

## **General Guidelines for Awards Funded by the Department of Defense (DoD)**

All awards issued by the DoD are subject to the regulatory policies and procedures of the DoD Grant and Agreement Regulations (DODGARs), DoD 3210.6-R, and of the U.S. Army Medical Research and Materiel Command (USAMRMC).

It should be noted that Activity Codes R01 and R34 are National Institutes of Health (NIH) terms. Any awards issued by the DoD will result in a similar type of award but will not be referred to as a R01 or R34.

In order to be considered for DoD funding, applications must address the technical merit(s) of the proposed research and development; and the potential relationship(s) of the proposed research and development to DoD missions.

### **1. Award Information**

The type of instrument used to reflect the business relationship between the recipient and the DoD will be a matter of negotiation prior to award. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC 6301-6308, provides the legal criteria to select an assistance agreement. An assistance agreement is appropriate when the Federal Government transfers a “thing of value,” to a “state, local government or “other recipient,” to carry out a public purpose or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the United States Government. The nature of the research, as well as all the recipient’s obligations to the Government under the instrument, indicates that the principal purpose of the award is to stimulate research of a public purpose. If there is “no substantial involvement” on the part of the funding agency, a grant award will be made (31 USC 6304). Conversely, if there is substantial involvement on the part of the funding agency, a cooperative agreement will be made (31 USC 6305). DoD funding will be executed by the U.S. Army Medical Research and Materiel Command (USAMRMC) and its supporting acquisition office, the U.S. Army Medical Research Acquisition Activity (USAMRAA), will process applications selected for funding.

### **2. Research Involving the Use of Animals, Human Subjects, or Human Anatomical Substances/Human Data**

Principal Investigators (PIs) and applicant organizations may not commence performance of research involving human subjects, human anatomical substances, and/or human data or laboratory animals or expend funding on such effort, until and unless applicable regulatory documents are reviewed, and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) to ensure that Department of Defense (DoD) regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, “Use of Animals in DoD Programs,” as issued September 13, 2010 available at

[https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections.acuro\\_regulations](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations) and DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," as issued on November 8, 2011, and available at <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

Studies involving animals and non-exempt research involving human subjects (to include direct intervention/interaction, obtaining individually identifiable information, and obtaining individually identifiable anatomical substances) must be approved through a regulatory review process by the PI's local Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) and by the USAMRMC Office of Research Protections (ORP). The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research. The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects. ***Research involving human subjects that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI's institution as well as the ORP HRPO at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

Concurrent with the U.S. Army Medical Research Acquisition Activity negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form (to be submitted upon request).

#### **A. Research Involving Animal Use**

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding (these documents should not be submitted with the application). The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: [https://mrmc.amedd.army.mil/index.cfm?pageid=Research\\_Protections.acuro\\_Animalappendix](https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix). Allow 2 months for Government regulatory review and approval processes for animal studies.

For additional information, send questions via email to ACURO ([ACURO@amedd.army.mil](mailto:ACURO@amedd.army.mil)).

#### **B. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers**

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadavers 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](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview)). The USAMRMC Office of Research Protections (ORP) is the Action Office ([hrpo@amedd.army.mil](mailto:hrpo@amedd.army.mil)) for this policy. Approval must be obtained from the Head of the Army organization that is supporting/funding the activity involving cadavers as described in the policy. For certain activities involving cadavers, approval must also be obtained from ORP. Award recipients must

coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the recipient.

### **C. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances**

*In addition to local IRB review, all USAMRMC-funded research involving human subjects and human anatomical substances must receive a USAMRMC Headquarters-level Administrative Review and be approved by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate that the IRB review was appropriate and ensure DoD, Army, and USAMRMC regulatory requirements have been met.*

Questions regarding applicable human subject protection regulations, policies, and guidance should be directed to the local IRB, the USAMRMC ORP HRPO ([hrpo@amedd.army.mil](mailto:hrpo@amedd.army.mil)) and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms refer to the ORP HRPO website([https://mrmc.amedd.army.mil/index.cfm?pageid=Research\\_Protections.hrpo](https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo)).

*ORP HRPO-specific language must be inserted into the consent form, and compliance with DoD regulations may require additional information be included in the protocol.*

The ORP HRPO ensures that DoD supported and/or conducted research complies with specific laws and directives governing research involving human subjects. These laws and directives may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the “Information for Investigators” found at [https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections.hrpo](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo). The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. ***Allow at least 2 months for Government regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances can be found at [https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections.hrpo](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo).

**Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DoD Assurance.

**Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.

**Informed Consent Form:** The following must appear in the consent form:

- A statement that the U. S. Army Medical Research and Materiel Command is providing funding for the study.
- A statement that representatives of the DoD are authorized to review research records.
- In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, DoD must be listed as one of the parties to whom private health information may be disclosed.

**Intent to Benefit:** The requirements of Title 10 United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained *in advance*; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an experimental subject in a DoD-supported study unless the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that the definition of experimental subject as defined in the DoDI 3216.02 has a much narrower definition than human subject. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

*10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at [hrpo@amedd.army.mil](mailto:hrpo@amedd.army.mil) if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.*

**Research Monitor Requirement:** For research determined to be greater than minimal risk, DoDI 3216.02 requires **that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.** The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities.

The research monitor’s duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI’s institution. Research monitor functions may include:

- observing recruitment and enrollment procedures and the consent process for individuals, groups or units,
- overseeing study interventions and interactions,
- reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports;
- overseeing data matching, data collection, and analysis

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report;
- shall have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study Health Information Portability and Accountability Act authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

**Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator who will be familiar with service-specific requirements.

A letter of support from Commanders of military facilities or units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

**Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order service members to participate in a research study. For greater than minimal risk research, an ombudsman must be employed when conducting group**

**briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted service members who are trained to follow orders are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized if possible.**

**Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed \$50 per blood draw. They may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

**Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

**Site Visits:** The USAMRMC ORP HRPO conducts random 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.

*Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: [https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections.hrpo](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo).*

**Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.

**If you have difficulty accessing any of the <https://mrmc> web sites related to Research Protection, go to [www.usamraa.army.mil](http://www.usamraa.army.mil), click on Customers, select U.S. Army Medical Research and Material Command, and then the Research Protection link for the appropriate web sites.**

### **3. Administrative and National Policy Requirements**

a. **Information Release:** Award recipients are required to agree to the release of information pertaining to the research and development supported by the USAMRMC. Statement 1 shall be included in all such releases; statements 2-5 shall be included if relevant to the research being conducted:

1. “This work was supported by the US Army Medical Research and Materiel Command under Award No. \_\_\_\_\_. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.”

2. In conducting research using humans and/or human anatomical substances, the investigator is required to include approvals, documents and information specified on the Human Research Protection Office (HRPO) website: [https://mrmc.detrick.army.mil/index.cfm?pageid=Research\\_Protections.hrpo](https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.hrpo)

3. “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents and information specified on the Animal Care and Use Review Office (ACURO) website [https://mrmc.detrick.army.mil/index.cfm?pageid=Research\\_Protections.acuro&rn=1](https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1).

4. “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” ([www.nih.gov](http://www.nih.gov))

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.” ([www.cdc.gov/od/ohs/biosfty/biosfty.htm](http://www.cdc.gov/od/ohs/biosfty/biosfty.htm))

6. “Information” includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

**Failure to include Statement 1 on all information releases and Statements 2-5 when required may result in loss of funding.**

b. **Freedom of Information Act Requests:** The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official Government records. “Records” are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act. ([www.usdoj.gov/oip/index.html](http://www.usdoj.gov/oip/index.html))

When a FOIA request asks for information contained in a successful application that has been incorporated into an award document, the submitter will be contacted and given an opportunity

to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

c. **Site Visits:** During the term of the award, the PI is encouraged to visit USAMRMC laboratories and institutes to discuss related work with USAMRMC scientists. All such visits must have prior approval and should be coordinated through the USAMRAA Grants Officer. Funding for visits may be made available through the award instrument. The USAMRMC laboratory personnel, as well as other DoD personnel, are also encouraged to visit the PI during the award efforts. All visits must be coordinated with the Grants Officer and are intended for technical discussion and monitoring of progress of the funded project.

d. **J-1 VISA Waiver:** Organizations located outside of the U.S. have the responsibility to ensure that the research staff is able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the United States. **In addition, the Government will not provide funds to support scientists from terrorist countries.** Additional information on J-1 VISA Waivers can be located at the following Department of State web site: [travel.state.gov/visa/temp](http://travel.state.gov/visa/temp).

e. **Funding:** Funding may be provided incrementally during the life of the award.

f. **Titles to Inventions and Patents:** In accordance with the Bayh-Dole Act (Title 35, United States Code, Section 200 et seq.), title to inventions and patents resulting from Federally funded research may be held by the recipient or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

g. **Contracted Fundamental Research:** Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DoD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the 6.2-funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

h. **Conflict of Interest:** There are certain post-employment restrictions on former Federal officers and employees as defined in Section 207 of Title 18 United States Code and Federal Acquisition Regulation (FAR), Part 3.104-4(c). If a submitter believes a post-employment restriction or conflict of interest exists, the situation should be discussed with the

USAMRMC legal staff (telephone 301-619-6598) prior to expending time and effort in preparation of an application.

i. **Disclosure of Information Outside the Government:** Applications will only be disclosed outside of the Government for the sole purpose of technical evaluation. Evaluators must agree that information in the application will only be used for evaluation purposes and will not be further disclosed. Applications for funded projects will be subject to public release under the FOIA to the extent that they are incorporated into an award document; applications that are not selected for funding will not be subject to public release.

j. **Government Obligation:** Only a warranted Grants Officer may obligate the Government to the expenditure of funds for awards. The Government does not fund preparation of applications or support research that is inferred from discussions with technical project officers.

k. **Information Service:** Submitters may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; telephone: 703-605-6000 ([www.ntis.gov](http://www.ntis.gov)) to acquire information of existing research to avoid duplication of scientific and engineering effort.

1. **2 CFR Part 170 - Requirements for Federal Funding Accountability and Transparency Act Implementation - Appendix A to Part 170--Award Term**

I. Reporting Subawards and Executive Compensation

A. Reporting of first-tier subawards.

1. Applicability. Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates \$25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph e. of this award term).

2. Where and when to report.

i. You must report each obligating action described in paragraph a.1. of this award term to <http://www.fsrs.gov>.

ii. For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2012, the obligation must be reported by no later than December 31, 2012.)

3. What to report. You must report the information about each obligating action that the submission instructions posted at <http://www.fsrs.gov> specify.

B. Reporting Total Compensation of Recipient Executives.

1. Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if--

i. the total Federal funding authorized to date under this award is \$25,000 or more;

ii. in the preceding fiscal year, you received—

(A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

iii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/excomp.htm>.)

2. Where and when to report. You must report executive total compensation described in paragraph b.1. of this award term:

i. As part of your registration profile at <https://www.sam.gov>.

ii. By the end of the month following the month in which this award is made, and annually thereafter.

C. Reporting of Total Compensation of Subrecipient Executives.

1. Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if--

i. in the subrecipient's preceding fiscal year, the subrecipient

received--

(A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and

ii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>.)

2. Where and when to report. You must report subrecipient executive total compensation described in paragraph c.1. of this award term:

i. To the recipient.

ii. By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

D. Exemptions. If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

i. Subawards, and

ii. The total compensation of the five most highly compensated executives of any subrecipient.

E. Definitions. For purposes of this award term:

1. Entity means all of the following, as defined in 2 CFR part 25:

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

ii. A foreign public entity;

iii. A domestic or foreign nonprofit organization;

- iv. A domestic or foreign for-profit organization;
- v. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

2. Executive means officers, managing partners, or any other employees in management positions.

3. Subaward:

i. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

ii. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ---- .210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

iii. A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

4. Subrecipient means an entity that:

i. Receives a subaward from you (the recipient) under this award;  
and

ii. Is accountable to you for the use of the Federal funds provided by the subaward.

5. Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

i. Salary and bonus.

ii. Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

iii. Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.

iv. Change in pension value. This is the change in present value of

defined benefit and actuarial pension plans.

v. Above-market earnings on deferred compensation, which is not tax-qualified.

vi. Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

m. **2 CFR Part 25 - Financial Assistance Use of Universal Identifier and Central Contractor Registration** - Appendix A to Part 25--Award Term)

I. Central Contractor Registration and Universal Identifier Requirements

Note: The Central Contractor Registration process has been moved to the System for Award Management at [www.sam.gov](http://www.sam.gov).

A. Requirement for Central Contractor Registration (CCR)/System for Award Management (SAM). Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain the currency of your information in the SAM until you submit the final financial report required under this award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term.

B. Requirement for Data Universal Numbering System (DUNS) Numbers. If you are authorized to make subawards under this award, you:

1. Must notify potential subrecipients that no entity (see definition in paragraph C of this award term) may receive a subaward from you unless the entity has provided its DUNS number to you.

2. May not make a subaward to an entity unless the entity has provided its DUNS number to you.

C. Definitions. For purposes of this award term:

1. Central Contractor Registration (CCR) (now System for Award Management (SAM)) means the Federal repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at <http://www.sam.gov>).

2. Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (currently 866-705-

5711) or the Internet (currently at <http://fedgov.dnb.com/webform>).

3. Entity, as it is used in this award term, means all of the following, as defined at 2 CFR part 25, subpart C:

- a. A Governmental organization, which is a State, local government, or Indian Tribe;
- b. A foreign public entity;
- c. A domestic or foreign nonprofit organization;
- d. A domestic or foreign for-profit organization; and
- e. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

4. Subaward:

a. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

b. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ----.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

c. A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

5. Subrecipient means an entity that:

- a. Receives a subaward from you under this award; and
- b. Is accountable to you for the use of the Federal funds provided by the subaward.

**3..Reporting:** Reports are necessary for continuation of the research efforts and funding. Each award instrument will state the necessary reports that are due to the government. Reporting requirements may include the following:

a. Periodic technical reports that outline the accomplishments and progress for that period. This may include updating of a quad chart (if a template was provided at time of award) that details the study aims, objectives, designs, timeline progress, and challenges.

- b. Annual technical reports that consist of detailed summaries of scientific issues, accomplishments and animal research usage during the project.
- c. Final technical report that details the findings and issues of the completed project.
- d. For non-exempt human subjects' research, documentation of local Institutional Review Board (IRB) continuing review (in the intervals specified by the local IRB, but at least annually); approval for continuation must be submitted directly to the USAMRMC Office of Research Protections.
- e. Copies of all scientific publications as a result of funding.
- f. Abstracts that are suitable for publication in relation to planned meetings.
- g. Oral Presentations that detail the status of a project to a panel of subject matter experts.
- h. Quarterly Standard Form Report, SF425, Federal Financial Report, used for grants and cooperative agreements that tracks the expenditure of funds on the project.
- i. Programmatic Meetings that include discussions regarding findings, accomplishments and direction for the program.