

AWARD NUMBER: W81XWH-13-2-0080

TITLE: Study of Tranexamic Acid During Air Medical  
Prehospital Transport Trial (STAAMP Trial)

PRINCIPAL INVESTIGATOR: Jason L. Sperry, MD, MPH

RECIPIENT: University of Pittsburgh  
Pittsburgh, PA 15213

REPORT DATE: October 2016

TYPE OF REPORT: Annual

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

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# REPORT DOCUMENTATION PAGE

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<b>1. REPORT DATE</b> October 2016			<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 30-Sep-2015 to 29-Sep-2016	
<b>4. TITLE AND SUBTITLE</b>  Study of Tranexamic Acid During Air Medical Prehospital Transport Trial (STAAMP Trial)					<b>5a. CONTRACT NUMBER</b>	
					<b>5b. GRANT NUMBER</b> W81XWH-13-2-0080	
					<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b>  Jason L. Sperry, Barbara Early, Meghan Buck, Ashley Ryman  E-Mail: <a href="mailto:sperryjl@upmc.edu">sperryjl@upmc.edu</a> ; <a href="mailto:earlybj@upmc.edu">earlybj@upmc.edu</a> ; <a href="mailto:buckml@upmc.edu">buckml@upmc.edu</a> ; <a href="mailto:rymanam@upmc.edu">rymanam@upmc.edu</a>					<b>5d. PROJECT NUMBER</b>	
					<b>5e. TASK NUMBER</b>	
					<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  University of Pittsburgh Pittsburgh, Pennsylvania 15213					<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
					<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b> Approved for Public Release; Distribution Unlimited						
<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b>  The enrollment for this study began at the University of Pittsburgh on 11-JUN-2015. External sites are in the process of submitting their initial IRB application and the community consultation plan is either in the development stage or recently initiated.  Pittsburgh Coordinating Center is awaiting IRB approval regarding changes to the protocol language.						
<b>15. SUBJECT TERMS</b> Prehospital ; Tranexamic acid						
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b>	
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>			<b>USAMRMC</b>	
U	U	U	UU	24	<b>19b. TELEPHONE NUMBER (include area code)</b>	

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## INTRODUCTION:

- The primary hypothesis is that the prehospital infusion of tranexamic acid in patients at risk for bleeding will reduce the incidence of 30 day mortality. The secondary hypotheses include that prehospital tranexamic acid will reduce the incidence of hyperfibrinolysis, acute lung injury, multiple organ failure, nosocomial infection, mortality, early seizures, pulmonary embolism and early resuscitation needs, reduce or prevent the early coagulopathy as demonstrated by improving presenting INR and rapid thromboelastography parameters, reduce the early inflammatory response, plasmin levels, leukocyte, platelet and complement activation, and determine the optimal dosing of tranexamic acid post-injury.

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

- Prehospital
- Tranexamic acid

### 2. **OVERALL PROJECT SUMMARY:** Summarize the progress during appropriate reporting period (single annual or comprehensive final). This section of the report shall be in direct alignment with respect to each task outlined in the approved SOW in a summary of Current Objectives, and a summary of Results, Progress and Accomplishments with Discussion. Key methodology used during the reporting period, including a description of any changes to originally proposed methods, shall be summarized. Data supporting research conclusions, in the form of figures and/or tables, shall be embedded in the text, appended, or referenced to appended manuscripts. Actual or anticipated problems or delays and actions or plans to resolve them shall be included. Additionally, any changes in approach and reasons for these changes shall be reported. **Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) requires review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.**

- Pittsburgh site received IRB approval for protocol modification v1.6 on 30-SEP-2015.
- Coordinating Center received IRB approval for protocol modification v1.6 on 20-OCT-2015
- University of Arizona received initial IRB approval on 27-OCT-2015.
- Coordinating Center received IRB approval for subject info sheet v.1 07-DEC-2015
- Pittsburgh site received IRB approval for subject info sheet v.1 11-DEC-2015
- An investigator teleconference was held 16-DEC-2015 with UTSA; investigator and coordinators from site was present.
- Utah received initial IRB approval for community consultation 19-JAN-2016
- San Antonio received full IRB approval on 28-JAN-2016
- San Antonio Site Initiation Visit (SIV) conducted on 22-FEB-2016
- University of Pittsburgh Coordinating Center received IRB approval for protocol modification v1.7 on 10-MAR-2016
- Arizona Site Initiation Visit (SIV) conducted on 31-MAR-2016.
- University of Pittsburgh Site received IRB approval for protocol modification v1.7 on 04-APR-2016
- Arizona Site submitted their community consultation results to their local IRB on 11-MAY-2016.
- An investigator teleconference was held in MAY-2016 with each participating site; investigator and coordinator from each site were present.
- University of Pittsburgh Coordinating Center received IRB Annual Renewal approval on 14-JUN-2016.

- An investigator teleconference was held 16-AUG-2016 with UTSA; investigator and coordinators from site was present.
- STAAMP Investigator Meeting was held at AAST SEP-2016, representatives from all sites were present.

**3. KEY RESEARCH ACCOMPLISHMENTS:** Bulleted list of key research accomplishments emanating from this research. Project milestones, such as simply completing proposed experiments, are not acceptable as key research accomplishments. Key research accomplishments are those that have contributed to the major goals and objectives and that have potential impact on the research field.

- Data entry web based platform has been developed and subjects are actively being entered (this is a secure web based Electronic Data Capture).
- Secretary of Defense approval for UTSA performing site was received on 28-JUL-2016.
- UTSA site began enrollment on 19-SEP-2016.
- Utah site submitted to HRPO for initial protocol approval on 28-SEP-2016.
- No Cost Extension (NCE) approval received

**4. CONCLUSION:** Summarize the importance and/or implications with respect to medical and /or military significance of the completed research including distinctive contributions, innovations, or changes in practice or behavior that has come about as a result of the project. A brief description of future plans to accomplish the goals and objectives shall also be included.

- Commence enrollment at Arizona in JAN-2017
- Commence enrollment at Utah in first quarter of 2017

**5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:**

a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry shall include the author(s), article title, journal name, book title, editors(s), publisher, volume number, page number(s), date, DOI, PMID, and/or ISBN.

- (1) Lay Press: ***Nothing to report***
- (2) Peer-Reviewed Scientific Journals: ***Nothing to report***
- (3) Invited Articles: ***Nothing to report***
- (4) Abstracts: ***Nothing to report***

b. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.

- ***Nothing to report***

**6. INVENTIONS, PATENTS AND LICENSES:** List all inventions made and patents and licenses applied for and/or issued. Each entry shall include the inventor(s), invention title, patent application number, filing date, patent number if issued, patent issued date, national, or international.

- ***Nothing to report***

**7. REPORTABLE OUTCOMES:** Provide a list of reportable outcomes that have resulted from this research. 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. This list may include development of prototypes, computer programs and/or software (such as databases and animal models, etc.) or similar products that may be commercialized.

- ***Nothing to report***

**8. OTHER ACHIEVEMENTS:** This list may include degrees obtained that are supported by this award, development of cell lines, tissue or serum repositories, funding applied for based on work supported by this award, and employment or research opportunities applied for and/or received based on experience/training supported by this award.

- ***Nothing to report***

For each section, 4 through 9, if there is no reportable outcome, state “Nothing to report.”

**9. REFERENCES:** List all references pertinent to the report using a standard journal format (i.e., format used in *Science*, *Military Medicine*, etc.).

**10. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

**NOTE:**

**TRAINING OR FELLOWSHIP AWARDS:** For training or fellowship awards, in addition to the elements outlined above, include a brief description of opportunities for training and professional development. Training activities may include, for example, courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.

- ***Nothing to report***

**COLLABORATIVE AWARDS:** For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

**QUAD CHARTS:** If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

**MARKING OF PROPRIETARY INFORMATION:** Data that was developed partially or exclusively at private expense shall be marked as “Proprietary Data” and Distribution Statement B included on the cover page of the report. Federal government approval is required before including Distribution Statement B. The recipient/PI shall coordinate with the GOR to obtain approval. REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE. It is the responsibility of the Principal Investigator to advise the GOR when

restricted limitation assigned to a document can be downgraded to “Approved for Public Release.” DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS. See term entitled “Intangible Property – Data and Software Requirements” and [https://mrmc.amedd.army.mil/index.cfm?pageid=researcher\\_resources.technical\\_reporting](https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting) for additional information.

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE <b>S</b>	PAGE OF PAGES <b>1   17</b>
2. AMENDMENT/MODIFICATION NO. <b>P00001</b>	3. EFFECTIVE DATE <b>16-Feb-2017</b>	4. REQUISITION/PURCHASE REQ. NO. <b>0010373948-0001</b>		5. PROJECT NO.(If applicable)
6. ISSUED BY USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	CODE <b>W81XWH</b>	7. ADMINISTERED BY (If other than item 6) <b>See Item 6</b>		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) UNIVERSITY OF PITTSBURGH THE JENNIFER E WOODWARD 3520 FIFTH AVE PITTSBURGH PA 15213-3320		9A. AMENDMENT OF SOLICITATION NO.		
		9B. DATED (SEE ITEM 11)		
		X 10A. MOD. OF CONTRACT/ORDER NO. <b>W81XWH-13-2-0080</b>		
		X 10B. DATED (SEE ITEM 13) <b>30-Sep-2013</b>		
CODE <b>1DQV3</b>	FACILITY CODE			
<b>11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS</b>				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
<b>13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.</b>				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
X D. OTHER (Specify type of modification and authority) IAW the Terms and Conditions of this award				
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: <b>swinter171602</b> Principal Investigator: <b>Jason Sperry</b> Project Title: <b>Study of Tranexamic Acid During Air Medical Prehospital Transport Trial (STAAMP trial) - TACR.</b> Period of Performance: <b>30 September 2013 - 29 September 2017</b> Award and obligated amount: <b>\$4,098,229.00</b> The purpose of this modification (P00001) is to: 1). Provide a One (1) year Extension Without Funds (EWOFF) to 29 September 2017 per the recipient request received 04 January 2017. The final technical report is due no later than 29 December 2017. Submission of the financial report, and the quarterly technical report, shall continue during the EWOFF period. 2). Update various other e-mail addresses within the terms and conditions of the award.  All other Terms and Conditions remain unchanged  Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JANET P KUHNIS / CONTRACTING OFFICER TEL: 301-619-2827 EMAIL: janet.p.kuhns.civ@mail.mil		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY <i>Janet P. Kuhnis</i> (Signature of Contracting Officer)	16C. DATE SIGNED <b>16-Feb-2017</b>	
(Signature of person authorized to sign)				



## SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

## SECTION 00010 - SOLICITATION CONTRACT FORM

The standard size code 1,000 has been added.

The NAICS code 541712 has been added.

The 'administered by' organization has changed from

US ARMY MEDICAL RESEARCH ACQUISITION ACT  
ATTN: DOUGLAS MEDCALF  
DOUGLAS.A.MEDCALF.CIV@MAIL.MIL  
FORT DETRICK MD 21702

to

USA MED RESEARCH ACQ ACTIVITY  
820 CHANDLER ST  
FORT DETRICK MD 21702-5014

## DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
POP 30-SEP-2013 TO 29-SEP-2016	N/A	USA MED RESEARCH MAT CMD TMED AND ADV TECH RSRCH CTR TATRC 504 SCOTT STREET FORT DETRICK MD 21702-5012 FOB: Destination	W90ERG

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
POP 30-SEP-2013 TO 29-SEP-2017	N/A	USA MED RESEARCH MAT CMD TMED AND ADV TECH RSRCH CTR TATRC 504 SCOTT STREET FORT DETRICK MD 21702-5012 FOB: Destination	W90ERG

The following have been added by full text:

PI NAME & PROPOSAL TITLE

PI Name: Jason Sperry

Proposal Title: "Study of Tranexamic Acid During Air Medical Prehospital Transport Trial (STAAMP Trial)"

Administered by:

Tom Winter

Grants Specialist  
US Army Medical Research Acquisition Activity  
Phone: 240-357-1590  
Email: thomas.s.winter2.civ@mail.mil

The following have been deleted:

PI NAME & PROPOSAL TITLE

#### SECTION 00800 - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

**TERMS AND CONDITIONS**  
**U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)**  
**U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY (USAMRAA)**  
**Effective February 1, 2013**

#### TERMS AND CONDITIONS INCORPORATED BY REFERENCE

The recipient shall comply with the terms and conditions below that are applicable to its type of organization:

a. **For Educational and Non-Profit Organizations:** This award incorporates by reference, with the same force and effect as if they were included in full text, the Research Terms and Conditions dated June 2011 (<http://www.nsf.gov/awards/managing/rtc.jsp>) and the USAMRAA Agency Specific Requirements dated October 1, 2011 (<http://www.usamraa.army.mil>).

b. **For Commercial (For-Profit) Organizations:** This award incorporates by reference, with the same force and effect as if they were included in full text, the USAMRAA General Terms and Conditions for Assistance Awards with For-Profit Organizations dated April 1, 2012 (<http://www.usamraa.army.mil>).

Any apparent inconsistency between Federal statutes and regulations and the terms and conditions contained in this award shall be referred to the USAMRAA Grants Specialist for guidance.

#### AWARD SPECIFIC TERMS AND CONDITIONS

This award is made under the authority of 10 U.S.C. 2371 and 10 U.S.C. 2358. The recipient's Statement of Work (SOW) and the revised budget dated 11 September 2013 for the application submitted in response to the Fiscal Year 2012 Department of Defense (DOD) Combat Casualty Care Joint Program Committee Tranexamic Acid Clinical Research Program Announcement (Funding Opportunity Number: W81XWH-12-CCCJPC-TACR, which closed 28 January 2013) are incorporated herein by reference. The Catalog of Federal Domestic Assistance Number relative to this award is CFDA 12.420.

#### COOPERATIVE AGREEMENT: DOD SUBSTANTIAL INVOLVEMENT

This award is a cooperative agreement due to the anticipated DoD substantial involvement in performance of the project. The following USAMRMC laboratory(s) or other DOD participants(s) are anticipated to have substantial scientific and/or programmatic involvement which may include collaboration and participation in the project to be performed under this award:

Telemedicine & Advanced Technology Research Center

## **SPECIAL TERMS/REQUIREMENTS**

### **ADDITIONAL RECIPIENT TERMS**

As mutually agreed the recipient will:

1. Participate in a proactive program management construct where funded investigators meet periodically to share lessons-learned, review of programs.
2. Provide all data to DoD for inclusion in the Systems Biology Database “Data Cube.”
3. Participate in the NHLBI Ancillary Studies Program.
4. Accept DoD input into the final study design.
5. To negotiate under a separate procurement the requirement of providing samples to the DoD for placement in a sample repository. The volume, number, and collection methods for these specimens is to be determined at a future date.

## **ACCEPTANCE OF AWARD**

The recipient is not required to countersign this award. In case of disagreement, the recipient shall notify the USAMRAA Grants Officer and not assess the award any costs until such disagreement(s) is resolved.

## **ADMINISTRATIVE AND COST PRINCIPLES**

The following Administrative and Cost Principles, as applicable, effective the earlier of (i) the start date of this award or (ii) the date on which the recipient incurs costs to be assessed against the award, are incorporated as part of this award by reference:

- a. CFR, Title 2, Part 220, “Cost Principles for Educational Institutions (OMB Circular A-21).”
- b. CFR, Title 2, Part 225, “Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87).”
- c. OMB Circular A-102, “Grants and Cooperative Agreements with State and Local Governments.”
- d. CFR, Title 2, Part 215, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations (OMB Circular A-110).”
- e. CFR, Title 2, Part 230, "Cost Principles for Non-profit Organizations (OMB Circular A-122).” [For those nonprofit organizations specifically excluded from the provisions of OMB Circular A-122, Subpart 31.2 of the Federal Acquisition Regulations (FAR 48 CFR Subpart 31.2) shall apply].
- f. OMB Circular A-133, “Audits of States, Local Governments, and Non-Profit Organizations.”
- g. Federal Acquisition Regulation, Part 31.2, for Commercial Organizations and those nonprofit organizations specifically excluded from the provisions of OMB Circular A-122.
- h. Department of Defense Grant and Agreement Regulations 3210.6-R.

These publications may be obtained from:

Office of Management and Budget  
EOP Publications Office  
New Executive Office Building  
725 17<sup>th</sup> Street, NW, Room 2200  
Washington, DC 20503  
Telephone: (202) 395-7332  
Website: <http://www.whitehouse.gov/omb/>

## **RECIPIENT RESPONSIBILITY**

In addition to the responsibilities of the recipient as defined in the award or incorporated by reference herein:

- a. The recipient will bear primary responsibility for the conduct of the research and will exercise sound judgment within the limits of the award's terms and conditions.
- b. The Principal Investigator (PI) specified in the award document will be continuously responsible for the conduct of the research project and will be closely involved with the research effort. The PI, operating within the policies of the recipient, is in the best position to determine the means by which the research may be conducted most effectively.
- c. The recipient shall request the USAMRAA Grants Officer's prior approval to change the PI or any key personnel named in the award, for the PI or key personnel named in the award to be absent from the project during any continuous period of 3 months or more, or for the PI or key personnel to reduce effort devoted to the project by 25 percent or more from the level that was approved at the time of award or last approved level.

## **AWARD MODIFICATION**

The only method by which this award may be modified is by a formal, written modification signed by the USAMRAA Grants Officer. No other communications, whether oral or in writing, are valid to change the terms and conditions of this award. See the USAMRAA Agency Specific Requirements for changes requiring USAMRAA Grants Officer's prior approval.

## **MAXIMUM OBLIGATION**

The maximum obligation of the Government for support of this award will not exceed the amount specified in the award, as modified. Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.

## **DISALLOWED COSTS**

Funds shall not be used for the support of any costs disallowed by the Program Announcement, either as a direct or an indirect cost.

## **SUPPORTING INFORMATION**

Information such as subawards, consultant agreements, vendor quotes, and personnel work agreements may be required in order to support proposed costs or to determine the employment status of personnel. The Government's receipt of this information does not constitute approval or acceptance of any term or condition included therein.

## **FINANCIAL INSTABILITY, INSOLVENCY, BANKRUPTCY OR RECEIVERSHIP**

- a. The recipient shall immediately notify the USAMRAA Grants Officer of the occurrence of the following events: (1) the recipient's financial instability that would negatively impact performance of this award;

(2) the recipient's or recipient's parent's filing of a voluntary case seeking liquidation or reorganization under the Bankruptcy Act; (3) the recipient's consent to the institution of an involuntary case under the Bankruptcy Act against the organization or organization's parent; (4) the filing of any similar proceeding for or against the recipient or recipient's parent, or its consent to, the dissolution, winding-up or readjustment of the recipient's debts, appointment of a receiver, conservator, trustee, or other officer with similar powers over the organization, under any other applicable state or federal law; or (5) the recipient's insolvency due to its inability to pay its debts generally as they become due.

b. Such notification shall be in writing and shall: (1) specifically set out the details of the occurrence of an event referenced in paragraph a; (2) provide the facts surrounding that event; and (3) provide the impact such event will have on the project being funded by this award.

c. Upon the occurrence of any of the five events described in paragraph "a" above, the Government reserves the right to conduct a review of this award to determine the recipient's compliance with the required elements of the award (including such items as cost share, progress towards technical project objectives, and submission of required reports). If the USAMRAA Grants Officer's review determines that there are significant deficiencies or concerns with the recipient's performance under the award, the Government reserves the right to impose additional requirements, as needed, including (1) change the payment method; (2) institute payment controls, and (3) require additional reporting requirements.

d. Failure of the recipient to comply with this term may be considered a material failure by the recipient to comply with the terms of this award and may result in termination.

## **PROHIBITION OF USE OF LABORATORY ANIMALS**

### **\*\* PROHIBITION – READ FURTHER FOR DETAILS \*\***

Notwithstanding any other terms and conditions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USAMRMC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRMC ACURO to the recipient. Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. For each fiscal year, the recipient shall maintain, and upon request from ACURO, submit animal usage information.

Non-compliance with any of these terms and conditions may result in withholding of funds and/or the termination of the award.

## **PROHIBITION OF USE OF HUMAN SUBJECTS**

### **\*\* PROHIBITION – READ FURTHER FOR DETAILS \*\***

Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information, shall not begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRMC ORP, under separate notification to the recipient. Written approval from the USAMRMC ORP is also required for any subrecipient that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRMC. Research records shall be stored in a confidential manner so as to protect the confidentiality of subject information.

The recipient is required to adhere to the following reporting requirements:

Submission of major modifications to the protocol, continuing review documentation, and the final report are required as outlined in the USAMRMC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRMC ORP.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRMC ORP.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

## **PROHIBITION OF USE OF HUMAN CADAVERS**

### **\*\* PROHIBITION – READ FURTHER FOR DETAILS \*\***

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadavers under this award shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012

([https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections.overview](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview)). The USAMRMC Office of Research Protections (ORP) is the Action Office ([Usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil](mailto:Usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil)) for this policy. Written approvals to begin the activity will be issued under separate notification to the recipient.

Noncompliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

## **CLINICAL TRIAL REGISTRY**

Certain clinical trials are required by U.S. law to be registered on the National Institutes of Health database entitled "ClinicalTrials.gov." For those trials required to be registered (see <http://prsinfo.clinicaltrials.gov/>, "Support Materials, including Data Element Definitions"), PIs shall register clinical trials individually on <http://www.clinicaltrials.gov>. PIs shall use a Secondary Protocol ID number designation of "TATRC-13335001". If several protocols exist under the same application, the Secondary Protocol ID number must be designated "TATRC-103335001-A-B-C". Clinical trials must be registered prior to enrollment of the first patient. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of award funds as per U.S. Public Law 110-85.

## **INTANGIBLE PROPERTY - DATA AND SOFTWARE REQUIREMENTS**

a. Government rights. All software and data first produced under the award are subject to the Federal Purpose license in accordance with applicable DODGAR requirements. The recipient grants to the Government all necessary and appropriate licenses as a condition of this award. Technical reports shall include Distribution Statement A on the cover page, which is unlimited distribution.

b. Non-releasable information. If the technical report contains information such as proprietary data that is not to be released to the public, include all such information in a separate attachment to the report. Coordinate with the Grants Officer's Representative for obtaining government approval to mark data as proprietary. Once final approval is received by the USAMRAA Grants Officer, mark the cover page of the attachment as "Proprietary" and include Distribution Statement B. **DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.** The recipient shall maintain records sufficient to justify the validity of any restrictive markings. The Government has the right to review and challenge the validity of any restrictive

markings. REPORTS NOT PROPERLY MARKED WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE.

c. For additional information regarding distribution statements, see DOD Instruction 5230.24 (available at <http://www.dtic.mil/whs/directives>).

## **PATENTS AND INVENTIONS REPORTING REQUIREMENTS**

a. iEdison and annual reporting. The recipient shall electronically file Invention Disclosures and Patent Applications using the Interagency Edison (iEdison) system through the National Institutes of Health (<https://s-edison.info.nih.gov/iEdison>) within the times specified for reporting. In addition, inventions made during the year shall also be reported annually (within 30 days of the anniversary date of the award) on a DD Form 882, "Report of Inventions and Subcontracts." The report shall be sent electronically to [Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil). If there are no inventions during the year, no annual DD Form 882 is required. The DD Form 882 can be accessed at <https://www.usamraa.army.mil>.

b. Closeout report. A final DD Form 882 is required. The form shall be submitted electronically to [Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil) within 90 days of end of the term of award and shall list all inventions made during the term of the award, or state "none," as applicable. The award will NOT be closed until all reporting requirements have been met.

## **FINANCIAL REPORTING REQUIREMENTS**

The recipient shall use the Standard Form (SF) 425, "Federal Financial Report," for reporting individual awards. Quarterly and final reports are required for those awards receiving advance payments. Annual and final reports are required for those awards receiving cost reimbursement payments.

The Federal Financial Reporting period end dates fall on the end of the calendar quarter for quarterly reports (3/31, 6/30, 9/30, 12/31), end of the calendar year for annual reports (12/31), and the end date of the term of award for the final report. Reports are due 30 days after the reporting period end date for quarterly and annual reports and 90 days after the end date of the term of the award for the final report.

### **Submission Instructions:**

- a. All SF425 reports must be submitted electronically through the web site <https://www.usamraa.army.mil/pages/sf425>. The form and instructions can be obtained on this site.
- b. Do not report multiple awards on one report. Each award must be reported separately on its own SF425.
- c. Do not combine multiple SF425s into one submission. Each form must be saved as a separate PDF and submitted individually.

## **QUARTERLY TECHNICAL REPORTING REQUIREMENTS**

For each year of the entire performance period of the award, the Principal Investigator (PI) shall submit a Quarterly Technical Progress Report covering research results (positive and negative data) during each of the first three quarters. A Quarterly Technical Progress Report for the fourth quarter is not required, as the Annual Technical Report shall incorporate all four quarters of progress.

The Quarterly Technical Progress Report Format, available on web site <https://www.usamraa.army.mil>, is required. Each item of the report format shall be completed. In accordance with the Program Announcement requirement, an updated Quad Chart, also available on this web site, shall be included with the Quarterly Technical Progress Report.

Quarterly reports are the most immediate and direct contact between the PI and the Grants Officer's Representative (GOR). The reports provide the means for keeping the USAMRMC advised of developments and problems as the research effort proceeds. The reports also provide a measure against which funding decisions are made.

Each report shall be submitted electronically, within 15 days after the end of each quarter, to the Grants Specialist and the GOR at the e-mail addresses specified below. Name your file with your award number, followed by "QtrlyTechProgReport Month Year." If you have questions, contact the GOR.

Grants Specialist E-mail: Thomas.s.winter2.civ@mail.mil

GOR E-mail: [wilbur.w.malloy.civ@mail.mil](mailto:wilbur.w.malloy.civ@mail.mil)

The Quarterly Technical Progress Report shall be brief, factual, and informal, and shall be prepared in accordance with the following:

**(1) FRONT COVER:**

- (a) Award Number:
- (b) Log Number:
- (c) Project Title:
- (d) Principal Investigator Name:
- (e) Principal Investigator Organization and Address:
- (f) Principal Investigator Phone and Email:
- (g) Report Date:
- (h) Report Period:
- (i) Grants Officer's Representative:

**(2) SECTION 1 -- Project Status:**

**(a) Accomplishments:** This may include completion of milestones, objectives, and/or tasks, regulatory approval received, publication of papers, presentations at conferences, filing of intellectual property, etc., for this quarter, followed by date in DD-MM-YYYY. Write salient bullet points to highlight the requested information.

**(b) Reportable Outcomes:** This may include development of a product, prototype, a new methodology, or any other similar items that have resulted from this research. Write salient bullet points to highlight the requested information.

**(c) Progress Details:** Describe each Statement of Work (SOW) task or logical segment of work on which effort was expended during this quarterly reporting period only. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved or problems encountered. A succinct description of the methodology used shall be provided. For an award that includes the recruitment of human subjects for clinical research or a clinical trial, (i) report progress on subject recruitment, screening, enrollment, completion, and numbers of each compared to original planned target(s) (e.g., number of subjects enrolled versus total number proposed), (ii) report amendments submitted to the IRB and USAMRMC HRPO for review, and (iii) report any adverse events.

**(3) SECTION 2 -- Future Plans:** Present a brief statement of plans or milestones for the next quarter. If any of the plans deviate from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.), they will require review by the GOR and final approval by the USAMRAA Grants Officer through an award modification prior to initiating any changes.

**(4) SECTION 3 -- Problems/Issues:** Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) will require review by the GOR and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.



**(a) Current Problems/Issues:** Provide a description of current problems or issues that may impede performance or progress of this project, along with proposed corrective actions. This may include administrative, technical, and/or logistical issues. For an award that includes the recruitment of human subjects for clinical research or a clinical trial, discuss any problems or barriers encountered, if applicable, and what has been done to mitigate those issues. Discussion may highlight enrollment problems or retention problems, and actions taken to increase enrollment and/or improve retention.

**(b) Anticipated Problems/Issues:** Provide a description of anticipated problems or issues that have a potential to impede performance or progress and what corrective action is planned should the problem materialize.

**(5) SECTION 4 – Financial Health:** Comment on the financial health of the study. Was the study financially on track during this quarterly reporting period and cumulatively for completion as proposed within the period of performance? If not, describe the causes, whether this will have a short-term or long-term impact, the likelihood this can be overcome, and provide remediation strategy. Provide amount expended this quarter and cumulatively. State if there was any major equipment procured, sub-award implemented, and/or travel conducted.

**(6) SECTION 5 – Personnel Effort:** Provide names of current key personnel, along with their roles and percent effort of each on this project. Add additional rows if necessary to list the complete team. If there is more than one project on this award, break down according to each project (one table per project).

**(7) SECTION 6 – Protocol and Activity Status:** For awards involving the use of human subjects, use of human cadavers, and/or use of animal subjects, prepare a summary in accordance with the following subsections. For all other awards, including those involving the use of human anatomical substances (such as tissue or cells or identifiable private information), mark as directed below.

**(a) Human Use Regulatory Protocols**

**TOTAL PROTOCOLS:** State the total number of human use protocols required to complete this project (e.g., “5 human subject research protocols will be required to complete the Statement of Work”). If not applicable, write “No human subjects research will be performed to complete the Statement of Work.”

**PROTOCOLS:** List all human use protocols to be performed to complete the project, and include approved target number for clinical significance, followed by type of submission and type of approval with associated dates, and performance status.

The following format shall be used:

**Protocol 1:** [Human Research Protection Office (HRPO) assigned A-number]

**Title:**

**Targets required and approved for clinical significance:**

**Submitted to and Approved by:** Provide a bullet point list of protocol development, submission, amendments, and approvals (include IRB in addition to HRPO).

**Status:** Provide bullet point list of performance and / or progress status relating to the above protocol and discuss recruitment number, enrollment number, and issues that may impact performance or progress of the study (e.g., slow enrollment, large dropouts, or adverse events) for the above HRPO approved protocol.

**(b) Use of Human Cadavers for RDT&E, Education or Training**

“Cadaver” is defined as a deceased person or portion thereof, and is synonymous with the terms “human cadaver” and “post-mortem human subject” or “PMHS.” The term includes organs, tissue, eyes, bones, arteries or other specimens obtained from an individual upon or after death. The term “cadaver” does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a “cadaver” under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

**TOTAL ACTIVITIES:** State the total number of RDT&E, education or training activities that will involve cadavers. If not applicable, write “No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).”

**ACTIVITIES:** Provide the following information in a bulleted list for all RDT&E, education or training activities involving human cadavers conducted or supported during the quarter:

- Title of the RDT&E, education or training activity
- SOW task/aim associated with the activity
- Date the activity was conducted
- Identification of the organization’s responsible individual (e.g., PI or individual primarily responsible for the activity’s conduct)
- Brief description of the use(s) of cadavers in the activity and the total number of cadavers used during the reporting period
- Brief description of the Department of Army organization’s involvement in the activity
- Status of document submission and approvals
- Problems encountered in the procurement, inventory, use, storage, transfer, transportation and disposition of cadavers used for RDT&E, education or training. Examples of problems include but are not limited to: loss of confidentiality of cadaveric donors, breach of security, significant deviation from the approved protocol, failure to comply with state laws and/or institutional policies and public relations issues.

**(c) Animal Use Regulatory Protocols**

**TOTAL PROTOCOLS:** State the total number of animal use protocols required to complete this project (e.g., “2 animal use research protocols will be required to complete the Statement of Work”). If not applicable, write “No animal use research will be performed to complete the Statement of Work.”

**PROTOCOLS:** List all animal use protocols to be performed to complete the project. Include the approved target number for statistical significance, followed by type of submission and type of approval with associated dates, and performance status for each.

The following format shall be used:

***Protocol 1:*** [Animal Care and Use Review Office (ACURO) assigned Number]:

***Title:***

***Targets required and approved for statistical significance:***

***Submitted to and Approved by:*** Provide a bullet point list of protocol development, submission, amendments, and approvals (include Institutional Animal Care and Use Committee (IACUC) in addition to ACURO).

***Status:*** Provide a bullet point list of performance and/or progress status relating to the above protocol and discuss any administrative, technical, or logistical issues that may impact performance or progress of the study (e.g., animal use protocol needs revision to minimize animal suffering, animal protocol modification to include additional staff) for the above ACURO approved protocol.

**TECHNICAL REPORTING REQUIREMENTS**

Format Requirements for Annual/Final Reports

a. Annual reports shall provide a complete summary of the research results (positive or negative) to date in direct alignment to the approved Statement of Work. Journal articles can be substituted for detailed descriptions of specific aspects of the research, but the original articles shall be attached to the report as an appendix and

appropriately referenced in the text. The importance of the report to decisions relating to continued support of the research cannot be over-emphasized. An annual report shall be submitted within 30 calendar days of the anniversary date of the award for the preceding 12 month period. If the award period of performance is extended by the USAMRAA Grants Officer, then an annual report shall still be submitted within 30 days of the anniversary date of the award. A final report will be due upon completion of the extended performance date that describes the entire research effort.

b. A final report summarizing the entire research effort, citing data in the annual reports and appended publications shall be submitted within 90 calendar days of the award performance end date. The final report shall provide a complete reporting of the research findings. Journal publications can be substituted for detailed descriptions of specific aspects of the research, but an original copy of each publication shall be attached as an appendix and appropriately referenced in the text. All final reports shall include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort.

Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the accomplishments with respect to the approved SOW. Submission of the report in electronic format (PDF or Word file only), shall be submitted to <https://ers.amedd.army.mil>.

All reports shall have the following elements in this order:

**FRONT COVER:** Sample front cover is provided at [https://mrmc.amedd.army.mil/index.cfm?pageid=researcher\\_resources.technical\\_reporting](https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting). The Accession Document (AD) Number should remain blank.

**MARKING OF PROPRIETARY INFORMATION:** Data that was developed partially or exclusively at private expense shall be marked as "Proprietary Data" and Distribution Statement B included on the cover page of the report. Federal government approval is required before including Distribution Statement B. The recipient/PI shall coordinate with the GOR to obtain approval. **REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE.** It is the responsibility of the Principal Investigator to advise the GOR when restricted limitation assigned to a document can be downgraded to "Approved for Public Release." **DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.** See term entitled "Intangible Property – Data and Software Requirements" and [https://mrmc.amedd.army.mil/index.cfm?pageid=researcher\\_resources.technical\\_reporting](https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting) for additional information.

**STANDARD FORM 298:** Sample SF 298 is provided at [https://mrmc.amedd.army.mil/index.cfm?pageid=researcher\\_resources.technical\\_reporting](https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting). The abstract shall be provided in Block 14 and shall state the purpose, scope, and major findings and be an up-to-date report of the progress in terms of results and significance. Abstracts will be submitted to the Defense Technical Information Center (DTIC) and shall not contain proprietary information. Subject terms are keywords that may have been previously assigned to the proposal abstract or are keywords that may be significant to the research. The number of pages shall include all pages that have printed data (including the front cover, SF 298, table of contents, and all appendices). Count pages carefully to ensure legibility and that there are no missing pages as this delays processing of reports. Page numbers shall be typed; do not hand number pages.

**TABLE OF CONTENTS:** Sample table of contents is provided at [https://mrmc.amedd.army.mil/index.cfm?pageid=researcher\\_resources.technical\\_reporting](https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting).

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.
2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).
3. **OVERALL PROJECT SUMMARY:** Summarize the progress during appropriate reporting period (single annual or comprehensive final). This section of the report shall be in direct alignment with

respect to each task outlined in the approved SOW in a summary of Current Objectives, and a summary of Results, Progress and Accomplishments with Discussion. Key methodology used during the reporting period, including a description of any changes to originally proposed methods, shall be summarized. Data supporting research conclusions, in the form of figures and/or tables, shall be embedded in the text, appended, or referenced to appended manuscripts. Actual or anticipated problems or delays and actions or plans to resolve them shall be included. Additionally, any changes in approach and reasons for these changes shall be reported. **Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) requires review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.**

4. **KEY RESEARCH ACCOMPLISHMENTS:** Bulleted list of key research accomplishments emanating from this research. Project milestones, such as simply completing proposed experiments, are not acceptable as key research accomplishments. Key research accomplishments are those that have contributed to the major goals and objectives and that have potential impact on the research field.
5. **CONCLUSION:** Summarize the importance and/or implications with respect to medical and /or military significance of the completed research including distinctive contributions, innovations, or changes in practice or behavior that has come about as a result of the project. A brief description of future plans to accomplish the goals and objectives shall also be included.
6. **PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:**
  - a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry shall include the author(s), article title, journal name, book title, editors(s), publisher, volume number, page number(s), date, DOI, PMID, and/or ISBN.
    - (1) Lay Press:
    - (2) Peer-Reviewed Scientific Journals:
    - (3) Invited Articles:
    - (4) Abstracts:
  - b. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.
7. **INVENTIONS, PATENTS AND LICENSES:** List all inventions made and patents and licenses applied for and/or issued. Each entry shall include the inventor(s), invention title, patent application number, filing date, patent number if issued, patent issued date, national, or international.
8. **REPORTABLE OUTCOMES:** Provide a list of reportable outcomes that have resulted from this research. 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. This list may include development of prototypes, computer programs and/or software (such as databases and animal models, etc.) or similar products that may be commercialized.
9. **OTHER ACHIEVEMENTS:** This list may include degrees obtained that are supported by this award, development of cell lines, tissue or serum repositories, funding applied for based on work supported by this award, and employment or research opportunities applied for and/or received based on experience/training supported by this award.

For each section, 4 through 9, if there is no reportable outcome, state "Nothing to report."
10. **REFERENCES:** List all references pertinent to the report using a standard journal format (i.e., format used in *Science, Military Medicine*, etc.)

11. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Pages shall be consecutively numbered throughout the report. **DO NOT RENUMBER PAGES IN THE APPENDICES.**

**NOTE:**

**TRAINING OR FELLOWSHIP AWARDS:** For training or fellowship awards, in addition to the elements outlined above, include a brief description of opportunities for training and professional development. Training activities may include, for example, courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.

**COLLABORATIVE AWARDS:** For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

**QUAD CHARTS:** If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

**DELINQUENT REPORTS**

If the recipient is delinquent on reporting requirements for other USAMRAA-sponsored awards, payments on this award may be withheld until acceptable delinquent reports have been submitted.

**INTERIM PROGRESS REVIEW**

In addition to quarterly, annual, and final technical progress reports, the PI shall prepare for and participate in at least one Interim Progress Review (IPR) for each year of the project's term of award. Generally, the IPR will last no longer than two days and require no more than two overnight stays. It most likely will be held in the Fort Detrick, Maryland area, but may occur elsewhere in the U.S. The invitation and format for the IPR will be provided by the GOR at least 90 days prior to the scheduled date. Participation in the IPR will be in lieu of submitting the next scheduled quarterly technical progress report.

**MANUSCRIPTS/REPRINTS**

Copies of manuscripts or subsequent reprints resulting from the research shall be submitted to the GOR at [usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil).

**REQUEST FOR ADVANCE PAYMENTS WITH FULL FUNDING**

a. Payments. Advance payments will be made to the recipient upon receipt of a grant voucher submitted through Wide Area Work Flow (WAWF) in accordance with the Contract Line Item Number (CLIN) structure set forth in this award. It is anticipated that Defense Finance and Accounting Service (DFAS) will disburse funds within 30 days of receipt of a proper grant voucher.

b. **A copy of the most recently submitted Federal Financial Report (SF 425) shall be attached in WAWF and submitted with each grant voucher for all grant voucher submissions subsequent to the initial grant voucher submission.**

c. Electronic Funds Transfer (EFT). All payments will be made by EFT to the recipient's financial institution account listed in the System for Award Management (SAM) (located at <https://www.sam.gov>). Failure to update SAM and ensure your account is in an active status will result in nonpayment.

d. If the recipient fails to perform or if the WAWF grant voucher submission does not have the most recent SF425 attached, the grant voucher will be rejected.

e. Interest Bearing Account. Unless exempted by applicable Treasury-State agreements in accordance with the Cash Management Improvement Act (CMIA) (31 U.S.C. 3335), the recipient shall deposit all advance payments into an interest bearing account. Interest over the amount of \$250 per year shall be remitted annually to the U.S. Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, Maryland 20852. A copy of the transmittal letter stating the amount of interest remitted shall be sent electronically to Usarmy.detrick.medcom-[Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil).

f. Request Schedule for Advances

Year One \$1,458,866

<u>Amount</u>	<u>Grant Voucher Submission Periods</u>	<u>CLIN/Subclin</u>
\$364,716	2013/09/30 – 2013/12/29	(CLIN 0001)
\$364,716	2013/12/30 – 2014/03/29	(CLIN 0001)
\$364,717	2014/03/30 – 2014/06/29	(CLIN 0001)
\$364,717	2014/06/30 – 2014/09/29	(CLIN 0001)

**NOTE: This award is comprised of a clinical study or trial that requires Human Use approval from the USAMRMC Office of Research Protection (ORP). Grant vouchers may be submitted for payments scheduled for the first 12 months of this award. No grant vouchers may be submitted thereafter until the recipient provides a copy of the ORP approval notification to the cognizant Grants Specialist ([Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:Usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil)).**

Year Two \$1,257,878

<u>Amount</u>	<u>Grant Voucher Submission Periods</u>	<u>CLIN/Subclin</u>
\$314,469	2014/09/30 – 2014/12/29	(CLIN 0001)
\$314,469	2014/12/30 – 2015/03/29	(CLIN 0001)
\$314,470	2015/03/30 – 2015/06/29	(CLIN 0001)
\$314,470	2015/06/30 – 2015/09/29	(CLIN 0001)

Year Three \$1,381,485

<u>Amount</u>	<u>Grant Voucher Submission Periods</u>	<u>CLIN/Subclin</u>
\$345,371	2015/09/30 – 2015/12/29	(CLIN 0001)
\$345,371	2015/12/30 – 2016/03/29	(CLIN 0001)
\$345,371	2016/03/30 – 2016/06/29	(CLIN 0001)
\$345,372	2016/06/30 – 2016/09/29	(CLIN 0001)

## ELECTRONIC PAYMENT INSTRUCTIONS

**Wide Area Work Flow (WAWF) is the required method to electronically process recipient requests for payments.** WAWF allows DOD recipients to submit and track grant vouchers electronically.

Recipients shall (i) register to use WAWF at <https://wawf.eb.mil> and (ii) ensure an electronic business point of contact (POC) is designated in the System for Award Management (SAM) site at

<https://www.sam.gov> within ten (10) calendar days prior to requesting a payment for this award.

Questions concerning specific payments should be directed to the Defense Finance and Accounting Service (DFAS) Indianapolis at 1-888-332-7366. You can also access payment and receipt information using the DFAS web site at <http://www.dfas.mil/dfas/contractorsvendors.html>. The award number or grant voucher number will be required to inquire about the status of the payment.

**The following codes and information are required to initiate the grant voucher and assure successful flow of WAWF documents.**

TYPE OF DOCUMENT: **Grant Voucher**

CAGE CODE: **1DQV3**

ISSUE BY DODAAC: **W81XWH**

ADMIN BY DODAAC: **W81XWH**

INSPECT BY DODAAC: **W81XWH**

ACCEPT BY DODAAC: **W81XWH**

SHIP TO DODAAC: **W81XWH**

LOCAL PROCESSING OFFICE DODDAC: **Not Applicable**

PAYMENT OFFICE FISCAL STATION CODE: **HQ0490**

EMAIL POINTS OF CONTACT LISTING:

INSPECTOR: **usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil**

ACCEPTOR: **usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil**

RECEIVING OFFICE POC: **usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil**

GRANT ADMINISTRATOR:

GRANTS OFFICER:

ADDITIONAL CONTACT: **usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil**

**Additional Instructions for Advance Payments Only:**

For successful processing of the grant voucher, requests for advances must be submitted **in advance of the start date** of the quarter being billed. Requests can be submitted up to 30 days in advance of the start date of the quarter, but cannot be submitted in excess of 30 days of the start date of the quarter.

In the fields entitled "Period From Date" and "Period To Date," enter the complete quarterly period being billed (e.g., 2013/04/01 through 2013/06/30). Quarterly dates entered must be identical to the quarterly "Grant Voucher Submission Periods" shown in the "Request for Advance Payments" term in this award.

In the event that the grant voucher is submitted **after the start date** of the quarter being billed, enter the date the voucher is being submitted in the field entitled "Period From Date." **Additionally**, in the "Initiator" section in the "Comments" field, **you are required by DFAS to** enter the actual beginning and ending dates of the quarter being billed as shown in the "Request for Advance Payments" term, "Grant Voucher Submission Periods."

**AWARD CLOSE OUT**

- a. The following documents shall be submitted within 90 calendar days of the end of the term of the award:

- (1) Final SF425, "Federal Financial Report." Submit to: <https://www.usamraa.army.mil/pages/sf425>. Form and instructions are available on the web site.
  - (2) Final Technical Report. Submit to <https://ers.amedd.army.mil>.
  - (3) Final DD Form 882, "Report of Inventions and Subcontracts" (form available on web site <https://www.usamraa.army.mil>). Submit to [usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil).
  - (4) Cumulative listing of only the nonexpendable personal property acquired with award funds for which title has not been vested to the recipient, if applicable. This may be submitted on institution letterhead. Submit to [usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil).
  - (5) Statement that there is or is not a residual inventory of unused supplies exceeding \$5,000 in total aggregate value. This may be submitted on institution letterhead. Submit the statement to [usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil](mailto:usarmy.detrick.medcom-usamraa.mbx.aa4@mail.mil).
- b. In the event a final audit has not been performed prior to the closeout of the award, the sponsoring agency retains the right to recover an appropriate amount after fully considering the recommendations on disallowed costs resulting from the final audit.
  - c. The recipient shall promptly refund any unspent balances of funds the DoD Component has paid that is not authorized to be retained by the recipient. **Make check payable to the U.S. Treasury and mail to:**

USAMRAA  
Attn: MCMR-AAP-C  
Award No. W81XWH-13-2-0080  
820 Chandler Street  
Fort Detrick, Maryland 21702-5014

(End of Summary of Changes)