

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING		PAGE OF PAGES 1 30	
2. CONTRACT (Proc. Inst. Ident.) NO. W81XWH-15-1-0671		3. EFFECTIVE DATE 30 Sep 2015		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0010706490-0003			
5. ISSUED BY USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014		CODE W81XWH		6. ADMINISTERED BY (If other than Item 5)		CODE	
				See Item 5			
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) MCGUIRE RESEARCH INSTITUTE, INC. 1201 BROAD ROCK BLVD RICHMOND VA 23249-0001				8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days			
				10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM	
CODE 4QEB5		FACILITY CODE					
11. SHIP TO/MARK FOR W03J USA MED RESEARCH MAT CMD W03J USA MED RESEARCH MAT CMD 1077 PATCHEL STREET FORT DETRICK MD 21702-5024		CODE W91ZSQ		12. PAYMENT WILL BE MADE BY DFAS-INDY VP GFEB5 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800		CODE HQ0490	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [] 10 U.S.C. 2304(c)() [] 41 U.S.C. 253(c)()				14. ACCOUNTING AND APPROPRIATION DATA See Schedule			
15A. ITEM NO.	15B. SUPPLIES/ SERVICES		15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT	
SEE SCHEDULE							
15G. TOTAL AMOUNT OF CONTRACT						\$1,908,055.00	
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/ CONTRACT FORM	1	I	CONTRACT CLAUSES		
	B	SUPPLIES OR SERVICES AND PRICES/ COSTS		PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
	C	DESCRIPTION/ SPECS./ WORK STATEMENT		J	LIST OF ATTACHMENTS		
	D	PACKAGING AND MARKING		PART IV - REPRESENTATIONS AND INSTRUCTIONS			
	E	INSPECTION AND ACCEPTANCE		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
	F	DELIVERIES OR PERFORMANCE		L	INSTRS., CONDS., AND NOTICES TO OFFERORS		
	G	CONTRACT ADMINISTRATION DATA		M	EVALUATION FACTORS FOR AWARD		
	H	SPECIAL CONTRACT REQUIREMENTS					
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17. [] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. [X] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ REF: SEE: Section 00800 including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print)				20A. NAME OF CONTRACTING OFFICER CHRISTINE HELMAN / CONTRACTING OFFICER TEL: 301-619-2265 EMAIL: christine.e.helman.civ@mail.mil			
19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign)		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA BY  (Signature of Contracting Officer)		20C. DATE SIGNED 16-Sep-2015	

Section 00010 - Solicitation Contract Form

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Grant. Log #SC140119. CDMRP W91ZSQ COST Spinal Cord Injury Research Program. W81XWH-14-SCIRP-CTA. FOB: Destination PURCHASE REQUEST NUMBER: 0010706490-0003				\$1,908,055.00
				ESTIMATED COST	\$1,908,055.00
	ACRN AA CIN: GFEB001070649000001				\$1,908,055.00

PI NAME AND PROPOSAL TITLE

PI Name: Dr. Ashraf Gorgey

Proposal Title: Skeletal Muscle Hypertrophy and Cardiometabolic Benefits after Spinal Cord Injury.

Administered By:

Chris Meinberg

Grants Specialist

U.S. Army Medical Research Acquisition Activity

Phone: 301-619-2657

Email: christopher.l.meinberg.civ@mail.mil

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC
0001	POP 30-SEP-2015 TO 29-SEP-2019	N/A	W03J USA MED RESEARCH MAT CMD W03J USA MED RESEARCH MAT CMD 1077 PATCHEL STREET FORT DETRICK MD 21702-5024 301-619-7416 FOB: Destination	W91ZSQ

Section 00800 - Special Contract Requirements

ACCOUNTING AND APPROPRIATION DATA

AA: 09720142015013000018310333338410 R.0002690.4.1 6100.9000021001
COST CODE: A7444
AMOUNT: \$1,908,055.00
CIN GFEB001070649000001: \$1,908,055.00

CLAUSES INCORPORATED BY FULL TEXT

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)
U. S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY (USAMRAA)

TERMS AND CONDITIONS FOR ASSISTANCE AGREEMENTS
WITH FOR-PROFIT ORGANIZATIONS

Effective February 2015

AWARD SPECIFIC TERMS AND CONDITIONS

This award is a grant made under the authority of 10 U.S.C. 2358 and 10 U.S.C. 2371. The recipient's revised statement of work (SOW) dated 01 September 2015 and the revised budget dated 03 September 2015 for the application submitted in response to the Fiscal Year 2014 Department of Defense (DoD) Spinal Cord Injury Research Program, Clinical Trial Award Program Announcement (Funding Opportunity Announcement Number W81XWH-14-SCIRP-CTA, which closed 30 October 2014) are incorporated herein by reference.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 12.420

TERMS AND CONDITIONS INCORPORATED BY REFERENCE

This award is governed by provisions of Chapter I, Subchapter C of Title 32, Code of Federal Regulations (CFR), "DoD Grant and Agreement Regulations" (DoDGARs), other than Parts 32 and 33, incorporated herein by reference, with applicability as stated in those provisions.

Also, the guidance in 2 CFR Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," as modified and supplemented by the Department of Defense's (DoD) interim implementation found at 2 CFR Part 1103, "Interim Grants and Cooperative Agreements Implementation of Guidance in 2 CFR Part 200" (79 FR 76047, December 19, 2014), are incorporated herein by reference, with applicability as stated in those provisions.

For commercial organizations and those nonprofit organizations identified in Appendix VIII to 2 CFR Part 200, "Nonprofit Organizations Exempted From Subpart E – Cost Principles," the cost principles in Part 31 of Chapter 1 of Title 48, CFR, "Federal Acquisition Regulation" (FAR), and Part 231 of Chapter 2 of Title 48, "Department of Defense FAR Supplement," are incorporated herein by reference, with applicability as stated in those provisions.

Copies of the above can be obtained from:

Office of Management and Budget
EOP Publications Office

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

ORDER OF PRECEDENCE

Any inconsistencies in the requirements of this award shall be resolved in the following order:

- a. Federal statutes
- b. Federal regulations
- c. 2 CFR Part 200, as modified and supplemented by DoD's interim implementation found at 2 CFR Part 1103
- d. Award-specific terms and conditions

ACCEPTANCE OF AWARD

The recipient is not required to countersign this award. In case of disagreement with any requirements of this award, the recipient shall contact the USAMRAA Grants Officer in order to resolve the issue(s). The recipient shall not assess any costs to the award or accept any payments until the issue(s) is resolved.

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, in coordination with the recipient's Office of Sponsored Projects/Business Office, is in the best position to determine the means by which the research may be conducted most effectively.

RESEARCH INTEGRITY AND MISCONDUCT

The recipient shall comply with the requirements of DoD Instruction 3210.7, "Research Integrity and Misconduct," Enclosure 4, "Requirements for Extramural Research Institutions" (available at: <http://www.dtic.mil/whs/directives/corres/pdf/321007p.pdf>), incorporated herein by reference.

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.

PRIOR APPROVAL REQUIREMENTS

a. **Administrative Requirements.** Prior approvals required by DoDGAR 34.15 are waived except those identified below. Recipients shall request prior written approval from the USAMRAA Grants Officer for:

(1) Change in the scope or the objectives of the project as stated in the approved Statement of Work or approved modifications thereto, such as a change in the phenomenon(a) under study, even if there is no associated budget revision.

(2) The need for additional Federal funding.

- (3) Change in the PI or any key personnel specified in the award document.
 - (4) The absence for more than 3 months, or a 25 percent reduction in time devoted to the project, by the approved PI or Project Director.
 - (5) The inclusion of pre-award costs.
 - (6) The subaward, transfer, or contracting out of any work not approved under the original award. This provision does not apply to the purchase of supplies, materials, equipment, or general support services, except that procurement of equipment or other capital items of property always is subject to the USAMRAA Grants Officer's prior approval under DoD GAR 34.21(a) or DoD GAR 34.13(a)(7).
 - (7) Expenditures for individual items of general-purpose equipment and specific-purpose equipment, costing \$5,000 or more, unless identified in the budget that is incorporated as part of the award.
 - (8) The transfer of funds among direct cost categories, functions and activities for awards in which the Federal share of the project exceeds \$100,000 and the cumulative amount of such transfers exceeds or is expected to exceed 10 percent of the total budget as last approved by the USAMRAA Grants Officer. A transfer that would cause any Federal appropriation or part thereof to be used for purposes other than those consistent with the original intent of the appropriation is prohibited.
- b. **Cost Principles.** Recipients shall request prior written approval from the USAMRAA Grants Officer for the inclusion of costs that require prior approval in accordance with 48 CFR Parts 31 and 231, 2 CFR Part 200 Subpart E, and 45 CFR Part 74 Appendix E, as applicable. In accordance with those cost principles, the recipient must request prior written approval from the USAMRAA Grants Officer for: (1) those selected items of cost requiring prior approval; and (2) the incurrence of special or unusual costs.

CHANGE IN PERFORMANCE PERIOD

In accordance with the DoD GAR 34.15(c)(2)(v), the recipient may initiate, without prior approval, a one-time extension without funds to the expiration date of the award, as long as the extension without funds does not involve a change in the approved objectives or scope of the project. The recipient shall notify the USAMRAA Grants Officer in writing at least 10 calendar days prior to the expiration date of the award. The notification shall state: the additional time needed, up to a maximum of 12 months; the reasons for the extension; and the work to be completed during the extension period. The recipient must be current with all financial and technical reporting requirements and be in compliance with all other terms and conditions of the award. This one-time extension without funds may not be exercised merely for the purpose of using unobligated balances. An official modification to the award document must be issued by the USAMRAA Grants Officer to extend the period of performance.

UNOBLIGATED BALANCES

The recipient is authorized to carry forward unobligated balances to subsequent funding periods of the award agreement without prior written 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.

FEE AND PROFIT

In accordance with 32 CFR 22.205(b), fee or profit is not an allowable cost for the recipient or under a subaward at any tier.

DISALLOWED COSTS

Funds shall not be used for the support of any costs disallowed by the Funding Opportunity 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.

PROPERTY STANDARDS

The recipient shall manage, use and dispose of property in accordance with the requirements established in DoD GAR 34.20 through 34.24.

TITLE TO REAL PROPERTY AND EQUIPMENT

The purchase of real property or equipment acquired in whole or in part with Federal funds requires prior approval of the USAMRAA Grants Officer. Title to such real property or equipment vests in the recipient upon acquisition, subject to the conditions of DoD GAR 34.21.

FEDERALLY OWNED PROPERTY

Title to Federally-owned property vests in the Federal Government. DoD GAR 34.22 governs the requirements for Federally-owned property.

PROPERTY MANAGEMENT SYSTEM

The recipient's property management system for property that is Federally-owned and for equipment that is acquired in whole or in part with Federal funds, or that is used as matching share, is subject to the requirements of DoD GAR 34.23.

SUPPLIES

Title to supplies acquired with Federal funds under this award vests in the recipient upon acquisition. Upon completion or termination of the project, disposition of supplies shall be handled in accordance with DoD GAR 34.24.

INTANGIBLE PROPERTY - DATA AND SOFTWARE REQUIREMENTS

Rights in technical data, patents, inventions, and computer software are subject to the requirements of DoD GAR 34.25. All software and data first produced under the award are subject to the Federal Purpose license in accordance with applicable DoD GAR requirements. The recipient grants to the Government all necessary and appropriate licenses as a condition of this award.

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." 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 within 90 days of end of the term of award. 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.

c. All reports shall be sent electronically to usarmy.detrick.medcom-usamraa.mbx.aa1@mail.mil.

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. Quarterly reports shall be submitted no later than 30 days after the end of each quarter. Annual reports shall be submitted no later than 90 days after the end of the calendar year. Final reports shall be submitted no later than 90 days after the end date of the term of award.

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.

Do not combine multiple SF425s into one submission. Each form must be saved as a separate PDF and submitted individually.

AUDITS

Any recipient that expends \$500,000 or more in a year under Federal awards shall have an audit made by an independent auditor in accordance with the requirements of DoD GAR 34.16. The recipient shall make the auditor's report available upon request.

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 "(enter CDMRP-CDMRP Log Number)" (e.g., CDMRP-BC151111). If several protocols exist under the same application, the Secondary Protocol ID number must be designated "CDMRP-CDMRP Log Number-A, B, C, etc." (e.g., CDMRP-BC151111-A). 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.

FDA REGULATORY REQUIREMENTS

This award includes research regulated by the U.S. Food and Drug Administration (FDA) or a foreign counterpart. This award may result in an FDA-approved product and is subject to the following:

Definitions:

- a. "Regulatory Application" means investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing [510(k)] or another regulatory filing submitted to the U.S. Food and Drug Administration (FDA) related to a product or an analogous foreign filing.
- b. "Sponsor" means, in accordance with the definition in 21 C.F.R. 312.3, an organization or individual who assumes legal responsibility for supervising or overseeing clinical trials with a test article, and is sometimes referred to as the IND "holder." For the purposes of U.S. law for this project, the recipient is the Sponsor for the conduct of the study contemplated under this award and will be responsible for those obligations at 21 C.F.R. 312.50 for Sponsors.

Requirements:

- a. The Sponsor of any Regulatory Application contemplated under this award shall provide the USAMRAA Grants Officer (GO) and the Grants Officer's Representative (GOR) with copies of all written communications to and from the FDA regarding this project and provide the GO and GOR with advance written notification of all meetings or teleconferences with the FDA to allow the Government the opportunity to participate in any such communications with the FDA related to such Regulatory Application. It is anticipated the Government will have at least two representatives in all such meetings or teleconferences. The recipient shall provide a copy of the official minutes of each such meeting to the Government within three (3) days of receipt of the official minutes. Further, the recipient agrees the Government may communicate directly with the FDA and the Government may offer information of regulatory relevance to the FDA.
- b. Where this award is either: (i) terminated prior to end of the project; or (ii) in the event recipient ceases to commercially market the FDA-approved product, the recipient agrees, upon reasonable terms to be negotiated in good faith, to:

(1) Transfer a right of reference and possession or ownership of the Regulatory Application, regulatory correspondence, and supporting regulatory information to the U. S. Government;

(2) Transfer sponsorship of any Regulatory Application permitting investigational use of the products developed under this award or transfer any Regulatory Application approved by FDA or a foreign regulatory authority resulting from this project, including any remaining marketing exclusivity awarded, and inform FDA of any such transfer ; and

(3) Negotiate in good faith an exclusive, royalty-bearing license to each trademark covering the product developed under this award.

QUARTERLY TECHNICAL REPORTING REQUIREMENTS

For each year of the entire performance period of the award, the 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.

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.

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.

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 Year X Quarter Y Report (example: W81XWH-15-1-0000 Year 1 Quarter 1 Report.) If you have questions, contact the GOR.

Grants Specialist E-mail: christopher.l.meinberg.civ@mail.mil

GOR E-mail: usarmy.detrick.medcom-cdmrp.mbx.cdmrp-reporting@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:

(2) SECTION 1 -- Accomplishments: The PI is reminded that the recipient organization is required to obtain prior written approval from the USAMRAA Grants Officer whenever there are significant changes in the project or its direction.

- What were the major goals of the project?
- What was accomplished under these goals?
- Describe the Regulatory Protocol and Activity Status (if applicable).

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

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project identify these dates and show actual completion dates or the percentage of completion.

What was accomplished under these goals?

For this quarterly reporting period only describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided.

Describe the Regulatory Protocol and Activity Status (if applicable).

Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state "Nothing to Report."

(a) Human Use Regulatory Protocols

TOTAL PROTOCOL(S): 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."

PROTOCOL(S): List the identifier and title for all human use protocols needed to complete the project. Include information about the approved target number for clinical significance, type of submission, type of approval with associated dates, and performance status.

The following format shall be used:

Protocol of total:

Human Research Protection Office (HRPO) assigned A-number:

Title:

Target required for clinical significance:

Target 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: Report on activity status: (i) 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) amendments submitted to the IRB and USAMRMC HRPO for review; and (iii) any adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation.

(b) Use of Human Cadavers for Research Development Test & Evaluation (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, tissues, 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 PROTOCOL(S): 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.”

PROTOCOL(S): List the identifier and title for all animal use protocols needed to complete the project. Include information about the approved target number for statistical significance, type of submission, type of approval with associated dates, and performance status.

The following format shall be used:

Protocol of total:

Animal Care and Use Review Office (ACURO) assigned Number:

Title:

Target required for statistical significance:

Target 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.

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

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives in accordance with the approved SOW.

- (3) **SECTION 2 – Products:** List any products resulting from the project during the reporting period. If there are no products to report for the current quarter, state “Nothing to report.”

Examples of products include:

- publications, conference papers, and presentations;
- website(s) or other Internet site(s);
- technologies or techniques;
- inventions, patent applications, and/or licenses; and
- other products, such as data or databases, biospecimen collections, germplasm, audio or video products, software, models, educational aids or curricula, instruments or equipment, data and research material, clinical or educational interventions, or new business creation.

- (4) **SECTION 3 - Participants & Other Collaborating Organizations**

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort).

Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project. Show the most senior role in which the person worked on the project for any significant length of time. For example, if an undergraduate student graduated, entered graduate school, and continued to work on the project, show that person as a graduate student, preferably explaining the change in involvement.

Describe how this person contributed to the project. If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name:	Mary Smith
Project Role:	Graduate Student
Researcher Identifier (e.g., ORCID ID):	1234567
Nearest person month worked:	5
Contribution to Project:	Ms. Smith has performed work in the area of combined error-control and constrained coding

- (5) **SECTION 4 –Changes/Problems:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

1. Actual Problems or delays and actions to resolve them

Provide a description of current problems or issues that may impede performance or progress of this project along with proposed corrective action. Also describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

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, retention problems, and actions taken to increase enrollment and/or improve retention.

2. Anticipated Problems/Issues

Provide a description of anticipated problems or issues that have a potential to impede performance or progress. Also provide course of actions planned to mitigate problems or to take should the problem materialize.

(6) SECTION 5 – Special Reporting Requirements: Quad Charts

Quad Charts: The Quad Chart (available on <https://www.usamraa.army.mil>) shall be updated and submitted as an attachment to the Quarterly Technical Report.

ANNUAL/FINAL TECHNICAL REPORTING REQUIREMENTS

Format Requirements:

a. Annual reports shall be prepared in accordance with the Research Performance Progress Report (RPPR). The RPPR is the uniform format for reporting performance progress on Federally-funded research projects and research-related activities. 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 (SOW). 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 shall also be prepared in accordance with the RPPR and shall be submitted within 90 calendar days of the award performance end date. The report shall summarize the entire research effort, citing data in the annual reports and appended publications.

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. Reports, 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 http://mrhc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting. The Accession Document (AD) Number should remain blank.

Distribution: Reports must include one of two distribution statements:

(1) Unlimited Distribution: If the distribution will be unlimited (i.e., approved for public release), choose the form entitled “Award/Contract Front Cover – Unlimited Distribution A.” Results of fundamental research should be public distribution except in rare and exceptional circumstances.

(2) Limited Distribution: If the distribution is to be limited, choose the form entitled “Award/Contract Cover – Limited Distribution B.” After report submission, the GOR will review the appropriateness of using this distribution statement. The GOR has the right to challenge the validity of any restrictive markings. Reports that may be eligible for limited distribution may be ones that contain proprietary data that is not to be released to the public. If so, mark the cover page as “Proprietary”. DO NOT USE THE WORD “CONFIDENTIAL” WHEN MARKING DOCUMENTS. The recipient shall maintain records sufficient to justify the validity of any restrictive markings. REPORTS NOT PROPERLY MARKED WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE.

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

For general information regarding report preparation, access the Research Resources, Technical Reporting, website at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting.

STANDARD FORM 298: Sample SF 298 is provided at http://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.

Pages shall be numbered. The number of pages shall include all pages that have printed data (including the front cover, SF 298, table of contents, and all appendices). Page numbers must match the numbering shown on the Table of Contents.

TABLE OF CONTENTS: Sample table of contents is provided at http://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting.

Example Table of Contents

Page No.

1. Introduction
2. Keywords
3. Accomplishments
4. Impact
5. Changes/Problems
6. Products
7. Participants & Other Collaborating Organizations
8. Special Reporting Requirements
9. Appendices

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. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the USAMRAA Grants Officer whenever there are significant changes in the project or its direction.

- What were the major goals and objectives of the project?
- What was accomplished under these goals?
- What opportunities for training and professional development did the project provide?
- How were the results disseminated to communities of interest?
- What do you plan to do during the next reporting period to accomplish the goals and objectives?

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Generally, the goals will not change from one reporting period to the next and are unlikely to change during the final reporting period. However, if the awarding agency approved changes to the goals during the reporting period, list the revised goals and objectives. Also explain any significant changes in approach or methods from the agency approved application or plan.

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

How were the results disseminated to communities of interest?

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

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

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

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

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

4. IMPACT: This component is used to describe ways in which the work, findings, and specific products of the project have had an impact during this reporting period. Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

- the development of the principal discipline(s) of the project;
- other disciplines;
- technology transfer; or
- society beyond science and technology.

What was the impact on the development of the principal discipline(s) of the project?

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

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (*Scientific American style*).

How the field or discipline is defined is not as important as covering the impact the work has had on knowledge and technique. Make the best distinction possible, for example, by using a “field” or “discipline,” if appropriate, that corresponds with a single academic department (i.e., physics rather than nuclear physics).

What was the impact on other disciplines?

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

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

What was the impact on technology transfer?

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

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

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

What was the impact on society beyond science and technology?

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

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

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

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

- Changes in approach and reasons for change.
- Actual or anticipated problems or delays and actions or plans to resolve them.
- Changes that have a significant impact on expenditures.
- Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.

Changes in approach and reasons for change

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

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Changes that had a significant impact on expenditures

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

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

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

6. PRODUCTS: List any products resulting from the project during the reporting period. Examples of products include:

- publications, conference papers, and presentations;
- website(s) or other Internet site(s);
- technologies or techniques;
- inventions, patent applications, and/or licenses; and
- other products.

If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award. There is no restriction on the number. However, agencies are interested in only those publications that most reflect the work under this award in the following categories:

Journal publications. List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Include any peer-reviewed publication in the periodically published proceedings of a scientific society, a conference, or the like. A publication in the proceedings of a one-time conference, not part of a series, should be reported under “Books or other non-periodical, one-time publications.”

Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Books or other non-periodical, one-time publications. Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like.

Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Other publications, conference papers, and presentations. Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

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

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

- **Other Products**

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

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

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Provide the following information on participants:

- what individuals have worked on the project?
- has there been a change in the other active support of the PD/PI(s) or senior/key personnel since the last reporting period?
- what other organizations have been involved as partners?

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort).

- Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project. Show the most senior role in which the person worked on the project for any significant length of time. For example, if an

undergraduate student graduated, entered graduate school, and continued to work on the project, show that person as a graduate student, preferably explaining the change in involvement.

Describe how this person contributed to the project and with what funding support. If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name:	Mary Smith
Project Role:	Graduate Student
Researcher Identifier (e.g., ORCID ID):	1234567
Nearest person month worked:	5
Contribution to Project:	Ms. Smith has performed work in the area of combined error-control and constrained coding
Funding Support:	The XYZ Foundation (Complete only if the funding support is provided from other than this award.)

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

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

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission.

Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

What other organizations were involved as partners?

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

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- Financial support;
- In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);
- Facilities (e.g., project staff use the partner’s facilities for project activities);
- Collaboration (e.g., partner’s staff work with project staff on the project);
- Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and
- Other.

8. SPECIAL REPORTING REQUIREMENTS: Quad Chart

QUAD CHARTS: The Quad Chart (available on <https://www.usamraa.army.mil>) shall be updated and submitted as an appendix.

9. 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.

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. No new awards will be issued to the recipient until all delinquent reports are submitted.

MANUSCRIPTS/REPRINTS

Copies of manuscripts or subsequent reprints resulting from the research shall be submitted to usarmy.detrick.medcom-cdmrp.mbx.cdmrp-reporting@mail.mil.

PUBLICATION, ACKNOWLEDGEMENT, AND PUBLIC RELEASE

Publication. The recipient is encouraged to publish results of the research, unless classified, in appropriate media. One copy of each paper shall be submitted to the GOR simultaneously with its submission for publication. Copies of all publications resulting from the research shall be forwarded to the USAMRAA Grants Officer or Grants Specialist as they become available, even though publication may in fact occur subsequent to the termination date of the award.

Acknowledgment. The recipient agrees that in the release of information relating to this award such release shall include the statements below, as applicable. "Information" includes, but is not limited to, news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

- a. "The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office" and;
- b. "This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs through the Spinal Cord Injury Research Program under Award No. W81XWH-15-1-0671. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense."
- c. "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture."
- d. "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules." (<http://www.nih.gov>)
- e. "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (<http://www.cdc.gov/biosafety>)

Public release. Prior to release to the public, the recipient shall notify the USAMRAA Grants Officer and the GOR of the following: planned news releases, planned publicity, advertising material concerning grant/cooperative agreement work, and planned presentations to scientific meetings. This provision is not intended to restrict dissemination of research information; the purpose is to inform the USAMRMC of planned public release of information on USAMRMC-funded research, in order to adequately respond to inquiries and to be alert to the possibility of inadvertent release of information which could be taken out of context.

Failure to include the above statements and adhere to the above regulations, when required, may result in loss of funding and/or termination of this award.

SITE VISITS

The USAMRAA Grants Officer, or authorized representative, has the right to make site visits to review project accomplishments and to provide such technical assistance as may be required. If any site visit is made by the Government representative on the premises of the recipient or subrecipient, the recipient shall provide, and shall require its subrecipients to provide, all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All site visits and evaluations will be performed in such a manner as will not unduly interfere with or delay the work.

REQUEST FOR COST REIMBURSEMENT PAYMENTS WITH FULL FUNDING

a. Payments. Cost reimbursement payments will be made to the recipient upon receipt of a “grant voucher” (used for grants and cooperative agreements) submitted through the Wide Area Work Flow (WAWF) e-Business Suite 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. **Failure to voucher at least quarterly may raise concerns about research progress and the need for continued funding.**

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 costs incurred during the first 12 months. No grant voucher may be submitted thereafter until the recipient provides a copy of the ORP approval notification to the cognizant Grants Specialist at usarmy.detrack.medcom-usamraa.mbx.aa1@mail.mil. The total amount available for disbursement for the first 12 months is \$472,095.

b. 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.

c. No payment will be made if the recipient fails to perform, or if the recipient fails to submit the required documents.

ELECTRONIC PAYMENT INSTRUCTIONS

The Wide Area Work Flow (WAWF) e-Business Suite is the required method to electronically process recipient requests for payments. Once on the WAWF e-Business Suite web site, select the Invoicing, Receipt, Acceptance, and Property Transfer (iRAPT) button to electronically submit “grant vouchers” (used for both grants and cooperative agreements). 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) DFAS Indianapolis’ number is 1-888-332-7366. You can also access payment and receipt information using the “myInvoice” button in WAWF at <https://wawf.eb.mil>. 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: **4QEB5**

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 = DFAS Indianapolis**

EMAIL POINTS OF CONTACT LISTING:

INSPECTOR: **usarmy.detrick.medcom-usamraa.mbx.aa1@mail.mil**

ACCEPTOR: **usarmy.detrick.medcom-usamraa.mbx.aa1@mail.mil**

RECEIVING OFFICE POC: **usarmy.detrick.medcom-usamraa.mbx.aa1@mail.mil**

GRANT ADMINISTRATOR: **Leave Blank**

GRANTS OFFICER: **Leave Blank**

ADDITIONAL CONTACT: **usarmy.detrick.medcom-usamraa.mbx.aa1@mail.mil**

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.aa1@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.aa1@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.aa1@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-15-1-0671
820 Chandler Street
Fort Detrick, Maryland 21702-5014

TERMINATION AND ENFORCEMENT

The USAMRAA Grants Officer may terminate or suspend, in whole or in part, this agreement by written notice to the recipient upon a finding that the recipient materially fails to comply with the terms and conditions of this agreement, if the recipient materially changes the objective of the agreement, or if appropriated funds are not available to support the program. However, the USAMRAA Grants Officer may immediately suspend or terminate the award without prior notice when such action is necessary to protect the interests of the Government.

No costs incurred during a suspension period or after the effective date of a termination will be allowable, except those costs which, in the opinion of the USAMRAA Grants Officer, the recipient could not reasonably avoid or eliminate, or which were otherwise authorized by the suspension or termination notice, provided such costs would otherwise be allowable under the terms of the award and the applicable Federal cost principles. In no event will the total of payments under a terminated award exceed the amount obligated in the award.

DISPUTES AND APPEALS

The procedures of 32 CFR 22.815 govern for processing recipient claims and disputes and for deciding appeals of a USAMRAA Grants Officer's decision.

Disagreements regarding issues concerning assistance agreements between the recipient and the USAMRAA Grants Officer shall, to the maximum extent possible, be resolved by negotiation and mutual agreement at the USAMRAA Grants Officer level. If agreement cannot be reached, it is our policy to use Alternative Dispute Resolution (ADR) procedures that may either be agreed upon by the Government and the recipient in advance of the award or may be agreed upon at the time the parties determine to use ADR procedures. If the parties cannot agree on the use of ADR procedures, the recipient can submit, in writing, a disputed claim or issue to the USAMRAA Grants Officer. The USAMRAA Grants Officer will consider the claim or disputed issue and prepare a written decision within 60 calendar days of receipt. The USAMRAA Grants Officer's decision will be final. The recipient may appeal the decision within 90 calendar days after receipt of such notification.

Appeals of a USAMRAA Grants Officer's decision will be resolved by the Head of the Contracting Activity. The decision by the Head of the Contracting Activity will be final and not subject to further administrative appeal. However, the recipient does not waive any legal remedy, such as formal claims, under Title 28 U.S.C. 1491, by agreeing to such provision.

The enforcement remedies identified in this section, including suspension and termination, do not preclude a recipient from being subject to debarment and suspension under 2 CFR Part 1125.

PROHIBITION OF USE OF LABORATORY ANIMALS

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.

The Animal Care and Use Office requirements can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro.

PROHIBITION OF USE OF HUMAN SUBJECTS

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.

DoD requirements for human subjects research, including 32 CFR Part 219, DoD Instruction 3216.02 and the USAMRMC ORP Human Research Protection Office requirements and instructions can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

PROHIBITION OF USE OF HUMAN CADAVERS

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.

RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

The recipient assures that all work involving the use of recombinant DNA will be in compliance with guidance provided at <http://www4.od.nih.gov/oba>.

NATIONAL POLICY REQUIREMENTS:

NONDISCRIMINATION

By accepting funds under this award, the recipient assures that it will comply with applicable provisions of the following national policies prohibiting discrimination:

- a. On the basis of race, color, or national origin, in Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, et seq.), as implemented by DOD regulations at 32 CFR Part 195.
- b. On the basis of sex or blindness, in Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, et seq.), as implemented by DOD regulations at 32 CFR Part 196.
- c. On the basis of age, in the Age Discrimination Act of 1975 (42 U.S.C. 6101, et seq.) as implemented by Department of Health and Human Services regulations at 45 CFR Part 90.
- d. On the basis of handicap, in Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), as implemented by Department of Justice regulations at 28 CFR Part 41 and DOD regulations at 32 CFR Part 56, and the Architectural Barriers Act of 1968 (42 U.S.C. 4151, et seq.).

DEBARMENT AND SUSPENSION

The recipient assures that it will comply with the requirements regarding debarment and suspension in Subpart C of the OMB guidance in 2 CFR Part 180, as implemented by the DOD in 2 CFR part 1125. The recipient shall communicate the requirement to comply with Subpart C to persons at the next lower tier with whom the recipient enters into transactions that are “covered transactions” under Subpart B of 2 CFR Part 180 and the DOD implementation in 2 CFR Part 1125.

ENVIRONMENTAL STANDARDS

By accepting funds under this award, the recipient assures that it will:

Comply with applicable provisions of the Clean Air Act (42 U.S.C. 7401, et seq.) and Clean Water Act (33 U.S.C. 1251, et seq.), as implemented by Executive Order 11738 [3 CFR, 1971-1975 comp., p. 799] and Environmental Protection Agency (EPA) rules at 40 CFR Part 32. In accordance with the EPA rules, the recipient further agrees that it will:

Not use any facility on the EPA’s List of Violating Facilities in performing any award that is nonexempt under 40 CFR 15.5 (awards of less than \$100,000, and certain other awards, exempt from the EPA regulations), as long as the facility remains on the list.

Notify the awarding agency if it intends to use a facility in performing this award that is on the List of Violating Facilities or that the recipient knows has been recommended to be placed on the List of Violating Facilities.

Identify to the awarding agency any impact this award may have on:

The quality of the human environment, and provide help the agency may need to comply with the National Environmental Policy Act (NEPA, at 42 U.S.C. 4321, et seq.) and to prepare Environmental Impact Statements or other required environmental documentation. In such cases, the recipient agrees to take no action that will have an adverse environmental impact (e.g., physical disturbance of a site such as breaking of ground) until the agency provides written notification of compliance with the environmental impact analysis process.

Coastal barriers, and provide help the agency may need to comply with the Coastal Barriers Resource Act (16 U.S.C. 3501, et seq.), concerning preservation of barrier resources.

Any existing or proposed component of the National Wild and Scenic Rivers system, and provide help the agency may need to comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271, et seq.).

DRUG FREE WORKPLACE

By accepting funds under this award, the recipient assures that it will comply with the “Government –Wide Drug-Free Workplace (Grants)” requirements specified by DoD GAR Part 26, Subpart B (or Subpart C, if the recipient is an individual) of 32 CFR Part 26 (2004), which implements sec.5151-5160 of Drug-Free Workplace Act of 1988 (41 U.S.C. 701,et seq.).

OFFICIALS NOT TO BENEFIT

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this award, or to any benefit arising from it, in accordance with 41 U.S.C. 22.

PREFERENCE FOR U.S. FLAG AIR CARRIERS

Travel supported by U.S. Government funds under this award shall use U.S.-flag air carriers (air carriers holding certificates under 49 U.S.C. 41102) for international air transportation of people and property to the extent that such service is available, in accordance with the International Air Transportation Fair Competitive Practices Act of 1974 (49 U.S.C. 40118) and the interpretative guidelines issued by the Comptroller General of the United States in the March 31, 1981, amendment to Comptroller General Decision B138942.

CARGO PREFERENCE

The recipient assures that it will comply with the Cargo Preference Act of 1954 (46 U.S.C. 1241), as implemented by Department of Transportation regulations at 46 CFR 381.7, which require that at least 50 percent of equipment, materials or commodities procured or otherwise obtained with U.S. Government funds under this award, and which may be transported by ocean vessel, shall be transported on privately owned U.S.-flag commercial vessels, if available.

RADIOACTIVE MATERIALS

The recipient assures that it will comply with Title 10 CFR 21. This regulation established procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

TRAFFICKING VICTIMS PROTECTION ACT

Trafficking in persons.

a. Provisions applicable to a recipient that is a private entity.

1. You as the recipient, your employees, subrecipients under this award, and subrecipients’ employees may not—

i. Engage in severe forms of trafficking in persons during the period of time that the award is in effect;

ii. Procure a commercial sex act during the period of time that award is in effect; or

iii. Use forced labor in the performance of the award or subawards under the award.

2. We as the Federal awarding agency may unilaterally terminate this award, without penalty, if you or a subrecipient that is a private entity—

i. Is determined to have violated a prohibition in paragraph a.1 of this award term; or

ii. Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in paragraph a.1 of this award term through conduct that is either—

A. Associated with performance under this award; or

B. Imputed to you or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR 180, “OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement),” as implemented by our agency at 2 CFR part 1125.

b. Provision applicable to a recipient other than a private entity. We as the Federal awarding agency may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity--

1. Is determined to have violated an applicable prohibition in paragraph a.1 of this award term; or
2. Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph a.1 of this award term through conduct that is either—
 - i. Associated with performance under this award;
 - ii. Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, “OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement),” as implemented by our agency at 2 CFR part 1125.

c. Provision applicable to any recipient.

1. You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph a.1 of this award term.
2. Our right to terminate unilaterally that is described in paragraph a.2. or b. of this section:
 - i. Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 U.S.C. 7104(g)), and
 - ii. Is in addition to all other remedies for noncompliance that are available to us under this award.
3. You must include the requirements of paragraph a.1 of this award term in any subaward you make to a private entity.

d. Definitions. For the purpose of this award term:

1. “Employee” means either:
 - i. An individual employed by you or a subrecipient who is engaged in the performance of the project or program under this award; or
 - ii. Another person engaged in the performance of the project or program under this award and not compensated by you including, but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing or matching requirements.
2. “Forced labor” means labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.
3. “Private entity” means:
 - i. Any entity other than a State, local government, Indian tribe, or foreign public entity, as those terms are defined in 2 CFR 175.25.
 - ii. Includes:
 - A. A nonprofit organization, including any nonprofit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe at 2 CFR 175.25(b).
 - B. A for-profit organization.
4. “Severe forms of trafficking in persons,” “commercial sex act,” and “coercion” have the meanings given at section 103 of the TVPA, as amended (22 U.S.C. 7102).

REQUIREMENTS FOR FEDERAL FUNDING ACCOUNTABILITY AND TRANSPARENCY ACT IMPLEMENTATION

Reference 2 CFR part 170, Appendix A to Part 170.

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.fsrc.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:

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

FINANCIAL ASSISTANCE USE OF UNIVERSAL IDENTIFIER AND CENTRAL CONTRACTOR REGISTRATION

Reference 2 CFR part 25, Appendix A to Part 25.

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.