

**US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY (USAMRAA)
GENERAL RESEARCH TERMS AND CONDITIONS
WITH FOR-PROFIT ORGANIZATIONS
EFFECTIVE FEBRUARY 2017**

DIVISION III – GENERAL RESEARCH TERMS AND CONDITIONS

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SUBDIVISION A – PREAMBLE

TERMS AND CONDITIONS

1. Applicability (NOVEMBER 2015)

These general research terms and conditions are applicable to all assistance agreement awards (grants and cooperative agreements) issued by the US Army Medical Research Acquisition Activity (USAMRAA) to for-profit organizations.

2. Use of Plain Language (NOVEMBER 2015)

The use of personal pronouns is included in these terms and conditions in order to more effectively communicate requirements. The use of “you” denotes the recipient and “we” or “us” denotes the Department of Defense (DoD) awarding agency.

3. Use of English Language (NOVEMBER 2015)

You must:

a. Translate any of the award content (including attachments to it and any material incorporated by reference) into another language to the extent that your compliance with the award’s terms and conditions depends upon a significant number of its employees who are not fluent in English being able to read and comprehend that content.

b. If you do translate any award content into another language, either as required by paragraph a. of this section or at your own initiative, the original award content in the English language will take precedence in the event of an inconsistency between the award requirements in the English and translated versions.

4. Definitions (NOVEMBER 2015)

The following are definitions for frequently used terms. For a more comprehensive set of definitions, see the Department of Defense Grant and Agreement Regulations (DoDGARs) 34.2.

Advance payment. *Advance payment* means a payment that DoD or a recipient or subrecipient makes by any appropriate payment mechanism, including a predetermined payment schedule, before the recipient or subrecipient disburses the funds for project or program purposes.

Approved budget. *Approved budget* means, in conjunction with a DoD Component award to a recipient, the most recent version of the budget the recipient submitted and the DoD Component approved (either at the time of the initial award or subsequently), to summarize planned expenditures for the project or program under the award. It includes:

- a. All Federal funding made available to the recipient under the award to use for project or program purposes.
- b. Any cost sharing or matching that the recipient is required to provide under the award.
- c. Any options that have been exercised but not any options that have not yet been exercised.

Assistance. *Assistance* means the transfer of a thing of value to a recipient to carry out a public purpose of support or stimulation authorized by a law of the United States (see 31 U.S.C. 6101(3)). Grants, cooperative agreements, and technology investment agreements are examples of legal instruments that DoD Components use to provide assistance

Cooperative Agreement. *Cooperative agreement* means a legal instrument which, consistent with 31 U.S.C. 6305, is used to enter into the same kind of relationship as a grant (see definition of “grant” in this part), except that substantial involvement is expected between the DoD and the recipient when carrying out the activity contemplated by the cooperative agreement. The term does not include “cooperative research and development agreements” as defined in 15 U.S.C. 3710a.

Equipment. *Equipment* means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of:

- a. \$5,000; or
- b. The recipient’s or subrecipient’s capitalization threshold for financial statement purposes.

Excepted property. *Excepted property* means tangible personal property acquired in whole or in part with Federal funds under a DoD Component’s awards, for which the DoD Component:

- a. Has statutory authority to vest title in recipients (or allow for vesting in subrecipients) without further obligation to the Federal Government or subject to conditions the DoD Component considers appropriate; and
- b. Elects to use that authority to do so.

An example of excepted property authority is contained in the Federal Grant and Cooperative Agreement Act (31 U.S.C. 6306) for tangible personal property acquired under an award to conduct basic or applied research by a nonprofit institution of higher education or nonprofit organization whose primary purpose is conducting scientific research.

Fixed-amount award. *Fixed-amount award* means a DoD Component grant or cooperative agreement that provides for the recipient to be paid on the basis of performance and results, rather than the actual, allowable costs the recipient incurs.

Fixed-amount subaward. *Fixed-amount subaward* means a subaward:

- a. That a recipient or subrecipient makes to another entity at the next lower tier; and
- b. Under which the total amount to be paid to the other entity is based on performance and results, and not on the actual, allowable costs that entity incurs.

Grant. *Grant* means a legal instrument which, consistent with 31 U.S.C. 6304, is used to enter into a relationship:

- a. Of which the principal purpose is to transfer a thing of value to the recipient to carry out a public purpose of support or stimulation authorized by a law of the United States, rather than to acquire property or services for the DoD’s direct benefit or use.

b. In which substantial involvement is not expected between the DoD and the recipient when carrying out the activity contemplated by the grant.

Grants Officer. *Grants officer* means a DoD official with the authority to enter into, administer, and/or terminate grants and cooperative agreements.

Non-excepted property. *Non-excepted property* means tangible personal property acquired in whole or in part with Federal funds under a USAMRAA award, for which USAMRAA has given the recipient a conditional title. The conditional title is subject to the terms and conditions DoDGARs 34.20-25.

Period of performance. *Period of performance* means the time during which a recipient or subrecipient may incur new obligations to carry out the work authorized under an award or subaward, respectively.

Property. *Property* means real property and personal property (equipment, supplies, intangible property, and debt instruments), unless stated otherwise.

Research. *Research* means basic, applied, and advanced research.

Small Award. *Small award* means a DoD grant or cooperative agreement or a subaward with total value over the life of the award that does not exceed the simplified acquisition threshold.

Subaward. *Subaward* means a legal instrument by which a recipient or subrecipient at any tier below a DoD Component prime award, transfers--for performance by an entity at the next lower tier--a portion of the substantive program for which the DoD Component's prime award provided financial assistance.

Subrecipient. *Subrecipient* means an entity that receives a subaward.

Substantial Involvement. *Substantial involvement* means that in addition to DoD's normal stewardship (i.e., site visits, program reviews, performance reporting, and financial reporting activities), it is anticipated that DoD may be involved through collaboration, participation, or intervention in the research to be performed under the award. DoD may become directly involved in performing the research, managing the effort, and/or reviewing and providing approval before work can proceed.

Total value. *Total value* of a DoD grant or cooperative agreement award means the total amount of costs that are currently expected to be charged to the award over its life, which includes amounts for:

- (a) The Federal share and any non-Federal cost sharing or matching required under the award; and
- (b) Any options, even if not yet exercised, for which the costs have been established in the award.

SUBDIVISION B – ADMINISTRATIVE REQUIREMENTS

TERMS AND CONDITIONS

5. Administrative Requirements Incorporated by Reference (NOVEMBER 2015)

You are required to comply with the “Administrative Requirements for Grants and Agreements with For-Profit Organizations” of the DoDGARs, located at 32 CFR part 34, incorporated herein by reference. The DoDGARs is available in full text at <http://www.gpo.gov/fdsys/pkg/CFR-2011-title32-vol1/xml/CFR-2011-title32-vol1-subtitleA-chapI-subchapC.xml>.

6. Your Responsibility (NOVEMBER 2015)

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

a. You 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 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 your Office of Sponsored Projects/Business Office, is in the best position to determine the means by which the research may be conducted most effectively.

7. Supporting Information (NOVEMBER 2015)

Information such as subaward agreements, 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. Our receipt of this information does not constitute approval or acceptance of any term or condition included therein.

8. Financial Instability, Insolvency, Bankruptcy or Receivership (NOVEMBER 2015)

a. You must immediately notify the USAMRAA Grants Officer of the occurrence of the following events: (1) your financial instability that would negatively impact performance of the award; (2) you or your parent's filing of a voluntary case seeking liquidation or reorganization under the Bankruptcy Act; (3) your consent to the institution of an involuntary case under the Bankruptcy Act against your organization or organization's parent; (4) the filing of any similar proceeding for or against you or your parent, or consent to, the dissolution, winding-up or readjustment of your debts, appointment of a receiver, conservator, trustee, or other officer with similar powers over your organization, under any other applicable state or federal law; or (5) your insolvency due to its inability to pay your debts generally as they become due.

b. Such notification must be in writing and must: (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 the award.

c. Upon the occurrence of any of the five events described in paragraph "a" above, we reserve the right to conduct a review of the award to determine your 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 your performance under the award, we reserve 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. Your failure to comply with this term may be considered a material failure by you to comply with the terms of the award and may result in termination.

9. Financial Assistance Use of Universal Identifier and Central Contractor Registration* (NOVEMBER 2015)

Reference Appendix A to 2 CFR part 25. Unless you are exempted from this requirement based on the criteria provided in the Office of Management and Budget guidance in section 25.110 of 2 CFR part 25, you must maintain the currency of information about yourself in the system the Federal Government specifies as the repository for information about its business partners (currently the System for Award Management (SAM)).

*The Central Contractor Registration is now part of the Federal repository entitled SAM, accessible at <https://www.sam.gov>.

10. Allowable Costs (NOVEMBER 2015)

Allowability of costs will be determined in accordance with the cost principles applicable to the type of entity incurring the costs, as follows:

a. For-profit organizations. Allowability of costs incurred by for-profit organizations that are recipients of prime awards from DoD Components, and those that are subrecipients under prime awards to other organizations, is to be determined in accordance with:

(1) The for-profit cost principles in 48 CFR parts 31 and 231 (in the Federal Acquisition Regulation, or FAR, and the Defense Federal Acquisition Regulation Supplement, or DFARS, respectively).

(2) The supplemental information on allowability of audit costs, in DoDGARs 34.16(f).

b. Other types of organizations. Allowability of costs incurred by other types of organizations that may be subrecipients under a prime award to a for-profit organization is determined as follows:

(1) Institutions of higher education, nonprofit organizations, States, local governments, and Indian tribes. Allowability is determined in accordance with the cost principles in Subpart E of 2 CFR part 200. Note that section 200.401(c) of that subpart provides that a nonprofit organization listed in Appendix VIII to 2 CFR part 200 is subject to the FAR and DFARS cost principles specified in paragraph (a)(1) of this section for for-profit organizations.

(2) Hospitals. Allowability is determined in accordance with the cost principles identified in Appendix IX to 2 CFR part 200 (currently 45 CFR part 75).

11. Maximum Obligation (FEBRUARY 2017)

The maximum obligation of the Federal Government for support of the award will not exceed the award amount specified in the award cover pages, 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, changes in exchange rates, or other costs. You may rebudget allowable costs in accordance with applicable cost principles and in accordance with the prior approval requirements as stated in this award.

12. Disallowed Costs (NOVEMBER 2015)

You must not use funds for the support of any costs disallowed by the Funding Opportunity Announcement, either as a direct or an indirect cost.

13. Prior Approval Requirements (FEBRUARY 2017)

You must request prior approval from us for any of the following program or budget revisions:

a. A change in the scope or objective of the project or program under the award, even if there is no associated budget revision that requires our prior approval.

b. A change in a key person(s) identified in cover pages of the award.

c. The approved principal investigator's or project director's disengagement from the project for more than three months, or a 25 percent reduction in his or her time devoted to the project.

d. The inclusion of pre-award costs.

e. The inclusion of direct costs that require prior approval in accordance with the applicable cost principles, as identified in the Federal Acquisition Regulations (FAR) part 31 and the Defense FAR Supplement part 231.

(1) In accordance with applicable cost principles, you must request prior written approval for the incurrence of special or unusual costs.

(2) Expenditures for individual items of general-purpose equipment and specific-purpose equipment, costing \$5,000 or more, unless identified in the approved budget that is incorporated as part of the award. **Note that equipment acquired under the award and charged as direct project costs must be necessary for the conduct of the research project supported by the award. You are prohibited from acquiring equipment under the award merely for the purpose of using unobligated balances.**

f. A subaward to another entity under which it will perform a portion of the substantive project or program under the award, if it was not included in the approved budget. This does not apply to your contracts for acquisition of supplies, equipment, or general support services you need to carry out the project or program.

g. The transfer (relocation) of the PI and/or research project to another entity.

h. Reimbursing a DoD Military Treatment Facility (MTF) for costs incurred if the MTF is involved in the project. Reimbursement of these costs is generally prohibited and only approved under unusual and extraordinary circumstances.

i. The transfer of funds among direct cost categories, functions and activities for awards in which the Federal share of the project exceeds the simplified acquisition threshold 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.

j. Any change in the cost sharing or matching you provide under the award that is included in the approved budget.

k. The need arises for additional Federal funds to complete the project or program.

14. Extension of the Period of Performance (FEBRUARY 2017)

a. You may initiate, without prior approval, a one-time, extension without additional funds to the expiration date of the award for a period of up to 12 months, as long as the extension without funds does not involve a change in the approved objectives or scope of the project. You must notify the USAMRAA Grants Officer in writing at least 30 calendar days prior to the expiration date of the award. The notification must state the additional time needed, the reasons for the extension, and the work to be completed during the extension period. You 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.

b. Reference "Expiration of Funds" in your Award Specific Research Terms and Conditions for the impact of the availability of funds on extensions to your award.

c. Collaborating awards (two or more USAMRAA-issued awards completing the same Statement of Work) may have to have identical periods of performance. Each collaborating recipient's business office must contact the Grants Specialist regarding extensions.

d. Any extension without funds beyond the initial extension requires prior approval from the USAMRAA Grants Officer.

15. Unobligated Balances (NOVEMBER 2015)

You are authorized to carry forward unobligated balances to subsequent funding periods of the award agreement without prior written approval.

16. Fee and Profit (NOVEMBER 2105)

In accordance with DoDGARs 22.205(b), the use of an assistance agreement (grant or cooperative agreement) shall not be used to carry out programs where fee or profit is necessary to achieving program objectives. The payment of fee or profit to you or to any subaward at any tier under an award is prohibited.

17. Exercise of Option (NOVEMBER 2015)

The award specific research terms and conditions will identify if an option(s) is included in your award. The USAMRAA Grants Officer may exercise an option to provide additional funds for supplemental work as identified in the statement of work (SOW) or in any special term and condition of the award. Exercise of the option will be by issuance of a written modification to the award signed by the USAMRAA Grants Officer. The modification will be issued prior to the expiration date of the period of performance. Inclusion of an option in the award does not commit the Federal Government to an extension or to any additional funding.

18. Payment Requests (FEBRUARY 2017)

a. Payments. Reimbursement payments should generally be the method used under the award. Advance payments may be used in exceptional circumstances, subject to DoDGARs 34.12(b)(2). Payments will be made to you upon receipt of a “grant voucher” (used for both 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 your award. It is anticipated that the Defense Finance and Accounting Service (DFAS) will disburse funds within 30 days of receipt of a proper grant voucher.

b. Electronic Funds Transfer (EFT). All payments will be made by EFT to your organization’s financial 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. Failure to submit required Technical Reports or Federal Financial Reports (SF425s) may delay payments or result in nonpayment.

d. Interest Bearing Account. You must deposit all advance payments into an interest bearing account unless one of the following applies:

- (1) You receive less than \$120,000 in Federal awards per year.
- (2) The best reasonably available interest bearing account would not be expected to earn interest in excess of \$500 per year on Federal cash balances.
- (3) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-Federal cash resources.

c. Interest over the amount of \$500 per year must be remitted annually to the U.S. Department of Health and Human Services, Payment Management System, P. O. Box 6021, Rockville, Maryland 20852. You must send a copy of the transmittal letter stating the amount of interest remitted to the email address of the Grant Specialist identified in the award specific research terms and conditions.

19. Electronic Payment Instructions (NOVEMBER 2015)

The Wide Area Work Flow (WAWF) e-Business Suite is the required method to electronically process your 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). You must (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 the award. The award specific research terms and conditions will include instructions on how to submit grant vouchers and who to contact for assistance, if needed.

20. Property Standards (NOVEMBER 2015)

You must manage, use and dispose of property in accordance with the requirements established in DoDGARs 34.20 through 34.24.

21. Title to Real Property and Equipment (NOVEMBER 2015)

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 DoDGARs 34.21. Title is a conditional title. You are required to request disposition instructions from the USAMRAA Grants Officer at the conclusion of the period of performance or when the real property or equipment is no longer needed to conduct the project.

22. Federally Owned Property (NOVEMBER 2015)

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

23. Property Management System (NOVEMBER 2015)

Your property management system for Federally-owned property and for equipment that is acquired in whole or in part with Federal funds is subject to the requirements of DoDGARs 34.23.

24. Supplies (NOVEMBER 2015)

Title to supplies acquired with Federal funds under the award vests in the recipient upon acquisition. Upon termination or completion of the project, you may retain any unused supplies. If the inventory of unused supplies exceeds \$5,000 in total aggregate value and the items are not needed for any other Federally sponsored project or program, you can retain the items for use on non-Federal sponsored activities or sell them, but must, in either case, compensate us for our share.

25. Intangible Property – Data and Software Requirements (NOVEMBER 2015)

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

26. Patents and Inventions (NOVEMBER 2015)

a. iEdison and annual reporting. You must 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 must 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 and must be submitted electronically within 120 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 you have met all reporting requirements.

c. See the award specific research terms and conditions for submission instructions.

27. Financial Reporting Requirements (FEBRUARY 2017)

a. You must use the Standard Form (SF) 425, "Federal Financial Report," for reporting individual awards. Annual and final reports are required.

b. The Federal Financial Reporting period end dates fall on the end of the calendar year for annual reports (12/31), and the end date of the term of award for the final report. Submit annual reports no later than 90 days after the end of the calendar year. Submit final reports no later than 120 days after the end date of the period of performance.

c. See the award specific terms and conditions for submission instructions.

28. Audits (NOVEMBER 2015)

Any recipient that expends \$750,000 or more in a year under Federal awards shall have an audit made by an independent auditor in accordance with the requirements of DoDGARs 34.16. You must make the auditor's report available upon request.

29. Technical Reporting Requirements (FEBRUARY 2017)

Quarterly Technical Reports (*optional*)

a. For each year of the award, the PI must submit Quarterly Technical Progress Reports covering research results (positive and negative data) over a three month period (quarter). A reporting quarter begins with the start date of the award and restarts annually from that date for the entire period of performance. A Quarterly Technical Progress Report for the fourth quarter each year is not required, as the Annual Technical Report must incorporate all four quarters of progress.

b. 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 US Army Medical Research and Materiel Command (USAMRMC) advised of developments and problems as the research effort proceeds. The reports also provide a measure against which funding decisions are made.

c. Prepare all Quarterly reports in accordance with the Quarterly Technical Progress Report format, available at <http://www.usamraa.army.mil/index.cfm?ID=12&Type=3>. Each item of the report format must be completed.

d. Each report must be submitted electronically, within 15 days after the end of each quarter, to the Grant Specialist and the GOR at the e-mail addresses specified in the cover pages of the award. Name your file with your award number, followed by Year X Quarter Y Report (example: W81XWH-17-1-0000 Year 1 Quarter 1 Report.) If you have questions, contact the GOR.

e. Special Reports, if required, will be included in the Award Specific Terms and Conditions. Examples of special reports are:

Collaborative Awards: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks must be clearly marked with the responsible PI and research site.

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

Annual/Final Technical Reporting Requirements

a. Annual Reports

(1) Annual reports are required and must 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.

(2) Annual reports must 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 must 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 must still be submitted within 30 days of the anniversary date of the award. A final report that describes the entire research effort is due upon completion of the extended performance date.

b. Final Reports. A final report must also be prepared in accordance with the RPPR and must be submitted within 120 calendar days of the end of the period of performance. The report must summarize the entire research effort, citing data in the annual reports and appended publications.

c. Prepare the annual and final reports in accordance with the RPPR format, available at <http://www.usamraa.army.mil/index.cfm?ID=12&Type=3>. Although there is no page limitation for the reports, each report must be of sufficient length to provide a thorough description of the accomplishments with respect to the approved SOW.

d. Reports, in electronic format (PDF or Word file only), must be submitted to <https://ers.amedd.army.mil>.

Additional information is available on the Researcher Resources website, available at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting

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Collaborative Awards: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks must be clearly marked with the responsible PI and research site.

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

30. Delinquent Technical Reports (FEBRUARY 2017)

If you are delinquent on technical reporting requirements for other USAMRAA-sponsored awards, no new awards will be issued to you until all delinquent reports have been submitted.

31. Manuscripts/Reprints (NOVEMBER 2015)

Copies of manuscripts or subsequent reprints resulting from the research must be submitted to the GOR identified in the cover pages of the award.

32. Abstracts (NOVEMBER 2015)

An abstract suitable for publication in the proceedings of a special conference may be requested. Instructions for the abstract format and submission will be provided prior to the conference.

33. Reporting Requirements for Federal Funding Accountability and Transparency Act Implementation (NOVEMBER 2105)

You must report first-tier subaward and executive compensation in accordance with the Federal Funding Accountability and Transparency Act of 2006 and associated 2008 amendments (the "Transparency Act" or "FFATA"). See 2 CFR part 170, Appendix A to part 170 for applicability and reporting requirements.

34. Reporting of Matters Related to Recipient Integrity and Performance (NOVEMBER 2015)

a. General Reporting Requirement

Effective January 1, 2016, if the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of [Public Law 110-417](#), as amended ([41 U.S.C. 2313](#)). As required by section 3010 of [Public Law 111-212](#), all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

b. Proceedings about Which You Must Report

Submit the information required about each proceeding that:

(1) Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;

(2) Reached its final disposition during the most recent five year period; and

(3) Is one of the following:

(a) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

(b) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;

(c) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or

(d) Any other criminal, civil, or administrative proceeding if:

(i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;

(ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and

(iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

c. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

d. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total

value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

e. Definitions

For purposes of this award term and condition:

(1) Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (*e.g.*, Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

(b) Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of *nolo contendere*.

(c) Total value of currently active grants, cooperative agreements, and procurement contracts includes—

(i) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and

(ii) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

35. Prohibition on Using Funds under Grants and Cooperative Agreements with Entities that Require Certain Internal Confidentiality Agreements (NOVEMBER 2015)

a. The recipient may not require its employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting them from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

b. The recipient must notify its employees, contractors, or subrecipients that the prohibitions and restrictions of any internal confidentiality agreements inconsistent with paragraph (a) of this award provision are no longer in effect.

c. The prohibition in paragraph (a) of this award provision does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d. If the Government determines that the recipient is not in compliance with this award provision, it:

(1) Will prohibit the recipient's use of funds under this award, in accordance with section 743 of Division E of the Consolidated and Further Continuing Resolution Appropriations Act, 2015, (Pub. L. 113-235) or any successor provision of law; and

(2) May pursue other remedies available for the recipient's material failure to comply with award terms and conditions.

36. Site Visits (NOVEMBER 2015)

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 Federal Government representative on your or your subrecipient's premises, you must provide, and must require your subrecipients to provide, all reasonable facilities and assistance for the safety and convenience of the Federal

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.

37. Retention and Access Requirements for Records (NOVEMBER 2015)

a. With the exception of types of records described in DoDGARs 34.42, you must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of an award, or may reasonably be considered pertinent to an award, for a period of 3 years from the date of submission of the final Financial Status Report (SF 425).

b. If the information described in this section is maintained on a computer, you must retain the computer data on a reliable medium for the time periods prescribed. You may transfer computer data in machine readable form from one reliable computer medium to another. Your computer data retention and transfer procedures must maintain the integrity, reliability, and security of the original computer data. You must also maintain an audit trail describing the data transfer. For the record retention time periods prescribed in this section, you must not destroy, discard, delete, or write over such computer data.

38. Termination (NOVEMBER 2015)

The USAMRAA Grants Officer may terminate or suspend, in whole or in part, the award by written notice to you upon a finding that you have failed to comply with the material provisions of the award, if you materially change the objective of the award, 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 Federal 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, you 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.

39. Enforcement (NOVEMBER 2015)

The procedures of DoDGARs 22.815 govern the processing of claims and disputes and for deciding appeals of Grants Officers' decisions. Appeals of a Grants Officer's decision will be resolved by the Head of the Contracting Activity (HCA). The decision by the HCA will be final and not subject to further administrative appeal. However, you do not waive any legal remedy, such as formal claims, under Title 28 United State Code 1491, by agreeing to such provision. The enforcement remedies identified in this section, including suspension and termination, do not preclude you from being subject to debarment and suspension under DoDGARs part 1125.

40. Grant Appeal Authority (NOVEMBER 2015)

USAMRAA's Grant Appeal Authority to decide formal, administrative appeals in accordance with 32 CFR 22.815 is the Head of the Contracting Activity for the US Army Medical Command.

41. Closeout Requirements (NOVEMBER 2015)

a. The following documents must be submitted within 120 calendar days of the end of the period of performance. The award specific research terms and conditions provide submission instructions.

(1) Final SF425, "Federal Financial Report." Form and instructions are available at <https://www.usamraa.army.mil/pages/sf425>.

(2) Final Technical Report. Forms and instructions are available at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting

(3) Final DD Form 882, "Report of Inventions and Subcontracts." Form and instructions are available at <https://www.usamraa.army.mil>.

(4) Property Acquired with Award Funds

(a) You must provide a cumulative listing of nonexpendable personal property acquired with award funds, if applicable. You may submit this on your organization's letterhead. Reference DoDGRs 34.21.

(b) You must submit a statement that (i) there is, or is not, a residual inventory of unused supplies exceeding \$5,000 in total aggregate value; and (ii) if there is, state whether or not the items are needed for any other Federally sponsored project or program. You may submit this on your organization's letterhead. Reference DoDGARs 34.24.

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 must promptly refund any unspent balances of funds the DoD Component has advanced or paid that is not authorized to be retained by you.

SUBDIVISION C – National Policy Requirements

You are required to comply with the National Policy Requirements, as applicable, incorporated herein by reference. The National Policy Requirements are available in full text at <http://www.onr.navy.mil/Contracts-Grants/submit-proposal/grants-proposal/grants-terms-conditions.aspx> and at <http://www.usamraa.army.mil/index.cfm?ID=12&Type=3>.

SUBDIVISION D – Programmatic Requirements

42. Publication, Acknowledgement, and Public Release (NOVEMBER 2015)

a. Publication. You are encouraged to publish results of the research, unless classified, in appropriate media. Submit one copy of each paper to the GOR simultaneously with its submission for publication. Forward copies of all publications resulting from the research 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.

b. Acknowledgment. You agree that in the release of information relating to the award, such release must 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.

(1) "The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office" and;

(2) The award specific research terms and condition will contain requirements for specific language acknowledging the funding agency within the DoD.

(3) "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture."

(4) "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules."

(5) “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.”

c. Public release. Prior to release to the public, you must notify the USAMRAA Grants Officer and the GOR of the following: planned news releases, planned publicity, advertising material, 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 the award.

43. Research Involving Recombinant DNA Molecules (NOVEMBER 2015)

By signing this award or accepting funds under the award, you assure that all work involving the use of recombinant DNA will be in compliance with guidance provided at <http://osp.od.nih.gov/office-biotechnology-activities>.

44. Prohibition of Use of Laboratory Animals (NOVEMBER 2015)

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 must 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.

45. Prohibition of Use of Human Subjects (NOVEMBER 2015)

Research under this award involving the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, cannot begin until the USAMRMC’s Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification to you. Written approval to proceed from the USAMRMC ORP is also required for any subrecipient that will use funds from this award to conduct research involving human subjects.

The USAMRMC ORP conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must 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 substantive modifications to the protocol, continuing review documentation, and the final report 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, must be promptly reported to the USAMRMC ORP.

Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRMC ORP HRPO.

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, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, must 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 USAMRMC ORP Human Research Protection Office submission instructions can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

46. Prohibition of Use of Human Cadavers (NOVEMBER 2015)

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens 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. Approval must be obtained from the USAMRMC ORP. Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. ORP will issue written approvals to begin under separate notification to the recipient. Written approval to proceed from the USAMRMC ORP is also required for any subrecipient that will use funds from this award to conduct RDT&E, education or training involving human cadaveric specimens.

Recipients must promptly report problems related to the conduct of the activity involving cadavers or the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers to the USAMRMC ORP.

Recipients must maintain complete records of the activity.

The USAMRMC or designees must be permitted to observe the activity upon request and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.

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

47. National Security (NOVEMBER 2015)

The award is intended for unclassified, publicly releasable research. You will not be granted access to classified information. We do not expect that the results of the research project will involve classified information. If, however, in conducting the activities supported under the award, you or the PI is concerned that any of the research results involve potentially classifiable information that may warrant Government restrictions on the dissemination of the results, you must promptly notify the USAMRAA Grants Officer.

48. Use of Non-Federal Personnel (NOVEMBER 2015)

Some program offices use contractor personnel to assist GORs with review of technical reports. All review processes are conducted confidentially. Contractor personnel are required to sign agreements to protect the confidentiality of the information. Violations by reviewers that compromise the confidentiality of the reviews may result in suspension or debarment of the individual or contractor from Federal awards.