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Award Number: W81XWH-11-1-0749

TITLE: New York Medical College Bioterrorism: CDM Disaster Medicine and Emerging Infections Training Center

PRINCIPAL INVESTIGATOR: David Markenson, MD

CONTRACTING ORGANIZATION: New York Medical College, Valhalla, NY 10595

REPORT DATE: October 2013

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				<i>Form Approved</i> <i>OMB No. 0704-0188</i>	
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INTRODUCTION:

This project supports training that focuses on emergency operations center roles and functions, hospital decontamination capacity, emergency preparedness and terrorism operations, and public health emergency management training to be delivered to local responders, health care agencies, public health departments and available to both staff at Keller Army Hospital and the Cadet Medical Intervention Team at the US Military Academy at West Point. The pilot training program developed in this program will be delivered to the target groups (local responders, health care agencies, public health departments and available to both staff at Keller Army Hospital and the Cadet Medical Intervention Team at the US Military Academy at West Point). Pre and post course cognitive, affective, and psychomotor evaluations will be performed to determine the effectiveness of the instructional content and delivery method. The results will guide our center in creating more targeted and effective training programs in these critical areas in the future.

BODY:

As defined in the original grant submission year one would be predominantly devoted to Goal 1 which is listed below for reference. Goal 1 is targeted at assessing baseline and developing draft course type, outline and objective. In addition year one is devoted to identifying partners and target audience for course pilots. Due this first year being project infrastructure creation, baseline and initial draft development with review of drafts and finalization not occurring until 1st quarter year two, there were no specific deliverables or publically distributable outcomes planned for year one.

Goal 1: Design curricula and course materials for two pilot training programs consistent with recent regional needs assessments for the public health and disaster medical response to CBRNE events and public health emergencies.

Timeline and Activities:

Month 1-4:

- Review of existing NYMC disaster educational needs assessment (initially performed 2007 and updated annually). Review of existing courses and reference materials for possible inclusion in courses to be developed.
- Preliminary identification of training partners and possible courses based on educational needs assessment data.
- Development of expert advisory group to help provide input and feedback on course creation

Month 4-6:

- Final identification of 2 pilot courses to be created from possible list created. Courses to be classroom delivered using combination of lecture and multimedia presentation and delivered in 8 hours to include lunch and break periods.

- Identification of appropriate educational competencies for each of 2 courses.
- Draft of overarching learning objectives.

Months 6-8: Development of learning objectives for all three domains of learning (cognitive, affective, and psychomotor) for each course; Draft course content outline for each course including solicitation of external input from advisory board.

Months 8-14: Review and finalization of course content; Identification of delivery method(s); Drafting of course materials including external review from advisory board.

For Goal 1 the following the tasks which have been completed in Year 1 are as follows:

- Review of existing NYMC disaster educational needs assessment (initially performed 2007 and updated annually). Review of existing courses and reference materials for possible inclusion in courses to be developed.
- Preliminary identification of training partners and possible courses based on educational needs assessment data.
- Development of expert advisory group to help provide input and feedback on course creation
- Final identification of 2 pilot courses to be created from possible list created. Courses to be classroom delivered using combination of lecture and multimedia presentation and delivered in 8 hours to include lunch and break periods.
- Identification of appropriate educational competencies for each of 2 courses.
- Draft of overarching learning objectives.

As described in our No Cost Extension request which was approved for several reasons and to the benefit of the project and 18 month extension was requested and granted. This resulted in the following changes in goals and milestones.

Goal	Current Grant Period	Y1Q1	Y1Q2	Y1Q3	Y1Q4	Y2Q1	Y2Q2	Status
1								Partially completed during current grant period and will complete during extension.
2								Will complete during extension period
3								Will complete during extension period
4								Will complete during extension period
5								Will complete during extension period

Note: Yellow represents delayed activities for original grant period. Green represents old activities underway and blue represents activities to be started and completed during extension period.

Goal 1: Design curricula and course materials for two pilot training programs consistent with recent regional needs assessments for the public health and disaster medical response to CBRNE events and public health emergencies.

Timeline and Activities to be completed during extension period:

Month 1-3:

- Review of Changes in national courses to include BDLS, ADLS, TEEX PER-211, Medical Preparedness and Response to Bombing Incidents and Pediatric Preparedness to determine if update needed in our prior created educational gap analysis. Also to determine if these programs contain items or concepts which would warrant inclusion in the courses we are developing and or change the courses or content of the courses we have planned to develop.
- Additional Review of existing and updated NYMC courses and reference materials for possible inclusion in courses to be developed.
- Review of updated National Response Plan and developed National Response Framework to determine if these programs contain items or concepts which would warrant inclusion in the courses we are developing and or change the courses or content of the courses we have planned to develop.

Month 3-5:

- Re-assessment of 2 pilot courses chosen and possible new pilot course choice based on additional reviews.
- Determination of new or altered educational competencies for each of 2 courses are needed and if needed creation of them.
- Updated draft of overarching learning objectives.
- Re assessment and as needed modification of learning objectives for all three domains of learning (cognitive, affective, and psychomotor) for each course; Update as needed draft course content outline for each course including solicitation of external input from advisory board.
- Review and finalization of updated course content; final evaluation and identification of delivery method(s); Drafting of course materials including external review from advisory board.

Goal 2: Pilot courses in health care setting to target audience.

Timeline and Activities to be completed during extension period:

Months 6-8:

- Identification of pilot sites and audiences
- Draft of evaluation tool; training of instructors; preparation of course materials.

Months 8-11:

- Delivery of a minimum 2 pilot courses for each course developed
- Collection and analysis of assessment data
- Preliminary review of findings and determination of next steps/improvement planning.

Goal 3: Evaluate cognitive, affective and psychomotor knowledge and learning pre and post course delivery to determine if baseline level knowledge has been increased in the workforce.

Timeline and Activities to be completed during extension period:

Months 11-15:

- Delivery of a minimum 2 pilot courses for each course developed
- Collection and analysis of assessment data; preliminary review of findings and determination of next steps/improvement planning.

Goal 4: Revise course content and delivery methods based on empirical data.

Timeline and Activities to be completed during extension period:

Months 16-17:

- Review of pilot data with advisory board to determine if modifications needed
- Revision of 2 course as needed

Goal 5: Preparation and Submission to TATRC of Final Deliverable

Timeline and Activities to be completed during extension period:

Months 17-18:

- Draft of final report of results of evaluation of cognitive, affective and psychomotor knowledge and learning pre and post course delivery.
- Submission of final report to TATRC.

KEY RESEARCH ACCOMPLISHMENTS:

- Developed research team and advisors
- Initial list of possible target course delivery locations and audiences
- Reviewed multiple national and local existing course for possible models and to avoid duplication
- Draft course target topics and objectives developed

REPORTABLE OUTCOMES:

As the first period of this grant was the development of the research team, obtaining baseline data and surveying existing programs, defining targets and developing draft course topics and outlines, there are no reportable outcomes. The second year was the beginning in of work on original Goals #2 and 3 and has been modified as above.

CONCLUSION:

The first two years of this project has been exceptionally helpful in developing our infrastructure. In addition the evaluation of our past gap analysis and national assessment of existing programs has helped to focus our efforts to course creation of a program which addresses the needs of our region and builds on existing excellent program with the addition our materials. Furthermore the modified plan approved in the No Cost Extension we feel will further enhance the project. We look forward to the completion of this project in this coming grant period to include the extension period..

REFERENCES:

Not applicable for this report

APPENDICES:

No Cost Extension Request

August 12, 2013

Gay Hayden
Grants Specialist
US Army Medical Research Acquisition Activity

Manja Lenkin
Contracting/Grants Officer Representative
TATRC West

On behalf of the New York Medical College Center for Disaster Medicine, I am respectfully requesting an 18 month no-cost extension. In order to develop this request, we have considered the work currently completed and tasks which remain, the benefits of a no cost extension and the time required to maximize the quality of the project and of the outcome.

As we have discussed with the Contracting/Grants Officer Representative TATRC West, there are several reasons which has both convinced us of the need for this extension and which in our evaluation justify this extension. These reasons are:

1. **Allow us to leverage skills of changed and enhanced staff** – As discussed on our previous quarterly reports a key center staff member Dr. Michael Reilly had left the center but has now returned. His expertise in disaster medicine and disaster medicine education will truly enhance both our evaluation of existing programs and development of our programs.
2. **New and changed national courses** – At that time when we conducted our initial evaluation of national courses to determine both the standard for disaster medicine and where gaps would exist, the AMA NDLS suite of programs was in its second edition and the DHS TEEX programs were not scheduled for revision. Since that time all NDLS courses including BDLS and ADLS have had major revisions with release of the 3rd editions and the TEEX programs have been revised including a new program on response to bombing incidents and the beginning development of a pediatric course. While a revision was anticipated in our original program plan, one could not have foreseen this timing of revision and creation of new programs. These programs existence and/or revision both alter our baseline assessment of national standards and existing educational gaps. As such a critical evaluation of all of these programs is essential for the creation of quality programs and also to evaluate whether a change is warranted in either the programs we plan to develop or the content of those programs.
3. **Incorporation of revised national response plan and discussion of new national recovery framework** – Since the submission of our proposal and the beginning of our project to major changes have occurred, revision and additions to the national response plank and

the development of the national recovery framework. An educational program would not in our view be complete without inclusion of these new and changed items. As such additional time is required for evaluation of these items and inclusion as appropriate in the educational programs we will be developing.

The remaining unspent balance for this contract is \$81,865.63 and it is anticipated that the full funds will be needed for completion of the added and remaining tasks.

The tasks to be performed during this period and milestones are listed below and represent the completion of all remaining tasks, repeating of certain tasks as justified above and the addition of new tasks. The new tasks being review of new and changed programs listed above as items 2 and 3, incorporation as appropriate of these programs and concepts into our course development, resources and if needed change in target courses to develop.

Goal	Current Grant Period	Y1Q1	Y1Q2	Y1Q3	Y1Q4	Y2Q1	Y2Q2	Status
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2								Will complete during extension period
3								Will complete during extension period
4								Will complete during extension period
5								Will complete during extension period

Note: Yellow represents delayed activities for original grant period. Green represents old activities underway and blue represents activities to be started and completed during extension period.

Goal 1: Design curricula and course materials for two pilot training programs consistent with recent regional needs assessments for the public health and disaster medical response to CBRNE events and public health emergencies.

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- Review of Changes in national courses to include BDLS, ADLS, TEEX PER-211, Medical Preparedness and Response to Bombing Incidents and Pediatric Preparedness to determine if update needed in our prior created educational gap analysis. Also to determine if these programs contain items or concepts which would warrant inclusion in the courses we are developing

and or change the courses or content of the courses we have planned to develop.

- Additional Review of existing and updated NYMC courses and reference materials for possible inclusion in courses to be developed.
- Review of updated National Response Plan and developed National Response Framework to determine if these programs contain items or concepts which would warrant inclusion in the courses we are developing and or change the courses or content of the courses we have planned to develop.

Month 3-5:

- Re-assessment of 2 pilot courses chosen and possible new pilot course choice based on additional reviews.
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- Re assessment and as needed modification of learning objectives for all three domains of learning (cognitive, affective, and psychomotor) for each course; Update as needed draft course content outline for each course including solicitation of external input from advisory board.
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Goal 5: Preparation and Submission to TATRC of Final Deliverable

Timeline and Activities to be completed during extension period:

Months 17-18:

- Draft of final report of results of evaluation of cognitive, affective and psychomotor knowledge and learning pre and post course delivery.
- Submission of final report to TATRC.

We appreciate your review of this request for a no-cost extension and look forward to your approval. We feel this project will be enhanced and we will be able to produce improved courses based on this additional time. If you have any additional questions or require additional information please feel free to contact me (david_markenson@nymc.edu) or the Center Director, Dr. Michael Reilly (Michael_reilly@nymc.edu) at 914-594-4909.

Sincerely,



David Markenson, MD
Center for Disaster Medicine
New York Medical College



Catharine Crea
Associate Dean for Research Admin
New York Medical College

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE S		PAGE OF PAGES 1 14	
2. AMENDMENT/MODIFICATION NO. P00001		3. EFFECTIVE DATE 23-Sep-2013		4. REQUISITION/PURCHASE REQ. NO. W23RYX1137N612		5. PROJECT NO.(If applicable)	
6. ISSUED BY USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014		CODE W81XWH		7. ADMINISTERED BY (If other than item 6) US ARMY MEDICAL RESEARCH ACQUISITION ACT ATTN: GAY HAYDEN GAY.C.HAYDEN.CIV@MAIL.MIL 301-619-9883 FORT DETRICK MD 21702		CODE W81XWH	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) NEW YORK MEDICAL COLLEGE 40 SUNSHINE COTTAGE RD VALHALLA NY 10595-1690				9A. AMENDMENT OF SOLICITATION NO.			
				9B. DATED (SEE ITEM 11)			
				X 10A. MOD. OF CONTRACT/ORDER NO. W81XWH-11-1-0749			
				X 10B. DATED (SEE ITEM 13) 12-Sep-2011			
CODE 4B851		FACILITY CODE					
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS							
☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ 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)							
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.							
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) USAMRAA T&Cs							
E. IMPORTANT: Contractor ☒ is not, ☐ 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: ghayden136376 Principal Investigator: Dr. David Markenson Proposal No.: 11294006 Proposal Title: "New York Medical College Bioterrorism: CDM Disaster Medicine and Emerging Infections Training Center" POP: 12 September 2011 - 11 April 2015 (research ends 11 March 2015) Total Award and Funded Amount: \$115,000.00 The purpose of this modification is to: (1) provide a 18-month no-cost extension (NCE), extending the POP end date to 11 March 2015; (2) make administrative changes to the Award Special Terms and Conditions (see highlighted areas); and (3) replace the term entitled "Prohibition of Use of Human Cadavers." See SUMMARY of CHANGES.							
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) PAMELA L. FISHER / CONTRACTING OFFICER TEL: 301-619-2805 EMAIL: pamelal.fisher.civ@mail.mil			
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA BY <u>Pamela L. Fisher</u> (Signature of Contracting Officer)		16C. DATE SIGNED 23-Sep-2013	

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION 00010 - SOLICITATION CONTRACT FORM

CLIN 0001

The CLIN extended description has changed from Period of Performance: 12 September 2011 - 11 October 2013 (research ends 11 September 2013) to Period of Performance: 12 September 2011 - 11 April 2015 (research ends 11 March 2015).

DELIVERIES AND PERFORMANCE

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
POP 12-SEP-2011 TO 11-OCT-2013	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	UIC
POP 12-SEP-2011 TO 11-APR-2015	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

SECTION 00800 - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

A. 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 and the budget of the proposal dated 03 March 2011 are incorporated herein by reference. The Catalog of Federal Domestic Assistance Number relative to this award is CFDA 12.420.

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

C. USAMRAA GENERAL TERMS AND CONDITIONS: This assistance agreement is subject to the USAMRAA General Terms and Conditions and to any special considerations as contained in the below mentioned Section titled "Special Terms and Conditions". These USAMRAA General Terms and Conditions are incorporated by reference with the same force and effect as if they were given in full text. The full text of the USAMRAA General Terms and Conditions may be accessed electronically at <http://www.usamraa.army.mil>.

D. SPECIAL TERMS AND CONDITIONS

1. TECHNICAL REPORTING REQUIREMENTS (DEC 2008) (USAMRAA)

PROGRAMMATIC LINE REVIEW (PLR)

a. The reporting requirements for Telemedicine and Advanced Technology Research Center (TATRC) include quarterly, annual and final reports and the Principal Investigator's (PI's) participation in at least one programmatic line review (PLR) for this project each year of the project's period-of-performance.

b. The PI shall prepare for and participate in at least one PLR for this project for each year of the project's term, at the Grants Officer's Representative's (GOR's) request. The invitation and format for the programmatic review will be provided by TATRC at least 90 days prior to the meeting. The meetings will generally be held in the Fort Detrick, Maryland, area, but may occur elsewhere in the U.S. Participation in the PLR will be in lieu of submitting next scheduled Quarterly report required under the award.

QUARTERLY REPORTS

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

b. In accordance with Section C., a Quarterly Report shall be submitted for each three-month period beginning with the effective date of the assistance agreement. This requirement includes all three-month periods of the assistance agreement.

c. Copies of each report shall be submitted in the quantities indicated to the addresses shown below within fifteen (15) days after the end of each quarter. Internal Government distribution will be made by those offices (electronic submission preferred).

(1) One (1) copy of the report to:

Email: manja.lenkin@tatrc.org

(2) One (1) copy of the report to:

Email: gay.c.hayden.civ@mail.mil

d. The Quarterly Report sample (See following Quarterly Report Format) shall serve as the format. Each item of the report format shall be completed.

QUARTERLY REPORT FORMAT

1. Award No. _____ 2. Report Date _____

3. Reporting period from _____ to _____

4. PI _____ 5. Telephone No. _____

6. Institution _____

7. Project Title _____

8. Current staff, with percent effort of each on project.

_____ % _____ %

_____ % _____ %

9. Award expenditures to date (as applicable):

This Qtr/Cumulative**This Qtr/Cumulative**

Personnel _____ / _____ Travel _____ / _____

Fringe Benefits _____ / _____ Equipment _____ / _____

Supplies _____ / _____ Other _____ / _____

This Qtr/Cumulative

Subtotal _____ / _____

Indirect Costs _____ / _____

Fee _____ / _____

Total _____ / _____

10. Comments on administrative and logistical matters.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this assistance agreement.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

1. TECHNICAL REPORTING REQUIREMENTS (DEC 2008) (USAMRAA)

Format Requirements for Annual/Final Reports

a. Annual reports must provide a complete summary of the research accomplishments to date with respect to the approved Statement of Work. Journal articles can be substituted for detailed descriptions of specific aspects of the research, but the original articles must 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 can not 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 Grants Officer, then an annual report must 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 at the end of the award performance period. The final report will 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 must be attached as an appendix and appropriately referenced in the text. All final reports must 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 Statement of Work. 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 provided at <https://mrmc.amedd.army.mil/rpindex.asp>. The Accession Document (AD) Number should remain blank.

STANDARD FORM 298: Sample SF 298 provided at <https://mrmc.amedd.army.mil/rpindex.asp>. The abstract in Block 13 must state the purpose, scope, major findings and be an up-to-date report of the progress in terms of results and significance. Subject terms are keywords that may have 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). Please count pages carefully to ensure legibility and that there are no missing pages as this delays processing of reports. Page numbers should be typed: please do not hand number pages.

TABLE OF CONTENTS: Sample table of contents provided at <https://mrmc.amedd.army.mil/rpindex.asp>.

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

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the

Army Grants Officer's Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include:

manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; informatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award.

CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

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

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.

Mark all pages of the report which contain proprietary or unpublished data that should be protected by the U.S. Government. 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 U.S. Army Medical Research and Materiel Command when restricted limitation assigned to a document can be downgraded to Approved for Public Release. DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.

2. ADVANCE PAYMENTS AND FULL FUNDING (APRIL 2011) (USAMRAA)

a. Payments. Advance payments will be made to the recipient. Questions relative to payment issues involving Defense Finance and Accounting Service shall be directed to Usarmy.detrick.medcom-ysamraa.mbx.aa1@mail.mil.

b. Electronic Funds Transfer. All advance payments to the recipient will be made by electronic funds transfer (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.

c. If the recipient fails to perform, the Grants Officer shall notify DFAS in writing to withhold payments.

d. Advance Payment Schedule

24 MONTHS - \$115,000

<u>Amount</u>	<u>On or About</u>
\$14,375	12 September 2011
\$14,375	12 December 2011
\$14,375	12 March 2012
\$14,375	12 June 2012
\$14,375	12 September 2012
\$14,375	12 December 2012
\$14,375	12 March 2013
\$14,375	12 June 2013

e. Financial Reporting Requirements:

Federal Financial Report (SF 425): Quarterly and Final Reports (For reporting individual assistance agreements)

Reporting period end dates fall on the end of the calendar quarter for quarterly reports (3/31, 6/30, 9/30, 12/31) and the end date of the assistance agreement period of performance for the final report. Reports are due 30 days after the reporting period end date for quarterly reports and 90 days after the end date of the assistance agreement for the final report.

The SF425 and instructions for completion can be obtained from <https://usamraa.army.mil>. All SF425's shall be submitted electronically to Usarmy.detrick.medcom-usamraa.mbx.sf425@mail.mil. The award number assigned by USAMRAA, which looks similar to [W81XWH-11-1-0749](#) shall be included in the subject line of the electronic submission.

NOTE: The SF425 is a single form that consolidates and replaces the Federal Cash Transaction Report (SF272.SF272A) and the Financial Status Report (SF269/SF269A)

f. 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 in an interest bearing account. Interest over the amount of \$250 per year shall be remitted annually to the Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, MD 20852. A copy of the transmittal letter stating the amount of interest remitted shall be sent electronically to Usarmy.detrick.medcom-usamraa.mbx.aa1@mail.mil.

3. PROHIBITION OF USE OF LABORATORY ANIMALS (JAN 2007) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS ****

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office (ACURO). The contractor will receive written approval to begin research under the applicable protocol proposed for this award from the US Army Medical Research and Materiel Command, ACURO, under separate letter. A copy of this approval will be provided to the US Army Medical Research and Acquisition Activity for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

4. PROHIBITION OF HUMAN RESEARCH (JAN 2007) (USAMRAA)

**** PROHIBITION – READ FURTHER FOR DETAILS ****

Research under this award involving the use of human subjects, to include the use of human anatomical substances and/or human data, may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the contractor. A copy of this approval will be provided to the US Army Medical Research Acquisition Activity for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

5 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). The USAMRMC Office of Research Protections (ORP) is the Action Office (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.

6. MAXIMUM OBLIGATION (SEP 2006) (USAMRAA)

The maximum obligation for support of the project will not exceed the amount specified in the award, as amended. USAMRAA does not amend assistance agreements 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.

7. SUPPORTING INFORMATION (APR 2008) (USAMRAA)

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 under the assistance agreement. The Government's receipt of this information does not constitute approval or acceptance of any term or condition included therein. The terms and conditions of the assistance agreement take precedence over any term or condition included in supporting information.

8. PROGRAMMATIC SCIENCE/REVIEW (AUG 2010) (USAMRAA)

The PI shall budget for, prepare for, and participate in a programmatic/science review, lasting not more than two days and including up to two overnight stays, for each year of the project's term, at the Grant Officer's Representative / Contracting Officer's Representative's (GOR/COR) request. The invitation and format for the programmatic/science review will be provided by the GOR/COR at least ninety (90) days prior to the meeting. The meetings will generally be held in the Fort Detrick, MD area but could occur elsewhere in the U.S.

9. REQUIREMENTS FOR FEDERAL FUNDING ACCOUNTABILITY AND TRANSPARENCY ACT IMPLEMENTATION (2 CFR Part 170)

Appendix A to Part 170--Award Term

I. Reporting Subawards and Executive Compensation

A. Reporting of first-tier subawards.

1. Applicability. Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates \$25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph e. of this award term).

2. Where and when to report.

i. You must report each obligating action described in paragraph a.1. of this award term to <http://www.fsrs.gov>.

ii. For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

3. What to report. You must report the information about each obligating action that the submission instructions posted at <http://www.fsrs.gov> specify. must report the information about each obligating action that the submission instructions posted at <http://www.fsrs.gov> specify.

B. Reporting Total Compensation of Recipient Executives.

1. Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if--

i. the total Federal funding authorized to date under this award is \$25,000 or more;

ii. in the preceding fiscal year, you received--

(A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

iii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>.)

2. Where and when to report. You must report executive total compensation described in paragraph b.1. of this award term:

i. As part of your registration profile at <http://www.ccr.gov>.

ii. By the end of the month following the month in which this award is made, and annually thereafter.

C. Reporting of Total Compensation of Subrecipient Executives.

1. Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of

each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if--

i. in the subrecipient's preceding fiscal year, the subrecipient received--

(A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and

ii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>.)

2. Where and when to report. You must report subrecipient executive total compensation described in paragraph c.1. of this award term:

i. To the recipient.

ii. By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

D. Exemptions. If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

i. Subawards, and

ii. The total compensation of the five most highly compensated executives of any subrecipient.

E. Definitions. For purposes of this award term:

1. Entity means all of the following, as defined in 2 CFR part 25:

i. A Governmental organization, which is a State, local government, or Indian tribe;

ii. A foreign public entity;

iii. A domestic or foreign nonprofit organization;

iv. A domestic or foreign for-profit organization;

v. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

2. Executive means officers, managing partners, or any other employees in management positions.

3. Subaward:

i. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

ii. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ---- .210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

iii. A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

4. Subrecipient means an entity that:

- i. Receives a subaward from you (the recipient) under this award; and
- ii. Is accountable to you for the use of the Federal funds provided by the subaward.

5. Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

- i. Salary and bonus.
- ii. Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- iii. Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- iv. Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- v. Above-market earnings on deferred compensation which is not tax-qualified.
- vi. Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

End of clause

10. FINANCIAL ASSISTANCE USE OF UNIVERSAL IDENTIFIER AND CENTRAL CONTRACTOR REGISTRATION (2 CFR Part 25)

Appendix A to Part 25--Award Term

I. Central Contractor Registration and Universal Identifier Requirements

A. Requirement for Central Contractor Registration (CCR). Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain the currency of your information in the CCR until you submit the final financial report required under this award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term.

B. Requirement for Data Universal Numbering System (DUNS) Numbers. If you are authorized to make subawards under this award, you:

1. Must notify potential subrecipients that no entity (see definition in paragraph C of this award term) may receive a subaward from you unless the entity has provided its DUNS number to you.
2. May not make a subaward to an entity unless the entity has provided its DUNS number to you.

C. Definitions. For purposes of this award term:

1. Central Contractor Registration (CCR) means the Federal repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR Internet site (currently at <http://www.ccr.gov>).

2. Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (currently 866-705-5711) or the Internet (currently at <http://fedgov.dnb.com/webform>).

3. Entity, as it is used in this award term, means all of the following, as defined at 2 CFR part 25, subpart C:

- a. A Governmental organization, which is a State, local government, or Indian Tribe;
- b. A foreign public entity;
- c. A domestic or foreign nonprofit organization;
- d. A domestic or foreign for-profit organization; and
- e. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

4. Subaward:

a. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

b. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ----.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

c. A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

5. Subrecipient means an entity that:

- a. Receives a subaward from you under this award; and

- b. Is accountable to you for the use of the Federal funds provided by the subaward.

End of Clause

(End of Summary of Changes)