

ASSURANCES

The following Assurances, as applicable, will be included in the terms and conditions of an assistance agreement award:

PROHIBITION OF USE OF LABORATORY 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 laboratory animals in any manner whatsoever without the express written approval of the USAMRMC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRMC ACURO to the recipient. Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. For each fiscal year, the recipient shall maintain, and upon request from ACURO, submit animal usage information.

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

PROHIBITION OF USE OF HUMAN SUBJECTS

Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information, shall not begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRMC ORP, under separate notification to the recipient. Written approval from the USAMRMC ORP is also required for any subrecipient that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRMC. Research records shall be stored in a confidential manner so as to protect the confidentiality of subject information.

The recipient is required to adhere to the following reporting requirements:

Submission of major modifications to the protocol, continuing review documentation, and the final report are required as outlined in the USAMRMC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRMC ORP.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRMC ORP.

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

PROHIBITION OF USE OF HUMAN CADAVERS

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadavers under this award shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections_overview). The USAMRMC Office of Research Protections (ORP) is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Written approvals to begin the activity will be issued under separate notification to the recipient.

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

NONDISCRIMINATION

By accepting funds under this award, the recipient assures that it will comply with applicable provisions of the following national policies prohibiting discrimination:

- a. On the basis of race, color, or national origin, in Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, et seq.), as implemented by DOD regulations at 32 CFR Part 195.
- b. On the basis of sex or blindness, in Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, et seq.), as implemented by DOD regulations at 32 CFR Part 196.
- a. On the basis of age, in the Age Discrimination Act of 1975 (42 U.S.C. 6101, et seq.) as implemented by Department of Health and Human Services regulations at 45 CFR Part 90.
- d. On the basis of handicap, in Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), as implemented by Department of Justice regulations at 28 CFR Part 41 and DOD regulations at 32 CFR Part 56, and the Architectural Barriers Act of 1968 (42 U.S.C. 4151, et seq.).

DEBARMENT AND SUSPENSION

The recipient assures that it will comply with the requirements regarding debarment and suspension in Subpart C of the OMB guidance in 2 CFR Part 180, as implemented by the DOD in 2 CFR Part 1125. The recipient shall communicate the requirement to comply with Subpart C to persons at the next lower tier with whom the recipient enters into transactions that are “covered transactions” under Subpart B of 2 CFR Part 180 and the DOD implementation in 2 CFR Part 1125.

ENVIRONMENTAL STANDARDS

By accepting funds under this award, the recipient assures that it will:

Comply with applicable provisions of the Clean Air Act (42 U.S.C. 7401, et seq.) and Clean Water Act (33 U.S.C. 1251, et seq.), as implemented by Executive Order 11738 [3 CFR, 1971-1975 comp., p. 799] and Environmental Protection Agency (EPA) rules at 40 CFR Part 32. In accordance with the EPA rules, the recipient further agrees that it will:

Not use any facility on the EPA’s List of Violating Facilities in performing any award that is nonexempt under 40 CFR 15.5 (awards of less than \$100,000, and certain other awards, exempt from the EPA regulations), as long as the facility remains on the list.

Notify the awarding agency if it intends to use a facility in performing this award that is on the List of Violating Facilities or that the recipient knows has been recommended to be placed on the List of Violating Facilities.

Identify to the awarding agency any impact this award may have on:

The quality of the human environment, and provide help the agency may need to comply with the National Environmental Policy Act (NEPA, at 42 U.S.C. 4321, et seq.) and to prepare Environmental Impact Statements or other required environmental documentation. In such cases, the recipient agrees to take no action that will have an adverse environmental impact (e.g., physical disturbance of a site such as breaking of ground) until the agency provides written notification of compliance with the environmental impact analysis process.

Coastal barriers, and provide help the agency may need to comply with the Coastal Barriers Resource Act (16 U.S.C. 3501, et seq.), concerning preservation of barrier resources.

Any existing or proposed component of the National Wild and Scenic Rivers system, and provide help the agency may need to comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271, et seq.).

DRUG FREE WORKPLACE

By accepting funds under this award, the recipient assures that it will comply with the “Government–Wide Drug-Free Workplace (Grants)” requirements specified by DODGAR Part

26, Subpart B (or Subpart C, if the recipient is an individual) of 32 CFR Part 26 (2004), which implements sec.5151-5160 of Drug-Free Workplace Act of 1988 (41 U.S.C. 701,et seq.).

OFFICIALS NOT TO BENEFIT

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this award, or to any benefit arising from it, in accordance with 41 U.S.C. 22.

PREFERENCE FOR U.S. FLAG AIR CARRIERS

Travel supported by U.S. Government funds under this award shall use U.S.-flag air carriers (air carriers holding certificates under 49 U.S.C. 41102) for international air transportation of people and property to the extent that such service is available, in accordance with the International Air Transportation Fair Competitive Practices Act of 1974 (49 U.S.C. 40118) and the interpretative guidelines issued by the Comptroller General of the United States in the March 31, 1981, amendment to Comptroller General Decision B138942.

CARGO PREFERENCE

The recipient assures that it will comply with the Cargo Preference Act of 1954 (46 U.S.C. 1241), as implemented by Department of Transportation regulations at 46 CFR 381.7, which require that at least 50 percent of equipment, materials or commodities procured or otherwise obtained with U.S. Government funds under this award, and which may be transported by ocean vessel, shall be transported on privately owned U.S.-flag commercial vessels, if available.

CAMPUS ACCESS FOR MILITARY RECRUITING AND RESERVE OFFICER TRAINING CORPS

The following requirement applies to domestic institutions of higher education.

As a condition for receipt of funds available to the Department of Defense (DOD) under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 CFR part 216) that has a policy or practice that either prohibits, or in effect prevents:

(A) The Secretary of a Military Department from maintaining, establishing, or operating a unit of the Senior Reserve Officers Training Corps (in accordance with 10 U.S.C. 654 and other applicable Federal laws) at that institution (or any subelement of that institution);

(B) Any student at that institution (or any subelement of that institution) from enrolling in a unit of the Senior ROTC at another institution of higher education;

(C) The Secretary of a Military Department or Secretary of Homeland Security from gaining access to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of military recruiting in a manner that is at least equal in quality and scope to the access to campuses and to students that is provided to any other employer; or

(D) Access by military recruiters for purposes of military recruiting to the names of students (who are 17 years of age or older and enrolled at that institution or any subelement of that institution); their addresses, telephone listings, dates and places of birth, levels of education, academic majors, and degrees received; and the most recent educational institutions in which they were enrolled.

If the recipient is determined, using the procedures in 32 CFR Part 216, to be such an institution of higher education during the period of performance of this agreement, the Government will cease all payments of DOD funds under this agreement and all other DOD grants and cooperative agreements to the recipient, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of award.

RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

The recipient assures that all work involving the use of recombinant DNA will be in compliance with guidance provided at <http://www4.od.nih.gov/oba>.

RADIOACTIVE MATERIALS

The recipient assures that it will comply with Title 10 CFR 21. This regulation established procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.