

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

DIVISION III – GENERAL RESEARCH TERMS AND CONDITIONS

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SUBDIVISION A – PREAMBLE

TERMS AND CONDITIONS

1. Applicability

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

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

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

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:

1 a. All Federal funding made available to the recipient under the award to use for project or program
2 purposes.

3
4 b. Any cost sharing or matching that the recipient is required to provide under the award.

5
6 c. Any options that have been exercised but not any options that have not yet been exercised.

7
8 **Assistance.** *Assistance* means the transfer of a thing of value to a recipient to carry out a public purpose of
9 support or stimulation authorized by a law of the United States (see 31 U.S.C. 6101(3)). Grants, cooperative
10 agreements, and technology investment agreements are examples of legal instruments that DoD Components use to
11 provide assistance.

12
13 **Cooperative Agreement.** *Cooperative agreement* means a legal instrument which, consistent with 31 U.S.C.
14 6305, is used to enter into the same kind of relationship as a grant (see definition of “grant” in this part), except that
15 substantial involvement is expected between the DoD and the recipient when carrying out the activity contemplated
16 by the cooperative agreement. The term does not include “cooperative research and development agreements” as
17 defined in 15 U.S.C. 3710a.

18
19 **Equipment.** *Equipment* means tangible personal property (including information technology systems) having a
20 useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of:

21 a. \$5,000; or

22
23 b. The recipient’s or subrecipient’s capitalization threshold for financial statement purposes.

24
25 **Excepted property.** *Excepted property* means tangible personal property acquired in whole or in part with
26 Federal funds under a DoD Component’s awards, for which the DoD Component:

27
28 a. Has statutory authority to vest title in recipients (or allow for vesting in subrecipients) without further
29 obligation to the Federal Government or subject to conditions the DoD Component considers appropriate; and

30
31 b. Elects to use that authority to do so.

32
33 An example of excepted property authority is contained in the Federal Grant and Cooperative Agreement Act (31
34 U.S.C. 6306) for tangible personal property acquired under an award to conduct basic or applied research by a
35 nonprofit institution of higher education or nonprofit organization whose primary purpose is conducting scientific
36 research.

37
38 **Fixed-amount award.** *Fixed-amount award* means a DoD Component grant or cooperative agreement that
39 provides for the recipient to be paid on the basis of performance and results, rather than the actual, allowable costs
40 the recipient incurs.

41
42 **Fixed-amount subaward.** *Fixed-amount subaward* means a subaward:

43 a. That a recipient or subrecipient makes to another entity at the next lower tier; and

44
45 b. Under which the total amount to be paid to the other entity is based on performance and results, and
46 not on the actual, allowable costs that entity incurs.

47
48 **Grant.** *Grant* means a legal instrument which, consistent with 31 U.S.C. 6304, is used to enter into a
49 relationship:

50
51 a. Of which the principal purpose is to transfer a thing of value to the recipient to carry out a public
52 purpose of support or stimulation authorized by a law of the United States, rather than to acquire property or
53 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* (GO) 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

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

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

1 a. You will bear primary responsibility for the conduct of the research and will exercise sound judgment
2 within the limits of the award's terms and conditions.

3
4 b. The Principal Investigator (PI) specified in the award will be continuously responsible for the conduct of
5 the research project and will be closely involved with the research effort. The PI, in coordination with your Office
6 of Sponsored Projects/Business Office, is in the best position to determine the means by which the research may be
7 conducted most effectively.

8 9 **7. Supporting Information**

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

13 14 15 **8. Financial Instability, Insolvency, Bankruptcy or Receivership**

16
17 a. You must immediately notify the USAMRAA GO of the occurrence of the following events:
18 (1) your financial instability that would negatively impact performance of the award; (2) you or your parent's filing
19 of a voluntary case seeking liquidation or reorganization under the Bankruptcy Act; (3) your consent to the
20 institution of an involuntary case under the Bankruptcy Act against your organization or organization's parent; (4)
21 the filing of any similar proceeding for or against you or your parent, or consent to, the dissolution, winding-up or
22 readjustment of your debts, appointment of a receiver, conservator, trustee, or other officer with similar powers over
23 your organization, under any other applicable state or federal law; or (5) your insolvency due to its inability to pay
24 your debts generally as they become due.

25
26 b. Such notification must be in writing and must: (1) specifically set out the details of the occurrence of an
27 event referenced in paragraph "a"; (2) provide the facts surrounding that event; and (3) provide the impact such
28 event will have on the project being funded by the award.

29
30 c. Upon the occurrence of any of the five events described in paragraph "a" above, we reserve the right to
31 conduct a review of the award to determine your compliance with the required elements of the award (including
32 such items as cost share, progress towards technical project objectives, and submission of required reports). If the
33 USAMRAA GO's review determines that there are significant deficiencies or concerns with your performance under
34 the award, we reserve the right to impose additional requirements, as needed, including (1) change the payment
35 method; (2) institute payment controls, and (3) require additional reporting requirements.

36
37 d. Your failure to comply with this term may be considered a material failure by you to comply with the terms
38 of the award and may result in termination.

39 40 **9. Financial Assistance Use of Universal Identifier and Central Contractor Registration***

41
42 Reference Appendix A to 2 CFR part 25. Unless you are exempted from this requirement based on the criteria
43 provided in the Office of Management and Budget guidance in section 25.110 of 2 CFR part 25, you must maintain
44 current information about your organization in the system the Federal Government specifies as the repository for
45 information about its business partners (currently the System for Award Management (SAM)).

46
47 *The Central Contractor Registration is now part of the Federal repository entitled SAM, accessible
48 at <https://www.sam.gov>.

49 50 **10. Allowable Costs**

51
52 Allowability of costs will be determined in accordance with the cost principles applicable to the type of entity
53 incurring the costs, as follows:

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

4
5 (1) The for-profit cost principles in 48 CFR parts 31 and 231 (in the Federal Acquisition Regulation, or
6 FAR, and the Defense Federal Acquisition Regulation Supplement, or DFARS, respectively).

7
8 (2) The supplemental information on allowability of audit costs, in DoDGARs 34.16(f).

9
10 b. Other types of organizations. Allowability of costs incurred by other types of organizations that may be
11 subrecipients under a prime award to a for-profit organization is determined as follows:

12
13 (1) Institutions of higher education, nonprofit organizations, States, local governments, and Indian tribes.
14 Allowability is determined in accordance with the cost principles in Subpart E of 2 CFR part 200. Note that section
15 200.401(c) of that subpart provides that a nonprofit organization listed in Appendix VIII to 2 CFR part 200 is subject
16 to the FAR and DFARS cost principles specified in paragraph (a)(1) of this section for for-profit organizations.

17
18 (2) Hospitals. Allowability is determined in accordance with the cost principles identified in Appendix IX
19 to 2 CFR part 200 (currently 45 CFR part 75).

20 21 **11. Maximum Obligation**

22
23 The maximum obligation of the Federal Government for support of the award will not exceed the award amount
24 specified in the award cover pages, as modified. Awards will not be modified to provide additional funds for such
25 purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates
26 or for increases in salaries, fringe benefits, changes in exchange rates, or other costs. You may rebudget allowable
27 costs in accordance with applicable cost principles and in accordance with the prior approval requirements as stated
28 in this award.

29 30 **12. Prior Approval Requirements**

31
32 You must request prior approval from us for any of the following program or budget revisions:

33
34 a. A change in the scope or objective of the project or program under the award, even if there is no associated
35 budget revision that requires our prior approval.

36
37 b. A change in a key person(s) identified in cover pages of the award.

38
39 c. The approved principal investigator's or project director's disengagement from the project for more than
40 three months, or a 25 percent reduction in his or her time devoted to the project.

41
42 d. The inclusion of pre-award costs.

43
44 e. The inclusion of direct costs that require prior approval in accordance with the applicable cost principles, as
45 identified in the Federal Acquisition Regulations (FAR) part 31 and the Defense FAR Supplement part 231.

f. Expenditures for equipment costing \$5,000 or more, unless identified in the approved budget that is incorporated as part of the award, require the GO's written 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.

g. 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.

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

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 GO. 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.

13. No-cost Extension of the Period of Performance

a. You may initiate one time, without prior approval, a no-cost extension to the expiration date of the award for a period of up to 12 months, as long as the no-cost extension does not involve a change in the approved objectives or scope of the project. You must notify the USAMRAA GO in writing at least 10 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 no-cost extension 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 GO 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 GO.

14. Unobligated Balances

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

15. Fee and Profit

1 In accordance with DoDGARs 22.205(b), the use of an assistance agreement (grant or cooperative agreement) shall
2 not be used to carry out programs where fee or profit is necessary to achieving program objectives. The payment of
3 fee or profit to you or to any subaward at any tier under an award is prohibited.
4

5 **16. Authorization of Optional Research**

6
7 This award includes an option to provide additional funds for the optional research effort(s) as identified in the SOW.
8 Authorization of the optional research effort(s) will be by issuance of a written modification to this award signed by
9 the USAMRAA GO. The modification will be issued prior to the expiration date of the period of performance.
10 Inclusion of this term does not commit the Federal Government to an extension or to any additional funding.
11

12 **17. Payment Requests**

13
14 a. Payments. Reimbursement payments should generally be the method used under the award. Advance
15 payments may be used in exceptional circumstances, subject to DoDGARs 34.12(b)(2). Payments will be made to
16 you upon receipt of a "grant voucher" (used for both grants and cooperative agreements)) submitted through the
17 Procurement Integrated Enterprise Environment (PIEE) e-Business Suite in accordance with the Contract Line Item
18 Number (CLIN) structure set forth in this award. The Defense Finance and Accounting Service (DFAS) will
19 generally make payments within 30 calendar days after we receive the request for reimbursement unless we
20 reasonably believe the request is improper.
21

22 b. All payments will be made by Electronic Funds Transfer (EFT) to the bank account registered in the
23 System for Award Management (SAM) (located at <https://www.sam.gov>). You must maintain current information
24 about your organization in SAM, including information necessary to facilitate payment via EFT. We cannot be held
25 responsible for any misdirection or loss of payment which occurs as a result of your failure to maintain
26 correct/current EFT information within your SAM registration. Failure to update SAM and ensuring active account
27 status will result in nonpayment.
28

29 c. If you fail to comply with project objectives, the terms and conditions of the award, or Federal reporting
30 requirements, the GO may take enforcement actions in accordance with DoDGARs 34.52.
31

32 d. Interest Bearing Account. You must deposit all advance payments into an interest bearing account unless
33 one of the following applies:
34

- 35 (1) You receive less than \$120,000 in Federal awards per year.
- 36 (2) The best reasonably available interest bearing account would not be expected to earn interest in
37 excess of \$500 per year on Federal cash balances.
- 38 (3) The depository would require an average or minimum balance so high that it would not be feasible
39 within the expected Federal and non-Federal cash resources.
40

41 c. Interest over the amount of \$500 per year must be remitted annually to the U.S. Department of Health and
42 Human Services, Payment Management System, P. O. Box 6021, Rockville, Maryland 20852. You must send a
43 copy of the transmittal letter stating the amount of interest remitted to the email address of the Grant Specialist
44 identified in the award specific research terms and conditions.
45

46 **18. Electronic Payment Instructions**

- 47
48 i. The Procurement Integrated Enterprise Environment (PIEE) e-Business Suite is the required method to
49 electronically process your requests for payments. Once on the PIEE e-Business Suite web site, select the
50 Wide Area Workflow (WAWF) button to electronically submit "grant vouchers" (used for both grants and
51 cooperative agreements). You must (i) register to use WAWF at <https://wawf.eb.mil> and (ii) ensure an
52 electronic business point of contact (POC) is designated in the System for Award Management (SAM) site at
53 <https://www.sam.gov> within ten (10) calendar days prior to requesting a payment for this award. The Award
54 specific Research Terms and Conditions will include additional instructions on how to submit grant vouchers
55 and who to contact for assistance if needed.
56

57 **19. Property Standards**

58
59 You must manage, use and dispose of property in accordance with the requirements established in DoDGARs 34.20
60 through 34.24.

20. Title to Real Property and Equipment

The purchase of real property or equipment acquired in whole or in part with Federal funds requires prior approval of the USAMRAA GO. 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 GO at the conclusion of the period of performance or when the real property or equipment is no longer needed to conduct the project.

21. Federally Owned Property

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

22. Property Management System

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.

23. Supplies

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.

24. Intangible Property – Data and Software Requirements

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.

25. Patents and Inventions

- a. iEdison and annual reporting. You must electronically file Invention Disclosures and Patent Applications using the Interagency Edison (iEdison) system through the National Institute of Standards and Technology (<https://s-edison.info.nih.gov/iEdison>) within the times specified for reporting.
- b. Report of Inventions and Subcontracts. 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. Submit the final DD882 reports electronically to <https://ebrap.org/eBRAP/public/index.htm>
- c. See the award specific research terms and conditions for submission instructions.

26. Financial Reporting Requirements

- 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.

27. Audits

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(b). You must make the auditor's report available upon request.

28. Technical Reporting Requirements

Quarterly Technical Reports *(optional)*

a. For each year of the award, you 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 you and the Grants Officer's Representative (GOR). The reports provide the means for keeping the US Army Medical Research and Development Command (USAMRDC) 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 <https://www.usamraa.army.mil/Pages/Resources.aspx>. Each item of the report format must be completed.

d. Each report must be submitted electronically, within 30 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: W81XWH1710000 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 organizations. 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/Pages/Resources.aspx>) 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 GO, 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 <https://www.usamraa.army.mil/Pages/Resources.aspx>. 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://ebrap.org/eBRAP/public/index.htm>. The form and instructions can be found by selecting the *Funding Opportunities & Forms* tab. The form will be located under *Resources and Reference Material*.

Additional information is available on the Researcher Resources website, available at https://mrdc.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 organizations. 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/Pages/Resources.aspx>) must be updated and submitted as an appendix.

Award Charts: The Award Chart (available on <https://ebrap.org/eBRAP/public/Program.htm>) must be submitted as an appendix to the annual and final report.

Award Expiration Transition Plan: The Award Expiration Transition Plan (available on <https://ebrap.org/eBRAP/public/Program.htm>) must be submitted as an appendix to the final report.

Inclusion Enrollment Report: Inclusion enrollment data distributed on the basis of sex/gender, race, and ethnicity must be updated and submitted as an appendix to the annual and final report. The suggested Inclusion Enrollment Report format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

29. Delinquent Technical Reports

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.

30. Manuscripts/Reprints

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

31. Abstracts

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.

32. Reporting Requirements for Federal Funding Accountability and Transparency Act Implementation

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.

33. Reporting of Matters Related to Recipient Integrity and Performance

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 (FAPIIS)) 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.

34. Prohibition on Using Funds under Grants and Cooperative Agreements with Entities that Require Certain Internal Confidentiality Agreements

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.

35. Retention and Access Requirements for Records

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.

36. Termination

The USAMRAA GO 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 GO 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 GO, 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.

37. Enforcement

The procedures of DoDGARs 22.815 govern the processing of claims and disputes and for deciding appeals of GOs' decisions. Appeals of a GO'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.

38. Grant Appeal Authority

Grant Appeal Authority Head of Contracting Activity or Designee, U.S. Army Contracting Command, Mail to: USAMRAA, Attn: GEO, 820 Chandler Street, Fort Detrick, MD 21702.

39. Closeout Requirements

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://ebrap.org/eBRAP/public/index.htm>. The form and instructions can be found by selecting the *Funding Opportunities & Forms* tab. The form will be located under *Organizational Forms*.

(2) Final Technical Report. Forms and instructions are available at https://mrdc.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/Pages/Resources.aspx>

(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 DoDGARs 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.

(5) Delinquent Final Reports and Timeframe for Closeout

- (a) We intend to closeout this award no later than one year after the end date of the period of performance.
- (b) If you or your lower tier entities (e.g., subrecipients) do not have negotiated final indirect costs rates before the due date of the final financial reports, the final reports must be based on the best information at the time (e.g., proposed final indirect rates). You will have post-closeout continuing responsibilities related to the finalization of those rates in accordance with DoDGARs 34.60.
- (c) If you do not provide timely and/or accurate final reports or do not respond timely to our requests to reconcile discrepancies in these reports or other records, we may initiate closeout based on information we have on hand. For example, if you fail to submit a timely final financial report, we may use amounts provided in the latest interim financial report and/or payment request to determine final amounts to be paid for closeout purposes.
- (d) Failure to submit timely and accurate final reports may result in our taking one or more remedies as specified in DoDGARs 34.52 and reporting your material failure to comply with the terms and conditions of this award in the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS).

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.

40. Prohibition of Use of Covered Telecommunications Equipment or Services (August 2020)

Section 889 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Public Law 115-232) prohibits the head of an executive agency from obligating or expending loan or grant funds to procure or obtain, extend, or renew a contract to procure or obtain, or enter into a contract (or extend or renew a contract) to procure or obtain the equipment, services, or systems prohibited systems as identified in section 889 of the NDAA for FY 2019.

To implement this requirement DoD GOs shall include a condition in all awards that are issued on or after August 13, 2020 that provides:

(a) Recipients and subrecipients are prohibited from obligating or expending loan or grant funds to:

(1) Procure or obtain;

(2) Extend or renew a contract to procure or obtain; or

(3) Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

(i) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

(ii) Telecommunications or video surveillance services provided by such entities or using such equipment.

(iii) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal

Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

(b) In implementing the prohibition under Public Law 115-232, section 889, subsection (f), paragraph (1), heads of executive agencies administering loan, grant, or subsidy programs shall prioritize available funding and technical support to assist affected businesses, institutions and organizations as is reasonably necessary for those affected entities to transition from covered communications equipment and services, to procure replacement equipment and services, and to ensure that communications service to users and customers is sustained.

(c) See Public Law 115-232, section 889 for additional information.

COVERED FOREIGN COUNTRY means the People's Republic of China.

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 <https://www.usamraa.army.mil/Pages/Resources.aspx>.

SUBDIVISION D – Programmatic Requirements

41. Publication, Acknowledgement, and Public Release

- 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 GO or Grants Specialist as they become available, even though publication may in fact occur subsequent to the termination date of the award. (See Section C of the DoD R&D General Terms and Conditions for the charging of publication costs incurred after the period of performance.)
- b. Acknowledgment. You agree that in the release of information relating to this award such release will 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.
 - i. "The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office" and;
 - ii. "This work was supported by the (enter name of sponsoring agency identified in item no.0001), through the (enter program name), in the amount of (enter total costs), under Award No. (enter award number). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the (enter Department of Defense or U.S. Army as identified in item no.0001)."
 - iii. "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture."
 - iv. "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules."
 - v. "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 GO and the GOR of the following: planned news releases, planned publicity, advertising material concerning project work, and planned presentations to scientific meetings. This provision is not intended to restrict dissemination of research information; the purpose is to inform the USAMRDC of planned public release of information on

USAMRDC-funded research in order to adequately respond to inquiries and to be alerted to the possibility of inadvertent release of information.

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

42. Research Involving Recombinant DNA Molecules

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 <https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/>.

43. Prohibition of Use of Animals

Prohibition of Use of Animals

Notwithstanding any other terms and conditions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of animals in any manner whatsoever without the express written approval of the USAMRDC's Office of Research Protections (ORP) 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 USAMRDC ORP ACURO to the recipient with a copy to the USAMRAA GO. 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. The recipient must promptly inform the USMRDC ORP ACURO of adverse events regarding animals under applicable protocol(s) associated with this award. These requirements are defined in the approval letter from the USAMRDC ORP ACURO.

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

The USAMRDC ACURO requirements can be accessed at https://mrhc.amedd.army.mil/index.cfm?pageid=research_protections.acuro.

44. Prohibition of Use of Human Subjects

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

*This prohibition does not apply to research under this award that **solely** uses **only** one or more of the following types of human biospecimens to accomplish its aims: (1) established/existing commercially available human cell lines; (2) established/existing patient-derived xenograft (PDX) models; (3) commercially available human organoids; (4) commercially procured **pooled** human biospecimens.

The USAMRDC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Recipients and subrecipients must comply with all applicable human research protections requirements. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC 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 and subrecipients must adhere to the following reporting requirements:

Submission of study documents to the USAMRDC ORP HRPO for review and approval and provide the following reports: substantive modifications to the approved protocol, continuing review documentation (if applicable), and the final report as outlined in the USAMRDC ORP HRPO approval memorandum.

Prompt reporting of the following study events to the USAMRDC ORP HRPO.

- (1) All unanticipated problems involving risk to subjects or others.
- (2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.
- (3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.
- (4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.
- (5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.
- (6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO. The report must include actions taken by the institution and the IRB.

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

Submission instructions and investigator guidance on DoD requirements for human subjects research, including 32 CFR Part 219, DoD Instruction 3216.02, and USAMRDC ORP HRPO submission instructions can be accessed at https://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

45. Prohibition of Use of Human Cadavers

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens (with the exception of activities solely using established/existing human cadaveric cell lines) under this award shall not begin until USAMRDC approval in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 5 November 2019. (https://mrdc.amedd.army.mil/index.cfm?pageid=research_protections.overview).

The USAMRDC ORP is the Action Office (usarmy.detrick.medcom-usamrdc.other.hrpo@mail.mil) for this policy. Approval must be obtained from the USAMRDC 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. USAMRDC ORP written approval 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 USAMRDC ORP.

Recipients must maintain complete records of the activity.

The USAMRDC 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 USAMRDC withholding of funds and/or the termination of the award.

46. National Security

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 GO.

47. Use of Non-Federal Personnel

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.

