DIVISION III- USAMRAA ADDENDUM TO THE DoD GENERAL TERMS AND CONDITIONS AND USAMRAA PROGRAMMATIC REQUIREMENTS

Preamble

This award incorporates by reference the Department of Defense (DoD) Research and Development (R&D) General Terms and Conditions available at https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions. The USAMRAA Addendum to the DoD R&D General Terms and Conditions provides additional content relevant to USAMRAA awards for sections of specified articles from those general research terms and conditions. **The five asterisks indicate that there is content from the DoD R&D General Terms and Conditions within the identified parts and articles that remains unchanged and is not restated in this document. To understand the requirement for a given article, the DoD R&D General Terms and Conditions must be read in tandem with this USAMRAA Addendum.** The second portion of this addendum is comprised of the programmatic requirements portion of the general terms and conditions that apply to USAMRAA awards subject to the DoD R&D General Terms and Conditions.

USAMRAA Addendum to the DoD R&D General Terms and Conditions

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Part 1: Financial and Program Management (FMS Articles)

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FMS Article II. Payments

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Section C. Electronic Funds Transfer and other payment procedural instructions or information

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2. Other payment procedural instructions or information

a. Request for Payments

i. Payments. Payments will be made to you upon receipt of a "grant voucher" (used for both grants and cooperative agreements) submitted through the Procurement Integrated Enterprise Environment (PIEE) e-Business Suite in accordance with the Contract Line Item Number (CLIN) structure set forth in this award. The Defense Finance and Accounting Service (DFAS) will generally make payments within 30 calendar days after we receive the request for reimbursement unless we reasonably believe the request is improper.

ii. You must select "advance" or "reimbursement" on the grant voucher in PIEE.

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

b. Electronic Payment Instructions

See Division II of the USAMRAA Award Specific Terms and Conditions

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FMS Article IV. Revision of budget and program plans.

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Section B. Revisions requiring prior approval from the Grants Officer.

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e**. USAMRAA Specific Prior Approval Requirements**

i. The transfer (relocation) of the PI and or research project to another entity.
ii. Reimbursing a DoD Military Treatment Facility (MTF) for costs incurred if the MTF is involved in the award. Reimbursing these costs is generally prohibited and only approved under unusual and extraordinary circumstances.
iii. A change in a subrecipient or performance site within a foreign country or the addition of a subrecipient or performance site in a country other than that specified in the approved application.
iv. The transfer of work by a domestic subrecipient to a foreign subrecipient.

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Section C. Pre-award costs, carry forward of unobligated balances, and one-time no-cost extensions.

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3**. 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 Grants Officer (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 Division I Award Cover Pages to understand the impact of the availability of funds on award extensions.

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

d. Any subsequent no-cost extensions require prior approval from the USAMRAA GO.

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Part 4. Financial Programmatic, and Property Reporting (REP Article)

REP Article I. Performance management, monitoring, and reporting.

Section A. Required reporting form, format, or data elements for interim and final performance reports.

2. <u>Annual Technical Report</u>

a. 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. Annual reports must provide a complete summary of the research results (positive or negative) to date in direct alignment to the approved SOW. The importance of the report to decisions relating to continued support of the research cannot be over-emphasized.
b. Special Reporting Requirements for Annual Reports-−Refer to Division II.

3. Final Technical Report

a. A final report must be prepared in accordance with the RPPR. The report must summarize the entire research effort, citing data in the annual reports and appended publications.
b. Special Reporting Requirements for Final Reports−Refer to Division II.

4. Format

Prepare the annual and final reports in accordance with the RPPR format, available at https://usamraa.health.mil/resources/. 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.

Section B. Frequency, reporting periods, and due dates for interim performance reports.

An annual technical 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.

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Section F. Performance Reporting Procedures

Annual and Final Technical Reports, in electronic format (PDF or Word file only), must be submitted through the Electronic Biomedical Research Application Portal (eBRAP) at https://ebrap.org/eBRAP/public/index.htm. The form and instructions can be found 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.health.mil/index.cfm/resources/researcher_resources/reporting/technical

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REP Article II. Financial Reporting.

Section A. Required reporting form, format, or date elements for interim and final financial reports.

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Section B. Interim financial reports; frequency, reporting periods, and due dates.

The Federal Financial Reporting period end dates fall on the end of the calendar year for annual reports (12/31). You must submit annual reports no later than 90 days after the end of the calendar year.

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Section E. Where and how to submit financial reports.

1. You must submit all interim and final Standard Form 425 (SF 425) "Federal Financial Reports" electronically through the eBRAP 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. Do not report multiple awards on one report. Each award must be reported separately on its own SF 425.

3. Do not combine multiple SF 425 reports into one submission. Each form must be saved as a separate PDF and submitted individually.

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REP Article III. Reporting on Property.

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Section D. Intangible Property.

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1**. Inventions developed under this award.**

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a. Patents and Inventions Reporting Requirements

i. 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://www.nist.gov/iedison) within the times specified for reporting.

ii. 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

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Part 5: Other Administrative Requirements (OAR Articles)

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OAR Article IV. Claims, disputes, and appeals.

Section A. Definitions

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2. Grant Appeal Authority- Head of Contracting Activity or Designee, Defense Health Agency, Mail to: USAMRAA, Attn: GEO 808 Schreider Street, Fort Detrick, MD 21702.

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OAR Article VI. Closeout

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Section B. Refunds of Unobligated balances.

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a) Make check payable to the U.S. Treasury and mail to:
USAMRAA
Attn: FCMR-ABB-BU
(Insert Federal Award No. W81XWH or HT9425-_____)
808 Schreider Street
Fort Detrick, Maryland 21702-5014

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Part 7: National Policy Requirements

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NP Article III. National policy requirements concerning live organisms.

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Section C. Other requirements concerning live organisms

1. **Research Involving Recombinant DNA Molecules**

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 https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/.

2. **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 Human and Animal Research Oversight (OHARO) 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 OHARO 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 USAMRDC OHARO 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 OHARO 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://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro.

3. **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 OHARO's Office of Human Research Oversight (OHRO) provides authorization that the research may proceed. The USAMRDC OHARO OHRO will issue written approval to begin research under separate notification. Written approval to proceed from the

USAMRDC OHARO OHRO 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 OHARO 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 OHARO OHRO 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 OHARO OHRO approval memorandum.

Prompt reporting of the following study events to the USAMRDC OHARO OHRO.

(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 OHARO OHRO. 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 OHARO OHRO's submission instructions can be accessed at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

4. **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.health.mil/index.cfm/collaborate/research_protections).

The USAMRDC OHARO is the Action Office (https://mrdc.health.mil/index.cfm/collaborate/research_protections) for this policy. Approval must be obtained from the USAMRDC OHARO. Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. OHARO will issue written approvals to begin under separate notification to the recipient. USAMRDC OHARO 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 OHARO.

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.

The Cadaver Use Submission Form and the Army policy can be accessed at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo .

Programmatic Requirements Portion of the General Terms and Conditions

1. **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 Grants Officer's Representative (GOR) **simultaneously** with its submission for publication. Forward copies of all publications resulting from the research to the USAMRAA GO or Grants Management Specialist as they become available, even though publication may in fact occur subsequent to the period of performance end date. (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, 808 Schreider 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), in the amount of (enter total costs), through the (enter program name) under Award No. (enter award number). Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the (enter sponsoring agency 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.

2. **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.

3. **Use of Non-Federal Personnel**

Some USAMRDC 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.