant General-level approvals continued with ARNG in Pennsylvania, Florida, & Tennessee.

**Task 25 (Months 73-84) Continue data quality control checks and preliminary analyses for Study 4: Following each data collection trip, the newly collected data are entered into database and cleaned and preliminary data checks conducted – COMPLETED**

Data quality control checks were carried out on an ongoing basis as data collection activities were completed at each approved site. Preliminary analyses were performed on data from three states in which data collection was completed (AZ, MT, ME) and were presented (posters) at professional conferences (*See Appendices A & B*).

**Task 26 (Months 85-96) Conduct data collection procedures for Study 4 (cont'd) – CARRIED OUT**

Data collection was completed with ARNG in two states (KY, TX) and efforts to coordinate data collection with New Hampshire were ongoing. Efforts continued to coordinate TAG-level approvals with two states (Pennsylvania, Tennessee).

Data collection was completed in Kentucky with approximately 64% of the target sample (300) for this state completed. Data collection also continued in Texas with approximately 63% of the target sample completed for the state (300). Additional trips to complete data collection in Texas, Kentucky and New Hampshire were coordinated.

Current enrollment by state is presented in **Table 9**.

**Table 9: Current Study 4 enrollment**

<b>State</b>	<b># Completed</b>
Arizona	223
Maine	248
Montana	302
Minnesota	306
Kentucky	193
Texas	188
<b>Total</b>	<b>1460</b>

**Task 27 (Months 85-96) Continue data quality control checks and preliminary analyses for Study 4: Following each data collection trip, the newly collected data are entered into database and cleaned and preliminary data checks conducted – CARRIED OUT**

Data quality control checks were carried out as planned. Preliminary analyses have been performed on data from three states in which data collection was completed (AZ, MT, ME). These data were presented (posters) at professional conferences (*See Appendix A and B*).

**Task 28 (Months 97-104) Complete 100% data collection goal for Study 4 (with ARNG national sample from at least 8 geographically representative US states) – GOAL NOT REACHED**

Data collection activities were carried out and completed to the extent possible in six states: MT, ME, MN, AZ, TX, and KY. Roughly half of our target sample of 3000 individuals were recruited

and tested. Two states declined participation. Coordination for TAG approval in one state (Pennsylvania), while ongoing, was not achieved during the funding period. Data collection activities received TAG-level approval in New Hampshire, however, we were unable to gain access to appropriate units.

**Task 29 (Months 97-104) Complete data analyses for Study 4: With 100% data collected, complete data analyses to address Study 4 research hypotheses – PENDING**

Data management and data quality control checks have been completed with all data collected as part of this effort. Preliminary data analyses have been completed for data obtained from all six states (ME, MT, AZ, MN, TX, KY) Additional data analyses to address study-specific aims are pending receipt of additional data from DMDC data request and will be completed in the remaining (extended) performance period.

**Task 30 (Months 97-104) Prepare Study 4 manuscript(s) for peer review: With completion of Study 4 analyses and manuscript preparation, travel to present findings at national conference forum is planned – PENDING**

**Task 31 (Months 97-104) Preparation of Project Final Report - PENDING**

## SUPPLEMENTAL PROJECT

A supplemental, 16-month project extending the original project period of performance to 31 December 2017 was approved in August 2016. The supplemental project has 2 primary objectives:

- Recommend cognitive assessment tools/approaches (toolkit) from existing tools/approaches that have been validated for use within military-relevant environments and for evaluation of performance of military personnel;
- Propose the way- ahead (roadmap) for the execution of an integrated research program to address novel/emerging cognitive assessment strategies for use in future military-relevant environments

The supplemental project has two primary deliverables:

- Proposed Toolkit of cognitive assessment tools/approaches from existing tools/approaches that have been validated for use within military-relevant environments;
- Proposed Roadmap for an integrated research program on cognitive assessment strategies for cognitive readiness metrics for use in operational environment

Table 10 provides the statement of work for the supplemental project:

**Table 10**

<b>Year 1</b>	<b>Months 1-2 (Beginning Sept 2016)</b>	<b>Task 1</b>	Assemble the Advisory Group of SMEs, stakeholders, etc (8-10 max)
	<b>Months 3-4 (ending Dec 2016)</b>	<b>Task 2</b>	Assemble the Steering Committee
		<b>Task 3</b>	Conduct series of periodic meetings (via teleconference) with the Advisory Group to (reaching out to Steering Committee members as needed): <ul style="list-style-type: none"> <li>• Summarize cognitive assessments currently in use in military relevant environments</li> <li>• Summarize the reliability/validity of these instruments</li> <li>• Summarize the environments in which these instruments are being implemented and in what way(s)/for what purpose they are being implemented</li> <li>• Identify gaps/needs in assessment of cognitive performance within military-relevant environments</li> </ul> Identify recommended cognitive performance tasks based on current knowledge/tests available
<b>Year 1</b>	<b>Month 5</b>	<b>Task 4</b>	Cont. work summarized under Task 34
	<b>Month 6-7</b>	<b>Task 5</b>	Convene the Advisory Group in-person Workshop to prepare Report Draft
		<b>Task 6</b>	Vet Final Report and Cognitive performance recommendations through Steering Committee
		<b>Task 7</b>	Provide Toolkit Report

	<b>Months 8-12</b>	<b>Task 8</b>	Conduct series of periodic meetings (via teleconference) with MRMC Advisory Group to: <ul style="list-style-type: none"> <li>• Present several course-of-action case-studies to depict implementation of the cognitive toolkit within training, garrison, and forward, operational settings</li> <li>• Make recommendations for identification of existing metrics or development of new assessment instruments to address gaps</li> </ul>
		<b>Task 9</b>	Convene MRMC Advisory Group in-person meeting to prepare Report Draft for roadmap
<b>Year 2</b>	<b>Months 13-16 (ending Dec 2017)</b>	<b>Task 10</b>	Finalize recommendations for an implementation approach/roadmap to address gaps in cognitive performance assessment within military-relevant environments & integrate/update performance toolkit (e.g., new/modified task area plan)
		<b>Task 11</b>	Provide Roadmap recommendations

**Task 1 (Months 1-2): Assemble the Advisory Group of SMEs, stakeholders, etc (8-10 max) – COMPLETED**

Advisory group consisting of 8 SMEs from USARIEM, WRAIR and USAARL has been convened.

**Task 2 (Months 3-4): Assemble the Steering Committee – IN PROGRESS**

Members for the Steering Committee have been and continue to be identified and invited to participate.

**Tasks 3 & 4 (Months 3-5): Conduct series of periodic meetings (via teleconference) with the Advisory Group to (reaching out to Steering Committee members as needed): 1) Summarize cognitive assessments currently in use in military relevant environments, 2) Summarize the reliability/validity of these instruments, 3) Summarize the environments in which these instruments are being implemented and in what way(s)/for what purpose they are being implemented, and 4) Identify gaps/needs in assessment of cognitive performance within military-relevant environments. Identify recommended cognitive performance tasks based on current knowledge/tests available. - COMPLETED**

Advisory group members have reviewed and provide input for progress reports and briefings to MRMC Director.

**Task 5 (Month 6-7): Convene the Advisory Group in-person Workshop to prepare Report Draft – IN PROGRESS**

An in-person meeting of the Advisory Group is scheduled to be held at USARIEM in early January 2017

**Task 6 (Month 6-7): Vet Final Report and Cognitive performance recommendations through Steering Committee - PENDING**

**Task 7 (Months 6-7): Provide Toolkit Report -- PENDING**

**Task 8 (Months 8-12): Conduct series of periodic meetings (via teleconference) with MRMC Working Group to 1) Present several course-of-action case-studies to depict implementation**



of the cognitive toolkit within training, garrison, and forward, operational settings and 2) Make recommendations for identification of existing metrics or development of new assessment instruments to address gaps. - - PENDING

**Task 9 (Months 8-12):** Convene MRMC Working Group in-person meeting to prepare Report Draft for roadmap. - PENDING

**Task 10 (Months 8-12):** Finalize recommendations for an implementation approach/roadmap to address gaps in cognitive performance assessment within military-relevant environments & integrate/update performance toolkit (e.g., new/modified task area plan) - - PENDING

**Task 11 (Months 8-12):** Provide Roadmap recommendations -- PENDING

## **KEY RESEARCH ACCOMPLISHMENTS**

Key research accomplishments during the current study period include:

- Progress on Study 4 data collection continued but was slower than anticipated given scheduling challenges at the ARNG sites. Several trips were coordinated and scheduled but cancelled due to ARNG changes/conflicts.
- Reports related to Studies 1-3 were revised and refined to include additional analyses related to the ANAM Composite Score and Effort Measure metrics, and also to include additional information generated within the laboratory. Three manuscripts are being finalized for submission.
- USARIEM Protocol Continuing Review was reviewed and approved by the USARIEM IRB (5 August 2016); Army HRPO acknowledgment was received 22 August 2016.
- As described above, seven states agreed to participate in Study 4 data collection prior to the end of the funding period and provided ARNG Adjutant General-level approval; approvals continued to be coordinated with two additional states under the end of the funding period.
  - During this reporting period, data collection activities were carried out in Texas;
  - ARNG Adjutant -level approval was secured for NH; coordination of data collection activities continued until the end of the funding period
  - Communications with ARNG headquarters staff in one state (PA) continued with approvals pending.
- Progress on the Supplemental Project is on track.
  - Preliminary reports have been provided to MRMC Director (November) detailing progress to date
  - Database has been developed and is being populated with assessment-relevant information for use by advisory group members
  - In-person meeting of Advisory Group members is scheduled for January 2017

## REPORTABLE OUTCOMES

### Reportable outcomes during the current study period include:

#### 1. Reports, manuscripts, abstracts (included as Appendices)

None this reporting period.

#### 2. Degrees and research training opportunities

In addition to Drs. Proctor and Heaton, one doctoral-level researcher, one pre-doctoral intern, six masters-level interns and 1 Bachelor-level intern have been trained to administer the Study 4 protocol for this project.

#### 3. Collaborative funding applications related to work supported by this award

- “Eye-Tracking Rapid Attention Computation (EYE-TRAC)” (USARIEM Protocol # H09-07; Site PI: Heaton). This project was funded as a FY08 CDMRP Advanced Technology Award to Dr. Jamshid Ghajar, Brain Trauma Foundation, New York, NY (W81XWH-08-2-0646). This study examines the efficacy of a novel visual tracking system for assessing the integrity of the attention system. The ANAM4-TBI-MIL battery was used in this study to provide cognitive performance outcomes for validation of the visual tracking paradigm. Healthy military volunteers were subjected to a 26-hour period of sleep loss during which cognitive and visual tracking performance were evaluated. Test-retest reliability of the ANAM4-TBI-MIL was examined across a 2 week interval and sensitivity of the ANAM4 TBI battery to central fatigue were determined. One paper (pending) and one abstract (presented) involve ANAM4-TBI-MIL data collected from this study:

Heaton, K.J., Laufer, A.S., Maule, A., Vincent, A.S. Effects of acute sleep deprivation on ANAM4 TBI Battery performance in healthy US Army Service Members. *In preparation*

- “Identifying biomarkers that distinguish post-traumatic stress disorder and mild traumatic brain injury using advanced magnetic resonance spectroscopy,” was funded via a Department of Defense Congressionally Directed Medical Research Programs Psychological Health/Traumatic Brain Injury (PH/TBI) Research Program award to Dr. Alex Lin, Brigham and Women’s Hospital, Boston, MA. Dr. Heaton is a co-Investigator and site PI on this project. This study proposes a multi-parametric approach using major advances on spectroscopic methods and neuroimaging to identify biomarkers that can be used to distinguish between post-traumatic stress disorder, traumatic brain injury, and their co-occurrence. This will be achieved in part by correlating quantitative MR spectroscopy results with behavioral and neuropsychological metrics (including ANAM4TBI) using newly developed algorithmic approaches that are capable of revealing discriminating metabolic markers in MR spectroscopy measurements. Data collection for this project is ongoing.
- “Multimodal Assessment of Cognitive Readiness and Recovery: Initial Modeling of Physiological and Neurological Inputs” (USARIEM Protocol 15-05HC; PI: Heaton), was

funded by Defense Health Program (DHPE, RDT&E, Operational Performance Sustainment; “Multimodal Assessment of Cognitive Readiness and Recovery: Modeling and Analysis of Physiological and Neurological Inputs”) to Dr. Heaton and MIT Lincoln Laboratory investigator, Dr. Thomas Quatieri. This study will examine the sensitivity of a multi-modal platform for detecting change in cognitive functioning under different cognitive load conditions. The platform consists of vocal, facial, physiological (heart rate, skin conductance, respiration), and cognitive data inputs. The ANAM4 is included in the cognitive test battery. Data collection for this project is ongoing.

#### **4. Related projects and collaborations initiated**

“Analyses of ANAM4™TBI Predeployment Assessment Data: USARIEM-OTSG Research Collaborative” (USARIEM #11-07HC; PI: Proctor) involves the creation of a research database system (ANAM4TBI Military Performance Database (AMP-D)) which incorporates all mandated pre-deployment ANAM4TBI assessment data from DoD military personnel (maintained by the Office of the Surgeon General, ANAM Program Office). We have initiated the process of linking these neurocognitive data with individual military service, demographic, and injury and clinical disease histories. A paper comparing ANAM pre-deployment test results (extracted from the AMP-D) between Army Active Duty and National Guard groups and examining the role of deployment-related factors on neurocognitive health and performance was published in 2015 and reported in a previous Annual Report.

- “Validation of Select Neurobehavioral Assessments for Concussion/Mild Traumatic Brain Injury (MTBI)” (USARIEM #H09-08), was intramurally funded (MRMC MOMRP) to Drs. Proctor and Heaton (co-PIs). This study seeks to validate the ANAM4TBI Battery against a standard neuropsychological screening battery for mild traumatic brain injury. Data collection for this project has been completed; data analyses and manuscript preparation are underway.
- “Multidimensional MR Imaging to Assess Subtle Brain Changes Associated with Persistent Postconcussive Symptoms (PPCS) Following Mild Traumatic Brain Injury” (USARIEM Protocol #11-15-HC; PI: Palumbo, co-I: Heaton), was intramurally funded (MRMC MOMRP) to Dr. Palumbo (co-I: Heaton). This study examines neuropathological changes associated with PPCS following mTBI using multidimensional magnetic resonance imaging (MRI) to determine the independent and synergistic effects of structure, function, connectivity and blood flow of the brain in subjects with mTBI. ANAM4-TBI-MIL is being used in this study to examine cognitive performance outcomes. Data collection for this study has been completed; data analyses and manuscript preparation are underway.

## CONCLUSION

Analyses of data from Studies 1-3 have been completed and reports are being revised for submission. Our results (reported in conference proceedings included in the 2010 Annual Report for this project) provide evidence supporting the Automated Neuropsychological Assessment Metrics Version 4 (ANAM4) as a reliable and valid measure of cognitive performance under diverse administration scenarios.

Development of a nationally-representative normative dataset of Army National Guard service members' ANAM4 performance outcomes (Study 4) is currently pending receipt of additional data from DMDC. Preliminary results have been presented at professional conferences. The target reference dataset is intended to complement existing normative data by focusing on a subset of the general military population that research has shown differs on key demographic elements (e.g., dual career status, average age, marital/family status, and education) relative to other military components (e.g., Active Duty), and as such, is expected to facilitate the interpretation of individual National Guard service members' performance on ANAM4 tests.

Together, results from the original four studies in this project will add to ongoing efforts to develop and validate the ANAM4 (and ANAM4 Military Traumatic Brain Injury Battery) as an accurate, reliable, and objective measure of military service members' cognitive performance. The supplemental study currently in progress is expected to provide critical input for the selection and utilization of cognitive assessment tools and approaches for evaluating cognitive performance and readiness in Warfighters under operational conditions. In addition, it is anticipated that this study will provide actionable information regarding key gaps in cognitive assessment capabilities and recommendations for solutions to address these gaps.