

**US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
GENERAL RESEARCH TERMS AND CONDITIONS
WITH INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND
NON-PROFIT ORGANIZATIONS
NOVEMBER 2015**

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 institutions of higher education, hospitals, and other non-profit organizations.

2. Effective Date – NOVEMBER 2015

3. 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 USAMRAA.

4. Use of English Language (NOVEMBER 2015)

In accordance with OMB guidance in 2 CFR 200.111(b), 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 any inconsistency between the award requirements in the English and translated versions.

5. Definitions (NOVEMBER 2015)

The following are definitions for frequently used terms. For a more comprehensive set of definitions, see Part 1 of the DoD R&D General Terms and Conditions.

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 USAMRAA award to a recipient, the most recent version of the budget the recipient submitted and the USAMRAA Grants Officer 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 and cooperative agreements are examples of legal instruments that USAMRAA uses 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 USAMRAA award, for which USAMRAA:

- 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 USAMRAA 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 USAMRAA 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 USAMRAA 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 in PROP Articles II-IV, Section D of PROP Article I, and REP Article III of this award.

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 USAMRAA prime award, transfers--for performance by an entity at the next lower tier--a portion of the substantive program for which the USAMRAA'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), 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 USAMRAA 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

6. Administrative Requirements Incorporated by Reference (NOVEMBER 2015)

You are required to comply with the DoD R&D General Terms and Conditions, incorporated herein by reference in the Award Specific Research Terms and Conditions of the award. The DoD R&D General Terms and Conditions are available in full text at <http://www.onr.navy.mil/Contracts-Grants/submit-proposal/grants-proposal/grants-terms-conditions.aspx>.

7. Your Responsibility (NOVEMBER 2015)

In addition to your responsibilities as defined or incorporated elsewhere in the award:

- 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.

8. Supporting Information (NOVEMBER 2015)

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. Our receipt of this information does not constitute approval or acceptance of any term or condition included therein.

9. 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 organization'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.

10. Financial Assistance Use of Universal Identifier and Central Contractor Registration* (NOVEMBER 2105)

Reference Appendix A to 2 CFR part 25. Unless you are exempted from this requirement based on the criteria provided in OMB 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>.

11. Maximum Obligation (NOVEMBER 2015)

The maximum obligation of the Federal Government for support of the 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, or other costs.

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. Clarifications Concerning Charges of Publication Costs (NOVEMBER 2015)

You may charge to the award costs of publishing in professional journals publications incurred after the period of performance, as permitted under paragraph 2 CFR 200.461(b)(3), only if:

a. We receive the request for payment for such costs no later than the date on which REP Article II of the DoD R&D General Terms and Conditions require you to submit the final financial report to us (or, if we grant your request for an extension of the due date, that later date on which the report is due); and

b. Your reported expenditures on the final financial report include the amount you disbursed for those costs.

14. Prior Approval Requirements (NOVEMBER 2015)

You must request prior approval from the USAMRAA Grants Officer 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 direct costs that require prior approval in accordance with the applicable cost principles, as identified in FMS Article III of the DoD R&D General Terms and Conditions. Note the following requirements and limits:

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

(2) The requirement for prior written approval of capital expenditures for equipment that is to be used primarily in carrying out the project or program supported by the award is waived for equipment with a unit cost of \$25,000 or less. Capital expenditures for equipment with a unit cost over \$25,000 requires the USAMRAA Grants Officer's prior approval. **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.**

e. 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.

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

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

15. Extension of the Period of Performance (NOVEMBER 2015)

a. You may initiate, without prior approval, a one-time, extension without 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. Any extension without funds beyond the initial extension requires prior approval from the USAMRAA Grants Officer.

16. Exercise of Option (NOVEMBER 2015)

a. 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.

b. Election of an option, if included in the award, will be contingent upon receipt of appropriated funds, acceptable performance by the recipient, continued relevance of the project to the program objectives, and any requirements identified in the SOW or special terms and conditions.

17. Payment Requests (NOVEMBER 2015)

a. Payments. You are authorized to request advance or cost reimbursement payments. The award specific research terms and conditions will identify which payment type will be applicable to your award. 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. A copy of the most recently submitted Federal Financial Report (SF 425) must be attached in the WAWF e-Business Suite and submitted with each grant voucher for all grant voucher submissions subsequent to the initial grant voucher submission.

c. Electronic Funds Transfer (EFT). All payments will be made by EFT to 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.

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

e. Interest Bearing Account. Unless exempted by applicable Treasury-State agreements in accordance with the Cash Management Improvement Act (CMIA) (31 USC 3335), you must deposit all advance payments into an interest bearing account. 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.

18. 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.

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

All software and data first produced under the award are subject to the Federal Purpose license in accordance with the requirements of PROP Article VI of the DoD R&D General Terms and Conditions. You grant to the Federal Government all necessary and appropriate licenses as a condition of the award.

20. 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.

21. Financial Reporting Requirements (NOVEMBER 2015)

a. You must 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.

b. 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 must be submitted no later than 30 days after the end of each quarter. Annual reports must be submitted no later than 90 days after the end of the calendar year. Final reports must be submitted no later than 120 days after the end date of the term of award.

c. The award specific terms and conditions will contain submission instructions.

22. Technical Reporting Requirements (NOVEMBER 2015)

Quarterly Technical Reports (*optional*)

a. For each year of the entire period of performance of the award, the PI must 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 must 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 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.

b. 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.

c. 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-16-1-0000 Year 1 Quarter 1 Report.) If you have questions, contact the GOR.

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

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.

23. Delinquent Reports (NOVEMBER 2015)

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

24. 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.

25. 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.

26. 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.

27. 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.

28. 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 Funds, if applicable. [Reference PROP Article IV of the DoD R&D General Terms & Conditions (October 2015).]

(a) If title to property (equipment and supplies) is excepted property, there is no further obligation to the Federal Government.

(b) If title to equipment under the award is non-excepted property, you must provide a cumulative listing of nonexpendable personal property acquired with award funds. You may submit this on your organization's letterhead.

(c) If title to supplies under this award is non-excepted property, 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 unused items will be needed on other Federally sponsored projects or programs. You may submit this on your organization's letterhead.

b. In the event a final audit has not been performed prior to the closeout of the award, USAMRAA retains the right to recover an appropriate amount after fully considering the recommendations on disallowed costs resulting from the final audit.

c. You must promptly refund any unspent balances of funds that USAMRAA 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 included in Subchapter E of the DoD R&D General Terms and Conditions, 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

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

a. Publication. You are encouraged to publish results of the research, unless classified, in appropriate media. One copy of each paper must be submitted to the GOR simultaneously with its submission for publication. Copies of all publications resulting from the research must be forwarded to the USAMRAA Grants Officer or Grant Specialist as they become available, even though publication may in fact occur subsequent to the termination date of the award. (See paragraph 11 above regarding the charging of publication costs to 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 include 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.

30. Research Involving Recombinant DNA Molecules (NOVEMBER 2015)

By signing the 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>.

31. 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 applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRMC ACURO to the recipient with a copy to the USAMRAA Grants Officer. 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.

Noncompliance 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.

32. 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.

33. 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.

34. 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.

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

Some USAMRMC program offices use contractor personnel to assist the 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.