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TITLE: United States Navy Joint Capability Resource on En Route Care

SITE PRINCIPAL INVESTIGATOR: Mitchell Dukovich, PhD

CONTRACTING ORGANIZATION: Naval Medical Center San Diego,
34800 Bob Wilson Drive, San Diego, CA 92134

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14. ABSTRACT This Annual Report summarizes four projects that are encompassed within the awarded proposal entitled "United States Navy Joint Capability Resource on En Route Care". The first of these projects (Project # 1) is entitled: "Resuscitative Endovascular Balloon Occlusion of the Aorta: Can Nurses and Corpsmen Perform this Skill for En Route Care: A Pilot Study." Project #1A "Physiologic Effects of Hypobaria and REBOA in a Swine (<i>Sus scrofa domestica</i>) Hemorrhage Model is added on to Project # 1. Project # 2 is entitled: "Evaluation of Human Factors Issues Relating to Providing En Route Care Within the V-22 Osprey Aircraft." Project # 3 is entitled: "Search and Rescue Records Modernization and Evaluation." Project # 1 hypothesizes that provided proper training and practice, ERC nurses and Special Operations Independent Duty Corpsmen (IDC) can successfully acquire adequate knowledge on the use of REBOA, and successfully demonstrate skill placement competency among using simulation and cadaveric models. Project #1A: is determining the effects of altitude on REBOA placement. Project # 2 will explore the working space challenges confronting medical providers in the V-22 Osprey tiltrotor aircraft; a medical care evacuation transportation aircraft. Project # 3 is transforming approximately 45 years of the Navy's SAR Model Manager's (SARMM) historical records into a comprehensive SAR electronic database and developing a secure web-based electronic data collection system for new reports.					
15. SUBJECT TERMS Resuscitative Endovascular Occlusion of the Aorta, Level One and Level Two Combat Trauma Care, En Route Care, Training providers using simulation, controlling severe internal hemorrhage, preventing battlefield death due to hemorrhagic shock					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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PROJECT #1: “RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA; CAN NURSES AND CORPSMEN PERFORM THIS SKILL FOR EN ROUTE CARE: A PILOT STUDY”

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

This study hypothesizes that provided proper training and practice- including various methods of simulation to establish technical proficiency with vascular access and device placement- ERC nurses and Special Operations Independent Duty Corpsmen (IDC) can successfully demonstrate adequate knowledge acquisition on the use of REBOA, successfully demonstrate REBOA skill competence among various forms of simulation, report improved confidence in technical performance after simulation, and will demonstrate retained competence and confidence after six months. This specifically addresses Joint Program Committee-6 (JPC-6) ERC focus areas 3-6 (ERC provider skill levels, development of ERC protocols, and development of advanced ERC interventions and treatments). The specific aims include:

- 1) Establish whether highly trained nurses and corpsmen can acquire the requisite knowledge required to successfully perform REBOA, as demonstrated by written tests evaluating their understanding of the procedure, its indications and complications.
- 2) Upon completion of training, which includes didactic and multimodal simulation activities, evaluate nurses' and corpsmen's abilities to successfully perform REBOA on a perfused cadaver model of severe hemorrhage. Study metrics include: vascular access proficiency (time, attempts, complications, success), Time to occlusion, accuracy of device placement, appropriate inflation of balloon, estimated blood loss, and skill performance checklist.
- 3) After course completion, measure nurses and corpsmen confidence levels in their ability to identify the indication for and perform skills requisite for REBOA.
- 4) If participants can be summoned to return, we will determine if nurses and corpsmen can retain adequate REBOA performance skill set at least six months following initial training, by retaking knowledge test, replicating their procedural evaluations in a single mode simulation (task trainer), and confidence instrument.

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

REBOA, Nurses, Corpsmen, En Route Care, Combat Trauma Training Simulation

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.

Statement of Work Tasks

Note: As previously reported, study completed and closed 19 December 2019.

Major Task 1: Preparation for REBOA Training Research (Milestone 1)

Subtask 1.1: Research instruments reviewed and modified; curriculum refined

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Study Complete and Closed.

Sub task 1.2: Submission & approval of research plan to NMCSD & NMCP IRB and IACUC **Target:** months 2-3

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Study Complete and Closed.

Subtask 1.3: Submission of research study to USAMRRC HRO for 2nd level review and approval **Target:** months 3-4

Year 4, 1st Quarter Report thru 4th Quarter: No new items with regards to USAMRRC HRO 2nd level review and approval. Item closed and considered complete. Study Complete and Closed.

Subtask 1.4: Contracts administrative/execution and obligation of FY17 funds by 30 Sept 2019 (FY2017 Program Element 6 Funds are earmarked for two years and expire 30 Sep 2019) Target: months 1-2

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Study Complete and Closed.

Subtask 1.5: Equipment purchase, installation and pre-calibration of simulation devices & data collection systems **Target:** months 1-7 and annually as need for perishable items. .

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Study Complete and Closed.

Subtask 1.6: Student Subjects recruited **Target:** month 13

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Study Complete and Closed.

Milestone 1 Goal: REBOA Training requirements and components in place and tested. All requirements to begin study completed. (Target: 4-7 months)

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Milestone 1 Goal completed. Study Complete and Closed.

What were the major goals of the project? (continued):

Major Task 2: REBOA Performance Data Collection and Analysis (Milestone 2)

Subtask 2.1: Initial REBOA training & procedural testing.

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Data collection and analysis completed. Study Complete and Closed.

Subtask 2.2: Initial data analysis; interim data and conclusions presented for IPR as directed by sponsor (TBD). No new items to report. Subtask complete. Data collection and analysis completed. Study Complete and Closed.

Subtask 2.3: Retesting to evaluate skill retention (TBD)

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Data collection and analysis completed. Study Complete and Closed.

Subtask 2.4: Analysis of skill retention data

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Subtask complete. Data collection and analysis completed. Study Complete and Closed.

Milestone 2 Goal: REBOA training, comprehension, procedural performance and skill retention tested and analyzed (for first pilot group)

Year 4, 1st Quarter Report thru 4th Quarter: No new items to report. Milestone 2 Goal completed. Study Complete and Closed 19 December 2019..

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.

Noteworthy Period of Performance activities:

.Year 4, 1st Quarter Report:

1.) Poster Abstract on nurses' performance accepted to American College of Surgeons Surgical Simulation Summit- poster presentation (scheduled for March 12, 2020)

2.) Abstract on medics' accepted to Special Operations Medics Association Conference- podium presentation (Scheduled for May 11, 2020)

Year 4, 2nd Quarter Report: No new items to report. Scheduled conferences cancelled due to COVID-19 pandemic.

**Year 4, 3rd Quarter Report: Virtual presentation academic Research Competition 4/2020
Virtual presentation Special Operations Medics Association 8/2020**

Year 4, 4th Quarter Report: No new items to report.

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.

CY 2020:

1. Site PI and study PI planned to attend Military Health System Research Symposium and was selected to present a podium session for the En Route Care breakout session, however, due to COVID pandemic the symposium was cancelled.
2. Follow up for FY21 MHSRS is planned and pending.

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.

2020 Annual report:

Year 4, 1st Quarter Report:

Presented findings at American College of Surgeons Surgical Simulation Summit and Special Operations Medics Association Conferences (January 19-22, 2020). Completed phase III data analysis, and plan to submit manuscript to appropriate journal.

Year 4, 2nd Quarter Report: No new items to report, findings not presented due to COVID-19 impact. Will entertain presentations at later date when conferences re-open.

Year 4, 3rd Quarter Report: No new items to report, same as reported in 2nd Quarter report. Plan to present findings at next American College of Surgeons Surgical Simulation Summit. Will develop manuscript upon conclusion of follow on study in partner with Uniformed Service University of Health Sciences (2nd quarter 2021). Provided a Virtual presentation for the academic Research Competition April 2020, Naval Medical Center, San Diego. Provided a Virtual presentation to the Special Operations Medics Association August 2020.

Year 4, 4th Quarter Report: Data and findings scheduled to be presented at MHSRS August 2021 and any other cancelled scientific meetings.

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.

Nothing to report study is closed. Will continue to submit findings to appropriate meetings for dissemination of findings and conclusions.

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?

Background and future plans: Our Nation's largest group of potentially survivable wartime casualties succumbs to non-compressible truncal hemorrhage². These patients die before ever reaching surgical care, often times in the hands of Corpsmen, Medics, Physician Assistants and ERC Nurses. As medical treatment teams become smaller, more mobile, with increasing travel times from point of injury to definitive surgical care, our ERC medical teams need the tools to address these devastating injuries. REBOA has the potential to extend survival from point of injury to nearly 90 minutes and beyond¹⁵ in patients whom otherwise would die due to hemorrhage within minutes. En route care nurses and advanced practice medics are currently intubating, transfusing blood and performing advanced resuscitations – adding REBOA to their armamentarium against hemorrhage in this setting specifically addresses one of the largest current gaps in pre-hospital ERC capabilities today. If the pilot study is successful in demonstrating feasibility of training, and successful completion of, REBOA in Nurses and/or Corpsmen, several related follow-on studies are in the planning stages for project years 2 thru 5.

As directed in the Intramural Program Announcement for this award, the members of our collaborative team will work with our Site PI (Dr. Dukovich) and the JPC-6 ERC Working Group to refine future projects that align with the most current J-ERC priorities. For future consideration, this research team is developing protocols to evaluate the effects of altitude on REBOA in a swine model utilizing hypobaric chambers and flight plans patterned from the Osprey and Blackhawk. Swine would undergo a controlled hemorrhage, placement of REBOA catheter, then taken to altitudes for various periods of time, returned to ground pressure and observed. Swine would undergo continuous invasive (arterial lines, Transonic cardiac output monitoring, etc.) and non-invasive (Cheetah NICOM, ECG, spO2) physiologic monitoring, as well as hematologic measurements (blood gases, lactate, chemistries, etc.) at regular intervals. This would provide baseline data for future studies aimed at ameliorating the ischemic effects of aortic occlusion and hypoxia.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

The PI has been asked to support a replication study at Uniformed Services University of Health Sciences in similar and distinct populations. (Nurses and medical students)

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.*

Attempting to validate curriculum which may be of interest to pre-hospital / Para medical providers

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.*

Attempting to validate curriculum which may be of interest to prehospital medical providers

- 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:

Nothing to Report.

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.

Study is closed.

COVID Pandemic has had an impact on ability to present findings.

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. COVID Pandemic posed problems for dissemination of findings.

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.

None 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

. Nothing to report.

Significant changes in use or care of vertebrate animals

Nothing new to report.

Significant changes in use of biohazards and/or select agents

Not Applicable

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).*

None to report at this time. Developing manuscript submission for Journal of Surgical Simulation or Journal of Surgical Training.

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).*

None to report at this time

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.*

Poster presentation- MHSRS August 2019; MHSRS 2020 was cancelled.

- **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.

Not Applicable

- **Technologies or techniques**
Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

None 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.

Not Applicable

- **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.

None to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Year 4, Quarters 1 thru 4:

Name: Carmen N. Spalding, PhD, RN, CHSE

Project Role: Primary Investigator

Nearest Person Month worked 3

Contribution to Project: Dr. Spalding as PI, has authored the IRB and cadaveric use protocols for this study. She established sole source justifications for all unique equipment requirements and purchase. She has opportunistically attended REBOA training sessions to learn the techniques and refine the research curriculum. She has attended requisite military research conferences to learn about REBOA and its application for enroute care (ERC), as well as a "Simulation Training in Healthcare" conference to maintain currency in using simulation in healthcare research. She helped develop the test question bank for the trainees. She collected and managed all data from the study. She has organized all equipment, supplies, services, schedules, space reservations for each of the 2 study sessions held to date.

Name: James Stone, MD, PhD

Project Role: Associate Investigator

Nearest Person Month worked 1

Contribution to Project: As an AI, Dr. Stone developed the pre-course training materials for ultrasound guided vascular access. He has provided the pre-course ultrasound training to both sessions. He has been present at both study sessions. He regularly attends teleconferences. He attended MHSRS to keep abreast of REBOA uses in ERC.

Name: Carl Goforth, PhD

Project Role: Associate Investigator

Nearest Person Month worked 1

Contribution to Project: As an AI, Dr. Goforth has been present for both training sessions, he has attended MHSRS to keep abreast of REBOA uses in en-route-care.

Name: Matthew Bradley, MD

Project Role: Associate Investigator

Nearest Person Month worked 0.5

Contribution to Project: As an AI, Dr. Bradley has been present for both training sessions, he has attended MHSRS to keep abreast of REBOA uses in en-route-care.

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.

Naval Medical Research Center- Silver Spring, MD

Contributions:

Collaboration: research team members (CDR Carl Goforth and LCDR Matthew Bradley)
Provided Assistance in developing training curriculum, and test question bank

University of Virginia- Charlottesville, VA

Contributions:

Collaboration: Research team member (Dr. James Stone, Ms. Alisha Hawrylack)
Provided assistance in developing training curriculum and pre training vascular access learning materials

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS: Quad Chart Project # 1

Project 1: Resuscitative Endovascular Balloon Occlusion of the Aorta - Can Nurses and Corpsmen Perform this Skill for Life-Saving En Route Care? A Pilot Study



PI: Carmen N. Spalding, PhD, RN Org: Naval Medical Center San Diego Award Amount: \$ 761,000

Study/Product Aim(s)

- Prove highly trained nurses and corpsmen can demonstrate knowledge acquisition of REBOA indication and techniques.
- Prove nurses and corpsmen can demonstrate proper REBOA technique on a live tissue model.
- Explore nurses and corpsmen reports of level of confidence in their ability to identify the indication for and perform REBOA technique
- Determine retention of adequate knowledge, skills and attitudes of REBOA performance among trainees at least six months after initial training

Approach

Offer course to highly trained nurses and corpsmen as structured curriculum

Measure(s) Quantitative: Multiple measures of knowledge, skill acquisition and retention to include tests, performance checklists, confidence instrument, and hemostasis measures within various simulators, and overall length of survivability

Qualitative: Focus group on perceived opportunities and challenges to REBOA



Accomplishment: Vascular access and REBOA curricula (for both didactic and procedural testing) provided for three groups of research subjects. Data collected relating to study aims for 3 groups. Research Poster presented at MHSRS 2019.

Timeline and Cost

Activities CY	16/17	18	19	20	21
Purchase equipment, testing of systems, IRB approval					
Offer Course, Data Collection and Analysis					
Retest, data collection and Analysis					
Estimated 5 Yr Budget (\$1.214M)	258K	258K	258K	5K	5K
Expenditures (\$ To date, each yr)	243K	143K	245K	5K	---

Updated: Dec. 01, 2020

Goals/Milestones: Study complete; publications pending.

FY 17 Goals (1st - 4th Quarter) Milestone 1

- Submit proposal to IRB and IACUC: submit second level review
- Purchase equipment and supplies, contracts in place

FY 18 Goals (1st - 2nd Quarter) Milestone 2

- Develop and test course amongst research team, begin recruit research participants

FY 18 Goals (3rd - 4th Quarter, respectively) Milestone 2

- Provide REBOA technique to research participants
- Completed data collection for phases 1 & 2, no new recruitment
- Data analysis of first measure-post course – on going
- Quantitative and Qualitative Measures analyzed – on going

FY 19 (1st - 2nd Quarter) Milestone 2

- Retest at six month mark to determine retention of skills -ongoing

FY 19 Goals (1st Quarter) Milestones 2

- Prepare findings for dissemination at conferences and for publication, poster and podium presentation accepted

9. APPENDICES: None

Project # 1A: Physiologic Effects of Hypobaria and Resuscitative Endovascular Balloon Occlusion of the Aorta in a Swine (Sus scrofa domestica) Hemorrhage Model.

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15. Appendices: None	35

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

A recent review of United States military conflicts demonstrated that over 90% of preventable deaths were due to hemorrhage. Incompressible truncal hemorrhage was attributable to the cause of death in over 60% of these cases. The Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) catheter was developed to address the gap in temporarily controlling truncal hemorrhage in the combat theater. REBOA has evolved into a low-profile device inserted through the femoral artery and inflated either in the descending thoracic aorta (Zone I) or just proximal to the aortic bifurcation (Zone III). With the concern for more austere combat medical environments, there is the potential for this device being used closer to the point of injury. Temporary hemorrhage control with REBOA in a far forward location also may involve aeromedical transport of a casualty with a REBOA catheter in place. Aeromedical evacuation poses the risk of low oxygen and low atmospheric pressure (hypobaria), which can be deleterious to the casualty. The combined effects of REBOA and hypobaria on casualties are presently unknown. The overall objective of this proposed study is to evaluate the combined effects of REBOA and hypobaria. We aim to address these objectives in a swine hemorrhage model comparing REBOA in a hypobaric versus a normobaric environment. We hypothesize that the combination of hypobaria and REBOA will lead to greater physiological derangements compared to REBOA at normobaria. The Naval Medical Research Center (NMRC) is uniquely positioned to carry out the proposed study. Our research group developed a large animal intensive care unit to provide care of mechanically ventilated animals and has the ability to simulate flight with the use of large animal hypobaric chambers.

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

REBOA, Hypobaric Environment, En Route Care, Combat Trauma Training

- 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.

Statement of Work Tasks

Major Task 1: Assess the physiological effects of hypobaria in conjunction with REBOA balloon in Zone III for one hour at 8000 feet of simulated flight compared to normobaria.

Year 4: Quarters 2 thru 4:

No New items to report. Activity upcoming.

Currently, all NMRC projects with large animals and complicated procedures are on hold due to personnel restriction under the COVID-19 pandemic policies.

The impact of COVID-19 on the management of animal experimentation delayed the scheduling of our work and we are currently working closely with the veterinary staff to resume animal work.

Major Task 2: Assess the physiological effects of hypobaria in conjunction with REBOA in Zone III for one hour at 5000 feet of simulated flight compared to normobaria.

Year 4: Quarters 2 thru 4:

No New items to report. Activity upcoming.

Currently, all NMRC projects with large animals and complicated procedures are on hold due to personnel restriction under the COVID-19 pandemic policies.

The impact of COVID-19 on the management of animal experimentation delayed the scheduling of our work and we are currently working closely with the veterinary staff to resume animal work.

What were the major goals of the project? (continued):

	Timeline	Method	Status
Project 1A: Physiological Effects of Hypobaric and Resuscitative Endovascular Balloon Occlusion of the Aorta in a Swine (<i>Sus scrofa domestica</i>) Hemorrhage Model.	Months		
Major Task 1: IACUC/ACURO approval	14-16	Writing	In progress
Major Task 2: Reboa swine experiments	17-23	Animal experiment	
Major Task 3: Data analysis/manuscript/final report	20-24	Statistics/writing	

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.

Noteworthy Period of Performance activities:

Year 4, 1st Quarter Report:

- IACUC protocol was approved by IACUC Veterinary Staff committee on 8 August 2018.
- A revised protocol was submitted to address prolonged anesthesia in swine. Protocol approval is pending but anticipated to be approved soon.

Year 4, 2nd Quarter Report:

- Currently, all NMRC projects are on hold due to the COVID-19 pandemic.

Year 4, 3rd Quarter Report:

- Currently, all NMRC projects with large animals and complicated procedures are on hold due to personnel restriction under the COVID-19 pandemic policies.

Year 4, 4th Quarter Report:

- Currently, all NMRC projects with large animals and complicated procedures are on hold due to personnel restriction under the COVID-19 pandemic policies.

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.

FY20:

This project so far provided several training activities for new and current employees who will work as research assistants on this project. Through literature search and regular discussion groups within our team we were able to significantly increase their knowledge platform in regards to REBOA and en route care. Additionally, a medical student from USUHS was trained in research conduct and laboratory techniques while working on the protocol submission.

How were the results disseminated to communities of interest?

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

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

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

If this is the final report, state “Nothing to Report.”

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

Year 4 Quarter 4 :
15 November 2020 – 14 February 2021: Complete and submit new IACUC protocol, pending approval and in accordance with facility mandate. We also plan to initiate the pilot animal experiments.

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?

There is a growing need to provide a broad range of surgical solutions in forward surgical critical care. In particular, there is a need for reliable, safe, and simple methods to control severe hemorrhage. Rapid placement of an indwelling vascular balloon with the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) device has shown promise. Since August 2016, there are increasing reports of pre-hospital use of REBOA

The REBOA catheter is a simple vascular control device that is positioned in the aorta to immediately control any bleeding that is below an inflated balloon. Although details regarding these real-life scenarios are classified, the extension of bleeding control in the forward area is becoming reality. Placing a REBOA catheter far forward and closer to the point of injury (POI) has been demonstrated as a means to potentially decrease preventable deaths related to hemorrhage on the battlefield. After temporary hemostasis in the field, combat casualties are most frequently evacuated via aeromedical evacuation (rotor or fixed-wing aircraft) from the point of injury to a higher echelon of care with surgical capabilities. The stressors of flight, such as low pressure and low oxygen levels, combined with a REBOA device, on the outcomes of injured personnel are not yet known. The REBOA balloon, however, has proven to be functional at altitude. This proposed study will evaluate the physiologic effects of low pressure with a REBOA device in a swine hemorrhage model.

Ref: (Sadek et al, 2016, Singer, Morris et al. 2020)

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.” Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

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

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?

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

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. **CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

The COVID-19 pandemic has delayed protocol approvals and animal experimentations at NMRC.

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.

No major changes or problems to report

Year 4, 1st Quarter: Nothing to report

Year 4, 2nd Quarter Report: Nothing to report

Year 4, 3rd Quarter Report: No new items to report

Year 4, 4th Quarter Report: No new items 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.

Year 4, 1st Quarter: Nothing to report

Year 4, 2nd Quarter Report: Nothing to report

Year 4, 3rd Quarter Report: Nothing to report

Year 4, 4th Quarter Report: The COVID-19 pandemic has delayed protocol approvals and animal experimentations at NMRC. We are currently working closely with the veterinary staff to resume animal work.

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.

There were no changes that impacted expenditure during this reporting period.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

. Nothing to report.

Significant changes in use or care of vertebrate animals

A new IACUC protocol for project 1A is being submitted.

Significant changes in use of biohazards and/or select agents

Not Applicable.

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).*

None to report at this time

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).*

None to report at this time

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.*

List items

- **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.

Not Applicable

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

None 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.

Not Applicable

- **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.

None to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name: Carmen N. Spalding, PhD, RN, CHSE

Project Role: Primary Investigator

Nearest Person Month worked 3

Contribution to Project: Dr. Spalding as PI, has authored the IRB and cadaveric use protocols for this study. She established sole source justifications for all unique equipment requirements and purchase. She has opportunistically attended REBOA training sessions to learn the techniques and refine the research curriculum. She has attended requisite military research conferences to learn about REBOA and its application for enroute care (ERC), as well as a "Simulation Training in Healthcare" conference to maintain currency in using simulation in healthcare research. She helped develop the test question bank for the trainees. She collected and managed all data from the study. She has organized all equipment, supplies, services, schedules, space reservations for each of the 2 study sessions held to date.

Name: James Stone, MD, PhD

Project Role: Associate Investigator

Nearest Person Month worked 1

Contribution to Project: As an AI, Dr. Stone developed the pre-course training materials for ultrasound guided vascular access. He has provided the pre-course ultrasound training to both sessions. He has been present at both study sessions. He regularly attends teleconferences. He attended MHSRS to keep abreast of REBOA uses in ERC.

Name: CDR Matthew Bradley, MD

Project Role: Associate Investigator

Nearest Person Month worked 0.5

Contribution to Project: As an AI, Dr. Bradley has been present for both training sessions, he has attended MHSRS to keep abreast of REBOA uses in en-route-care.

Name: Dr. Anke Scultetus

Project Role: Associate Investigator

Nearest Person Month worked 0.75

Contribution to Project Dr. Scultetus provides overall project management, including laboratory integration, data analysis and interpretation, publication strategy and final editorial responsibility for publications. Dr. Scultetus is responsible for research program management with responsibility to plan, coordinate, and execute swine experiments in hypobaric chamber; collect physiological data and histopathological analysis obtained from animal experiments and prepare reports; interpret data and make adequate changes for subsequent experimental design, preparation of data for publication in journals or for presentations to peer groups. Coordinate database management, scientific publications and technical writing.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS (Continued):

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: Dr. Stephen Ahlers
Project Role: Site Principal Investigator
Nearest Person Month worked 0.25
Contribution to Project: As a Site PI, Dr. Ahlers has provided scientific management and oversight of the project.

Name: Dr. Francoise Arnaud
Project Role: Associate Investigator
Nearest Person Month worked 0.25
Contribution to Project: As an AI, Dr. Arnaud has provided scientific management and oversight of the project.

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.

Naval Medical Center San Diego – San Diego, CA

Contributions:

Collaboration:

University of Virginia- Charlottesville, VA

Contributions:

Collaboration: Research team member (Dr. James Stone, Ms. Alisha Hawrylack)

Provided assistance in developing training curriculum and pre training vascular access learning materials

8. SPECIAL REPORTING REQUIREMENTS .

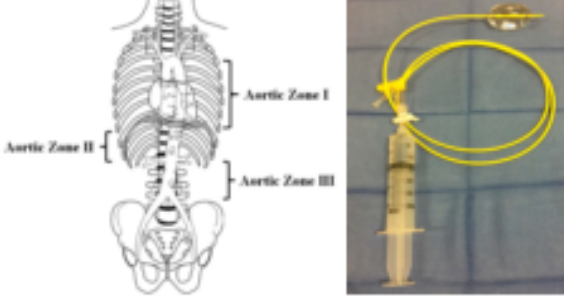
QUAD CHARTS: Quad Chart Project # 1A

Project 1A: Physiologic Effects of Hypobaria and Resuscitative Endovascular Balloon Occlusion of the Aorta in a Swine (*Sus scrofa domestica*) Hemorrhage Model



PI: LCDR Carolyn Gosztyla Org: Naval Medical Research Center

Award Amount: \$463,000

<p>Study/Product Aim(s)</p> <p>The study will assess the effects of hypobaria and hypoxia on the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA).</p> <p>Approach</p> <ul style="list-style-type: none"> Determine the physiological effects of hypobaria in conjunction with REBOA balloon in Zone II for one-hour at 8000 feet of simulated flight compared to normobaria. Assess the physiological effects of hypobaria in conjunction with REBOA in Zone III inflation for one-hour at 5000 feet of simulated flight compared to normobaria. 	 <p>Accomplishment: Initial protocol approved. Awaiting on protocol addendum approval by the IACUC.</p>																																				
<p>Timeline and Cost</p> <table border="1"> <thead> <tr> <th>Activities CY</th> <th>20</th> <th>21</th> <th></th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>Purchase supplies, testing of systems, IRB approval</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Assess the effects of hypobaria and hypoxia on REBOA</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Completion of experiments and clinical assessments studies and data analysis</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Estimated 2 Yr Budget (\$468K)</td> <td>\$233K</td> <td>\$238K</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Expenditures (\$ To date each yr)</td> <td>\$148K</td> <td>\$0</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Activities CY	20	21				Purchase supplies, testing of systems, IRB approval						Assess the effects of hypobaria and hypoxia on REBOA						Completion of experiments and clinical assessments studies and data analysis						Estimated 2 Yr Budget (\$468K)	\$233K	\$238K				Expenditures (\$ To date each yr)	\$148K	\$0				<p>Goals/Milestones</p> <p>FY 20 Goals - Milestone 1</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Submit protocol to IACUC <input type="checkbox"/> Purchase animals and supplies, contracts in place <input type="checkbox"/> Assessment of REBOA at normobaria Zone III- one hour occlusion <p>FY 20 Goals - Milestone 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assessment of REBOA at hypobaria Zone II – One hour occlusion at 8000 feet <p>FY 20 Goals - Milestone 3</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assessment of REBOA at normobaria Zone III – One hour occlusion <p>FY 20/21 Goals - Milestone 4</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assessment of REBOA at hypobaria Zone II – One hour occlusion at 5000 feet <input type="checkbox"/> Prepare findings for dissemination at conferences and for publication <p style="text-align: right;">Updated: Dec. 12, 2020</p>
Activities CY	20	21																																			
Purchase supplies, testing of systems, IRB approval																																					
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Expenditures (\$ To date each yr)	\$148K	\$0																																			

9. APPENDICES: None

PROJECT # 2: “EVALUATION OF HUMAN FACTOR ISSUES RELATING TO PROVIDING EN ROUTE CARE WITHIN THE V-22OSPREY AIRCRAFT”

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1. INTRODUCTION:

This project will explore the working space challenges confronting medical providers as the V-22 Osprey tiltrotor aircraft becomes a significant medical care evacuation transportation aircraft with future military scenarios emphasizing a "Pivot to the Pacific" operational strategy. As a result, En Route Care procedures will need to be developed or modified to meet the operational and physical environment of the V-22 aircraft. This project will expand on existing efforts, in collaboration with NMCSO, to further develop and maintain a static V-22 fuselage, housed in San Diego, as a research training platform for medical care providers to develop the requisite skills to perform En Route care medical procedures within the V-22 fuselage. This static training platform will simulate the noise and temperature characteristics of an operational V-22 along with the physical work space challenges of performing En Route Care medical procedures within the confines of an actual V-22 fuselage.

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

En Route Care, Osprey, V-22 aircraft, patient transport, medical transport; environmental constraints

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?

Statement of Work Tasks

Major Task 1: Operational / Logistics Support for the V-2 Fuselage

Subtask 1.1: Operational Costs to run simulated flight operations scenarios: labor, utilities, and supplies.

Year 4, 1st Quarter Report: No new items to report. Subtask complete

Year 4, 2nd Quarter Report: No new items to report. Subtask complete

Year 4, 3rd Quarter Report: No new items to report. Subtask complete

Year 4, 4th Quarter Report: No new items to report. Subtask complete

Subtask 1.2: Upgrades to research monitoring and simulation capability (i.e., noise, lighting, and temperature) and new capabilities as needed.

Year 4, 1st Quarter Report: No new items to report. Subtask complete

Year 4, 2nd Quarter Report: No new items to report. Subtask complete

Year 4, 3rd Quarter Report: No new items to report. Subtask complete

Year 4, 4th Quarter Report: No new items to report. Subtask complete

Subtask 1.3: Maintenance and structural support for exterior and interior upkeep of the fuselage.

Year 4, 1st Quarter Report: No new items to report. Subtask complete

Year 4, 2nd Quarter Report: No new items to report. Subtask complete

Year 4, 3rd Quarter Report: No new items to report. Subtask complete

Year 4, 4th Quarter Report: No new items to report. Subtask complete

Statement of Work Tasks - Continued

Major Task 2: Conduct Evaluations of Short, Mid, and Long Duration ERC Mission Evolutions

Subtask 2.1: Submission and approval of initial IRB protocol to NHRC, NMCSD, and USAMRRC HRPO.

Year 4, 1st Quarter Report: Activity ongoing.

Year 4, 2nd Quarter Report: No new items to report.

Year 4, 3rd Quarter Report: No new items to report.

Year 4, 4th Quarter Report: No new items to report.

Subtask 2.2: Evaluate human factor challenges for performing medical procedures during short duration ERC missions (20 min).

Year 4, 1st – 4th Quarter Report: Activity ongoing

Subtask 2.3: Evaluate human factor challenges for performing medical procedures during mid duration ERC missions (60 min – 90 min).

Changed duration of subtask 2.3 due to discussions with ERC Instructors at JERCC, Fort Rucker and 1st Med Bn, Camp Pendleton.

Year 4, 1st Quarter Report: Activity ongoing.

Year 4, 2nd Quarter Report: Activity ongoing.

Year 4, 3rd Quarter Report: Activity ongoing.

Year 4, 4th Quarter Report: Activity ongoing. No new items to report

Subtask 2.4: Evaluate human factor challenges for performing medical procedures during long duration ERC missions (120+ min).

Year 4, 1st Quarter Report: Activity ongoing. No new items to report

Year 4, 2nd Quarter Report: Activity ongoing.

Year 4, 3rd Quarter Report: Activity ongoing.

Year 4, 4th Quarter Report: Eliminated subtask 2.4 due to discussions with ERC Instructors at JERCC, Fort Rucker and 1st Med Bn, Camp Pendleton.

Major Task 3: Develop SOP Standards for V-22 Osprey ERC Missions

Subtask 3.1: Continued support for the maintenance and upgrades to the simulator capability of the V-22 as an En Route Care training tool.

Year 4, 1st Quarter Report: Activity ongoing.

Year 4, 2nd Quarter Report: Activity ongoing.

Year 4, 3rd Quarter Report: Activity ongoing

Year 4, 4th Quarter Report: Activity ongoing, no new items to report

Statement of Work Tasks - Continued

Major Task 3: Develop SOP Standards for V-22 Osprey ERC Missions continued:

Subtask 3.2: Conduct evaluation of more complex ERC missions as new gap areas are identified per Fleet and JPC-6 guidance.

Year 4, 1st Quarter Report: Activity ongoing.

Year 4, 2nd Quarter Report: Activity ongoing.

Year 4, 3rd Quarter Report: Activity ongoing

Year 4, 4th Quarter Report: Activity ongoing, no new items to report

Subtask 3.3: Complete summary report and project out brief to JPC-6.

Year 4, 1st Quarter Report: Activity upcoming

Year 4, 2nd Quarter Report: No new items to report.

Year 4, 3rd Quarter Report: No new items to report.

Year 4, 3rd Quarter Report: No new items to report.

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.

Noteworthy Period of Performance Activities:

Year 4, 1st Quarter: As noted above the PI was unavailable for the bulk of Qtr 2. Research staff and collaborators from Camp Pendleton have committed to focus on achieving significant accomplishments in Qtr 2.

Year 4, 2nd Quarter Report: NHRC established that only mission essential personnel reported to work onsite due to Covid-19. As a result, accomplishments were significantly impacted this quarter.

Year 4, 3rd Quarter Report: NHRC has started approving project data collection on a case-by-case basis. LT Alvarez and PI went to Camp Pendleton to meet with the En Route Care Division Officer, 1st Medical Battalion, 1st Marine Logistics Group.

Year 4, 4th Quarter Report: With the impending retirement of the current PI, LCDR Lee Sciarini, MSC, USN will become the new PI of this project. LCDR Sciarini has added staff at Field Medical Training Battalion – West to the list of military collaborators participating in this project.

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.

CY20:

This study is not intended to provide training, however, in the future the V-22 Osprey simulator developed for this study will serve as training platform for personnel to practice En Route Care training and Prolonged Field Care techniques in this realistic simulated environment.

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.

2020 Annual report: Nothing to report.

Results of this study (as briefed in the IPR) will help to determine concepts of operations for treating various conditions during ERC and will be disseminated to communities of interest via meetings, publications, and posters as necessary.

Project briefings have been provided to the following: 1st Medical Battalion, 1st MLG, and Field Medical Training Battalion -West, Camp Pendleton.

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.

Year 4, 1st Quarter: (taken from and as reported in this 4th year quarterly reports)

The proposed Year 3 Qtr 4 activities were delayed (described in section 4 below) and will be accomplished in Year 4 Qtr 1. Preparations are underway to initiate data collection. SimMan® 3G is a durable patient simulator created for high-quality simulation training in a multitude of different medical procedures and patient cases. The SimMan is designed to look and respond like a human patient. He (parts can be exchanged to be a female patient) is capable of auscultation, airway skills, and cardiac skills such as head tilt/chin lift and electrocardiogram (ECG) as well as complications related to those functions such as uni- and bi-lateral chest movements, trismus, and defibrillation. He can bleed, blink, lacrimate, sweat, and make auditory noises (moans, speaking). SimMan also responds to treatment, which includes but is not limited to, CPR, medication administration, tourniquet, intubation, and chest tubes. All subjects will be introduced to the SimMan 3G prior to their first trial and given adequate instruction about the capabilities and limitations of the SimMan and allowed to interact with him. The purpose of this introduction is to improve subject’s confidence with working with the SimMan, reduce the learning curve during trials, and help avert damage and/or unnecessary wear and tear on the simulator. Subjects will then be presented with the SimMan “the patient” either on a gurney or a litter and be given the MIST (mechanism of injury, injury sustained, signs/symptoms, treatment given) report on the patient. Variables that will be used to assess effective and efficient treatment response will include: heart rate, respiration rate, blood pressure, oxygen saturation, end tidal CO₂, core and skin temperature. After reviewing the MIST report the trial will begin with initial ERC evaluations focusing on 3 treatment procedures: pneumothorax, airway failure, and hemorrhage.

Year 4, 2nd Quarter Report:

Tasks for Year 4, 3rd Qtr (16 May 2020 – 15 August 2020) (taken from and as reported in this 4th year quarterly reports)

Acquisitions this Qtr will include aircraft headgear with communication capability, CASEVAC AMAL 347. Additionally, a MOVES® SLC™ which combines an O₂ concentrator, a unique O₂-conserving ventilator, suction, and complete vital signs monitoring into a single, compact, portable, battery-operated system will be acquired.

Year 4, 3rd Quarter Report:

Tasks for Year 4, 4th Qtr (16 Aug 2020 – 15 Nov 2020) (taken from and as reported in this 4th year quarterly reports)

A collaborative data collection with the En Route Care staff from 1st Med Battalion is planned for OCT. This group teaches an En Route Care orientation course each quarter. This collaboration will enhance the learning aspect for the students by scheduling the hands-on portion of the class to be held down in San Diego using the Navy's research Osprey. NHRC benefits by having the course students (all corpsman) available as study participants for this project. Additionally, NHRC has access to 1st Med Battalion's CASEVAC supplies.

Year 4, 4th Quarter Report: Year 5, Quarter 1: 15 November 2020 – 15 February 2021. We plan to continue with our SOW as described above. Staff from Field Medical Training Battalion – West will participate in the upcoming data collections.

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?

Nothing to Report at this time.

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.

The results from this study can be used to inform current and future clinical practice guidelines on the safety and efficacy of medical procedures performed within the V-22 Osprey environment. Along with a direct benefit to operational forces of all services, the knowledge and equipment procured as part of the study will support multiple clinical care oriented research projects and training programs offered by commands such as: the Naval Medical Center San Diego (NMCS), the Army Aviation Training Center (AATC) and the US Army School of Aviation Medicine (USASAM) Joint En Route Care Course, the Navy Flight Medic Course (FMC) located at the Naval Aviation Training Center (NATC) and Naval Aerospace Medical Institute (NAMI), and the USAFSAM Critical Care Air Transport Team (CCATT) and the Tactical Critical Care Evacuation Team (TCET) training program. The ultimate goal of this project is to utilize a V-22 Osprey fuselage as a research tool to prepare military personnel in providing effective and efficient En Route Care within that meets and exceeds the ever-increasing standards of medical care in ERC theater operations.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.” Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.” Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.” Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*

- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. CHANGES/PROBLEMS: The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Since March 2020, COVID-19 restrictions have had a significant impact on this project. For most of this timeframe, all human use research was put on hold. During this quarter, commencing data collections for research projects, with appropriate covid safety precautions, were reviewed on a case-by-case basis. The recent surge and new state restrictions in California have resulted in a pause to that approach.

The initial PI is retiring, LCDR Lee Sciarini, who is an Aerospace Experimental Psychologist, will become the new PI. LCDR Lee Sciarini, was previously the Director of Training Technology at the Naval Aviation Training Institute, Pensacola, FL.

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.

Change from Year 3 Annual Report:

Eliminated subtask 2.4 (120 min duration evolution) due to discussions with ERC Instructors at JERCC, Fort Rucker and 1st Med Bn, Camp Pendleton. It was determined that extending the duration of subtask 2.3 from 60 min to 60-90 min would provide adequate ERC information.

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.

Actual problems: (taken from and as reported in this 4th year quarterly reports)

Year 4, 1st Quarter:

The Principal Investigator was on medical leave during the majority of Qtr 1, Additionally, with the bulk of this Qtr falling over the holiday season, military participants were on various holiday leave schedules and unavailable.

Year 4, 2nd Quarter Report: LCDR Stewart has transferred from 1MEF. LT Dana Flieger, NC, USN is the En Route Care Division Officer, 1st Medical Battalion, 1st MLG, Camp Pendleton will be added to the protocol.

Year 4, 3rd Quarter Report: Meetings with staff from the En Route Care Division, 1st Medical Battalion, 1st MLG, Camp Pendleton have resulted in fostering a joint data collection for October.

Year 4, 4th Quarter Report: Meetings with staff from the Field Medical Training Battalion – West, Camp Pendleton have been added as additional collaborators on this project.

Anticipated Problems: (taken from and as reported in this 4th year quarterly reports)

Year 4, 1st Quarter: As noted above the PI was unavailable for the bulk of Qtr 2. Research staff and collaborators from Camp Pendleton have committed to focus on achieving significant accomplishments in Qtr 2.

Year 4, 2nd Quarter Report: Current Covid-19 workplace restrictions prevented achieving any significant progress this quarter. It is anticipated a return to work policy will occur within this Qtr allowing data collection to commence.

Year 4, 3rd Quarter Report: MEDLOG was unable to provide NHRC a CASEVAC AMAL 347 necessary to conduct this project. However, the collaboration with LT Flieger and the En Route Care staff at Camp Pendleton will provide access to their CASEVAC supplies.

Year 4, 4th Quarter Report: The continued impact of COVID-19 on human use research data collections is presently unknown.

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.

None 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

No changes since last annual report.

Significant changes in use or care of vertebrate animals

Not Applicable.

Significant changes in use of biohazards and/or select agents

Not Applicable.

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).*

None to report at this time.

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).*

None to report at this time.

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.*

None to report at this time.

- **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.

Not Applicable.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Year 4, 1st Quarter Report: No new staff additions to this project.

Jay Heaney, PI: Mr. Heaney is finalizing the transformation of the Osprey into the appropriate training environment. He is in discussions with the VMM-166 Flight Surgeon and 1 MEF Surgeon to arrange a collaboration with the V-22 medical staff and NHRC researchers to support this effort. The IRB is in draft form and will be submitted in QTR3 to support a summer data collection.

LT Carlos Alvarez, who is an Aerospace Physiologist, has been added to this project as a Co-Investigator, and will assume a supportive role.

Douglas Jones, Co-Investigator: Dr. Jones has assisted in the setup of the environmental capabilities of the Osprey.

Rebecca Weller, Research Assistant: Ms. Weller is working to acquire the necessary supplies and equipment to conduct this data collection.

LCDR Erik Hardy, LCDR, NC, USN, OIC Joint Enroute Care Course, NAMI-Fort Rucker Detachment has been added to this project as an Associate Investigator.

Year 4, 3rd Quarter Report: New staff additions to this project:

Rebecca McClintock, Research Assistant: Ms McClintock will assist with the data collection.

Year 4, 4th Quarter Report: LCDR Lee Sciarini, an Aerospace Experimental Psychologist, will become the new PI for this project. LCDR Lee Sciarini, was previously the Director of Training Technology at the Naval Aviation Training Institute, Pensacola, FL.

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

The current PI is retiring, LCDR Lee Sciarini, an Aerospace Experimental Psychologist, will become the new PI for this project. LCDR Lee Sciarini, was previously the Director of Training Technology at the Naval Aviation Training Institute, Pensacola, FL.

What other organizations were involved as partners?

- Fleet Surgeon and staff from COMNAVSURFOR and COMNAVAIRFOR.
Fleet Surgeon and staff from I Marine Expeditionary Force and 1st Medical Battalion, 1st MLG
Camp Pendleton
- Fleet Surgeon and staff from 3d MAW, MCAS Miramar
Flight Surgeon and staff from VMM-166, MAG-16, 3d MAW, MCAS Miramar
- Staff from NATC, Pensacola, FL
- Staff from AATC, Fort Rucker, AL
- Staff from Field Medical Training Battalion – West, Camp Pendleton

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS: Quad chart Project # 2.

Project 2: Evaluation of Human Factors Issues Relating to Providing En Route Care Within the V-22 Osprey Aircraft

PI: Jay H. Heaney, MA

Org: Naval Health Research Center

Award Amount: \$1.25M



Study/Product Aim(s)

- Naval Medical Center San Diego (NMCSD) has obtained a non-operational V-22 Osprey fuselage which will be housed in San Diego and configured to become a research tool for medical providers to learn/practice techniques for providing ERC medical care.
- This project will explore the working space challenges confronting medical providers as the V-22 becomes a significant medical ERC transportation aircraft as future military operational strategy becomes focused on a "Pivot to the Pacific".

Approach

- Outfit the static training V-22 fuselage with the necessary structural hardware to approximate the configuration of a V-22 equipped to perform medevac missions.
- Simulate the environmental conditions of a V-22 in-flight: noise, lighting, and temperature.
- Evaluate the human factor challenges confronting medical providers performing within the workspace of a V-22.



Accomplishment: Defense Health Board received concept briefing on this project per their request. 3G manikin obtained and pilot testing in the Osprey has begun.

Timeline and Cost

Activities	CY	17	18	19	20	21
Task 1: Operational / Logistics Support for the V-22 Fuselage						
Task 2: Conduct Evaluations of Short, Mid, and Long Duration ERC Mission Evolutions						
Task 3: Develop SOP Standards for V-22 Osprey ERC Missions						
Estimated 5 Yr Budget (\$1.26M)		250K	250K	250K	250K	250K
Expenditures (to date)		250K	250K	250K	250K	5K

Goals/Milestones

Task 1 Goals

- ✓ Operational Costs to run simulated flight operations scenarios: labor, utilities, and supplies and maintenance and structural support for exterior and interior upkeep of the fuselage.
- ✓ Upgrades to research monitoring and simulation capability (i.e., noise, lighting, and temperature) and new capabilities as needed.

Task 2 Goals

- ✓ Obtain 3G manikin and begin pilot testing short ERC scenarios (20-30 min) in the Osprey.
- ✓ IRB protocol being revised and with submission to NMCSD, and then USAMRRRC HIRPO review to follow.

Task 3 Goals

- Replace project #2 PI due to retirement of the initial PI.
- Complete summary report and project out brief to JPC-6.

Updated: December 2020

9. APPENDICES: None.

PROJECT # 3: “SEARCH AND RESCUE RECORDS MODERNIZATION AND EVALUATION”

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

There are 2 separate, but overlapping, efforts of the Search and Rescue (SAR) Records Modernization and Evaluation project. The major objectives for each effort are described below.

Records Modernization Objectives:

1. Establish the procedures to support the data collection, storage, maintenance, and analytics processes for a comprehensive SAR electronic database.
2. Using existing infrastructure, design, test, and implement an electronic CAC-enabled, web-based data collection system that is integrated fully with the SAR database to permit regular, recurring updates as new SAR records are received.
3. Transform approximately 45 years of historical records into a comprehensive SAR electronic database.

Records Evaluation Objectives:

4. Incorporate any additional SAR-specific records (e.g., SAR event SITREPs, Medical Rescue Reports) that are not part of SARMM's repository into the SAR database.
5. Investigate SAR and ERC research questions about longitudinal patient, provider, and SAR crew outcomes with a project-specific dataset created by merging records from the SAR database with other existing military medical and career records.

The historical records (objective #3) will be transformed in reverse chronological order, from the most recent to the oldest records. Work on the Records Evaluation objectives will begin once SAR records from 2001 to 2015 have been entered, cleaned, and verified in the SAR database. Work on both efforts will continue concurrently until all tasks are completed.

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

Search and Rescue, electronic health care records, point of injury documentation, records transformation, electronic data collection, optical character recognition, optical mark recognition, data processing

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.

Statement of Work Tasks

Task 1

Subtask 1.1: Submit IRB protocol and data-sharing agreements for review and approval

Target: months 1-5

Actual: IRB protocol #NHRC.2016.0029 approved on 4 OCT 2016 (covers Tasks 1 and 2 only; when appropriate, will submit protocol modification request to cover Task 3 as requested by NHRC's IRB)

HRPO Log Number: A-19851.1 – notified 19 DEC 2016 that no HRPO review required
IRB continuing review package for #NHRC.2016.0029 approved on 23 SEP 2017

Subtask 1.2: Execute contract funds, obligate in-house money, and finalize research team

Target: months 1-2

Actual: completed DEC 2016 No further reports for this item.

Task 2

Subtask 2.1: Design SAR database shell and establish procedures for secure data collection, storage, maintenance, and analytic processes with the database

Target: months 2-18

Actual: Began month 1 **Year 4, 4th Quarter:** work is on-going.

Subtask 2.2: Revise SAR event and patient information forms

Target: months 2-6

Actual: Revised forms distributed to SARMM in MAY 2017. **Year 2, 2nd Quarter:** Complete

Subtask 2.3: Design, test, and implement new SAR data collection system

Target: months 2-18

Actual: Began month 2;

Year 4, 4th Quarter: System designed and tested by Year 1, 4th Quarter. Since then, implementation paused, pending required IT approvals and hardware. Work to implement an electronic SAR data collection system effectively terminated, given the obstacles to securing required IT approvals and hardware.

Subtask 2.4: Determine standard operating procedures for transforming all historical records by report version and condition of physical record

Target: months 5-12

Actual: SOPs finalized and written documentation completed by 31 OCT 2017.

Subtask 2.5: Transform approx. 45 years of historical SAR records into the SAR database

Target: months 6-36

Actual: Began month 6; **Year 4, 4th Quarter:** work on-going. **Please see the running total of records processed by quarter in “Accomplishments Under These Goals” section below.**

Task 3

Subtask 3.1: Identify and incorporate additional SAR-specific records not held by SARMM into the SAR database

Target: months 15-36

Actual: **Year 4, 3rd Quarter:** Work pending.

Actual; Year 4, 4th Quarter: Work pending, contingent upon completion of Task 2.

Subtask 3.2: Generate project-specific dataset by merging records from sources including the SAR database, DMDC/DEERS, MDR, and EMED

Target: months 15-36

Actual: **Year 4, 3rd Quarter:** Work pending.

Actual; Year 4, 4th Quarter: Work pending, contingent upon completion of Task 2.

Subtask 3.3: Conduct longitudinal analyses of military medical and career outcomes of SAR patients, providers, and crew

Target: months 25-48

Actual: **Year 4, 3rd Quarter:** Work pending.

Actual: **Year 4, 4th Quarter:** Work pending, contingent upon completion of Task 2.

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.

Year 4 Qtr 1 (15 NOV 2019 – 14 FEB 2020) Accomplishments

- On-boarded 2 new contractors (part-time, temporary Research Assistants)
- Processed 1,548 Rescue Reports and 349 Medical Reports
- Abstract accepted for poster presentation at the 2020 Navy and Marine Corps Public Health Command Conference (later notified that the conference was cancelled)
- Abstracts submitted to the Naval Medical Center San Diego's Academic Research Conference 2020 announcement include:
 - U.S. Navy Search and Rescue Patient Transport Missions for Mental and Behavioral Health Conditions, 2009 - 2018
 - Combat Theater Medical Evacuations for Violence Ideations or Behaviors
 - U.S. Naval Aeromedical Evacuation of Patients with Confirmed or Suspected Communicable Diseases, 2009-2018
 - Navy Search and Rescue Operations for Pediatric Transports, 2009 - 2018
- Prepared CY2017 to CY2019 metrics tracker for SARMM
- IRB protocol (#NHRC.2016.0029) modification request to add new contract personnel approved 9 DEC 2019.
- IRB protocol (#NHRC.2016.0029) modification request to add new contract personnel approved 13 JAN 2020.

Year 4 Qtr 1: Number of reports processed this quarter and to date for the project

Running Project Totals of Historic Records Processed (Raw Electronic Data in SQL Database)

	Rescue Reports	Medical Reports
# Current Quarter	1,548	349
# Total To Date	13,349	4,251

Estimated number of reports still to be processed: approximately 11,700

Year 4 Qtr 2:

Please note: Due to COVID-19, all NHRC personnel were under mandatory telework orders by 20 MARCH 2020. At that time, the existing IRB protocol and Deployment Health Research Department contract with Leidos did not permit off-site work with PHI/PII documents. While awaiting approvals for requested protocol and contract modifications to allow off-site work with PHI/PII documents, work shifted to generating end-user and database manager documents.

Year 4 Qtr 2 (15 FEB 2020 – MAY 15 2020) Accomplishments:

- On-boarded 3 new contractors (part-time, temporary Research Assistants)
- Processed 458 Rescue Reports and 103 Medical Reports

Year 4 Qtr 2 (15 FEB 2020 – MAY 15 2020) Accomplishments (continued):

- Prepared a summary report of SAR missions between 2010 and 2019 for pilot ejections during aviation mishaps for SARMM
- Full research team completed new mandatory NHRC telework training
- Initiated department contract modification request to support off-site work with PHI/PII documents
- Prepared and submitted IRB protocol modification to support off-site work with PHI/PII documents
- Presented the following invited posters:
 - Hollingsworth, J and McWhorter, S. *U.S. Navy Search and Rescue Patient Transport Missions for Mental and Behavioral Health Conditions, 2009 – 2018*. 2020 Naval Medical Center San Diego Academic Research Conference (NMCSA ARC): San Diego, CA.
 - Powell, B, Wang, J and McWhorter, S. *Combat Theater Medical Evacuations for Violent Ideations or Behaviors*. 2020 NMCSA ARC: San Diego, CA.
 - Eyre, M, Reidt, C and McWhorter, S. *U.S. Naval Aeromedical Evacuation of Patients with Confirmed or Suspected Communicable Diseases, 2009-2018*. 2020 NMCSA ARC: San Diego, CA.
 - Nandi, R, Price, P and McWhorter, S. *Navy Search and Rescue Operations for Pediatric Transports, 2009 – 2018*. 2020 NMCSA ARC: San Diego, CA

Year 4 Qtr 2: Number of reports processed this quarter and to date for the project

Running Project Totals of Historic Records Processed (Raw Electronic Data in SQL Database)

	Rescue Reports	Medical Reports
# Current Quarter	458	103
# Total To Date	13,807	4,354

Estimated number of reports still to be processed: approximately 11,100

Year 4 Qtr 3 (16 MAY 2020 – 15 AUG 2020) Accomplishments:

- DHA data-sharing agreement (#19-2293) to extract MDR data to build a longitudinal project data set was approved on 21 MAY 2020
- IRB protocol modification request submitted via the eIRB system to update project personnel, support off-site work with PII/PHI paper documents, support off-site electronic data work via MobiKey access to NHRC's secure network was approved on 16 JUL 2020
- With command approval for specific contractors to resume on-site work in JUN 2020, restarted preparation and processing of historic records
- Completed all pre-processing work with the historic records to generate the working version of the Master CY Reports Tracker
- Processed 577 Rescue Reports and 219 Medical Reports
- Obligated all project funding received for FY21

Year 4 Qtr 3: Number of reports processed this quarter and to date for the project

Running Project Totals of Historic Records Processed (Raw Electronic Data in SQL Database)

	Rescue Reports	Medical Reports
# Current Quarter	577	219
# Total To Date	14,384	4,573

Estimated number of reports still to be processed: approximately 10,500

Year 4 Qtr 4 (16 AUG 2020 – 15 NOV 2020) Accomplishments:

- Front-loaded required on-site non-processing tasks so that processing work with the SAR documents can continue if another off-site telework order is issued. Approximately 3,000 individual SAR reports scanned to PDF, prepared for project's electronic Image Repository library, and awaiting processing into SQL tables via project's electronic OpenText LiquidOffice data collection system.
- Developed, tested, and implemented 3 new report templates and customized SQL tables.
- Revised and executed improved project procedures for processing the remaining reports into SQL tables. In particular, developed new rules to identify and then properly divide multi-mission reports into single mission reports, confirm reports arranged in proper chronological order and assigned corresponding serial report numbers, and prepared for processing into the appropriate SQL table.
- Prepared and submitted eIRB protocol modification request on 26 OCT 2020 to extend the project's period of performance through 15 NOV 2021 and add new contractors to the protocol.
- Processed 700 Rescue Reports and 87 Medical Reports. Please note: due to the migration of NHRC's IT network to DHA's network in August 2020, we lost all use of Teleform software for more than 8 weeks during this quarter.
- Extended job offers to fill 2 Research Assistant positions.

Year 4 Qtr 4: Number of reports processed this quarter and to date for the project

Running Project Totals of Historic Records Processed (Raw Electronic Data in SQL Database)

	Rescue Reports	Medical Reports
# Current Quarter	700	87
# Total To Date	15,084	4,660

Estimated number of reports still to be processed: approximately 9,500

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.

Year 4, 1st Quarter – Abstracts submitted to 2020 Navy and Marine Corps Public Health Command Conference (conference cancelled, so invited poster not presented) and Naval Medical Center San Diego’s Academic Research Conference 2020

Year 4, 2nd Quarter – Presented invited posters at Naval Medical Center San Diego’s Academic Research Conference 2020:

- Navy Search and Rescue Operations for Pediatric Transports, 2009 - 2018
- Combat Theater Medical Evacuations for Violent Ideations or Behaviors
- U.S. Navy Search and Rescue Patient Transport Missions for Mental and Behavioral Health Conditions, 2009 – 2018
- U.S. Naval Aeromedical Evacuation of Patients with Confirmed or Suspected Communicable Diseases, 2009-2018

Year 4, 3rd Quarter – Nothing to report

Year 4, 4th Quarter – Nothing to report

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.

Year 4 Quarter 1: Nothing to report

Year 4 Quarter 2: Invited posters presented during the Naval Medical Center San Diego Academic Research Conference 2020.

Eyre, M, Reidt, C and McWhorter, S. *U.S. Naval Aeromedical Evacuation of Patients with Confirmed or Suspected Communicable Diseases, 2009-2018*. 2020 Naval Medical Center San Diego Academic Research Conference (NMCSA ARC): San Diego, CA.

Hollingsworth, J and McWhorter, S. *U.S. Navy Search and Rescue Patient Transport Missions for Mental and Behavioral Health Conditions, 2009 – 2018*. 2020 NMCSA ARC: San Diego, CA.

Nandi, R, Price, P and McWhorter, S. *Navy Search and Rescue Operations for Pediatric Transports, 2009 – 2018*. 2020 NMCSA ARC: San Diego, CA.

Powell, B, Wang, J and McWhorter, S. *Combat Theater Medical Evacuations for Violent Ideations or Behaviors*. 2020 NMCSA ARC: San Diego, CA.

McWhorter, S. *Ejection Events, 2010 – 2019*. Data summary prepared for SARMM on 15 MAY 2020.

Year 4 Quarter 3: Nothing to report

Year 4 Quarter 4: Nothing to report

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

If this is the final report, state “Nothing to Report.”

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

Tasks for Year 4, 1st Qtr (15 November 2019 – 14 February 2020)

- Test an NMCI-configured electronic data collection IT system configuration (still awaiting NMCI and NHRC IT final approvals, and delivery of NMCI computer).
- Prepare poster for the 2020 Navy and Marine Corps Public Health Conference (if invited).
- Prepare and submit 5 poster abstracts to the 2020 Naval Medical Center San Diego Academic Research Conference.
- Finish and submit peer-reviewed journal manuscript for command review and approval.
- Recruit, hire and on-board 5 new contractors (4.0 FTE).
- Prepare and submit IRB modification requests to add new contractors to the project’s IRB protocol.
- Train new contractors to process SAR reports.
- Prepare and distribute updated CY2019 (to date) SARMM quarterly metrics tracking report with new Patient Tracker module.
- Continue to process historic reports with Teleform and Liquid Office software.

Tasks for Year 4, 2nd Qtr (15 February 2020 – 14 May 2020)

- Test an NMCI-configured electronic data collection IT system configuration (contingent upon NMCI and NHRC IT final approvals, and delivery of NMCI computer).
- If invited, prepare and present posters at the 2020 Naval Medical Center San Diego Academic Research Conference
- Prepare a manuscript with project results.
- Recruit, hire and on-board 4 new contractors (3.2 FTE).
- Prepare and submit IRB modification requests to add new contractors to the project's IRB protocol.
- Receive DHA data-sharing agreement approval (contingent upon DHA's review and approval process)
- Train new contractors to process SAR reports.
- Continue to process historic reports with Teleform and Liquid Office software.
-

Tasks for Year 4, 3rd Qtr (15 May 2020 – 15 August 2020)

- Test an NMCI-configured electronic data collection IT system configuration (contingent upon NMCI and NHRC IT final approvals, and delivery of NMCI computer).
- Prepare a manuscript with project results.
- Receive DHA data-sharing agreement approval (contingent upon DHA's review and approval process)
- Train new contractors to process SAR reports (pending IRB and contract modification approvals or assignment of MobiKey devices/licenses to IES contractors or approval to resume on-site work).
- Resume processing historic reports with Teleform and Liquid Office software (pending IRB and contract modification approvals or assignment of MobiKey devices/licenses to IES contractors or approval to resume on-site work).

Tasks for Year 4, 4th Qtr (16 August – 15 November 2020)

- Test an NMCI-configured electronic data collection IT system configuration (contingent upon NMCI and NHRC IT final approvals, and delivery of NMCI computer).
- Concentrate all available labor with on-site only tasks (i.e., Teleform processing, pre-Image Repository preparation for subsequent LiquidOffice processing, etc.) as possible.
- Should IT issues remain unresolved (especially the problems connecting to the Teleform server), continue with all other requirements to process historic reports, create the electronic Image Repository library, and conduct basic Q/A and reconciliation tasks per project procedures.

Please note: should project personnel be ordered to work from home again, records processing operations will not shut down entirely. While processing records in Teleform can only be done by on-site personnel, it will be possible for contractors to process reports through the LiquidOffice software while working off-site because they now have a MobiKey license and device.

Tasks for Year 5, 1st Qtr (15 November 2020 – 14 February 2021)

- Continue to front-load tasks that can only be completed on-site, including Teleform processing and scanning original paper reports to PDF for subsequent processing via LiquidOffice.
- Develop, test, and implement 3 more Teleform templates and customized SQL tables.
- On-board 2 newly hired contractors.
- Prepare a data summary of ejection events between 1990 and 2010 for SARMM.
- Prepare and submit abstracts to 2021 Navy and Marine Corps Public Health Command Conference and Naval Medical Center San Diego's Academic Research Conference 2021.
- Submit pre-proposal to JPC-5 Aviation Mishap Prevention working group. If invited, submit full proposal, accompanied by a letter of support from the Naval Safety Center, to JPC-5 Aviation Mishap Prevention working group for FY22 new start proposal to use an extract from the SAR database to build a longitudinal data set from FY01 to FY20 to investigate the most common injuries documented in air crew personnel's electronic medical records over their careers.

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 on technology transfer?

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

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?

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

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. CHANGES/PROBLEMS: The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

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.

Continuing Problems (i.e., Carried Over from Years 1-3) in Year 4

1. There has not been any progress on securing the required approvals and IT infrastructure for the electronic data collection system. At this time, we do not see a way forward to successfully complete Sub-task 2.3 and implement the system that we developed and fully tested as the start of the project.
2. Processing handwritten, damaged and degraded SAR paper reports via direct data entry with OpenText LiquidOffice software (versus Teleform OCR scanning software) remains a significant additional labor burden.
3. Projects funds originally allocated for FY20 labor will again be diverted to pay for NHRC’s required FY20 seat rate of \$25,872 per 1.0 FTE.
4. Project efforts will continue to concentrate on Sub-task 2.5 given the number of reports (approximately 11,700) that still await processing.
5. A data-sharing agreement application was submitted to the Defense Health Agency on 21 OCT 2019. We are still waiting for DHA to begin its review and approval process as of 15 FEB 2020.

Continuing Problems (i.e., Carried Over from Years 1 - 3 in Year 4

Update Year 4 Quarter 2:

6. All NHRC personnel were under mandatory telework orders by 20 MARCH 2020 because of the COVID-19 pandemic. At that time, the existing IRB protocol and Deployment Health Research Department contract with Leidos did not permit off-site work with PHI/PII documents. We initiated modification requests to permit off-site work with PHI/PII documents with NHRC's IRB committee and contracting representatives. We also requested that IES procure MobiKey devices and licenses for each IES employee. While awaiting approvals for requested protocol and contract modifications to allow off-site work with PHI/PII documents, contractors have been able to work off-site on tasks to generate required end-user and database manager documents. By doing so, existing trained and experienced contractors have been retained and fully employed with productive work as we await required approvals for future off-site work with PHI/PII documents.

Update Year 4, Quarter 3:

There were a number of positive developments this quarter, including:

- Project personnel were allowed to resume on-site work in JUN 2020
- JPC-6 approved funding to support an additional year, so the new POP ends in NOV 2021.
- DHA approved the project's DSA on MAY 2020 (although all work on Task 3 is paused, pending completion of Task 2)
- Contractors were issued MobiKey licenses and devices in AUG 2020

Items 1 to 4 (above) remain on-going issues. NHRC's FY21 is projected to increase over the FY20 rate. During AUG 2020, we experienced significant IT problems during the migration of NHRC's network to the MHS/DHA network. The Teleform server was down for nearly the entire month and still has not yet come back online (as of 4 SEP 2020) so we lost 5 weeks of processing reports in Teleform.

Update Year 4, Quarter 4:

- Items 1 to 4 (above) remain on-going issues.
- NHRC's FY21 seat rate increased from \$25,872 to \$26,796 per 1.0 FTE.
- All work on Task 3 continues to be on hold, pending successful competition of Task 2.
- Although IT problems regularly challenge our day-to-day operations, we generally are able to resolve the problems in a relatively timely manner. This quarter, however, once the migration of NHRC's network started in August 2020, we lost all access to the Teleform software system for more than 8 weeks.

Actual or anticipated problems or delays and actions or plans to resolve them (continued):
Anticipated problems:

This project's period of performance (POP) is scheduled to end on 14 NOV 2020. Unfortunately, we do not anticipate that it will be possible to successfully complete any of the sub-tasks that comprise Task 2 and Task 3. A lack of progress with securing the required approvals and IT infrastructure to execute an electronic data collection system (see Sub-task 2.3) will likely prevent us from ever deploying the system that we developed and fully tested at the start of the project.

We forwarded a data-sharing agreement (DSA) application to DHA on 21 OCT 2019. As of 15 FEB 2020, we are still waiting for DHA to begin its review and approval process. We cannot begin to build the project-specific data set that would be required to complete Task 3 until we have an approved DSA with DHA. Once we have an approved DSA, it may be possible to begin work on Task 3 so long as we have made sufficient progress with the remaining Task 2 sub-tasks (i.e., work to process the historic reports into SQL tables). Since we have less than 9 months until the project's end date, and approximately 11,700 reports still need to be processed into SQL tables, we do not anticipate that it will be possible to complete Task 3.

When this project was proposed, it was estimated that there were approximately 15,000 SAR records to be transformed into an electronic database. Once the project began and we received SARMM's comprehensive repository of all paper and electronic reports, our inventory of SARMM's repository identified an actual workload of an estimated 29,500 reports. As of 1 MAR 2020, we have processed more than 17,800 reports into SQL tables, which is an amount equal to our original estimate plus an extra 20%. We are making progress, but there are 11,700 reports waiting to be processed. Despite our best efforts, it is clear we cannot finish twice the amount of work by the current deadline.

Funding for an additional year to extend the project's POP until 14 NOV 2021 would give us the time and the resources necessary to successfully complete Task 2 (excluding Sub-task 2.3, given the issues with securing the required approvals and IT infrastructure to execute an electronic data collection system). If an approved DHA data-sharing agreement is executed within the next 3 months, it should also be possible to successfully complete Task 3. The budget estimate for the necessary labor (GS and contract), required NHRC seat rates, and mandatory department shared administrative costs is \$266,000 for a 12-month POP.

Since there is no guarantee that we will secure funding for an additional year, we are adhering to a project plan that is designed to maximize results with respect to Task 2, at the expense of Task 3. We plan to have project deliverables (i.e., raw SQL tables, codebooks and documentation for end users, etc.) ready for SARMM and other transition partners by the project's end date in NOV 2020. If, however, we are notified of a decision to fund the project for an additional year, we will immediately transition to a revised project plan to fully complete Tasks 2 and 3 by the end of the new POP in NOV 2021. There are important staffing and specific tasking differences between the current and the revised project plans, so a timely notification about the requested funding will help us to most efficiently use project resources, regardless of the funding decision.

Update Year 4 Quarter 2:

We submitted a request for an additional year of funding to JPC-6. We are scheduled to speak with JPC-6 representatives on 15 MAY 2020 about the request.

Update Year 4 Quarter 3:

We thank JPC-6 for its decision to authorize an additional year of funding for the project. Despite the IT issues in AUG 2020 resulting from the network migration, we are on track to complete the processing work of all historic reports and prepare accompanying documentation (for end user and database management purposes) before the end of the new POP.

While we now have the necessary data-sharing agreement approvals to extract data to build the Task 3 longitudinal data set, we must make more progress with processing the historic records into electronic tables before we can consider diverting project labor to work on Task 3.

Update Year 4 Quarter 4:

Despite the IT problems that extended into October 2020, we are still on track to complete the processing work of all historic reports and prepare accompanying documentation (for end user and database management purposes) before the end of the new POP. Unfortunately, we are not yet at a point where we can consider diverting project labor to work on Task 3.

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 other than what is indicated above.

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

Nothing to report – Not applicable to this study

Significant changes in use or care of vertebrate animals

Nothing to report – Not applicable to this study

Significant changes in use of biohazards and/or select agents

Nothing to report – Not applicable to this study

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).*

None 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).*

None 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.*

Year 4 Quarter 1: Nothing to report

Year 4 Quarter 2: Invited posters presented during the Naval Medical Center San Diego Academic Research Conference 2020.

Eyre, M, Reidt, C and McWhorter, S. *U.S. Naval Aeromedical Evacuation of Patients with Confirmed or Suspected Communicable Diseases, 2009-2018*. 2020 Naval Medical Center San Diego Academic Research Conference (NMCSA ARC): San Diego, CA.

Hollingsworth, J and McWhorter, S. *U.S. Navy Search and Rescue Patient Transport Missions for Mental and Behavioral Health Conditions, 2009 – 2018*. 2020 NMCSA ARC: San Diego, CA.

Nandi, R, Price, P and McWhorter, S. *Navy Search and Rescue Operations for Pediatric Transports, 2009 – 2018*. 2020 NMCSA ARC: San Diego, CA.

Powell, B, Wang, J and McWhorter, S. *Combat Theater Medical Evacuations for Violent Ideations or Behaviors*. 2020 NMCSA ARC: San Diego, CA.

Year 4 Quarter 3: Nothing to report

Year 4 Quarter 4: 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.

Not Applicable

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

None 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.

Not Applicable

- **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.*

None to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Current Project Personnel (Current for year 4 Qtr 4)

Ms. McWhorter prepared the IRB protocol submission package, requested a Theater Medical Data Store account, and obligated/executed all project funds. She generated SQL data shells for all versions of the SAR Rescue Report and Medical Report forms, began writing technical specification documentation for the SQL data shells and data processing protocols, and began developing SAS syntax for processing raw data. She also opened discussions with IT specialists and researchers at other military commands to identify an appropriate existing cloud computing research environment to test the planned data collection system. She is developing the pre-processing protocol to clean/check raw data for final processing and preparing written documentation for end users. She directs the development and execution of new TeleForm report templates. She is responsible for developing, testing, publishing, and distributing the SARMM quarterly metrics report template and regular quarterly metrics reports. She directed the project’s presentation of results at the Military HealthSystem Research Symposium (MHSRS) in 2017, 2018, and 2019 and the Naval Medical Center San Diego Academic Research Conference (NMCSA ARC) 2020.

Rima Nandi, Research Assistant, has assisted in organization of historical paper records and form design of the SAR Rescue Report through OpenText LiquidOffice. She has also assisted with template development/design through OpenText TeleForm Designer. Ms. Nandi has also supported efforts in scanning both electronic and paper SAR Rescue and Medical Reports through TeleForm Scan Station for subsequent batch processing through TeleForm Verifier. She presented an invited poster at the 2018 MHSRS and 2020 NMCSA ARC. Ms. Nandi has been responsible for training all new contractors to process records using OpenText Teleform.

Betsy Powell, Research Assistant, joined the research team in a part-time, temporary position to process, organize, and maintain historic SAR Records. She is assisting with template development/design through OpenText Teleform Designer. She presented an invited poster at the 2020 NMCSA ARC.

Julia Hollingsworth, Research Assistant, joined the research team in a part-time, temporary position to process, organize, and maintain historic SAR records. She is assisting with template development/design through OpenText Teleform Designer. She presented an invited poster at the 2020 NMCSA ARC.

Justine Wang, Research Assistant, joined the research team in a part-time, temporary position to process, organize, and maintain historic SAR records. She is assisting with template development/design through OpenText Teleform Designer.

Christopher Reidt, SAR SME/Research Assistant, joined the research team in a part-time, temporary position to process, organize, and maintain historic SAR records. He is assisting with template development/design through OpenText Teleform Designer and is the project's liaison officer with SAR commands to facilitate the collection of new reports.

Oliver Urbanowicz, Research Assistant, joined the research team in a part-time, temporary position to process, organize, and maintain historic SAR records. He is assisting with template development/design through OpenText Teleform Designer.

Maelyn Tanmajo, Research Assistant, joined the research team in a part-time, temporary position to process, organize, and maintain historic SAR records. She is assisting with template development/design through OpenText Teleform Designer.

Personnel Changes in Year 4 Qtr 2

Oliver Urbanowicz, Maelyn Tanmajo, and Victoria Jones joined the project, but will not begin to actively bill hours until work with PHI/PII documents resumes (pending IRB and contract modification approvals or assignment of MobiKey devices/licenses to IES contractors or approval to resume on-site work).

Personnel Changes in Year 4 Qtr 3

The following personnel left the research team:

Joshua Price, Fleet Marine Force SME/Research Assistant, joined the research team in a part-time, temporary position as a Fleet Marine Force SME/Research Assistant. He previously served as a FMF HM in the Navy. Mr. Price will process, organize, and maintain historic SAR records.

Victoria Jones, Research Assistant, joined the research team in a part-time, temporary position to process, organize, and maintain historic SAR records. She is assisting with template development/design through OpenText Teleform Designer.

Personnel Changes in Year 4 Qtr 4

The following personnel left the research team: Megan Eyre, Yohannes Haile, and Oliver Urbanowicz.

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.*

Navy Search and Rescue Model Manager, Naval Air Station North Island, Coronado, CA

- Provides Search and Rescue (SAR) Subject Matter Experts to advise and consult on the project.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHART Project # 3:

Project 3: Search and Rescue (SAR) Records Modernization and Evaluation Project

PI: Stephanie McWhorter, MA

Org: Naval Health Research Center

Award Amount: \$ 1.25M



Study/Product Aim(s)

- Transform all historical SAR records into an electronic database
- Demonstrate the value of the SAR database for medical and operational research by conducting longitudinal analyses of military medical and career outcomes of SAR patients, providers and crew members.

Approach

- SQL data base shell for SAR database
- Intelligent document recognition software (OpenText LiquidOffice and Teleform) and data entry to transform records into SAR database
- Appropriate statistical techniques (e.g., general linear mixed model, survival analysis, latent growth curve/structural equation model) for longitudinal analyses



Accomplishment: Approximately 20,000 of 30,000 historic reports processed.

Timeline and Cost

Activities	CY	17	18	19	20	21
Project approvals, hiring, contracts		■				
Design, test, implement data system and processes		■	■			
Process ~30,000 SAR records into SQL tables by report template			■	■	■	■
Prepare and merge SQL tables to generate SAR database				■	■	■
Prepare end user and database manager documentation						■
Estimated 5 Yr Budget (\$1.25M)		\$250K	\$250K	\$250K	\$250K	\$250K
Expenditures (To Date Each Yr)		\$250K	\$250K	\$250K	\$250K	—

Goals/Milestones

Task 1 Goals

- Secure required IRB and data-sharing approvals
- Contract in place

Task 2 Goals

- Revise report templates for new submissions
- Processing procedures for historic reports
- Process original reports into SQL tables
- Q/A SQL tables
- Merge standardized variables to create SAR database
- End user and database management documentation

Task 3 Goals (contingent upon Task 2 completion)

- Create longitudinal data set and conduct analyses

Updated: Dec 11, 2020

9. APPENDICES: None