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SITE PRINCIPAL INVESTIGATOR: Mitchell Dukovich, PhD

RECIPIENT: Naval Medical Center San Diego,
San Diego, CA 92134

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

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### 6. AUTHOR(S)
Mitchell Dukovich, PhD, Scientific Director, Naval Medical Center, San Diego

### 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Medical Center, San Diego
34800 Bob Wilson Drive
San Diego, CA 92134-1005

### 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

### 14. ABSTRACT
This Annual Report summarizes three unique 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 # 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 demonstrate adequate knowledge acquisition on the use of REBOA, and successfully demonstrate REBOA skill placement competence among various forms of simulation, including live tissue models. Project # 2 will explore the working space challenges confronting medical providers as the V-22 Osprey tiltrotor aircraft becomes a significant 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
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) 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

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

Subtask 1.1: Research instruments reviewed and modified; curriculum refined
Target: months 1-5

Year 2, 1st Quarter Report: Various meetings held with members of research team. All didactic materials, test questions, checklists, equipment, supplies, on hand for dry run to be held February 26-27, 2018.

Year 2, 2nd Quarter Report: Dry run held February 26-27 at NMCSD. Based upon the results of the dry run, amendments were needed. IRB amendments to the protocol submitted April 24, awaiting final approval of amendment. IACUC protocol closed, dated 4/23/18. Data collection forms updated, didactic materials reviewed and edited.

Year 2, 3rd Quarter Report: Pre-course and session 1 (n=10) completed phases I and II (July 9-12). All materials, test questions, checklists, and equipment and supplies were on hand and performed as expected.

Year 2, 4th Quarter Report: Ultrasound training lecture modified to include practice on human tissue (Subject’s arm)

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

Year 2, 1st Quarter Report: No changes to the approved protocols for this quarter. We plan to submit amendments to IRB, IACUC, and Cadaver Lab to reflect changes to personnel, as well as any study design amendments after dry run, to be held 26-27 February. Amendments to IRB and IACUC will only be conducted and reviewed locally since they are minor. All changes on Cadaver usage will be submitted to USAMRMC for acknowledgement and approval.

Year 2, 2nd Quarter Report: IRB amendments to the Human Subjects protocol submitted April 24, which included personnel additions and removals, elimination of porcine model-awaiting final approval of amendment. IACUC protocol closed, dated 4/23/18. Deleting: “Updated cadaveric specimen request to reflect the need for a total of 10 specimens, since we are no longer using the porcine model, submitted 3/27/18”.

Year 2, 3rd Quarter Report: no new items to report; Amendment to protocol approved 31 May 2018 and annual review approved 30 May, 2018. Document previously forwarded.

Year 2, 4th Quarter Report: no new items to report.

IACUC STATUS UPDATE:

Year 2, 1st Quarter Report
No change – Nothing to report.

Year 2, 2nd Quarter Report: IACUC protocol closed April 23, 2018

Year 2, 3rd Quarter Report: IACUC protocol closed April 23, 2018 Item considered closed.
Statement of Work Tasks continued:

USE OF CADAVERIC SPECIMENS

Year 2, 1st Quarter Report
No change – Nothing to report (changes may be pending depending on what is determined during the dry run conducted 27-28 February, 2018).

Year 2, 2nd Quarter Report: During the dry run, the porcine model was deemed to be inferior to the perfused cadaver model. Therefore the team agreed to eliminate the porcine model for the study. This necessitated an increase to the total number of specimens needed for the study to a total of 11 per session. Updated cadaveric specimen request submitted to NMCSD on 3/27/2018, however, NMCSD Clinical Investigations Department advised that no amendment was necessary, as the proposed change in the study only changes the overall number of cadavers needed, not the set up or use of the cadavers. We are addressing the change in total number of cadavers across the entire Period of Performance with USAAMRRC point of contract listed above (Ms. Natalie Klein, Cadaver Activity Oversight Coordinator, Human Research Protection Office, Office of Research Protections, U.S. Army Medical Research and Materiel Command (Natalie.m.klein,civ@mail.mil).

Year 2, 3rd Quarter Report: No new information.

Year 2, 4th Quarter Report: No new information

Subtask 1.3: Submission of research study to USAMRRC HRO for 2nd level review and approval
Target: months 3-4
No new items with regards to USAMRRC HRO 2nd level review and approval. Item closed and considered complete.

USE OF CADAVERIC SPECIMENS
1. USAMRC requested separate approval of the use of cadaveric specimens for this research study
2. All requested documentation sent to USAMRC 18 October 2017, approval notification received November 14, 2017 (see above)

Year 2, 3rd Quarter: No new items to report
Year 2, 4th Quarter report: No new items to report

IRB STATUS UPDATE: (Information only, no USAMRRC HRO 2nd Level required).

Year 2, 1st Quarter Report: No changes to the approved protocols this quarter. Will submit amendments to IRB, IACUC, and Cadaver Lab to reflect changes to personnel, as well as any study design amendments after dry run, to be held 26-27 February. Minor changes and amendments will be handled at the local NMCSD IRB level. Amendments will include additions and removals of members of research team, and addition of recruitment flyer.

Year 2, 2nd Quarter Report: As above, amendments to the human subjects protocol was submitted 4/24/18. The amendment to the human subjects protocol included personnel changes, elimination of the porcine model, and addition of a recruitment flyer. IACUC protocol closed 4/23/18.

Year 2, 3rd Quarter Report: Amendment to protocol approved 31 May 2018 and annual review approved 30 May, 2018. Document previously forwarded.

Year 2, 4th Quarter Report: No new items to report.
What were the major goals of the project? (continued):

Subtask 1.4: Contracts administrative/execution and obligation of FY16 funds by 30 Sept 2017  
(FY2016 Program Element 6 Funds are earmarked for two years and expire 30 Sep 2017)  
Target: months 1-2

Year 2, 1st Quarter Report: No new items to report. Purchases made this quarter may include cadaveric specimen, swine, perfused cadaver model service.  
Year 2, 2nd Quarter Report: Executed the perfused cadaver contract for the dry run. In process of ordering three additional ultrasounds. Also pending an order for micro-puncture kits.  
Year 2, 3rd Quarter Report: Service contracts for perfused cadavers executed July 9-12, 2018 for support of training session #1  
Year 2, 4th Quarter Report: Service contracts for perfused cadavers executed November 13-16, 2018 for support of training session #2

Subtask 1.5: Equipment purchase, installation and pre-calibration of simulation devices & data collection systems (NMCSD & NMCP Bio-simulation Laboratory/Vivarium)  
Target: months 1-7 and annually as need for perishable items. .

Year 2, 1st Quarter Report: Purchases made this quarter may include cadaveric specimen, swine, perfused cadaver model service,  
Year 2, 2nd Quarter Report: Executed the perfused cadaver contract for the dry run. In process of ordering three additional ultrasounds. Also pending an order for micro-puncture kits.  
Year 2, 3rd Quarter Report: three additional ultrasounds ordered, pending receipt. Micro-puncture kits received. Additional consumable supplies ordered to replenish stock (femoralLine Man™, micro-puncture needles).  
Year 2, 4th Quarter Report: FemoralLine Man™ (received (2))

Subtask 1.6: Student Subjects recruited (Target: month 13)

Year 2, 2nd Quarter Report: Awaiting approval of IRB amendments at local command (NMCSD IRB) level prior to recruiting participants. Do not expect any major delays due to amendments.  
Year 2 3rd Quarter Report: Recruited a total of 16 eligible participants. A total of 10 consented participants completed phase I and II of the study.  
Year 2 4th Quarter Report: Consented a total of 29 eligible participants (16 prior to session 1, plus an additional 15 prior to session #2). A total of 20 consented participants completed phase I and II of the study (10 for session 1 and 10 for session 2).

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

Year 2, 1st Quarter Report: All didactic materials, test questions, checklists, equipment, supplies, on hand for dry run, to be held February 26-27, 2018.  
Year 2, 2nd Quarter Report: Dry run held February 26-27. Didactic materials reviewed, edits suggested and made. Awaiting final approval of IRB protocol amendments.  
Year 2, 3rd Quarter Report: Approval for amendments and continuing review received (31 and 30 May respectively). A total of 16 participants have been recruited. A total of 10 have participated in phase I and II of the study. Recruitment underway for session #2.  
Year 2 4th Quarter Report: Consented a total of 29 eligible participants. A total of 20 consented participants completed phase I and II of the study between sessions 1 and 2 (Session 2 dates 13-16 November).
Major Task 2: REBOA Performance Data Collection and Analysis (Milestone 2)

Subtask 2.1: Initial REBOA training & procedural testing.
Year 2, 1st Quarter Report: Nothing new to report at this time. Anticipate data in following quarter after dry run, and in July when first offering of training session will be provided.

Year 2, 2nd Quarter Report: Data generated and analyzed from dry run. Data collected was used to make changes to the training plan and subsequent amendments to the various protocols. Data collection from subjects anticipated in the next quarter.

Year 2, 3rd Quarter Report: Phase I and II of session #1 completed. Phase I began June 4th 2018. Phase II held July 9-12, 2018. A total of 16 eligible participants consented to participate- a total of 10 consented participants completed Phase I and II. Data collected-anticipate collating data next quarter, and analyzing data after second training session (anticipated November 2018)

Year 2, 4th Quarter Report: Phase I and II of session #2 completed. Phase I began October 15th 2018. Phase II held November 13-16, 2018. A total of 15 additional eligible participants consented to participate- a total of 10 consented participants completed Phase I and II during the second session.

Subtask 2.2: Initial data analysis; interim data and conclusions presented for IPR as directed by sponsor (TBD).

Year 2, 1st Quarter Report: To be determined, activity upcoming
Year 2, 2nd Quarter Report: To be determined, training session planned for July 9-13.
Year 2, 3rd Quarter Report: No IPR scheduled, see preliminary data information above in subtask 2.1.
Year 2, 4th Quarter Report: Data analysis pending completion of Session #2

Subtask 2.3: Retesting to evaluate skill retention (TBD)

Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity pending
Year 2, 3rd Quarter Report: Phase III of the study which measures skills retention of participants at approximately the 6-month mark is anticipated to be collected in November and December 2018 for those who participated in session #1.

Year 2 4th Quarter Report: Activity upcoming

Subtask 2.4: Analysis of skill retention data

Year 2, 1st Quarter Report: Activity upcoming
Year 2 2nd Quarter Report: Activity upcoming
Year 2 3rd Quarter Report: Activity upcoming

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

Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
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 2, 1st Quarter Report:** Confirmed availability of all necessary spaces and services for training session launch July 9-13, 2018. Meetings held with potential study participants to generate interest/ availability. All elements prepared for dry run session (didactic materials, test questions, performance element checklists, case studies, swine, cadaver, perfused cadaver model service).

**Year 2, 2nd Quarter Report:** Dry run held 2/26-2/27. All didactic and simulation components reviewed. Team determined porcine model inferior to perfused cadaver model. Therefore, amendments were submitted to IRB, and IACUC protocols. A decision was made to increase the number of cadavers needed to support this training. Didactic materials edited after review, checklists edited after review. Approvals received for all protocols except IRB, expect to receive approval by 1 June.

**Year 2, 3rd Quarter Report:** Approvals for amendments and annual review received (31 and 30 May, 2018 respectively). A total of 16 consented participants attended the first phase of the training, of which 10 attended phase II on July 9-12. Various data collected, data analysis pending. Supplies ordered to replenish consumable items. Contracts for session two written for cadaveric specimens and perfused cadaver service.

**Year 2, 4th Quarter Report:** (17 August-17 November 2018) A total of 15 consented participants attended the first phase of the training, of which 10 attended phase II on November 13-16. Various data collected, data analysis pending.
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.

1. Site PI and study PI attended Military Health System Research Symposium and attended En Route Care breakout sessions where the use of REBOA was discussed (August 2018)
2. Study PI attended International Meeting for Simulation in healthcare to maintain currency in the latest science involving simulation based healthcare education. (February 2018)
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 3 Quarter 1: 15 November 2018-15 February 2019

- Complete Phase III for session #1 participants
- Amend protocol to increase the number to 32 total participants
- Create contracts for cadavers and perfused cadaver model for session 3
- Purchase Compass Manometers
- Travel to IMSH to to maintain currency in the latest science involving simulation based healthcare education.
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**

**Background and future plans:** Our Nation’s largest group of potentially survivable wartime casualties succumbs to non-compressible truncal hemorrhage. 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 beyond 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.**
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.

Year 2 1st Quarter: Swine removed from the curriculum due to the swine being an inferior model to the perfused cadaver, necessitating increase in total number of cadavers.
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 2

Year 2, 1st Quarter: Original training session dates proposed by research team needed to be pushed back due to lack of availability of the Vivarium on those dates.

Year 2, 2nd Quarter: Nothing to report

Year 2, 3rd Quarter: Nothing to report.

Year 2, 4th Quarter: Nothing to report.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

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

Swine model eliminated from study

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.

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: 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. |
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

Pt: Carmen N. Spalding, Ph.D., RN
Org: Naval Medical Center San Diego
Award Amount: $121,000

Study/Project Aim(s):
- Prove highly trained nurses and corpsmen can demonstrate knowledge acquisition of REBOA indication and technique
- Prove nurses and corpsmen can demonstrate proper REBOA technique on a live tissue model
- Explain nurses and corpsmen reports 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 with various simulators, and overall length of noninvasability
Qualitative: Focus group on increased opportunities and challenges to REBOA

Accomplishment: Vascular access and REBOA-cumulus for both didactic and procedural testing provided for first group of research subjects. Data collected from research study.

Goals/Milestones
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
Complete and test course amongst research team, begin recruit research participants

FY 18 Goals (3rd - 5th Quarter, respectively) Milestone 2
Provide REBOA technique to research participants
Collect data related to study arms (measure proficiency)
Quantitative and Qualitative Measures analyzed - on going
FY 19 (1st - 2nd Quarter) Milestone 2
Retall at six month mark to determine retention of skills
FY 19 Goals (1st Quarter) Milestones 2
Prepare findings for dissemination at conferences and for publication

Updated: Dec 01, 2018

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9. APPENDICES: None
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<td>8. Special Reporting Requirements</td>
<td>32</td>
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<td>9. Appendices: None</td>
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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 NMCSD, 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-22 Fuselage**
   
   **Target:** months 13-24
   Subtask 1.1: 3G simulation manikin acquired.
   Subtask 1.2: Continued maintenance and structural support for exterior and interior upkeep of the fuselage.

   **Major Task 2: Conduct Evaluations of Short, Mid, and Long Duration ERC Mission Evolutions**
   
   **Target:** months 25-36
   Subtask 2.1: Submission and approval of initial IRB protocol to NHRC, NMCSD, and USAMRRC HRPO ongoing.
   Subtask 2.2: Evaluate human factor challenges for performing medical procedures during short duration ERC missions (20-40) min).
   Subtask 2.3: Evaluate human factor challenges for performing medical procedures during mid duration ERC missions (60 min).
   Subtask 2.4: Evaluate human factor challenges for performing medical procedures during long duration ERC missions (120+ min).
Major Task 3: Develop SOP Standards for V-22 Osprey ERC Missions

Target: months 36-60
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.
Subtask 3.2: Conduct evaluation of more complex ERC missions as new gap areas are identified per Fleet and JPC-6 guidance.
Subtask 3.3: Complete summary report and project out brief to JPC-6.

What was accomplished under these goals?

Year 2, Qtr 1 (18 November 2017 to February 14, 2018) NHRC was able to acquire and install a complete set of Osprey seats. Upon review of current commercial products and with consultation with JECC instructors at Fort Rucker, the Laerdal 3G trauma manikin has been identified for use on this project. The PI was on medical leave most of QTR 1 due to knee surgery. As a result, progress on additional planned tasks was delayed but will be back on track in Qtr 2.

Pictures above show the impact of adding the standard seat configuration to the Osprey fuselage. As can be seen, the floor space is considerably decreased increasing the challenge for patient transport operations.
Year 2 Qtr 3 (16 May 2018 – 16 August 2018): IRB protocol is being revised for submission to NHRC IRB committee in Qtr 4. NMCSD staff assisted NHRC staff with training on the 3G manikin prior to NHRC receiving their own. NHRC acquired their 3G manikin in early August and subsequently completed the vendor supplied training module. NHRC staff then brought the manikin out to the Osprey fuselage and began pilot testing short duration ERC scenarios to fine tune methods and procedures. See pictures below.

Year 2 Qtr 4 17 September 2018 – 16 November 2018: IRB protocol in NHRC review. OIC (lead instructor) from Joint En Route Care course visited NHRC and worked with research staff to develop testing scenarios and reviewed testing methodology and evaluation criteria. This is critical to the project to ensure consistent En route care practices are consistent to what is covered in certification courses. NMCSD staff continued to assist NHRC staff with training on the 3G manikin and began pilot testing short duration ERC scenarios to fine tune methods and procedures.
What opportunities for training and professional development has the project provided?

Briefings on the capabilities of the OSPREY research training platform have been provided to the following groups:
- Surgeon and staff from 13th Marine Expeditionary Unit, Camp Pendleton.
- Lead Instructor from Army Aviation Training Center, Joint En Route Care Course.
- Flight Surgeon and staff from VMM-166, MAG-16, 3d MAW, MCAS Miramar

The Osprey research training platform has been utilized by the Navy Fleet Surgical team (ERSS) to enhance training evolutions being held in the vicinity of the Osprey.

Discussions continue on the potential of the Osprey research training platform to be a DoD West Coast educational asset that could be utilized in the recertification process for personnel who need refresher exposure or recertification check-offs for medical personnel such as: Flight Medical, Critical Care Transport, Search and Rescue, and Joint En Route Care.

How were the results disseminated to communities of interest?

Briefings and on-site demonstrations to various medical groups continue. Staff from the Army Aviation Training Center, Fort Rucker, 13th Marine Expeditionary Unit, and MAG-16, 3d MAW have come onsite to discuss collaborative research efforts.

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

Tasks for Year 3 Qtr 1 (16 Nov 18 – 15 Feb 2019)
- Initiate data collection.
- Continue collaborations with 13th MEU, Camp Pendleton, AATC JECC, and VMM-166, MAG-16, 3d MAW
- Submit En Route Care presentation to 2019 Military Heath System Research Symposium.

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.

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).

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 (NMCSD), 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 (TCCET) 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?

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.

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.

No changes since last annual 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.

Finalizing testing methodologies and evaluation criteria have been revised with SME input from lead JECC instructor and 13th MEU Sim Center Surgeon. IRB protocol in review process at NHRC.

**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.

Additional research staff have been added to this project along with two key Military collaborations established, LCDR Hardy AATC, JECC; and LCDR Stewart 13th Surgeon MEU.

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.

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.

Nothing to report.
7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the 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 an 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.

Eric Duckworth, Structural SME
Mr. Duckworth has worked with MCAS Miramar V-22 Osprey staff to get the fuselage painted and prepped on the inside to support the upcoming data collection.

Douglas Jones, Co-Investigator
Mr. 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.

Andrew Ordille, Research Assistant
Mr Ordille has been added to this project to assist with the proposed data collection.

LCDR Sean Stuart, MC, USN, Surgeon, 13th Marine Expeditionary Unit, Combat Trauma Research Group has been added to this project as an Associate Investigator.

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.

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

Nothing to report.

What other organizations were involved as partners?

- Fleet Surgeon and staff from COMNAVSURFOR and COMNAVAIRFOR.
- Fleet Surgeon and staff from 1 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
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
Pt: Jay R. Heaney, MA Org: Naval Health Research Center Award Amount: $1.25M

Study/Product Aim(s):
- Naval Medical Center San Diego (NMCD) 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 "Phot 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 medical 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 the project per their request; 3G manikin obtained and proto-test flight in Osprey has begun.

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Goals/Milestones:
Task 1 Goals:
- Operational costs to run simulated flight operations: scenarios labor, utilities, and supplies and maintenance and structural support for interior and exterior upkeep of the fuselage.
- Upgrade 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 scenario (20-30 min) in Osprey.
- ESB protocol being revised and with submission to NMCD, and then USAFRICOM HSPO review for approval.

Task 3 Goals:
- Conduct evaluation of more complex ERC missions as new gap areas are identified per JPC-4 guidance.
- Complete summary report and project out brief to JPC-4.

Updated: December 01, 2018

9. APPENDICES: None.
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<td>Special Reporting Requirements</td>
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<tr>
<td>9</td>
<td>Appendices: (SF 298) and Quad Chart</td>
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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*

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<th>Statement of Work Tasks</th>
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<tr>
<td><strong>Task 1</strong></td>
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<tr>
<td><strong>Subtask 1.1:</strong> Submit IRB protocol and data-sharing agreements for review and approval</td>
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<td>Target: months 1-5</td>
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<td>IRB continuing review package for #NHRC.2016.0029 approved on 13 SEP 2018</td>
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Statement of Work Tasks (continued):

Subtask 1.2: Execute contract funds, obligate in-house money, and finalize research team
   Target: months 1-2
   Actual: completed DEC 2016

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; work on-going.
Subtask 2.2: Revise SAR event and patient information forms
   Target: months 2-6
   Revised forms distributed to SARMM in MAY 2017.
Subtask 2.3: Design, test, and implement new SAR data collection system
   Target: months 2-18
   Began month 2; work on-going.
Subtask 2.4: Determine standard operating procedures for transforming all historical records by report version and condition of physical record
   Target: months 5-12
   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
   Began month 6; work on-going.
14 NOV 2017: 2,580 records processed (1,942 Rescue Reports and 638 Medical Reports).
14 NOV 2018: 7,074 records processed (4,380 Rescue Reports and 2,694 Medical Reports).

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: Work pending.
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: Work pending.
Subtask 3.3: Conduct longitudinal analyses of military medical and career outcomes of SAR patients, providers, and crew
   Target: months 25-48
   Actual: Work pending.
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 2 Qtr 1 (15 NOV 2017 – 14 FEB 2018) Accomplishments
- Processed all 2016 reports.
- Processed all 2017 reports, except for hurricane/disaster relief reports.
- Developed, tested and distributed new SARMM quarterly metrics tracking document for SARMM’s review and approval. This document is an Excel workbook that includes a Medical Report Summary Statistics metrics dashboard; a Rescue Report Summary Statistics metrics dashboard, and an Equipment chart. These 3 worksheets are linked to a hidden comprehensive data sheet for all variables from reports submitted within the past 12 months.
- Developed, tested and began executing the SAS syntax to generate the SARMM quarterly metrics tracking document’s comprehensive variable data sheet.
- Initial data processing/cleaning/QA SAS syntax for NAAD records written and tested.
- Finished processing all NAAD Rescue Reports.

Year 2 Qtr 1: Number of reports processed this quarter and to date for Year 2:
Running Project Totals of Historic Records Processed (Raw Electronic Data in SQL Database)
<table>
<thead>
<tr>
<th></th>
<th>Rescue Reports</th>
<th>Medical Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td># Current Quarter</td>
<td>755</td>
<td>310</td>
</tr>
<tr>
<td># Total To Date</td>
<td>2,697</td>
<td>948</td>
</tr>
</tbody>
</table>

Year 2 Qtr 2 (15 FEB 2018 – 14 MAY 2018) Accomplishments
- Processed all remaining 2017 reports.
- Processed more than half of all remaining handwritten NAAD medical reports.
- Presented an invited briefing to SAR operators during the Search and Rescue Model Manager Conference 2018 on 21 MAY 2018 at NAS North Island, Coronado, CA.
- Submitted 3 abstracts to the 2018 Military Health System Research Symposium call for abstracts.

Year 2 Qtr 2: Number of reports processed this quarter and to date for Year 2:
Running Project Totals of Historic Records Processed (Raw Electronic Data in SQL Database)
<table>
<thead>
<tr>
<th></th>
<th>Rescue Reports</th>
<th>Medical Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td># Current Quarter</td>
<td>22</td>
<td>570</td>
</tr>
<tr>
<td># Total To Date</td>
<td>2,676*</td>
<td>1,518</td>
</tr>
</tbody>
</table>

*The 2,676 number is reduced from the previous report due to removal of duplicate records of the same incident.
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.

Professional development opportunities:

Rima Nandi was the 1st author of an invited poster at the 2018 Military Health System Research Symposium in Orlando, Florida. She presented initial project findings related to the project’s work with the historic SARMM reports.

HMC Thomas Walsh IV was a co-author of an invited poster at the 2018 Military Health System Research Symposium in Orlando, Florida. He presented initial project findings concerning the 2515th Naval Air Ambulance Detachment patient care and operations from 2005 to 2012.
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.

An overview of the project was shared with the Search and Rescue community at its 2018 conference during an invited presentation:

Preliminary project results were shared at the 2018 Military Health System Research Symposium. Invited poster presentations included:

Invited panel presentation included:

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 3 Qtr 1 (15 NOV 2018 – 14 FEB 2018)
- Test an NMCI-configured electronic data collection IT system configuration (still awaiting NMCI and NHRC IT final approvals, and delivery of NMCI computer).
- Hire additional temporary, part-time contractors to process SAR records.
- Prepare and distribute updated SARMM quarterly metrics tracking report.
- Process reports so that the raw database includes CY2005 to CY2018.
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 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.
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.*

**Actual Problems Experienced in Year 2**

1. We are still waiting for final BUMED IT approvals for the project’s NMCI computer that will be linked to local NHRC servers. The request was submitted to BUMED more than 1 year ago. We cannot move to implement the new electronic data collection system until all required approvals and permission have been received. NHRC’s IRB chairman, Dr. William Becker, has been leading this effort and communicating directly with BUMED IT contacts. We have no specific plan to resolve this problem because we do not know why BUMED has not yet approved the request or who has made this decision.

2. The extra time required to process a handwritten SAR report is typically 2 to 3 times more than the time required to process a typed SAR report. The number of handwritten SAR reports received each year varies. Thus far, as many as 10% of all records submitted during a calendar year have been handwritten. We have revised processing time estimates to more accurately account for the extra time required to process handwritten reports. We have halted all work on Task 3 from the Statement of Work (see item #6 below) to concentrate on processing SAR’s historic reports.

3. NHRC replaced all on-site workstations and subsequent problems with correctly configuring required software packages halted all work to process SAR reports through Teleform for nearly 1 month. Throughout the year, other software configuration problems caused more minor delays with other tasks. As these sorts of IT problems emerge, it is very difficult to ameliorate these problems or devise temporary work-around solutions because we are limited to processing SAR reports with software installed on NHRC’s network and accessible through on-site NHRC workstations.

4. Given the delay and difficulties with item #1 (above), we have continued to divert project labor away from processing records to searching for alternative solutions to successfully stand-up the electronic data collection system. Options evaluated and ultimately dismissed include a cloud-based system through Amazon Web Services and OPM’s MAX.GOV system. By the end of Year 2, the PI decided that no more labor will be diverted from other tasks to trying to find a solution to this problem.

5. NHRC seat rates for FY18 were retroactively increased from $18,480 to $22,176 per 1.0 FTE for the year. We had to unexpectedly divert $10K from planned project labor to pay for NHRC’s increased overhead costs since seat rates are mandatory fees that must be paid.

6. Work to accomplish Task 3 from the Statement of Work has been delayed indefinitely. We are now concentrating all labor on processing the historic reports to ensure the completion of a SAR database with all its historic records within the next 2 years.
Actual or anticipated problems or delays and actions or plans to resolve them (continued):

Anticipated problems:

<table>
<thead>
<tr>
<th>Anticipated Problems and Potential Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. We do not anticipate finding solutions to resolve any of the IT infrastructure problems that were identified in Year 1 and continue to persist to the present. Please see the Year 1 Annual Report for a detailed discussion of these problems. By reclassifying the electronic data system as a research system, the requirement for Defense Business System (DBS) certification no longer applies. We cannot realistically plan to secure required approvals to use existing functional systems and services to electronically collect PHI and PII (e.g., Amazon Web Services, MAX.Gov). We also cannot find a solution to the interoperability issues between the host network (DHA) and the end-users networks (primarily NMCI, but also includes USAF and USA networks). Our current plan to run the electronic data collection system on a NMCI-networked computer that will be physically located at NHRC will support the electronic collection of most newly-submitted SAR reports. SAR commands that use other (non-NMCI) networks, particularly OCONUS commands that currently use the USAF network, will not be able to submit their new reports electronically.</td>
</tr>
<tr>
<td>We submitted our IT request to BUMED in SEP 2017. We are still waiting for a final decision. We cannot do anything else until BUMED approves the request. Once BUMED approves the request, we must then wait for SPAWAR to procure, set-up, and fully configure the NMCI computer in its assigned NHRC on-site office. If all this occurs prior to 1 OCT 2019, we may be able to successfully complete Statement of Work Sub-task 2.3 during the project’s POP.</td>
</tr>
<tr>
<td>2. We anticipate that the original project labor plan and requested budget will not be sufficient to complete all Statement of Work tasks within the planned 4-year POP. We are far behind our initial processing schedule for the historic SAR reports since (a) significant project labor was diverted from processing historic SAR reports to IT infrastructure problems during Years 1 and 2; (b) the additional time burden inherent with processing handwritten versus typed SAR historic reports was not correctly factored into the original schedule; (c) the retroactive increase in NHRC seat rates during FY18 required a shift of more than $10K in the Year 2 budget from contract labor to NHRC overhead and the further increase in FY19 NHRC seat rates will require a shift of more than $15K in the Year 3 budget from contract labor to NHRC seat rates; (d) constant change in research team contract personnel has contributed to lower team productivity because it takes months to get a CAC-holding contract replacement hired, plus at least an additional 3 to 5 weeks for the new person to complete all the required Navy, NHRC, and project-specific trainings, for each trained, experienced CAC-holding contractor that left the project; (e) problems with NHRC IT workstations, especially software configuration issues, during Year 2 effectively halted all work with OpenText Teleform and Liquid Office for more than a month; and (f) the stalled approval process for the requested NMCI computer to support the electronic data collection system for newly submitted SAR reports prevents any work on Sub-task 2.3.</td>
</tr>
<tr>
<td>During Year 3, project efforts will concentrate almost entirely on processing the historic SAR reports. Recruitment of new part-time, temporary contract personnel is underway. If we receive BUMED approval for our IT request during Year 3, we will immediately begin work to accomplish Sub-task 2.3 and electronically collect new SAR reports until the end of the project’s POP. Progress with processing the historic SAR reports will be reassessed in Year 3 Qtr 4 to determine the feasibility of successfully completing any part of Task 3 during the project’s final 12 months.</td>
</tr>
</tbody>
</table>
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 at this time.

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

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

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.


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.
• **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**

Stephanie McWhorter, PI
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 and testing the pre-processing protocol to clean/check raw data for final processing and preparing written documentation for end users.

Rima Nandi, Project Management/Research Assistant
Ms. Nandi managed the hiring, training, and tasking of new part-time, temporary project personnel. She assisted with the development and testing of a pre-processing records protocol, and is now managing the execution of the protocol project-wide. She is responsible for the design of SAR Medical and Rescue templates with OpenText LiquidOffice. Other responsibilities include: template development/design through OpenText TeleForm Designer; SAR Rescue and Medical Reports scanning and batch processing with TeleForm Scan Station and Verifier modules; SARMM metrics report pivot table and slicer improvements; and work on preparing a technical report, including literature searches, literature reviews, and writing.

Sarah Carinio, Research Assistant
Ms. Carinio joined the research team in a part-time, temporary 6-month position to process historic SAR records until 30 SEP 2018. She has accepted a job offer that begins 1 OCT 2018.

Scott Shaffer, Research Assistant
Mr. Shaffer joined the research team in a part-time, temporary 6-month position to process historic SAR records until 30 SEP 2018. He has accepted a job offer that begins 1 OCT 2018.

**Departed Project Personnel**

Kyle O’Donnell, Data System Specialist (Left in JAN 2018)
Mr. O’Donnell managed and oversaw the initial batch processing of 2515th NAAD rescue and medical reports for the years 2006 to 2013. This included data configuration, testing, and implementation between the TeleForm system and Microsoft SQL. Other responsibilities include: served as the technical POC for project inquiries and data processing issues and engaged extensively with OpenText to resolve TeleForm software issues; finalized and activated LiquidOffice comprehensive reports to existing SQL databases for future use in the records modernization process; served as the liaison between the project team, NHRC’s information technology department, and outside vendors to research alternative solutions to deploy a scalable, electronic data collection system, including included bi-weekly meetings with appropriate stakeholders and extensive outreach with external vendors; requested an Amazon Web Services (AWS) account to research a prototype for electronic data collection; and now developing the Excel framework and templates that will be used for the Search and Rescue quarterly reports.
Departed Project Personnel (cont.)

Jennifer Stark, Data Analyst (Left NOV 2017)
Ms. Stark developed syntax to clean, process, and format raw data values. These tasks included cleaning date and time values and other character strings in non-standard form, standardizing spacing and/or delimiters, establishing expected range of values and identifying outliers, standardizing names, and creating new variables as needed. Ms. Stark will use this syntax to assist in building the data dictionary that will auto clean and process future raw tables.

Brad Kowitz, Military Medical SME (Left JUL 2017)
Mr. Kowitz conducted monthly formal meetings with SAR SME's to provide project updates, review finalized rescue reports, coordinate current and future report form submission, and discuss network and cloud based database access solutions. Sorted and identified unique rescue and medical reports for Teleform creation. Conducted testing and evaluation of scanned rescue reports in Teleform, electronic file sharing, network access and cloud systems. Attended by-weekly meetings with Naval Health and Research Center IT staff to investigate database access options, information security, web based access, AWS and DOD cloud storage. Created a project plan of actions and milestones to prioritize and identified project goals.
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
Pt: Stephanie McVhorte, MA  Org: Naval Health Research Center  Award Amount: $ 999,931

<table>
<thead>
<tr>
<th>Study/Project Aim(s)</th>
<th>Timeline and Cost</th>
</tr>
</thead>
</table>
| • Transform all historical SAR records into an electronic database  
• Develop, test, and implement a secure SAR electronic data collection system (eDCS)  
• 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 | Activities | C716/7 | 17/8 | 18/9 | 19/20 |
| Approach | Project approvals, hiring, contracts |   |   |   |   |
| SQL database shell for SAR database | Design, test, implement data system and processes |   |   |   |   |
| Secure SAR eDCS | Transform 45 years of historical SAR records into new database |   |   |   |   |
| Intelligent document recognition software (OpenText LiquidOffice and Telorm) and data entry to transform records into SAR database | Merge SAR, medical, and career records to generate project outset |   |   |   |   |
| Longitudinal analyses of SAR patient, provider, and crew outcomes | Estimated 1 Yr Budget ($1M) | $250K | $250K | $250K | $250K |
| Expenditures (To Date) | $250K | $250K |

Goals/Milestones

Year 2 Goals
- Test SAR’s eDCS system
- Continue transforming historical SAR records
- Begin distribution of interim quality metrics report
- Begin collection reports with SAR’s eDCS system (awaiting receipt of IMC computer)

Year 3 – Year 4 Goals
- Complete transformation of all historical SAR records into the SAR database
- Generate a project-specific database by merging extracts from SAR database, DAMC DEEP, MPR, and EMED
- Conduct longitudinal analyses of military medical and career outcomes of SAR patients, providers, and crew members

Updated: December 01, 2018

9. APPENDICES: None