Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA Directive 1200.07
Transmittal Sheet
May 23, 2023

VA RESEARCH WITH ANIMALS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive sets forth the regulatory requirements that govern research with animals in the Department of Veterans Affairs (VA).

2. SUMMARY OF MAJOR CHANGES: This recertification clarifies the regulatory aspects of interinstitutional collaborations between VA and other institutions. This recertification includes many updates to reflect changes in VA policy and other applicable Federal animal research regulations and policies since 2010.

3. RELATED ISSUES: VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019, VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017; VHA Directive 1200.08(1), Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019; and VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020.

4. RESPONSIBLE OFFICE: The Office of Research and Development (ORD) is responsible for the contents of this VHA directive. Questions may be referred to the office of the Chief Veterinary Medical Officer (CVMO), contact information at https://www.research.va.gov/programs/animal_research/overview.cfm.

5. RESCISSIONS: VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on, or before, the last working date of May 31, 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Carolyn Clancy, MD
Assistant Under Secretary for Health for Discovery, Education, and Affiliate Networks

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on May 23, 2023.

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1. PURPOSE

This Veterans Health Administration (VHA) directive sets forth the compliance requirements for all animal research that is considered Department of Veterans Affairs (VA) research and the minimum standards for the facilities, husbandry, veterinary care and oversight of any VA research involving animal subjects. **AUTHORITY:** 38 U.S.C. § 7303.

2. BACKGROUND

a. Research involving animals has contributed and continues to contribute immeasurably to advancements in medical science. VA's insistence that all VA research be conducted according to the highest ethical and legal standards requires VA to support only research with animals that is necessary and conducted humanely, to address the needs of Veterans suffering from medical problems for which there are not yet cures or satisfactory treatments. VA is committed to both the moral imperative to protect human subjects in research by basing such work upon results of research with animal subjects, and the moral imperative to protect animal subjects in VA research by conducting such work in ways that recognize the importance of the well-being of the animals. For the latter, the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" were adopted by all US Government agencies, including VA, that work with or require work with animals in research. ***NOTE:*** *For additional information see https://olaw.nih.gov/policies-laws/gov-principles.htm.*

b. All VA research with animals must comply with the requirements of any sponsor providing funding support for the VA research and all applicable federal regulatory and policy requirements, regardless of the funding source, including but not limited to the following:

(1) The Animal Welfare Act (AWA, 7 USC §§ 2131-2159) and the Animal Welfare Regulations (AWR, 9 CFR §§ 1.1 – 3.168) and associated guidance from the Animal and Plant Health Inspection Service (APHIS). These apply to all research in the United States involving species regulated by the United States Department of Agriculture (USDA). Therefore, any VA research with USDA-regulated species may be conducted only if it complies with the AWA and AWR.

(2) The Health Research Extension Act of 1985 (HREA, Public Law 99-158, § 495), Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, and all associated guidance from the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW). VA has a formal agreement with the NIH for OLAW to provide oversight of VA research with animals according to PHS policy, regardless of whether PHS funds are involved. The conduct of VA research with animals is permitted only in the facilities of institutions covered by a PHS Assurance. The documented Assurance must be approved by OLAW and identify the Institutional Animal Care and

Use Committee (IACUC) that oversees the research with animals. ***NOTE****: For more information on the PHS Policy see https://olaw.nih.gov/policies-laws/phs-policy.htm.*

(3) The most recent versions of applicable Centers for Disease Control and Prevention (CDC)/NIH guidelines, which include:

(a) Biosafety in Microbiological and Biomedical Laboratories, for research involving infectious agents.

(b) NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ***NOTE:*** *For more information see* https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf*.*

(4) All VA research with animals must comply with all VA and VHA policies related to oversight of research. These include but are not limited to the most recent versions of the following related issues:

(a) VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019.

(b) VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017.

(c) VHA Directive 1200.08(1), Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019.

(d) VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020.

3. DEFINITIONS

a. **Affiliate.** Affiliate refers to any non-VA institution involved in interinstitutional collaboration with a local VA program, related to research with animals. Such an affiliate may or may not also have a formal relationship with the VA medical facility for purposes of clinical training.

b. **Animal.** VHA adopts the definitions of “animal” established in the PHS policy and the USDA AWR, with no additions or exceptions. ***NOTE:*** *For PHS policy and the USDA AWR see references paragraph.*

c. **Animal Activities.** The animal activities addressed by this directive include all procedures conducted with animals by VA for the purposes in the definitions of “animal” established in the PHS policy and the USDA AWR. The main VA animal activity is animal research, including not only animal research per se but also, and not limited to, training personnel to handle animals safely and to provide appropriate care for them, providing routine husbandry for animals and managing sentinel programs for monitoring animal colony health.

d. **Animal Research or Research with Animals.** Animal research, or research with animals, is any activity in which animals are the subjects of procedures that are necessary for specific research or teaching projects.

e. **Animal Research Program or Animal Care and Use Program.** The animal research program (also referred to as the animal care and use program) is the system of local administrative, husbandry, veterinary activities and IACUC activities required to support and oversee animal research. The animal research program consists primarily of the animal facilities and their operations and the IACUC and its functions. Each local VA animal research program includes all animal research for which the VA medical facility bears sole or shared responsibility, regardless of where the work is performed (all spaces where the animals involved in that research are housed or handled, within the Veterinary Medical Unit or associated spaces, at the facility or at an affiliate).

f. **Attending Veterinarian.** The Attending Veterinarian (AV) for a VA animal research program is the designated veterinarian who meets the requirements of the USDA AWR and PHS policy for that role.

g. **Clinical Veterinarian.** For the purposes of this directive, a clinical veterinarian is specifically a licensed veterinarian who is not necessarily qualified to serve as a Veterinary Medical Consultant (VMC) or Veterinary Medical Officer (VMO), but is appointed to provide supplementary veterinary clinical services in a VA animal research program. This term does not apply to every veterinarian who provides clinical care.

h. **Collaborative Animal Research.** Collaborative animal research is animal research that is collaborative according to VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019. Collaborative animal research always involves interinstitutional collaboration with joint oversight.

i. **External Affiliate-Appointed Institutional Animal Care and Use Committee**. An external affiliate-appointed Institutional Animal Care and Use Committee (IACUC) for a VA animal research program is hosted and managed by an affiliate and the members are appointed only by the affiliate's Chief Executive Officer (CEO).

j. **External Jointly-Appointed Institutional Animal Care and Use Committee**. An external jointly-appointed IACUC for a VA animal research program is hosted and managed by an affiliate, but the members appointed to the affiliate's IACUC by the affiliate's CEO are also appointed to the external VA IACUC by the VA medical facility Director. As a committee appointed by the VA medical facility Director, an external jointly-appointed IACUC is a subcommittee of the VA Research and Development (R&D) Committee.

k. **External VA Institutional Care and Use Committee.** An external VA IACUC is any VA IACUC that is not an internal VA IACUC. Both external affiliate-appointed IACUCs and external jointly-appointed IACUCs are external VA IACUCs.

l. **Institutional Animal Care and Use Committee**. The IACUC for a VA animal research program is the committee that meets the USDA AWR and PHS policy

requirements with regard to the composition and responsibilities of the committee that oversees the VA animal research program, and is identified in the PHS Assurance that covers that program.

m. **IACUC Member.** An IACUC member is an individual who has been officially appointed in compliance with the USDA AWR and PHS policy and has voting privileges. ***NOTE:*** *Individuals who participate in IACUC activities*, *but are not authorized to vote*, *are referred to as non-member attendees in this directive. Non-member attendees may be invited guests or consultants, and their presence during IACUC meetings is at the discretion of the IACUC members.*

n. **Institutional Official.** The Institutional Official (IO) for a VA animal research program is the individual with the legal authority to commit the institution to meeting the applicable regulatory requirements and is therefore responsible for committing the institutional resources needed to achieve that compliance.

o. **Interinstitutional Collaboration.** An interinstitutional collaboration is any relationship of a VA facility with an affiliate, related to animal research (beyond animal transport).

p. **Internal VA IACUC**. An internal VA IACUC is an IACUC that is operated by the local VA medical facility, administratively independent of any other institution, specifically for the oversight of all local VA research with animals, as part of an animal research program that has a Veterinary Medical Unit (VMU). An internal VA IACUC is a subcommittee of the local VA R&D Committee.

q. **Just-in-Time.** Just-in-Time (JIT) is the process of submission, review and approval of documentation for projects that have been selected for VA funding support. Completion of JIT processing is a pre-condition for release of the VA research funds. There are specific JIT requirements for projects that involve research with animals.

r. **VA Sensitive Species.** VA sensitive species are species that are of particular interest to the public, for which VA therefore has additional measures in place to assure the public about VA's oversight of research with these species. Protocols involving these species are subject to additional formal review processes. Guidance about the processes is posted on the ORD website as ORD Guidance Document AR2017-001 ***NOTE:*** *For more information see* *https://www.research.va.gov/programs/animal_research/guidance.cfm*.

s. **Veterinary Medical Unit.** The veterinary medical unit (VMU) is the integrated operational unit that includes the animal research facilities located on property owned or leased by VA, and the veterinary, husbandry and other technical personnel responsible for animal husbandry and veterinary care in those facilities.

t. **VMU Visitor.** A VMU visitor is anyone other than those with assigned duties that require entry to the VMU (for example, VMU and authorized research personnel, facilities support personnel (engineering, housekeeping, security), representatives of contractors providing services, and representatives of oversight entities responsible for

inspecting the VMU). VMU visitors include, but are not limited to, participants in training workshops, outside expert consultants and students participating in programs related to research with animals.

4. POLICY

It is VHA policy to conduct the research with animals that is needed to fulfill VA's mission of serving Veterans, in ways that meet or exceed established legal, ethical and veterinary standards for the appropriate care of the animals involved in research. The VA-specific performance standards are typically achieved by applying more broadly the requirements that generally apply to all US programs, as follows:

a. Although the USDA AWR establish requirements specifically only for the species that are regulated by USDA, it is VHA policy to apply many of those requirements to all species in VA research with animals. Specifics are detailed in this directive.

b. Although PHS policy specifically addresses only research that is supported by PHS funds, it is VHA policy to apply the requirements of PHS policy, including those related to reporting of noncompliance to OLAW, to all VA research with animals, regardless of the source of the funding that supports it.

c. Although AAALAC International offers accreditation to institutions that voluntarily meet its standards, it is VA policy that VA research with animals is permitted only in facilities of animal research programs that are accredited by AAALAC International.

d. Although the VA-specific performance standards can be achieved by applying the USDA AWR, PHS Policy and AAALAC International rules of accreditation to all VA research with animals, it is also VHA policy that the VHA Chief Research and Development Officer (CRADO) has the authority to specify other approaches appropriate to the specific local circumstances, by which a VA program can meet the same VA-specific performance standards.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks.** The Assistant Under Secretary for Health for Discovery, Education, and Affiliate Networks is responsible for addressing challenges associated with overall VHA compliance with this directive.

c. **Assistant Under Secretary for Health for Operations**. The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors in resolving implementation and compliance challenges in all VA medical facilities within their respective VISNs.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **VHA Chief Research and Development Officer.** The VHA CRADO is responsible for:

(1) Establishing VHA policy regarding VA research with animals and committing VHA to meeting its requirements.

(2) Reviewing each request to initiate or reactivate a VA animal research program and granting specific final approval in writing if the program may be initiated or reactivated.

(3) Leading VA compliance with legal requirements imposed by Congress on VA research with animals, including by establishing and implementing procedures as needed to review each application for a new VA research project involving a VA sensitive species, to secure appropriate approval for the work to be conducted as VA research, and to document that determination in writing.

(4) Providing written notification to field programs of new requirements imposed by Federal government entities other than those routinely responsible for regulating VA research with animals, or of changes in existing requirements, related specifically to VA research with animals.

(5) Delegating to the VHA Chief Veterinary Medical Officer (CVMO) at the CRADO's discretion, the authority to specify locally-appropriate approaches for an individual VA program of research with animals to meet the VA-specific performance standards for appropriate care of animals involved in VA research. Such delegation is only valid if documented in writing.

e. **VHA Chief Veterinary Medical Officer.** The VHA CVMO is responsible for:

(1) Formulating, interpretating and implementing VHA policies regarding VA research with animals.

(2) Advising senior VA administrators on animal research and other veterinary medical issues.

(3) Providing support and guidance tailored to the specific local circumstances of field personnel involved in VA research with animals or VA animal research programs. This includes, but is not limited to the following:

(a) Posting updates on the VA animal research website about changes in regulatory requirements, and recommendations for how to meet them.

(b) Evaluating local circumstances on a case-by-case basis to provide recommendations to the CRADO, or to act with authority delegated in writing by the CRADO, for determining whether to allow a local program to achieve the VA-specific veterinary performance standards by approaches other than the default approaches described by the VA-specific policies set forth in this directive, and providing written instructions to the local program with regard to the specific changes thus authorized.

f. **Veterans Integrated Services Networks Director.** The VISN Director is responsible for ensuring that all VA medical facilities with animal research programs within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for performing for the local VA animal research program the functions assigned to the Institutional Official (IO) and the Chief Executive Officer (CEO), as defined by the USDA AWR and PHS policy, working in partnership with the IACUC to maintain compliance with this directive and other applicable federal animal research regulations and policies. ***NOTE*:** *Depending on specific local circumstances, the VA medical facility Director is in some cases not the official IO or CEO for the local animal research program, but nonetheless shares with the official IO or CEO the responsibilities of those roles.*

(1) The functions of the IO for a VA animal research program include:

(a) Compliance with the USDA AWR.

1. If the VA animal research program has facilities that it has registered with USDA, the VA medical facility Director receives personally the IACUC's report of each semiannual evaluation of the animal research program and facilities.

2. If the facilities used by the VA animal research program are all covered by the USDA registration of an affiliate, an official at the affiliate (rather than the VA medical facility Director) serves as the designated IO for those facilities, but the VA medical facility Director still shares responsibility for maintaining compliance of the VA animal research program with the USDA AWR. This includes:

a. Receiving personally from, and reviewing with, the IACUC a copy of the report of each semiannual evaluation of the program and facilities, if the VA animal research program includes a VMU.

b. Receiving any information about the local VA animal research program that requires the VA medical facility Director's attention, if the VA animal research program does not include a VMU.

(b) Compliance with PHS policy.

1. If the VA animal research program has its own PHS Assurance, signing the PHS Assurance as the IO, committing to institutional adherence to the terms of that PHS Assurance.

2. If the VA animal research program is covered by the PHS Assurance of an affiliate, an official of that affiliate (rather than the VA medical facility Director) serves as the designated IO for PHS policy, for the VA animal research program, but the VA medical facility Director still shares responsibility for maintaining compliance of the VA animal research program with PHS policy.

(c) Accreditation by AAALAC International.

1. If the VA animal research program is independently accredited by AAALAC International, the VA medical facility Director serves personally, or identifies a designee to serve, as the "Responsible Institutional Official" for ensuring compliance with AAALAC International's Rules of Accreditation.

2. If the VA animal research program is accredited by AAALAC International as a component of the program of an affiliate, an official at that affiliate (rather than the VA medical facility Director) serves as the Responsible Institutional Official for AAALAC International accreditation, for the VA animal research program, but the VA medical facility Director still shares responsibility for maintaining compliance of the VA animal research program with the AAALAC International Rules of Accreditation.

(d) Ensuring that animal facility personnel responsible for husbandry or care of animals treated with hazardous agents receive proper training to perform their duties safely before they do so. ***NOTE:*** *This includes ensuring that applicable local policies or procedures are established in writing both for the specified training and for proper waste disposal procedures*.

(e) Stopping or delaying unilaterally any VA animal research, and authorizing others to do so, if necessary for the interests of the VA medical facility. PHS policy grants this authority to the IO, and this directive grants it to the VA medical facility Director, regardless of whether the Director is the designated IO for the PHS Assurance.

(2) The functions of the CEO for a VA animal research program include:

(a) If the VA animal research program is overseen by an internal IACUC or an external jointly-appointed IACUC, appointing each member (regular or alternate) of the IACUC identified in the PHS Assurance. ***NOTE:*** *The CEO of the affiliate may designate the IO of the affiliate or another individual to appoint the IACUC members for the affiliate, but the VHA policy does not allow the medical facility Director to delegate this authority.*

(b) If the VA animal research program is covered under the PHS Assurance of an affiliate, so the IACUC that oversees the VA animal research program is an external affiliate-appointed IACUC, recommending to the CEO of the affiliate at least one VA representative to serve on that external affiliate-appointed IACUC.

h. **VA Medical Facility Associate Chief of Staff for Research and Development.** The VA medical facility Associate Chief of Staff for Research and Development (ACOS/R&D) is responsible for administering and managing the local VA research

program, as described in VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019 and VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017. The ACOS/R&D may delegate specific tasks and responsibilities to the VA medical center Administrative Officer for Research and Development (AO/R&D) as necessary. For research with animals, administering and managing the local program generally involves, but is not limited to, the following:

(1) For a program with an internal IACUC,

(a) Coordinating administrative support for the work of the IACUC.

(b) Assisting the VA medical facility Director to ensure that the IACUC both has adequate administrative support and meets its responsibilities.

(2) For a program with an external IACUC,

(a) Ensuring communication between the external IACUC and the VA medical facility.

(b) Ensuring that information relevant to VA animal research is communicated to the R&D Committee, VA research administrators and VA facility leadership as needed for effective coordination of the actions of the external IACUC and the VA program.

(3) Ensuring that documents submitted for JIT processing are congruent with the projects that they are submitted to support. The ACOS/R&D and AO/R&D may delegate the evaluation of this congruency but remain responsible for ensuring that the documents accurately reflect the proposed work.

i. **VA Medical Facility Institutional Animal Care and Use Committee Members.** Each member of a VA medical facility's Institutional Animal Care and Used Committee (IACUC, internal or external) is responsible for:

(1) Participating regularly and engaging actively, as deemed appropriate by the IACUC and the IO, in the conduct of IACUC business, as specified by the AWR, applied to all local VA research with animals, regardless of whether species regulated by USDA are involved.

(2) Contributing to the functions of the IACUC specified by PHS Policy, applied to all local VA research with animals, regardless of the source of funding support.

(3) Meeting the training requirements defined by VA for IACUC members.

j. **VA Medical Facility Institutional Animal Care and Use Committee Manager.** The role of an IACUC manager is to be responsible for providing crucial day-to-day administrative support for IACUC functions at the VA medical facility.

k. **VA Medical Facility Veterinary Medical Officer.** A Veterinary Medical Officer (VMO) is a qualified laboratory animal veterinarian hired into a federal position and is

responsible for providing veterinary medical support and serving as an expert consultant with regard to laboratory animal medicine and regulatory compliance for the VA medical facility's animal research program, regardless of the level of effort. A VMO provides supervision of the VMU manager with regard to veterinary medical matters and may be assigned administrative supervision of the VMU manager as well. ***NOTE:*** *Appointment of any Veterinary Medical Officer to a VA animal research program with a VMU is subject to approval of the veterinarian's credentials by the CVMO.*

l. **VA Medical Facility Veterinary Medical Consultant.** A Veterinary Medical Consultant (VMC) is a qualified laboratory animal veterinarian hired through a formal agreement or contract and is responsible for providing veterinary medical support and serving as an expert consultant with regard to laboratory animal medicine and regulatory compliance for a VA medical facility's animal research program, regardless of the level of effort. A VMC provides supervision of the VMU manager with regard to veterinary medical matters. ***NOTE:*** *Appointment of any Veterinary Medical Consultant to a VA animal research program with a VMU is subject to approval of the veterinarian's credentials by the CVMO.*

m. **VA Medical Facility Attending Veterinarian.** One VMC or VMO in the VA medical facility's animal research program is appointed as the Attending Veterinarian (AV). In addition to the responsibilities of any VMC or VMO, the AV's responsibilities include:

(1) Supervising all other local veterinarians with regard to the practice of laboratory animal medicine.

(2) Serving ex officio as a voting member of the VA IACUC and advising the IACUC to ensure that the program meets veterinary and regulatory requirements.

(3) Reviewing the written Program of Veterinary Care (PVC) and signing it only if it meets the requirements of the AWR applied by VA to all VA programs of research with animals, and if it meets veterinary standards that are appropriate to the local program according to the professional veterinary judgement of the AV.

n. **VA Medical Facility Clinical Veterinarians.** Clinical Veterinarians are responsible for providing supplementary veterinary clinical services in the animal research program of a VA medical facility, in coordination with the AV, but do not take the place of a VMO or VMC.

o. **VA Medical Facility Veterinary Medical Unit Manager.** The role of a VMU manager is to be responsible for overseeing the practical details and management of day-to-day operations of the VMU, including daily animal husbandry and administrative management of the VMU at a VA medical facility. This includes, but is not limited to:

(1) Supervising any animal husbandry and veterinary technical personnel, and scheduling their work assignments.

(2) Providing orientation and other training for animal husbandry and veterinary technical staff.

(3) Assisting and providing training for research personnel, in routine procedures for work with animals in research.

(4) Maintaining essential VMU records (inventories, procurement records, quality control records for VMU equipment, etc.).

(5) Ensuring maintenance of a sound program of animal husbandry.

(6) Ensuring maintenance of appropriate housing environments for the animals present in the VMU by monitoring the function of temperature control, lighting and ventilation systems, and arranging for malfunctions to be addressed.

(7) Ensuring that unusual behavior or appearance of any animals is noted and promptly brought to the attention of the veterinarian(s).

p. **VA Medical Facility Animal Husbandry Personnel**. The animal husbandry personnel are responsible for providing the routine husbandry of the animals in the animal research program at a VA medical facility, under the supervision of the VMU manager and the veterinarian(s).

q. **VA Medical Facility Veterinary Technical Personnel**. The veterinary technical personnel are responsible for providing the veterinary technical care for the animals in the animal research program at a VA medical facility, under the supervision of the VMU manager and the veterinarian(s).

r. **VA Medical Facility Research Personnel**. The research personnel are responsible for conducting high quality research in compliance with the regulatory requirements that apply to animal research by a VA medical facility. All research personnel are responsible for:

(1) Staying up to date with the applicable regulatory requirements and maintaining compliance with them.

(2) Being familiar with the specifics of what is included in the current version of each IACUC-approved protocol for which they are assigned duties, and performing procedures only as approved.

(3) Recognizing the authority of the IACUC with regard to the activities with animals that may be conducted, and cooperating with requests from and requirements of the IACUC and its designees.

(4) Recognizing the authority of the AV with regard to veterinary care in the local program and complying with instructions from the AV about veterinary care of animals on protocols for which the research personnel are assigned duties.

(5) Completing the ongoing training required of research personnel.

s. **VA Medical Facility Principal Investigator**. The principal investigator (PI) has all of the responsibilities assigned to all research personnel in the animal research program of the VA medical facility, and is additionally responsible for all animal research activities conducted by research staff members under the PI's supervision, and for all activities conducted in research space assigned to the PI. This includes:

(1) Ensuring that all members of the PI's research staff meet their responsibilities for compliance with the regulatory and policy requirements that apply to VA animal research.

(2) Managing documentation of the work and communications with the IACUC to ensure compliance with regulatory requirements.

(3) Ensuring that:

(a) Protocols and protocol modifications are clearly and accurately documented and submitted according to locally recommended timelines for IACUC review and approval.

(b) Any concerns about protocols that are communicated from the IACUC to the PI are appropriately addressed, according to the IACUC's instructions.

(c) All personnel on the PI's protocols are well-informed of the specifics of what the currently approved protocols include.

(d) Work is done only according to currently approved protocols.

6. TYPES OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

This directive describes three types of IACUCs acceptable for VA research with animals:

a. **Internal VA-Appointed Institutional Animal Care and Use Committee**. Such an IACUC oversees research for a VA program that has a VMU and its own PHS Assurance, and is described in that Assurance. This type of IACUC is a subcommittee of the R&D Committee.

b. **External Jointly-Appointed Institutional Animal Care and Use Committee**. Such an IACUC oversees research with animals for a VA program that has a VMU and its own PHS Assurance, but for which the VA medical facility and the affiliate agree to share a single set of IACUC members, administered by the affiliate. The written agreement establishing this arrangement identifies the specific procedures that each party requires to meet its regulatory responsibilities, and commits both parties reciprocally to accommodating those procedures. The members are each appointed to two IACUCs, with each IACUC described in its own PHS Assurance: the affiliate's IACUC (described in the affiliate's PHS Assurance, with members appointed by the

affiliate's CEO) and the VA's external jointly-appointed IACUC (described in the VA's PHS Assurance, with members appointed by the VA medical facility Director).

c. **External Affiliate-Appointed Institutional Animal Care and Use Committee**. Such an IACUC oversees research for a VA program that does not have its own PHS Assurance, either by choice or because it does not have a VMU and is therefore not eligible to have an Assurance. The IACUC is the one described in the affiliate's PHS Assurance. The written agreement establishing this arrangement identifies the specifics of what VA requires for the VA animal research program to meet its regulatory responsibilities, and the specifics of what the VA is required to provide for the affiliate's IACUC to be able to oversee the VA program. Both parties commit to those specifics.

7. VA ANIMAL RESEARCH PROGRAMS

a. **Approval for Initiation of a VA Animal Research Program.** At any VA medical facility without an active animal research program, a new program may be initiated, or an inactive program reactivated, only with the specific approval of the ORD CRADO.

b. **Inactivation or Closure of a VA Animal Research Program.** Research with animals in the animal research program of any VA medical facility may be paused temporarily at any time and for any reason. Such a pause is mandatory if ordered by the CRADO or the CVMO. Inactivation or closure of a VA animal research program is a longer-term action that reflects a decision for the VA medical facility to no longer support the facilities, personnel and administrative functions necessary to maintain a compliant program. The CRADO and any of the medical facility personnel with authority to withhold the funds and resources each has the authority to inactivate all or any portion of any VA animal research program. Closure or inactivation by the CRADO takes effect on the date specified by the CRADO in a written notification to the VA medical facility Director and the CVMO. When the decision is made at the facility level, the medical facility Director is to provide prompt written notification to the CRADO, the CVMO and ORO, specifying the effective date. Routine reporting requirements continue to apply until each of the following is completed:

(1) The USDA registration of the facilities used in the program is cancelled by the IO responsible for the USDA registration, and no other arrangements are made for the research with animals to be conducted in other registered facilities.

(2) Coverage of the program by a PHS Assurance approved by OLAW is withdrawn by the IO responsible for that Assurance and is not replaced by another Assurance.

(3) Accreditation of the facilities used in the program is relinquished by the Responsible Institutional Official for AAALAC International accreditation, and no other arrangements are made for VA research with animals to be done in facilities that are accredited or are otherwise granted approval by the CVMO for use in VA research with animals.

c. **VA Animal Research Programs That Share Oversight with Other Institutions.** Many VA animal research programs share oversight with an affiliate. Even if the VA

animal research program is overseen by an external IACUC, the VA medical facility still bears responsibility for that program. Because of the variety and complexity of local circumstances, the office of the CVMO is available for consultation in developing the specific agreements and understandings appropriate to each case. The main categories of arrangements for joint oversight acceptable to VA include:

(1) The VA medical facility and the affiliate have independently administered internal IACUCs that together oversee collaborative animal research or use of the facilities of one institution by personnel of the other.

(2) The VA medical facility with its own VMU arranges for the IACUC of an affiliate to serve as an external IACUC (jointly-appointed, or affiliate-appointed, according to the PHS Assurance that covers the facility) for the VA animal research program**.**

(3) A VA program has no VMU at all, but instead conducts all of its research with animals in the animal facility of an affiliate. In this case, the VA station is not eligible to hold a PHS Assurance and therefore has no authority recognized by OLAW to appoint an IACUC, so the IACUC of the affiliate oversees the VA animal research program as an external affiliate-appointed IACUC.

d. **Requirement for Written Agreements.** Whenever VA research with animals involves shared oversight, the formal written understanding that is required by *The Guide* for defining the responsibilities and expectations of each party is key to protecting VA interests and VA's ability to meet regulatory requirements. Key elements of the understanding include:

(1) To meet their oversight responsibilities, both parties need access to, and agree to allow representatives of the other party access to, any of their facilities that are involved in the jointly overseen activities. For VA, these representatives include not only VA medical facility personnel, but also representatives from VA Central Office (e.g., ORO or the office of the CVMO).

(2) The interinstitutional collaboration on research with animals can only be established if the VA medical facility and the affiliate agree on which documentation they will provide to each other, how it will be transmitted and whether it will be shared routinely or on request. For any document shared with VA in support of jointly overseen research with animals, VA accepts redaction of any information that is irrelevant to the jointly managed work, provided arrangements can be made within three business days of each request to make the unredacted version of the document available for review by VA research representatives, at a mutually agreeable time and location. VA reserves the right to likewise redact documents shared with the affiliate and likewise allows review of the unredacted documents.

e. **Communication with the Office of the Chief Veterinary Medical Officer**. Regardless of the local supervisory structures, no local constraints are permitted on any individual who wishes to contact directly or consult freely with the office of the CMVO or ORO with regard to animal research and compliance issues. Local requirements to give

notice or to receive permission for such communications are prohibited. This applies to all individuals, including those involved in the animal research program, such as (but not limited to) internal or external IACUC members and support personnel, VMU personnel and research personnel from VA or affiliated institutions.

8. THE VETERINARY MEDICAL UNIT

a. **Budget.** The per diem rates and the technician support fees to be charged to investigators are to reflect the following:

(1) The projected costs of purchasing equipment (e.g., caging) needed for VMU operations.

(2) The total animal care costs.

(3) The costs of ensuring the availability of adequate staffing and supplies needed to provide high quality care to animals at all times.

(4) Other income available to the VMU.

b. **Heating, Ventilation and Air Conditioning.** These requirements apply not only to rooms in the VMU where animals are housed, but also to all other spaces owned or leased by VA where VA research animals are housed for 24 hours or more, including any housing areas outside the animal facility.

(1) **Design of HVAC System.** The HVAC system must be designed to reliably prevent overheating of animal housing rooms. This includes:

(a) Design of HVAC equipment for each animal housing room so that failure does not result in uncontrolled heating, and actual temperatures in the room are detected.

(b) Continuous central monitoring of the temperatures detected in the animal housing rooms, by facilities management personnel who coordinate prompt emergency responses appropriate to the sensitivity of rodents and other species to even short overheat events.

(2) **Required overheat testing.** At least every 12 months, the temperature sensor that monitors one of the animal housing rooms is to be intentionally and safely overheated, without advance notification of facilities management personnel. Their response is then to be reported to the IACUC at its next convened meeting, for evaluation.

(a) The IACUC is responsible for evaluating the adequacy of the response, according to what is needed for the well-being of the animals.

(b) If the IACUC finds that the response time was not adequate, it oversees implementation of corrective actions to achieve adequate responses, as verified by one

or more additional follow-up overheat tests within 60 days of when corrective actions are completed.

(c) Results of each overheat test and the IACUC's assessment of the results of the test are to be documented in the IACUC meeting minutes.

c. **Veterinary Medical Unit Facility Construction and Renovation**. Review and approval by a local VMO/VMC, and then by the CVMO, are required before work begins on any new construction or renovation of existing research animal facilities that is estimated to cost more than $100,000.

d. **Physical Security and Access.** The VA facility is required to maintain the physical security of the VMU, while also ensuring that personnel involved in oversight of the VA animal research program have ready access to the information, documents and physical spaces that they need, to meet their oversight responsibilities.

e. **Written Guidelines for Veterinary Medical Unit Operations**. To promote consistent care for the animals that meets or exceeds accepted standards, and optimal maintenance of equipment, guidelines appropriate to local circumstances are to be documented in writing, and reviewed and updated regularly, at least every three years, by the IACUC. The IACUC may, at its discretion, rely on the guidance and recommendations of subject matter experts to inform its review, but is responsible for integrating the input from those with expertise in different aspects of the guidelines, to ensure that the guidelines are coherent and meet the specific needs of the local program. The current guidelines are to be maintained as a collection that is readily accessible to all personnel with responsibilities that the guidelines address.

f. **Missing Pets.** VA does not obtain research animals from vendors that sell former pets. Nevertheless, if there is any credible expectation that a missing pet is in the VMU, staff will inspect the VMU for the presence of the pet, and promptly notify the IACUC, AO/R&D, ACOS/R&D, the facility Director and the CVMO of each such inquiry and the outcome of the inspection.

g. **Potentially Hazardous Agents Used in VA Animal Research**

(1) Any IACUC-approved protocol must include the requested information about all agents, including potentially hazardous agents, that are to be administered to the animals.

(2) Relevant experts are to be consulted on the development and implementation of appropriate strategies for the safe use of hazardous agents in VA research with animals. Examples of these experts are the VMU manager, local veterinarian(s), the Subcommittee on Research Safety (SRS) and Institutional Biosafety Committee (IBC), the facility safety officer, research personnel involved in the work and outside expert consultants, depending on the agents involved and the proposed uses.

h. **Use of Explosive Agents in VA Animal Research.** The use of explosive substances (such as certain anesthetics) in VA animal research, and the storage of

such substances in the VMU, are allowed only with the specific approval of both the IACUC and the SRS, and only if all of the following conditions are met:

(1) Scientific considerations preclude the use of non-explosive alternatives.

(2) The IACUC, working with the SRS, has ensured that all required precautions have been taken to prevent explosions. Safety measures for the IACUC to consider requiring include, but are not limited to, ensuring that:

(a) Procedures with explosive agents are performed only within a properly operating, ventilated safety hood.

(b) Electrical equipment to be used with explosive agents is located and powered outside the hood.

(c) Containers of explosive agents are stored properly and discarded when the contents have been used up or are no longer needed.

(d) Items (including empty containers and animal carcasses) that may contain traces of explosive agents are not included with waste that is to be incinerated.

(e) Potentially explosive fumes are allowed to dissipate before items (including tissue samples and animal carcasses) are placed into storage, and explosion-proof refrigerators and freezers are used when cold storage is necessary.

(3) The facility safety officer has been notified in advance of the acquisition and storage of the explosive agents; and the facility emergency response plan has been revised accordingly, to ensure that the associated risks are addressed.

i. **Emergency and Disaster Planning**. Because of the key role of the VMU in safeguarding the welfare of the animals, the IACUC is responsible for ensuring that the VMU emergency/disaster plan addressing the particular needs of the animals is documented in writing, readily accessible to VMU personnel, reviewed periodically and updated as needed by qualified experts such as the facility safety officer, the chief of facilities management and the local VA police, as well as the Attending Veterinarian and VMU manager. For programs with USDA-regulated species, the minimum interval between reviews is as specified by the AWAR, or three years, whichever is shorter. For programs with no USDA-regulated species, the minimum interval between reviews is three years. It is essential for the plan to cover:

(1) Not only normal business hours, but also after hours, weekends and holidays.

(2) Protection of both personnel and research animals.

(3) Coordination with the local facility Police Chief and Emergency Preparedness Manager to ensure that both the AV and the VMU manager have access to the VMU at any time, because their access is essential for situations that impact research animals.

j. **Contact Information for Those with Concerns about the Welfare of VA Research Animals.** VA welcomes input from anyone with concerns about the welfare of the animals involved in VA research and forbids adverse actions or reprisals against anyone for reporting such concerns.

(1) Prompt communication of such concerns to the IACUC, research administrators or VMU staff is essential to directing additional attention promptly to where it is needed, and to clarifying observations that may have been misinterpreted. To facilitate this, contact information for the following is to be posted prominently at the entrance to the VMU, and as needed inside the VMU:

(a) AV.

(b) VMU manager.

(c) ACOS/R&D and AO/R&D.

(d) Chair of the IACUC.

(e) Medical facility Director.

(f) CVMO.

(g) ORO's anonymous reporting hotline phone.

(2) The posted information must also include the following:

(a) Instructions for communicating concerns about the animal research program anonymously, if one so wishes and

(b) Assurance of protection from discrimination or other reprisals.

k. **Inspections.** Each VA medical facility with an animal research program is required to grant access as needed for site visits or other evaluations by recognized oversight entities, including but not limited to representatives of AAALAC International, NIH OLAW, ORO, the Office of the CVMO and the CRADO.

l. **Visitors.** The access of visitors is restricted to only those who are pre-approved by the IACUC and escorted at all times within the VMU by authorized VA personnel. At no times are minor children permitted in the VMU for purposes other than participating in programs related to research with animals.

m. **Recording Images.** Recording of any images (video or still) in the VMU or of animals in the VA program of research with animals is only permitted if pre-approved by the IACUC and the IACUC's approval is documented in writing. ***NOTE:*** *The requirement for IACUC pre-approval does not apply to authorized representatives of recognized oversight entities responsible for inspecting the VMU recording images required as part of the inspection process.*

9. GENERAL REQUIREMENTS REGARDING VA RESEARCH WITH ANIMALS

a. **Procurement and Receipt of Animals for VA Animal Research.** Animals for VA research may be procured only from legal sources that are compliant with the requirements of the USDA AWAR and PHS policy. The IACUC has the authority to establish, in consultation with the AV and the VMU manager, additional local standards that vendors are required to meet as sources of animals for research in the local program. Animals may be procured only for use according to specified IACUC-approved protocols, and only when appropriate housing is available. The VMU is responsible for arranging for qualified personnel to receive and inspect the animals promptly upon arrival.

b. **Provision of Adequate Veterinary Care**. All research animals are to be provided with care that meets current veterinary standards. VA requires each VA program to have a written PVC, regardless of the species of animals involved, and regardless of whether the Attending Veterinarian is appointed full-time. The PVC is to be a separate document, approved by the IACUC and signed by the Attending Veterinarian. At minimum, the PVC for a VA program includes the following:

(1) The minimum frequency of in-person rounds of all animals in the VMU by the AV, or another VMO or VMC who reports to the AV, is to be appropriate to the local programmatic needs. This performance standard is met by quarterly visits in any calendar quarter in which animals are present in the VMU, unless the CVMO provides written instructions for a different minimum frequency. The visits are to be documented in writing in any case.

(2) Communication at least monthly between the AV (or another VMO or VMC who reports to the AV) and VMU personnel who can provide updates on VMU operations. These communications are to be documented in writing.

(3) Communications as needed between the AV and VMU personnel regarding observations of the condition of individual animals or groups of animals in the VMU and what veterinary attention is needed. These communications are to be documented in writing.

c. **Adoption of Research Animals.** Whenever feasible, animals retired from participating in approved VA research protocols are to be placed as pets with suitable adoptive families, or in the case of non-human primates, provided with an appropriate retirement environment. (See paragraph 12 for details.)

d. **IACUC Oversight Reflects PHS Assurance.**

(1) VA animal research may be conducted only in environments covered by a PHS Assurance, and in compliance with PHS Policy, regardless of whether PHS funding is involved.

(2) OLAW will only approve a PHS Assurance for a VA program that has a VMU. A VA animal research program that does not have a VMU is therefore ineligible to hold a

PHS Assurance. The research for such a program may therefore only be conducted in the facilities of an affiliate that holds an approved PHS Assurance. In such cases, only the IACUC described in the affiliate's Assurance (an external affiliate-appointed IACUC for the VA program) is recognized by OLAW as meeting regulatory requirements.

e. **USDA Registration by VA Facilities.** Each VA animal research program is required to ensure that the numbers of animals of USDA-regulated species involved in the program each year are reported on a USDA Annual Report. This means that each VA program must be independently registered or covered under the registration of an affiliate, regardless of whether any work done in the VA program is with species regulated by USDA.

10. OVERSIGHT BY AN INTERNAL VA-APPOINTED INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

a. **Membership of an Internal VA IACUC.**

(1) The Director appoints members to the internal VA IACUC in writing (paper or electronic), identifying each appointee by name; stating explicitly which of the role(s) on the IACUC that the AWR and PHS Policy require to be filled, if any, the appointee will fill; specifying whether the member will serve as a regular or alternate member; and, in the case of alternate members, specifying the category or categories of individuals the alternate is authorized to serve in lieu of. Appointments are effective on the date the Director signs unless a later effective date is specified in the letter.

(2) Because of the commitments of time and effort that are required of the IACUC Chair, the Chair of the IACUC may not be the chair of another subcommittee of the R&D Committee (e.g., the Subcommittee on Research Safety (SRS)) at the same time.

b. **Routine Communications Within VA by an Internal VA IACUC.**

(1) **With the R&D Committee.** At least one individual who regularly attends internal VA IACUC meetings and is acceptable to the IACUC and the R&D Committee serves as liaison by also regularly attending meetings of the R&D Committee.

(2) **With an Internal SRS and Institutional Biosafety Committee**. At least one individual who regularly attends internal VA IACUC meetings and is acceptable to both the IACUC, and the internal SRS (and internal IBC, if the station has an internal IBC separate from the internal SRS) serves as liaison by also regularly attending meetings of the internal SRS (and internal IBC, if the station has one).

(3) **With the VA Medical Facility Director.** The medical facility Director is responsible for ensuring the regulatory compliance of the local animal research program and therefore depends on clear and regular communications from the internal VA IACUC about the status of the animal research program, regardless of whether those responsibilities are shared with officials at an affiliate. This includes, but is not limited to, communications from the internal VA IACUC to the Director about the results of each semiannual evaluation.

(4) **With the CVMO.** The IACUC is responsible for ensuring that the CVMO is kept informed of any matters relevant to the condition of the local animal research program.

(a) Documents to be shared routinely include, but are not limited to, copies of the following. Unless otherwise indicated these are to be provided within 30 days of approval, receipt, or submission:

1. The report of each semiannual evaluation of the program and facilities required by the PHS Policy and the USDA AWR, and signed by the Director, is to be provided within 90 days of when the IACUC approves it.

2. Self-reports about matters determined by the IACUC to be reportable

3. Annual reports required by OLAW and AAALAC International.

4. Reports and follow-up correspondence after site visits by any oversight entity.

5. Notifications required by USDA AWR about changes in the operation of the VA medical facility as a research facility registered with USDA

6. Notifications required by ORO about changes in the animal research program

(b) If the VA animal research program is covered by the USDA registration or the AAALAC International Accreditation of an affiliate, it is the responsibility of the IACUC to ensure that copies of reports and correspondence that are relevant to the VA animal research program are obtained from the affiliate and provided to the CVMO.

(c) If any document containing coded identifiers for personnel is submitted to the office of the CVMO, a separate key to the code is to be provided on request by the office of the CVMO.

c. **Conduct of Business by an Internal VA IACUC.** To promote the orderly and effective conduct of IACUC business, locally specific logistical guidelines are to be documented in writing and reviewed and updated at least every three years, by personnel with appropriate expertise. The goal of these guidelines is to support the routine conduct of IACUC business in a respectful and confidential manner, compliant with all relevant regulatory and policy requirements and with careful attention to avoiding the influence of conflicts of interest. The current guidelines are to be maintained as a collection that is readily accessible to all personnel with responsibilities that the guidelines address. Matters to be addressed include at least the following:

(1) **Quorum.** The IACUC is authorized to conduct official business only when a quorum of members is present. Members who participate in real time by teleconference or video conference are considered present. VA applies the definition of quorum given in the USDA AWR and the PHS policy to the internal VA IACUC.

(2) **Differences of Opinion.** Effective committee function depends on hearing the opinions of all IACUC members.

(a) It is not acceptable for anyone to attempt to suppress the opinion of a voting member, or to pressure an unwilling voting member to adopt a particular position with regard to any item of IACUC business. Anyone aware of such an extremely serious deviation from VHA policy is to notify the CVMO immediately.

(b) There is no requirement that any dissenting vote be supported with a written opinion, but if the IACUC receives from any IACUC member a written minority opinion about any documented IACUC business, it must be recorded and included in the documentation of the matter that it applies to. No alteration of the opinion is permitted without the approval of the member who submitted it. Written rebuttals to minority opinions by other members are permitted.

(3) **Conflicts of Interest**. Although the IACUC has the authority to invite anyone to provide information or answer questions for its consideration, no individual with an actual or perceived financial, professional or personal conflict of interest may vote, contribute to the quorum, or be present during deliberation or voting on that item.

(4) **Confidentiality.** For all internal VA IACUCs, VA applies the confidentiality requirements of the AWA, regardless of whether the species of animals in the animal research program are regulated by USDA. Additionally, for the sake of protecting the independence of the internal VA IACUC, all participants at any internal VA IACUC meeting are prohibited from disclosing the votes cast or the views expressed by identifiable individual IACUC members about matters under deliberation, to anyone who was not present or eligible to vote at the time of those votes or deliberations. ***NOTE:*** *The VA prohibition on disclosing votes or views of other IACUC members with regard to IACUC business does not apply when disclosure is necessary for consultation with, or in response to requests by, representatives of recognized oversight entities for regulatory or guidance purposes.*

(a) Vote tallies must be recorded, but there is no requirement to record the individual votes of IACUC members.

(b) At any time before a vote, the IACUC has the authority, by a majority vote of a quorum, to require that the vote be conducted by anonymous ballots, secured to ensure that only eligible individuals vote, and that each eligible voter votes only once.

(c) The Chair has the authority to call for any vote to be conducted by secure anonymous ballots, even without a majority vote of the committee to do so.

(5) **Protection of IACUC Independence.** Because of the potential for undue influence over the voting members of the internal VA IACUC, the participation of certain VA personnel in the work of the committee is limited.

(a) The following individuals are prohibited from serving as regular or alternate voting members on an internal VA IACUC. Their attendance at IACUC meetings is at the discretion of the IACUC.

1. The AO/R&D, the ACOS/R&D and others in similar administrative and leadership positions in the Research Service of the VA medical facility.

2. Members of the senior leadership of the VA medical facility.

3. The Research Compliance Officer (RCO) of the VA medical facility.

(b) At any time, the IACUC has the authority, by a majority vote of a quorum, to close its meeting to any or all non-voting attendees.

(c) The Chair has the authority to close any meeting to any or all non-voting attendees, even without a majority vote of the committee to do so.

(6) **Meeting Minutes.** The meeting minutes of an internal VA IACUC are official only after they are approved by the IACUC.

(a) The minutes may only be approved after all members (regular and alternate) have had access to them for review before voting on approval. The minutes may be approved by a majority vote at a convened meeting, or by a majority in a poll of the total voting membership.

(b) Alteration of official minutes is only permitted if the alteration is likewise approved by the IACUC. This requirement for IACUC approval does not apply to administrative changes (such as correction of misspellings) that do not alter the tone or factual content of the minutes.

d. **Protocol Review by an Internal VA IACUC.** Work on any VA animal research is permitted to begin only after the protocol describing that work has been reviewed and approved by the IACUC. The same requirements apply, regardless of whether the protocol being reviewed describes new work, work submitted for complete re-review, or a change to an approved protocol. ***NOTE:*** *Other approvals that may be required by VHA policy before work may begin, such as approval by the R&D Committee, are beyond the scope of this directive.*

(1) **Primary reviewers**. VA requires at least two voting members to be assigned as primary reviewers for the review of any protocol by any mechanism by an internal VA IACUC.

(2) **Methods of Protocol Review.** VA recognizes internal VA IACUC approval of a protocol only if it is granted by either Full Committee Review (FCR) or Designated Member Review (DMR) conducted according to the USDA AWR and PHS Policy. Only the following terminology and outcomes established by PHS policy are recognized by VA:

(a) FCR. For FCR, the required two or more primary reviewers present their evaluations to the committee for discussion at a convened meeting. There are no constraints on the method by which the primary reviewers are assigned. The possible outcomes of FCR that are recognized by VA are:

1. Approved. VA research with animals may be conducted, but only according to the approved protocol.

2. Approval Withheld. The internal VA IACUC has determined that the protocol will not be approved.

3. Requires Modifications to Secure Approval (RMSA). The protocol is not yet approved but the internal VA IACUC will reconsider approval after the protocol is modified to address the concerns of the IACUC.

(b) DMR. For DMR, the required two or more primary reviewers are the DMR reviewers assigned by the committee chair based on their qualifications to review the protocol on behalf of the internal VA IACUC.

1. VA accepts review by DMR for any protocol, including a protocol that has been revised after initial FCR.

2. The possible outcomes of DMR are as follows: ***NOTE:*** *Withholding approval is not a possible outcome of DMR.*

a. Approved. When all DMR reviewers recommend approval of a protocol, the protocol is approved on behalf of the IACUC, effective on the date specified in the written notification to the investigator. No further action by the internal VA IACUC is necessary.

b. RMSA. If any DMR reviewer has concerns that RMSA, the protocol is not yet approved, but may be approved by all DMR reviewers after it is modified to satisfy all concerns of all DMR reviewers.

c. FCR (send to FCR). This is the outcome if any DMR reviewer or other IACUC member calls for FCR or recommends withholding approval.

(3) **Forms.** When the VA animal research program has an internal VA IACUC, the VA Animal Component of Research Protocol (ACORP) form (available online at https://www.research.va.gov/programs/animal_research/documents.cfm#docs-c) is required for any protocol that is to undergo secondary review by the office of the CVMO. This includes each protocol for work with sensitive species (regardless of the source of funding support), and each protocol for work (with any species) that has been selected for possible VA funding and therefore requires JIT processing before that funding will be released. Only protocols for work that is not subject to secondary review, and for which the internal VA IACUC shares oversight responsibility with the IACUC of an affiliate, may be documented on the form used by the affiliate, provided that form addresses everything required by the PHS Policy and USDA AWR.

(4) **Notification of Determination about Approval.** For VA animal research programs, the regulatory requirement to notify the institution of the outcome of each protocol review is met by an internal VA IACUC when it submits its official meeting

minutes and any separate notifications to the R&D Committee, as required by VHA Directive 1200.01(1) for all subcommittees of the R&D Committee.

(5) **Continuing Review.** Internal VA IACUCs manage continuing review of approved protocols on a case-by-case basis according to the species, procedures, and complexity of the protocols involved.

(6) **Complete Review.** IACUC approval expires on the date specified by the internal VA IACUC, or at the end of the maximum period of approval allowed by the AWR or PHS policy, whichever comes first. For the work to continue after that, the approval of the IACUC must be secured for a new protocol covering the continuation of the work, prepared on the most current version of the appropriate form.

(7) **Protocol Documentation**. Each VA animal research program with an internal IACUC must ensure that at least the following are readily accessible to authorized personnel, including (but not limited to) each individual identified on the protocol and all those responsible for oversight of the protocol:

(a) A copy of each version of the protocol, and any separate protocol modifications or amendments, that have been approved by the internal VA IACUC, showing the effective date of the approval.

(b) Documentation of all actions of the internal VA IACUC on the protocol, including approval of the protocol and any modifications.

(c) Documentation of any IACUC suspensions of approval and lifting of IACUC suspensions.

e. **Protocol Review Considerations for an Internal VA IACUC.** An internal VA IACUC is to consider the following in the review of any protocol:

(1) **Veterinary Consultation.** VA requires the investigator to consult with the AV or designee during the planning of any protocol or modification of any procedure in an approved protocol, regardless of the species involved. Only consultations documented in writing to have been performed within one year before submission of the protocol to the internal VA IACUC for review satisfy this requirement.

(2) **Assignment to USDA Categories.** In protocols for VA research with animals, regardless of whether the species involved are regulated by USDA, the animals requested are to be assigned according to the categories defined by USDA in terms of potential pain or distress and how they are to be managed.

(3) **Numbers of Animals Needed.** The numbers of animals shown on the protocol must be justified in terms of the numbers needed for the work described in the protocol. Breaking down the numbers by the strains of rodents requested may be important to that justification for some protocols, and the IACUC is authorized to require it as needed, but there is no general VA requirement to include the breakdown by strain routinely on every VA animal research protocol.

(4) **Standardized Procedures for Work with Animals.** To reduce needless repetition, VA accepts the establishment of standardized procedures that are documented in writing and approved by the internal IACUC for referencing in animal protocol forms or for use as guidelines for developing descriptions of other similar procedures. These must be reviewed by the internal VA IACUC and updated as needed, at intervals no longer than the maximum allowed by PHS policy for standardized procedures.

(5) **Qualifications of Personnel.** Before conducting work with the animals, all research personnel on a protocol under review are expected to have completed the required training for working with the IACUC and for working with the species identified in the protocols that they are assigned to, as well as any additional protocol-specific training requirements related to assigned animal research duties that the IACUC overseeing those protocols deems appropriate.

(6) **Use of Human Clinical Care Areas or Equipment for Animal Research.** Use of human clinical diagnostic, treatment, or monitoring areas, or human clinical care equipment (either within the VA medical facility or elsewhere) for VA animal research is only allowed if it is specifically approved by the IACUC overseeing the work and by those responsible for ensuring that the area or equipment is appropriately cleaned, sanitized and disinfected for subsequent use by human patients. Part of the IACUC approval process is for an internal VA IACUC to ensure that all of the following conditions are met before it grants approval:

(a) There are no reasonable alternatives to the use of the human clinical care areas or equipment.

(b) The protocol includes procedures for cleaning, sanitizing and disinfecting any human patient care area or equipment used for research with animals. For areas and equipment that are to be used subsequently for human patients, the procedures must meet the established standards for equipment or areas to be used with human patients. This includes following any manufacturer’s instructions for use (MIFU).

(c) An internal VA IACUC is responsible for overseeing that approval has been granted by the following before VA human clinical care equipment or areas are used for research with animals:

1. The IACUC Chair.

2. The Attending Veterinarian.

3. The VA facility Chief of Staff.

(d) Appropriate provisions are included in the protocol for the work with animals in human clinical care areas to be discrete and secure.

(e) Transportation of animals into or through areas used by patients or visitors is to be avoided. When unavoidable, all reasonable precautions are to be taken to minimize

the exposure of patients and visitors to animal body fluids, wastes and aerosols. This includes transporting animals only when they are securely held in closed and covered carriers, such that individuals not involved in the animal research are not made aware of their presence by visual, olfactory or audible cues.

(7) **Responding to Concerns Noted in the Secondary Review by the Office of CVMO.** The CVMO's office performs a secondary review of each protocol submitted for JIT processing and as the first step of the expanded secondary review process for VA research with sensitive species. The reviewer may provide written comments for which the IACUC is responsible for managing the response according to the instructions included. The outcome of the secondary review does not directly affect the status of the IACUC approval of the protocol, but VA funding to support the work will be released to the station, and protocols for work with VA sensitive species will proceed to the next step of expanded secondary review, only after the concerns noted are addressed to the satisfaction of the office of the CVMO.

(8) **VA Research with VA Sensitive Species**. Since 2018, Congress has imposed additional constraints on the use of VA funds to support research with canine, feline and NHP subjects. The additional VA-specific review requirements for addressing these constraints are updated as needed in ORD guidance document AR2017-001, available at https://www.research.va.gov/programs/animal_research/CanineFelineNHP.pdf and are not limited to VA-funded research. Work on such protocols is permitted to proceed only when all of those review requirements have been met. Approval of the protocol by the internal VA IACUC is necessary, but alone is not sufficient.

f. **Changes to Protocols Approved by an Internal VA IACUC.** An internal VA IACUC is responsible for reviewing and making determinations about approval, in compliance with USDA AWR requirements and PHS policy for changes to protocols that it has already approved. Implementation of the changes is only permitted after the IACUC grants approval. VA recognizes as valid only the mechanisms described and authorized by PHS policy for making changes in approved protocols, including FCR, DMR and administrative methods including Veterinary Verification and Consultation (VVC), as applicable.

g. **Semiannual Evaluation by an Internal VA IACUC.** Each internal VA IACUC is subject to USDA AWR and PHS policy requirements, to evaluate at least semiannually the animal research program and facilities that it oversees.

(1) **Use of the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Form.** The most recent version of this form must be used for documenting semiannual evaluations by an internal VA IACUC and is available on the ORD website (https://www.research.va.gov/programs/animal_research/documents.cfm).

(2) **Signatures on the Report.** Dated signatures of a majority of the total voting membership of the IACUC are required to make the report official, regardless of the

species of animals involved. VA accepts as valid signatures on the semiannual report any form of signature that is acceptable to USDA and OLAW.

(3) **Participants in the Semiannual Evaluation.** No voting member of the IACUC (regular or alternate) who wishes to participate in any or all portions of the IACUC semiannual evaluation of the animal care and use program may be excluded.

(4) **Presentation of the Report to the VA Medical Facility Director.** It is essential for the internal VA IACUC to keep the VA medical facility Director well-informed of the status of the animal research program. The requirement of the USDA AWR and PHS Policy for the final report of the semiannual evaluation to be submitted to the IO is therefore expanded here to require the VA medical facility Director and the IACUC Chair (or a voting member delegated in writing by the Chair to represent the internal VA IACUC) to meet in real time (in person or by teleconference) to review the official report of each semiannual evaluation and discuss any administrative or other support needed to maintain or improve the quality and compliance of the program. No voting member of the internal VA IACUC who wishes to participate in the meeting may be excluded. After the review, the Director signs the report to document receipt and review. The Director may not change the IACUC's report of the semiannual evaluation and may not require the IACUC to do so, but may provide comments in a cover memo to accompany the report. If there are any serious disagreements about the report that the Director and internal VA IACUC cannot resolve, the office of the CVMO is to be contacted immediately.

(5) **Submission of the Report to the Office of the CVMO.** Regardless of whether the Director and the internal VA IACUC agree on the contents, a copy of the complete official semiannual report (Parts 1, 2 and 3), approved and signed by the internal VA IACUC and signed by the Director, is submitted to the office of the CVMO within 90 days of the IACUC's approval.

h. **Oversight of Guidelines and Standardized Procedures for the Animal Research Program by an Internal VA IACUC.** The internal VA IACUC is responsible for ensuring that each written guideline and standardized procedure that is established in the local VA animal research program (including, but not limited to, those for VMU operations, IACUC functions and protocol procedures) is reviewed and updated regularly by the IACUC. The maximum review intervals for standardized protocol procedures are to be as allowed by PHS policy, and for other guidelines no longer than three years. The IACUC may, at its discretion, rely on the guidance and recommendations of subject matter experts to inform its review, but is responsible for integrating the input from those with expertise in different aspects of the guidelines and procedures, to ensure that they are coherent and meet the specific needs of the local program. Reviews of written guidelines are to be documented in the IACUC minutes.

i. **Routine Reports to Oversight Entities from an Internal VA IACUC.** The USDA, OLAW and AAALAC International all require institutions that they oversee to report annually about the institutional animal research program. The internal VA IACUC is responsible for maintaining on file a copy of the final, signed version of each of these

reports. There is no requirement to download and maintain a copy of the information entered into the “VMU report” online database maintained by the office of the CVMO.

(1) The VA animal research program can only be overseen by an internal VA IACUC if it holds an independent PHS Assurance, so any internal VA IACUC is responsible for ensuring that the annual report to OLAW is submitted as required.

(2) For stations at which the local VA program is independently registered with USDA or independently accredited with AAALAC International, the internal VA IACUC is also responsible for ensuring that the annual reports to those oversight entities are submitted.

(3) For stations with a formal arrangement under which the local VA animal research program is covered by the USDA registration or AAALAC International accreditation of an affiliate, the affiliate is responsible for submitting those annual reports, but the internal VA IACUC is responsible for providing any information needed by the affiliate for those reports, and obtaining file copies of those reports.

(4) The internal VA IACUC is responsible for ensuring that the VMU Annual Report is submitted.

j. **Addressing Concerns Related to Local VA Animal Research (Internal VA IACUC).** Regardless of whether the program involves species regulated by USDA or whether the work is supported by PHS funds, VA applies to the internal VA IACUC the USDA AWR and PHS policy assignment of primary authority and responsibility for investigating, determining corrective actions needed and appropriately reporting all concerns that arise, related to the proper functioning of the local VA animal research program.

(1) **Bringing Concerns to the Attention of the IACUC.** To encourage those with concerns to bring them to the attention of the IACUC, the internal VA IACUC is responsible for ensuring that:

(a) Contact information is readily available for anyone concerned about animal welfare or possible violation of animal welfare regulations or policies in the local VA animal research program.

(b) Any request for anonymity or confidentiality on the part of individuals who notify the IACUC of concerns is respected.

(c) The IACUC avoids any appearance of hiding or suppressing deficiencies.

(2) **IACUC Response to Concerns.** An internal VA IACUC is responsible for applying the USDA AWR and PHS policy and complying with VHA Directive 1058.01 when addressing concerns that come to its attention about the animals or the proper functioning of the animal research program, regardless of the species or the source of funding support for the work. It is the responsibility of the IACUC to investigate, review and address such concerns, and to make determinations as to whether they are

reportable to oversight entities beyond the local facility (OLAW, AAALAC International, ORO, funding sponsors). In addition to those requirements, the following apply specifically to VA research with animals (***NOTE:*** *Local program personnel are free to consult with the office of the CVMO for guidance in this process.):*

(a) Reduce harm. The first priority is to take any immediate actions needed to reduce the potential for harm to animals or humans.

1. Any VA veterinarian has the authority and is expected to intervene as necessary to meet currently accepted standards of veterinary medical care appropriate to the IACUC-approved protocol each animal is assigned to.

2. Stopping Work. In addition to the IACUC's authority to suspend its approval of any portion of any protocol or the entire protocol, OLAW and VA recognize the authority of the IO, and anyone designated by the IO in writing, to stop any animal activity regardless of its IACUC approval status. Any such stoppage is considered a concern related to the animal research program that requires prompt notification of the internal VA IACUC, so that the IACUC can determine whether additional action by the IACUC is needed. In VA animal research programs, the following individuals have the authority to stop any animal activity unilaterally and immediately:

a. The VA medical facility Director and anyone designated in writing by the VA medical facility Director are authorized to stop the activity permanently, which means that it is not to resume. The Director and anyone designated in writing by the Director are also authorized to stop the activity temporarily, with the expectation that there is a possibility of it resuming after the IACUC reviews the circumstances, and together with the Director determines the conditions under which to allow it to resume.

b. The AV is authorized to stop the activity temporarily, with the expectation that there is a possibility of it resuming after the IACUC reviews the circumstances, and together with the AV determines the conditions under which to allow it to resume.

c. The Chair of the internal IACUC is authorized to stop the activity temporarily, with the expectation that there is a possibility of it resuming after the IACUC reviews the circumstances, and together with the Chair determines the conditions under which to allow it to resume.

(b) Investigative Subcommittee. The next priority is for the IACUC Chair to assign at least two voting members of the IACUC, with no conflicts of interest and appropriate expertise, to a subcommittee to investigate the matter without delay.

(c) Preliminary Notifications. To facilitate coordination of efforts, the IACUC is strongly encouraged, but not required, to provide informal preliminary notifications when a potentially reportable concern has come to its attention. Preliminary notifications do not presume anything about the outcome of any investigation but allow the recipients to assist the IACUC and to respond knowledgeably if questioned.

(d) Investigation. The voting members of the internal VA IACUC may, at their discretion, invite and accept the assistance of other individuals in the process of collecting and evaluating information. Due consideration to maintaining appropriate confidentiality or, when requested, anonymity, of the individual(s) bringing the concerns to the attention of the IACUC is required.

(e) IACUC Review. At each convened meeting after the matter comes to the attention of the internal VA IACUC, and until the matter is resolved, the IACUC oversees this process by reviewing and directing the progress of the investigation and the actions planned and taken to date to address the matter. When the investigation is complete, the IACUC reviews the findings of the subcommittee and approves a corrective action plan with an appropriate timetable based on the subcommittee's recommendations for remediating existing deficiencies and preventing recurrence. The IACUC then oversees implementation of the corrective action plan through its completion.

(f) Reportability. The internal VA IACUC is also responsible for deciding whether the matter meets the current criteria for reportability established by the applicable oversight entities (APHIS, OLAW, AAALAC International, ORO and any research sponsors involved).

(g) Follow-Up Notifications. If the IACUC determines that the matter is not reportable, it must follow-up with each recipient of a preliminary notification of the intent to investigate, confirming resolution of the matter.

(h) Restarting Work. IACUC approval by a majority vote of a quorum at a convened meeting is needed before any work for which IACUC approval was suspended can resume, fully or with limitations specified by the IACUC.

(3) **Reporting Deficiencies (Internal VA IACUC).** For any matter that the internal VA IACUC determines to be reportable, the preparation and submission of the reports must comply with the requirements of the entities receiving the reports. ***NOTE****: For any matter involving VA sensitive species, the IACUC is urged to communicate closely with the CVMO's office throughout the process of addressing it, beginning immediately on becoming aware of the matter, before providing written information about it to any non-VA entity.*

(a) Matters that are reportable. For VA research, reportable matters are just those defined as such by the USDA AWR, PHS policy, AAALAC, VHA Directive 1058.01 and any research sponsors.

(b) Information to Include in Reports. There are no VA requirements to include any information beyond what is specified by the USDA AWR, PHS policy (applied to all VA research, regardless of funding source), AAALAC, VHA Directive 1058.01 and associated ORO guidance and any research sponsors, in the reports to the corresponding entities.

(c) Recipients of Reports. A copy of the report goes to each entity for which the criteria for reporting are met, according to the determinations of the internal VA IACUC.

1. OLAW, if determined to be reportable to OLAW.

2. AAALAC International, if determined to be reportable to AAALAC.

3. ORO, if determined to be reportable to ORO.

4. The affiliate, according to the formal written understanding covering the interinstitutional collaboration.

5. The head of the Federal agency conducting the research in any VA animal research program (instead of APHIS), if determined to be reportable according to the AWR.

6. The office of the CVMO is to receive a copy of any report about a reportable matter sent to any other entity.

k. **VA Animal Research Program Records Held by an Internal VA IACUC.** The IACUC is responsible for ensuring that all records required by the USDA AWR and PHS policy are maintained and available to authorized VA and non-VA regulatory officials on request.

l. **Research with Animals Overseen Jointly by an Internal VA IACUC and the IACUC of an Affiliate.** Oversight of research with animals conducted in collaboration with an affiliate is shared according to the written understanding about that shared oversight, established by the two institutions.

11. OVERSIGHT OF LOCAL VA ANIMAL RESEARCH BY AN EXTERNAL VA INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

VA accepts reliance on an external IACUC, which must be either jointly-appointed or affiliate-appointed, to provide the oversight of a VA animal research program if that external IACUC provides the oversight needed for the VA animal research program to maintain compliance with VHA Policy, which includes compliance with both PHS policy and USDA AWR. This section focuses on the VA-specific requirements that apply when a VA animal research program is overseen by an external IACUC.

a. **Formal Written Understanding.** Oversight of a VA program of research with animals by an external VA IACUC is always a form of interinstitutional collaboration; such an arrangement is to be established by a formal written understanding that defines the responsibilities of each party.

b. **AAALAC International Accreditation.** An external IACUC is qualified to oversee a VA animal research program only if it is administered by an institution accredited by AAALAC International.

c. **Membership of an External VA IACUC.** For an external IACUC to provide oversight that maintains the compliance of the VA animal research program with VHA policy, the VA will:

(1) **Identify individuals mutually acceptable to both institutions** to serve as voting members on the external VA IACUC where they can keep the IACUC informed of VA-specific concerns and requirements, and help ensure good communications between the institutions, including:

(a) At least one scientist with a VA appointment who has animal research experience.

(b) The AV who oversees the VA research with animals.

(2) Ensure that the VA medical facility Director, as the CEO of the VA medical facility, appoints each member (including not only the VA representatives, but also all of the other members) to the external VA IACUC, if the VA program has its own separate PHS Assurance. As the affiliate's CEO will appoint the same individuals to the affiliate's IACUC, such an IACUC is referred to as an external jointly-appointed VA IACUC.

(3) Accept as members of the external IACUC, the members of the IACUC appointed by the affiliate's CEO alone, if the VA program is covered by the affiliate's PHS Assurance. Such an IACUC is referred to as an external affiliate-appointed VA IACUC.

(4) Ensure that VA personnel identified to represent VA on an external VA IACUC satisfy the same training requirements as apply to members of an internal VA IACUC.

d. **Critical Communications Between an External VA IACUC and the VA.** It is essential for the VA medical facility to stay well-informed about the findings and actions of the IACUC that oversees the local VA research with animals, even when the IACUC is external. The individuals identified to represent the VA medical facility in the work of the external IACUC serve as liaisons with VA and are authorized to communicate freely with VA about the actions of the external VA IACUC. Additional mutually agreeable, locally suitable methods of ensuring effective communications are to be established as needed by the VA medical facility and the affiliate, working together. Of particular importance are communications with the following:

(1) **The VA R&D Committee**. The findings, recommendations and actions of the external VA IACUC that are relevant to the collaborative work must be communicated to the VA R&D Committee, just as those of an internal VA IACUC are.

(2) **The VA SRS and IBC**.

(3) **The VA Medical Facility Director.** The VA medical facility Director must be kept informed about the status of the animal research program, because the VA medical facility Director shares the responsibility to ensure the regulatory compliance of the program, even when it is overseen by an external VA IACUC. This includes

communications about the results of semiannual evaluations, and about any concerns that come up about the program.

(4) **The CVMO.** An external IACUC, like an internal IACUC, is responsible for ensuring that the CVMO is kept informed of any matters relevant to the condition of the local animal research program.

(a) VA does not accept any local constraints on anyone contacting directly and consulting freely with the office of the CVMO or with ORO with regard to VA animal research and compliance issues.

(b) Documents to be shared routinely with the CVMO include, but are not limited to, copies of the following. Unless otherwise indicated, the documents are to be provided within 30 days of when the external IACUC approved, received, or submitted them.

1. The results of each semiannual evaluation of the program and facilities are to be provided within 90 days of when the external IACUC approved it.

a. The results documented in the report of the evaluation required by the PHS Policy and the USDA AWR, signed by the medical facility Director, are acceptable from any VA program.

b. For a VA program that does not have a VMU, a memo summarizing the results relevant to the VA program, signed by the IACUC Chair and then signed by the VA ACOS/R&D to document receipt, is also acceptable.

2. Self-reports by the external IACUC about matters relevant to the VA program and determined by the IACUC to be reportable

3. Annual reports required by OLAW and AAALAC International.

4. Reports and follow-up correspondence after site visits by any oversight or accreditation entity.

5. Notifications required by USDA AWR about changes in the operation of the VA medical facility as a research facility registered with USDA

6. Notifications required by ORO about changes in the animal research program

(c) All documents may be redacted of language not related to VA research, provided arrangements can be made within three business days of each request to make the unredacted version of the document available for review by VA research representatives, at a mutually agreeable time and location.

(d) If any document containing coded identifiers for personnel is submitted to the office of the CVMO, VA requires a separate key to the code to be provided on request by the office of the CVMO.

e. **Conduct of Business by an External VA IACUC.** VA accepts the conduct of IACUC business according to the requirements of the affiliate, provided those procedures are consistent with the requirements of USDA AWR and PHS policy.

(1) **Participation of VA Representatives**. The individuals identified in 11.c(1) to represent VA participate in and contribute to the activities of the external VA IACUC, regardless of whether they are eligible to vote.

(2) **Differences of Opinion**. On an external VA IACUC, as on an internal VA IACUC, it is not acceptable for anyone to attempt to suppress the opinion of a voting member, or to pressure an unwilling voting member to adopt a particular position, with regard to any item of VA IACUC business. Anyone aware of such an extremely serious deviation from VHA policy is to notify the CVMO immediately.

(3) **Conflicts of Interest**. VA policy regarding conflicts of interest, applies to the VA representatives to an external VA IACUC, just as to all members of an internal VA IACUC. The VA representatives must also comply with the Conflict of Interest policies of the affiliate, just as all other members of the external VA IACUC do.

(4) **Confidentiality**. VA representatives at any meeting of an external VA IACUC, just like any member of an internal IACUC, are prohibited from disclosing the votes cast or the views expressed by identifiable individual IACUC voting members about the matter under deliberation, to anyone who was not present or eligible to vote at the time of those votes or deliberations. ***NOTE:*** *This prohibition does not apply when disclosure is required for consultation with, or in response to requests by, agency officials for regulatory or guidance purposes.*

(5) **Meeting Minutes**. For an external jointly-appointed VA IACUC, VA accepts meeting minutes in whatever format the affiliate chooses, provided the minutes meet the requirements of USDA AWR and PHS policy, and it is documented clearly for each item of business whether the IACUC acted as the external VA IACUC, or as the affiliate's IACUC.

f. **Protocol Review by an External VA IACUC.** Except for the VA-specific requirements noted here, VA accepts protocol review and approval granted by an external VA IACUC as long as these are handled in compliance with the USDA AWR and PHS policy.

(1) **Primary reviewers**. The VA-specific requirement for at least two primary reviewers for each protocol reviewed by an internal VA IACUC, does not apply to an external VA IACUC. There is also no requirement for VA protocols to be assigned to VA representatives on the external VA IACUC.

(2) **Forms**.

(a) For any protocol that is to be reviewed by an external VA IACUC and then submitted for secondary review by the office of the CVMO, VA accepts protocols prepared on either the VA ACORP form or the form used by the affiliate that hosts the

external VA IACUC, provided all of the information that is requested in the ACORP for IACUC review is included on that form or in a supplement or appendix that is attached to it and is reviewed and approved as part of the protocol by the external VA IACUC.

(b) Other protocols may be reviewed on the affiliate's form, if that form addresses everything required by the PHS policy and USDA AWR.

(3) **Notification of Determination about Approval**. Institutional notification of the outcome of the protocol review, as required by USDA AWR and PHS policy, is accomplished by an external VA IACUC communicating with VA contacts such as the VA AO/R&D, ACOS/R&D, or other research personnel (as specified in the formal written agreement) in addition to with the PI directly.

(4) **Protocol Documentation to be Maintained by a VA Program with an External IACUC**. Authorized personnel of a VA animal research program with an external VA IACUC must at least have ready access to the documentation for each protocol approved by the external VA IACUC. Those personnel include (but are not limited to) each individual identified on the protocol and all those responsible for oversight of the protocol. For work done at the VA medical facility, the VA is required to have a copy (hard copy or electronic) of each document. For work done at an affiliate that hosts the external VA IACUC, having access to an electronic system containing the documents is acceptable instead of having a copy (hard copy or electronic) of each document provided the arrangements for the electronic access include sufficient redundancy to ensure that the authorized personnel have access as needed. The documents needed include:

(a) A dated copy of each version of the protocol, and any separate protocol modifications or amendments, that have been approved by the external VA IACUC.

(b) Documentation of all actions of the external VA IACUC on the protocol, including approval of the protocol and any modifications.

(c) Documentation of any IACUC suspensions of approval and lifting of IACUC suspensions.

(d) For programs with species regulated by USDA, other records required by the USDA AWR.

g. **Protocol Review Considerations for an External VA IACUC.**

(1) **Veterinary Consultation**. VA applies the USDA AWR requirement for veterinary consultation to every protocol or significant change, other than personnel modifications, of an approved protocol, for any species, submitted for review. Only consultations prior to, but no more than 1 year before, submission of the protocol to the VA IACUC for review, satisfy this requirement. The date of these consultations should be documented within the approved protocol or amendment.

(2) **Assignment to USDA Categories.** VA requires that all animals requested, regardless of whether the species involved are regulated by USDA, be assigned according to the categories defined by USDA in terms of potential pain or distress and how they are to be managed.

(3) **Standardized Procedures for Protocols.** VA requires any written standardized procedures referenced in an animal protocol form under review by the external VA IACUC to be also reviewed by the external VA IACUC according to the frequency specified by OLAW guidance.

(4) **Qualifications of Research Personnel**. Evaluation of personnel qualifications by the external VA IACUC as required by USDA AWR and PHS policy includes review of confirmation that all personnel have met ORD requirements for training, according to the responsibilities assigned to them on the protocol. An external VA IACUC may rely on the administrative offices of the local VA Research Service to provide confirmation that web-based training required by ORD has been completed.

(a) Each individual named on a VA protocol for research with animals, including those who supervise work with animals even if they do not personally handle animals, is required to meet VA training requirements.

(b) Like an internal VA IACUC, an external VA IACUC is authorized to determine the additional training that is required for personnel responsible for performing specialized procedures.

(c) Like an internal VA IACUC, an external VA IACUC is authorized to determine what training requirements apply to personnel with limited involvement in or responsibility for performing procedures on a VA animal use protocol.

(5) **Use of Human Clinical Care Areas or Equipment for Animal Research.** Use of human clinical diagnostic, treatment, or monitoring areas or human clinical care equipment (either within the VA medical facility or elsewhere) for VA animal research is only allowed if it is specifically approved by the IACUC overseeing the work and by those responsible for ensuring that the area or equipment is appropriately cleaned, sanitized and disinfected for subsequent use by human patients. An external VA IACUC is responsible for ensuring that all of the following conditions are met before it grants approval:

(a) There are no reasonable alternatives to the use of human clinical care areas or equipment.

(b) The protocol includes procedures for cleaning, sanitizing and disinfecting any human patient care area or equipment used for research with animals. For areas and equipment that are to be used subsequently for human patients, the procedures must meet the established standards for equipment or areas to be used with human patients. This includes following any manufacturer’s instructions for use (MIFU).

(c) An external VA IACUC is responsible for overseeing that approval has been granted by the following before VA human clinical care equipment or areas are used for research with animals:

1. The IACUC Chair.

2. The Attending Veterinarian.

3. The VA facility Chief of Staff.

(d) Appropriate provisions are included in the protocol for the work with animals in human clinical care areas to be discrete and secure.

(e) Transportation of animals into or through areas used by patients or visitors is to be avoided. When unavoidable, all reasonable precautions are to be taken to minimize the exposure of patients and visitors to animal body fluids, wastes and aerosols. This includes transporting animals only when they are securely held in closed and covered carriers, such that individuals not involved in the animal research are not made aware of their presence by visual, olfactory, or audible cues.

(6) **Responding to Concerns Noted in the CVMO Secondary Review**. For protocols subject to secondary review requirements, the office of the CVMO may provide written comments for the external VA IACUC and investigator to review. Instructions will be provided if a response to the office of the CVMO is required. The outcome of the secondary review does not directly affect the status of the IACUC approval of the protocol, but VA funding to support the work will only be released to the station, and VA approval for protocols with VA sensitive species will only be granted for the work to begin, after the concerns noted in the secondary review comments are addressed to the satisfaction of the office of the CVMO.

(7) **VA Research with VA Sensitive Species**. In 2018, Congress imposed additional constraints on VA research with canine, feline and NHP subjects. The additional VA-specific review requirements for addressing these constraints are updated frequently in ORD Guidance Document AR2017-001 and apply to all VA research protocols for work with sensitive species, regardless of the source of funding support. Work on such protocols is permitted to proceed only when all of those review requirements have been met. Approval of the protocol by the local external VA IACUC is necessary but alone is not sufficient.

h. **Changes to Protocols Approved by an External VA IACUC.** An external VA IACUC is responsible for reviewing and making determinations about approval, in compliance with USDA AWR requirements and PHS policy, for changes to protocols that it has already approved. Implementation of the changes is only permitted after the IACUC grants approval. VA recognizes as valid only the mechanisms described and authorized by PHS policy for making changes in approved protocols, including FCR, DMR and administrative methods including Veterinary Verification and Consultation (VVC).

i. **Semiannual Evaluation by an External VA IACUC.** The external VA IACUC is responsible for evaluating semiannually the VA animal research program, which includes any VMU and other spaces identified in the formal written agreement between the institutions.

(1) **Form to be Used.** VA accepts reports of semiannual program evaluations by an external VA IACUC on the form used by the affiliate, as long as that form that includes all of the elements of evaluation required by the USDA AWR and the PHS policy.

(2) **VA Participants.** VA requires that the individuals identified by VA to serve on the external IACUC be allowed to participate in any and all portions of the semiannual evaluation that are relevant to the VA animal research program.

(3) **Evaluation of VMU Physical Plant and Operations.** Any external IACUC that oversees a VA animal research program with a VMU is responsible for interacting as needed with VA medical facility personnel to oversee physical plant operations supporting that VMU. Local VA research administrators must provide support and information as needed for the external VA IACUC to monitor the program. The external VA IACUC is responsible for documenting, in the reports of semiannual evaluation or in separate documents, completion of the following:

(a) Review of a log of all work orders submitted (completed or outstanding) since the last review, for the maintenance and repair of the VMU, with evaluation of the timeliness of the responses to those work orders. The log is to be provided by VMU personnel at least semiannually.

(b) Evaluation of the results of annual overheat testing of HVAC equipment in the VMU by VMU personnel, and determination of whether the response is adequate. If not, the external VA IACUC is responsible for notifying the ACOS/R&D and reporting this to the VA medical facility Director, for prompt corrective action to ensure an adequate emergency response.

(c) Periodic review and update of the emergency/disaster plan for the VMU as needed by qualified experts. For programs with USDA-regulated species, the minimum interval between reviews is as specified by the AWAR, or three years, whichever is shorter. For programs with no USDA-regulated species, the minimum interval between reviews is three years.

(d) Establishment and maintenance of an updated written PVC that meets the requirements of the AWR, applied to the VA program regardless of whether the program includes species regulated by USDA and regardless of whether the AV holds a full-time appointment. Establishment of the PVC for a VA program that has a VMU requires approval by the external IACUC and the signature of the AV.

(4) **Communication of the Results to the VA Medical Facility.** The external VA IACUC is responsible for keeping the VA medical facility informed of the status of the VA animal research program, including by communicating the results of each semiannual evaluation to the VA medical facility.

(a) Any external VA IACUC overseeing a VA animal research program that has a VMU is required, as an internal VA IACUC is, to have at least one voting IACUC member representing the committee meet with the VA medical facility Director in real time (in person or by teleconference) to review the final report of each semiannual evaluation, and discuss any administrative or other support needed to maintain or improve the quality and compliance of the program. No voting member of the external VA IACUC who wishes to participate may be excluded. After the review, the Director signs the report to document receipt and review. The Director does not have the authority to change the IACUC's report of the semiannual evaluation, or to require the IACUC to do so, but may provide a cover memo with the Director's comments, to accompany the report.

(b) Any VA animal research program that does not have a VMU must rely on oversight by an external affiliate-appointed IACUC. In this case, an official at the affiliate is the designated IO, and VA will accept, instead of a copy of the final report of the semiannual evaluation reviewed with the VA medical facility Director, a report in the form of a memo from the external affiliate-appointed IACUC, submitted to the VA ACOS/R&D. The report memo summarizes any important concerns (or lack thereof) noted in the semiannual evaluation related to the local VA research with animals, and is to be signed by the IACUC Chair, representing the IACUC. The ACOS/R&D signs to indicate receipt, and communicates to the Director any information requiring the Director's attention. The Director may provide comments in a cover memo to accompany the report memo when it is submitted to the office of the CVMO.

(c) If the Director and the external VA IACUC cannot resolve serious disagreements about the report, the office of the CVMO is to be contacted immediately.

(5) **Submission of the Report to the Office of the CVMO.** VA policy requires a copy of the communications about the semiannual evaluation, signed by the external IACUC, and by the VA medical facility Director or ACOS/R&D, as appropriate, to be submitted to the office of the CVMO within 90 days of the external VA IACUC's approval of the semiannual report, regardless of whether the Director and the external VA IACUC agree on the contents. The administrative offices of the VA Research Service are responsible for submitting the signed copy to the office of the CVMO, and ensuring that the ACOS/R&D has a copy as well.

j. **Oversight of Guidelines for the Animal Research Program by an External VA IACUC.** The external VA IACUC, like an internal VA IACUC, is responsible for overseeing the review and updating of each set of written guidelines that is established for the local VA animal research program (including those for VMU operations, IACUC functions and protocol procedures), regardless of where the work is done (at the affiliate, on property owned or leased by VA, or elsewhere).

k. **Routine Reports to Oversight Entities from an External VA IACUC.**

(1) The IACUC identified in the PHS Assurance that covers the VA program is responsible for submitting the annual report required by OLAW.

(2) A VA medical facility can only independently register its animal research program with USDA or hold AAALAC International accreditation if it has a VMU. In this case, local VA research administrators and the external VA IACUC share responsibility, as defined in the formal written agreement, for submitting the annual reports about the VA animal research program as required by those oversight entities.

(3) For stations with a formal arrangement under which the local VA animal research program is covered by the USDA registration or AAALAC International accreditation of the affiliate, the affiliate is responsible for submitting those annual reports, including in each report the aspects of the VA program that it oversees. In agreeing to host the external VA IACUC, the affiliate commits to providing a copy of the final, signed version of each report to the VA facility Research Service.

(4) The external IACUC is responsible for providing to the VA the information about the VA program of research with animals that local VA research administrators are asked to submit to the office of the CVMO.

k. **Addressing Concerns Related to Local VA Animal Research (External VA IACUC).** An external IACUC has the same authority and responsibility as an internal VA IACUC has for investigating, determining corrective actions needed and appropriately reporting all concerns that arise regarding those aspects of the VA animal research program that it oversees. Additionally, the external VA IACUC is required to maintain close communications with the VA medical facility throughout this process.

(1) **Keeping VA Informed.**

(a) When concerns about animals involved in the VA animal research program come to the attention of an external VA IACUC, the external VA IACUC is to notify the VA ACOS/R&D informally but promptly that an investigation is underway, so that the ACOS/R&D can promptly provide informal notification to the CVMO's office.

(b) The preliminary notification is particularly important when the concerns relate to VA sensitive species, or are otherwise likely to be of public interest, in which case, VA requires the ACOS/R&D to notify the CVMO's office within three business days of becoming aware of the matter and, if possible, before any communication with external non-VA entities is initiated.

(c) Such preliminary notifications do not presume anything about the outcome of the investigation, but allow the ACOS/R&D and the CVMO to support and provide guidance to the IACUC as needed, and to respond knowledgeably if questioned.

(d) VA prohibits imposition of any local constraints on any individual who wishes to contact directly or consult freely with the office of the CMVO or the ORO with regard to animal research and compliance issues. This includes any member of the external VA IACUC, including the VA representatives, and any IACUC manager.

(e) The VA Research Service is responsible for facilitating the investigation by the external VA IACUC by providing access to documents, facilities and personnel, as needed.

(2) **Applicable Regulatory Requirements.** An external VA IACUC oversees compliance of the VA animal research program with VHA Directive 1058.01 and this directive, as well as with the USDA AWR and PHS policy. The VA representatives to the external VA IACUC serve as resources to the IACUC with regard to VA-specific regulatory requirements.

(3) **Corrective Actions.** The VA animal research program is required to comply with the requirements of the external VA IACUC and implement any corrective action plan approved by the committee.

(a) Stopping Work. OLAW and VA recognize the authority of the IO identified in the PHS Assurance, and anyone designated by the IO, to stop any animal activity regardless of its IACUC approval status. Any such stoppage is considered a concern related to the animal research program that requires prompt notification of the external VA IACUC, so that the IACUC can determine whether additional action by the IACUC is needed. VHA policy additionally authorizes the following to stop unilaterally and immediately any VA animal activity, either temporarily or permanently, as specified below:

1. The VA medical facility Director and anyone designated in writing by the VA medical facility Director are authorized to stop the activity permanently, which means that it is not to resume. The Director and anyone designated in writing by the Director are also authorized to stop the activity temporarily, with the expectation that there is a possibility of it resuming after the IACUC reviews the circumstances, and together with the Director determines the conditions under which to allow it to resume.

2. The VA AV is authorized to stop the activity temporarily, with the expectation that there is a possibility of it resuming after the IACUC reviews the circumstances, and together with the AV determines the conditions under which to allow it to resume.

3. The Chair of the external VA IACUC is authorized to stop the activity temporarily, with the expectation that there is a possibility of it resuming after the IACUC reviews the circumstances, and together with the Chair determines the conditions under which to allow it to resume.

(b) Suspending IACUC Approval. It is crucial that the local VA be informed immediately when the external VA IACUC suspends its approval of any VA protocol or part of a VA protocol, so that VA can act to support the stoppage of work, until the suspension is lifted. Reports required by the USDA AWR and the PHS Policy regarding the suspension and corrective actions taken by the external VA IACUC and the affiliate's IO are to be copied to the local VA. The VA medical facility Director is responsible for reporting to ORO according to VHA Directive 1058.01.

(4) **Reporting.** If an external VA IACUC determines that a matter related to VA research with animals is reportable, it is responsible for submitting the required reports to OLAW, AAALAC International and the head of the VA (for USDA species), with copies to the local VA medical facility. Because of VA's regulatory obligations, the external VA IACUC is additionally required to communicate promptly with the following, according to the document covering the interinstitutional collaboration:

(a) The VA medical facility Director. The external VA IACUC is responsible for notifying the VA medical facility Director according to the requirements of VHA Directive 1058.01.

(b) The ACOS/R&D, as the primary VA contact for research activities.

(c) The point of contact at the VA medical facility for routing documents to the CVMO. This point of contact is identified according to the formal written agreement establishing the collaborative relationship between the VA medical facility and the affiliate. The VA medical facility is responsible for providing to the office of the CVMO a copy of each report submitted by the external IACUC to other oversight entities.

(5) **Matters Determined to be Not Reportable.** If the external IACUC determines that the matter is not reportable to an oversight entity, an informal follow-up communication must be provided to the VA ACOS/R&D to confirm resolution of the matter. The ACOS/R&D will then notify the office of the CVMO without delay.

l. **VA Animal Research Program Records Held by an External IACUC.** For VA to meet applicable regulatory requirements, each external IACUC is expected to maintain the records required by the USDA AWR and PHS policy and to make them available to authorized VA and non-VA regulatory officials on request

12. ADOPTIONS OF RESEARCH ANIMALS

For larger species suitable as pets, such as canines and felines, VA requires that good faith efforts be made to arrange adoption into loving homes when the animals can be retired from research. For retired non-human primates, VA requires that arrangements be made for their accommodation in appropriate facilities to promote their well-being.

a. Guidance on arranging adoptions of retired VA research animals (see ORD Guidance Document AR2018-001) was developed in consultation with the Office of General Council Specialty Team Advising Research, and is updated as needed.

b. VA fully supports the retirement of NHPs from further research activities when the IACUC overseeing the work and other local stakeholders (including but not limited to the researchers, the AV and the VA medical facility Director) determine that retirement is appropriate.

c. Consultation with the CVMO is required before any canine, feline, or NHP is euthanized solely because of difficulties in arranging an adoption or retirement transfer.

13. OCCUPATIONAL HEALTH AND SAFETY

a. **The Occupational Health and Safety Program (OHSP).** The responsibilities of the medical facility Director, performing the functions of the IO to maintain compliance of the local animal research program with PHS Policy, include ensuring that the health program for personnel who work in laboratory animal facilities or have frequent contact with research animals includes the elements that PHS Policy and associated guidance require be described in the PHS Assurance that covers the local program. The facility OHSP covers all employees and includes elements specifically for protecting personnel appropriate to their exposure to animals, unfixed animal tissues or fluids and allergens from animals, associated with their assigned duties and appropriate to their personal medical history, in accordance with the guidance of Occupational Health and Safety in the Care and Use of Research Animals. All references to "OHSP" below are specific to the elements addressing the concerns of PHS policy, beyond the components that apply to all employees. ***NOTE:*** *Additional information can be found in Occupational Health and Safety in the Care and Use of Research Animals available at https://www.nap.edu/login.php?record_id=4988&page=https%3A%2F%2Fwww.nap.edu%2Fdownload%2F4988.*

(1) **Participation in the OHSP.** The responsibility of the IACUC manager to provide administrative support for IACUC functions, includes maintaining documentation of the participation of all personnel required by PHS policy to be covered. Participation requires all of the following:

(a) Documented notification is provided to an acceptable OHSP, that the individual's assigned duties involve risk of exposure to animals or their unfixed tissues, fluids, or allergens.

(b) The individual provides the information needed for the occupational health professionals in that OHSP to perform individual risk assessment,

(c) The individual receives the OHSP recommendations about services appropriate to the individual's risks

(d) The individual receives the services recommended by OHSP, or provides written documentation of the individual's election to decline those services.

(2) **Individuals Required to Participate.** The requirement to participate applies to personnel involved in the VA animal research program, with risk of work-related exposure to animals or unfixed animal tissues, fluids or allergens. Written notification of the requirement to participate is to be provided to each individual whose participation is required and to the IACUC manager. Participation is required of all personnel to whom any of the following applies:

(a) Named as a participant on an IACUC-approved protocol for research with animals, regardless of employment status or work site.

(b) Has assigned duties in the VMU.

(c) Frequently works in space where work is done by others with research animals or their unfixed tissues, fluids, or allergens.

(d) Assigned duties require occasional entry of the VMU or contact with animals or their unfixed tissues, fluids or allergens.

(e) Participation is otherwise warranted in the judgement of the local VA AV, the IACUC (internal or external) overseeing the work with animals, or the local occupational health professionals, evaluating the amount and nature of the exposure.

(3) **The VA OHSP.** Each individual who is required to participate in an OHSP because of risk of exposure to animals in VA research or their unfixed tissues, fluids, or allergens and who is eligible to participate in the VA OHSP, is required to do so, unless the individual is documented to be participating in another OHSP that meets the requirements of PHS policy.

(4) **Other OHSPs**. Each individual who is not eligible to participate in the VA OHSP may only be involved in VA research with animals if participation in another OHSP (e.g., one offered by the individual's home institution or employer) that meets the requirements of PHS policy is documented. An individual with a VA appointment may also choose to participate in such a program instead of the VA OHSP, but then is responsible for providing documentation of that participation to the VA.

(5) **Risk Assessment.** Each individual who is required to participate in the OHSP, is required to provide the occupational health professionals the information needed for assessing the specific risks associated with that individual's assigned duties and personal medical history.

(a) The AV serves as needed, personally or by delegating another qualified individual, as a consultant to the occupational health professionals, with regard to the risks posed by the animals and unfixed animal tissues, fluids and allergens to which the personnel may be exposed. The AV is not involved in assessing the specific risks of any individual.

(b) The privacy of each individual undergoing risk assessment is safeguarded by requiring the individual and the occupational health professionals to communicate directly with each other (not through the IACUC or VA Research Service) about the individual's personal medical history, and the specific recommendations of the occupational health professionals for that individual.

(c) VA relies on the judgement of the occupational health professionals to determine the appropriate frequency for re-assessment of each person's risks and needs for OHSP services. The information provided to the personnel who manage the VA program of research with animals must be limited to confirmation of whether or not each individual is current at any given time on interactions with the occupational health professionals and responses to recommendations about available services.

(6) **Option to Decline Services.** Each VA medical facility Director is authorized to limit access to spaces used in VA research with animals to those for whom access is safe for the individual, the animals and other personnel. This may require the individual to accept some specific OHSP services (e.g., tuberculosis testing or chest radiography to confirm that the risk of tuberculosis infection is low, before the individual begins working with non-human primates). Services that are not required for access may be declined, provided the refusal of the service(s) is documented in writing each time services are recommended by occupational health professionals subsequent to risk assessment.

14. CONFLICTS OF INTEREST

Any appearance of conflict of interest undermines the public trust in the integrity and quality of VA research and in VA stewardship of the public resources supporting research with animals. That trust is fundamental to VA's ability to conduct the research needed to fulfill VA's mission, so all VA animal research personnel and IACUC participants are responsible for being cognizant of potential conflicts of interest in the research they conduct or review and avoiding any action that gives the appearance of such conflicts.

a. VA veterinarians, veterinary technicians and husbandry staff are not considered to have conflicts of interest with regard to individual protocols for which their involvement is limited to providing routine standard surgical, veterinary medical or husbandry support.

b. If the local AV is named as a member of the research staff on a protocol that is subject to secondary review, the signature of a different VA VMO or VMC (from that facility or another VA medical facility) is required on the ACORP, before it can be submitted for secondary review.

15. TRAINING SPECIFIC TO VA RESEARCH WITH ANIMALS

Training requirements for conduct and oversight of VA research with animals is specific to the roles of the individuals.

a. **IACUC members**.

(1) VA training requirements for IACUC members apply to:

(a) Each of the appointed voting members (regular and alternate, including any members who are veterinarians) of an internal VA IACUC.

(b) Each of the individuals identified to represent the VA for an external IACUC

(2) The current specific VA training requirements for IACUC members are detailed on the ORD website (https://www.research.va.gov/programs/animal_research/required_training.cfm).

(a) These can be met by web-based training available without charge to VA medical facilities at http://www.citiprogram.org (CITI). ***NOTE:*** *This linked website is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

(b) Training available to personnel of VA facilities with locally paid institutional subscriptions to http://www.aalaslearninglibrary.org (ALL) also satisfies VA requirements.

(c) Alternate training will only be accepted in place of the designated web-based training if pre-approved by the CVMO's office.

(3) Lapses in training by IACUC members are to be rectified as soon as possible, but such lapses do not affect constitution of the IACUC.

b. **IACUC Manager** The VA medical facility is required to provide adequate funding support and to allow time for personnel in this role to participate in formal training and continuing education activities related to IACUC administration sufficient to gain and maintain familiarity with evolving regulatory requirements and expertise in best practices for meeting them.

c. **VMU staff** -- The local AV and IACUC jointly establish training requirements for VMU staff.

d. **Research personnel**

(1) **General Training Required for All Personnel Conducting VA Research with Animals**. The specific courses and renewal intervals required are posted on the ORD website https://www.research.va.gov/programs/animal_research/required_training.cfm.

(a) VA training requirements for research personnel apply to:

1. Each individual named with protocol-specific responsibilities on a VA protocol for research with animals.

2. The PI and any other supervisors of the work with animals, even if they will not personally handle any of the animals.

3. Personnel with limited responsibility for performing procedures on a VA animal use protocol, as specified by the VA IACUC (internal or external), which is responsible for determining how these training requirements apply, and whether alternate less stringent requirements are adequate.

(b) The current specific VA training requirements for research personnel are detailed on the ORD website (https://www.research.va.gov/programs/animal_research/required_training.cfm).

1. These can be met by web-based training available without charge to VA medical facilities at http://www.citiprogram.org (CITI). ***NOTE:*** *This linked website is*

outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

2. Training available to personnel of VA facilities with locally paid institutional subscriptions to http://www.aalaslearninglibrary.org (ALL) also satisfies VA requirements.

3. Alternate training will only be accepted in place of the designated web-based training if pre-approved in writing by the CVMO's office.

(2) **Specialized Protocol-Specific Training**. For protocols that require specialized procedures, personnel responsible for performing those procedures may be required to complete specialized protocol-specific training that the VA IACUC (internal or external) determines to be appropriate for compliance with PHS policy and USDA AWR.

16. TRAINING

There are no formal training requirements associated with this directive. Guidance on specific requirements pertaining to VA research with animals is outlined in paragraph 15 of this directive.

17. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive are to be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1). Questions regarding any aspect of records management are to be directed to the facility Records Officer.

18. REFERENCES

a. P.L. 99-158.

b. 7 U.S.C. §§ 2131-2159.

c. 38 U.S.C. § 7303.

d. 9 C.F.R. §§ 1.1 – 3.168.

e. VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020.

f. VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019.

g. VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017.

h. VHA Directive 1200.08(1), Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019.

i. VHA Records Control Schedule 10-1, dated January 2021, https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf.

j. AAALAC International. Rules of Accreditation. (http://www.aaalac.org/accreditation/rules.cfm) ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

k. American Association for Laboratory Animal Science. AALAS Learning Library (ALL). https://www.aalaslearninglibrary.org

l. Biosafety in Microbiological and Biomedical Laboratories, 6th edition, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, HHS Publication No. (CDC) 300859 (Government Printing Office, June 2020), (https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf).

m. CITI Program, Collaborative Institutional Training Initiative. (https://about.citiprogram.org/en/homepage) ***NOTE:*** *This linked website is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

n. Frequently Asked Questions: PHS Policy on Humane Care and Use of Laboratory Animals (OLAW FAQs). Office of Laboratory Animal Welfare. Last Revised February 15, 2023, https://olaw.nih.gov/faqs#/guidance/faqs.

o. Guide for the Care and Use of Laboratory Animals (*The Guide*), 8th edition. Institute for Laboratory Animal Research, National Research Council of the National Academies, Washington, DC: The National Academies Press, 2011, (http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf).

p. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). NIH, 2019. (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf).

q. NOT-OD-11-053, Guidance to Reduce Regulatory Burden for IACUC Administration Regarding Alternate Members and Approval Dates, release date March 18, 2011, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-053.html.

r. NOT-OD-12-049,Notice Regarding NIH plan to Transition from use of USDA Class B Cats to Other Legal Sources, release date February 8, 2012, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-049.html.

s. NOT-OD-14-034, Notice Regarding NIH Plan to Transition from Use of USDA Class B Dogs to Other Legal Sources, release date December 17, 2013, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-034.html.

t. Occupational Health and Safety in the Care and Use of Research Animals. National Research Council, Washington, DC: The National Academies Press, 1997.

(https://www.nap.edu/login.php?record_id=4988&page=https%3A%2F%2Fwww.nap.edu%2Fdownload%2F4988)

u. ORD Guidance Document AR2017-001, Canine, Feline and Non-Human Primate Research Protocols, April 22, 2020 (https://www.research.va.gov/programs/animal_research/CanineFelineNHP.pdf).

v. ORD Guidance Document AR2018-001, Adoption of Research Animals Covered by the USDA Animal Welfare Act Regulations, dated July 2, 2018, (https://www.research.va.gov/programs/animal_research/guidance.cfm).

w. Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Office of Laboratory Animal Welfare, National Institutes of Health, Revised August 2015, (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf).

x. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Prepared by the U.S. Interagency Research Animal Committee. 50 FR 20864 (May 20, 1985). https://www.govinfo.gov/content/pkg/FR-1985-05-20/pdf/FR-1985-05-20.pdf, pp. 20864-20865.