HUMAN SUBJECTS AND ANIMALS SUBJECTS RESEARCH

Last Updated: March 1st, 2024
Note: This document is subject to change.

Efforts Involving Humans

A. Protection of Human Subjects

1. The Performer agrees that any engagement in human subjects involved in research under this Agreement shall occur in accordance with 45 CFR Part 46 and the Performer's current Federal wide Assurance (FWA) on file with the HHS Office for Human Research Protections (OHRP). Similarly, Performer agrees that any human subjects research under this Agreement shall occur in accordance with any applicable law, regulation, or rule enforced by the U.S. Food and Drug Administration including, but not limited to 21 CFR 50, 56, 312, and 812. The Performer further agrees to provide certification to AOR that an overseeing Institutional Review Board has reviewed and approved, as required by applicable law and regulation, any human subjects research occurring under this Agreement prior to the engagement in such research.

2. The Performer shall retain full responsibility for the performance of all work and services involving human subjects research under this Agreement in accordance with the terms of this award.

3. If at any time during the performance of this Agreement, the AO has concerns the Performer is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the AO may immediately take action, including and up to suspension, in whole or in part, work and further payments under this Agreement until the Performer corrects the noncompliance or demonstrates it is in compliance. Notice of the action may be communicated by telephone and confirmed in writing. If the Performer fails to complete corrective action within the period of time designated in the AO's written notice of suspension, the AO may terminate this Agreement in a whole or in part.

B. Human Materials

1. The acquisition and supply of all human specimen material (including fetal material) used under this Agreement shall be obtained by Performer in full compliance with applicable Federal, State and Local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

2. The Performer shall provide written documentation that all human materials obtained as a result of engagement in non-exempt research involving human subjects conducted under this Agreement or by subawards identified under this Agreement, were obtained after acceptance and approval by the Office for Human Research Protections (OHRP) of the engaged entity's FWA. This restriction applies to all collaborating sites, whether domestic or foreign, and compliance must be ensured by the Performer.

3. The Performer shall provide to the AO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/ Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

C. Research Involving Human Fetal Tissue

All research involving human fetal tissue shall be conducted in accordance with 42 U.S.C. 289g-2 and 45 CFR 46.206. Additionally, all research involving the transplantation of human fetal tissue shall be conducted in accordance with 42 U.S.C. 289g-1, and for such research the Performer shall make available, for audit by the Secretary, HHS, the physician statements, and informed consents required by 42 U.S.C. 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Performer.

D. Human Embryo Research and Cloning

ARPA-H funding may not be used to support human embryo research. In addition, no funding may be used for cloning human beings.

Efforts Involving Animals

A. Care of Live Vertebrate Animals

1. The Performer agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this OT will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the National Academy of Sciences Institute of Laboratory Animal Resources, the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1- 4). In case of conflict between standards, the more stringent standard shall be used.

2. If at any time during performance of this Agreement, the AO's determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Performer is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the AO may immediately suspend, in whole or in part, work and further payments under this Agreement until the Performer corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Performer fails to complete corrective action within the period of time designated in the AO's written notice of suspension, the AO may, in consultation with OLAW, terminate this Agreement in whole or in part, and the Performer's name may be removed from the list of those organizations with approved PHS Animal Welfare Assurances.

Note: The Performer may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office below or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

B. Information on Compliance with Animal Care Requirements

Registration with the U.S. Department of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.). The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW). An essential requirement of the PHS Policy is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Performer does not have an assurance and will be utilizing a subaward to perform the animal work, then the Performer and subawardee must have an Inter-Institutional Assurance in place to allow the Performer to utilize the assurance of the subaward to meet the HHS requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by NIH on behalf of the Performer.

The PHS Policy requires assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals and that they comply with the regulations (9 CFR, Subchapter A) issued by USDA under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy. The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given" the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies.

C. Approval of Required Assurance by Law

Funds shall not be expended by the Performer for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Performer under this award unless a satisfactory assurance of compliance with the Animal Welfare Act, including 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28, the PHS Policy on Humane Care and Use of Laboratory Animals, the U.S. Government Principles and the Guide for the Care and Use of Laboratory Animals is submitted by the Performer to ARPA-H.