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CENTERS FOR DISEASE CONTROL AND PREVENTION
LABORATORY ANIMAL CARE AND USE POLICY

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I. PURPOSE

The directives presented in this policy govern the care and use of animals involved in research, biologic and toxicologic testing, reagent production, and training activities conducted or supported by the Centers for Disease Control and Prevention (CDC[1]). This policy is based on, and will adhere to any subsequent revisions of, the following materials:

Office of Laboratory Animal Welfare, Public Health Service (PHS) “Policy on Humane Care and Use of Laboratory Animals" reprinted 2000. http://grants.nih.gov/grants/olaw/references/phspol.htm

Title 9 CFR, Chapter 1, Parts 1 - 3.142, Animal Welfare Act and amendments, amended 1999. http://www.aphis.usda.gov/ac/publications.html

National Research Council "Guide for the Care and Use of Laboratory Animals” revised 1996. http://books.nap.edu/books/0309053773/html/index.html

Biosafety in Microbiological and Biomedical Laboratories,” 4th Edition, 1999. http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

National Research Council “Occupational Health and Safety in the Care and Use of Research Animals”, 1997. http://www.nap.edu/books/0309052998/html/index.html

If there are any statements in this policy that are unintentionally inconsistent with other regulations or agreements, this policy is superseded by regulations promulgated by the Office of Laboratory Animal Welfare under the PHS Policy and by the United States Department of Agriculture under the Animal Welfare Act authority. Since each of the CDC sites in Atlanta, Fort

[1] References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

Collins, and Morgantown has its own Public Health Service Assurance procedure, some statements within this policy may be inconsistent with the existing PHS Assurance or Association for the Assessment and Accreditation of Laboratory Animal Care International accreditation documents. Any such inconsistencies should be corrected by the time of Assurance renewal.

II. SCOPE

The directives presented in this policy apply to all CDC personnel who deal with laboratory animals. This policy applies to all activities involving animals in CDC-funded research – whether the activities are performed at CDC, at an awardee institution, or through collaboration.

III. ACRONYMS AND DEFINITIONS

A. For the purposes of this policy, the following acronyms will apply:

1. **AAALAC** – Association for the Assessment and Accreditation of Laboratory Animal Care International
2. **ARAC** – Animal Research Advisory Committee
3. **AVMA** – American Veterinary Medical Association
4. **AV** – attending veterinarian
5. **IACUC** – Institutional Animal Care and Use Committee
6. **ILAR** – Institute for Laboratory Animal Research
7. **IO** – institutional official
8. **NIH** – National Institutes of Health
9. **NRC** – National Research Council
10. **OLAW** – Office of Laboratory Animal Welfare
11. **PHS** – U.S. Public Health Service
12. **PI** – principal investigator
13. **PPE** – personal protective equipment
14. **SOP** – standard operating procedure
15. **USDA** – United States Department of Agriculture

B. For the purpose of implementing these guidelines, the following definitions apply:

1. AAALAC is the primary animal care accrediting organization in the United States.
2. Animal Use Protocol (protocol) refers to a complete description of the research objectives and procedures to be followed in a research project involving animals.
3. ARAC refers to the CDC committee that advises the IO on appropriate animal care and use guidelines for all CDC facilities. The CDC ARAC acts in an advisory capacity to the CDC IO and replaces the CDC Animal Policy Board, which is abolished. It does not provide oversight of the individual IACUCs.
4. AV refers to the veterinarian who is responsible for the care of animals being used in a specific research protocol.
5. IACUC refers to the committee appointed by the IO to oversee the institution's animal program, facilities, and procedures. CDC has an IACUC at each of the three sites where animal research is performed (Atlanta, Fort Collins, and Morgantown).
6. IO refers to the person who has the authority to sign the PHS Assurance – making a commitment on behalf of the institution that the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals are met.

7. OLAW is the office which is responsible for administering the PHS Policy on Humane Care and Use of Laboratory Animals. It is located within the National Institutes of Health, Office of Extramural Research.
8. PHS Assurance (or Animal Welfare Assurance) refers to the document filed with the OLAW that describes how an institution complies with the PHS Policy on Humane Care and Use of Laboratory Animals. An institution must have an OLAW-approved Assurance statement in order to conduct animal research using PHS funds.
9. PI is the principal investigator responsible for the proper execution of all animal research under an IACUC-approved animal use protocol.
10. USDA is responsible for administering the Animal Welfare Act and animal welfare regulations through the Animal and Plant Health Inspection Service.

IV. BACKGROUND

The use of animals in CDC research has been critical to understanding many public health problems, particularly in the area of infectious diseases, and to developing and evaluating potential public health intervention strategies. All CDC workers who care for or use animals in their work have the legal and ethical responsibility to do so humanely. This policy describes the administrative and procedural framework for assuring that laboratory animal care and use at CDC complies with federal regulations, including the PHS Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Act and subsequent animal welfare regulations.

V. POLICY

Each individual involved in the care or use of animals must adhere to the principles of humane and ethical policies as established or referenced herein. In particular, those designing protocols and working with animals should adhere to the principles of reduction of the number of animals used, refinement of experimental design to minimize pain and distress, and replacement of animals with alternative techniques where possible.

A. Acquiring Animals

Animals used for laboratory purposes must be acquired in accordance with applicable laws, rules, regulations, and procedures. Animals will be ordered only after a protocol has been approved by the appropriate IACUC.

B. Care, Treatment, and Use of Animals

An AV must provide adequate veterinary care at each facility. The AV's responsibilities include ensuring:

1. All animals are observed daily to assess their health and welfare.
2. Appropriate methods are used to prevent, control, diagnose, and treat diseases and injuries in animals.
3. Guidance is provided to animal users regarding appropriate methods for handling, immobilization, anesthesia, analgesia, and euthanasia of laboratory animals.
4. Adequate pre-procedural and post-procedural care is provided in accordance with established veterinary medical procedures.

Any proposed use of animals that may impose unusual pain or stress must be given careful review. The PI and AV must ensure that the animal use protocol follows the guidelines and procedures specified in the institution's PHS Assurance document and the guidelines described in the NRC Guide for the Care and Use of Laboratory Animals.

C. Euthanasia

Techniques for euthanasia will be those compatible with those recommended by the most recent AVMA Panel on Euthanasia. The recommendations have been published in the Journal of the AVMA and can be found at http://www.avma.org/resources/euthanasia.pdf.

It is essential that euthanasia is performed by personnel skilled in the methods for the species in question and that it is performed in a professional and compassionate manner.

D. Transportation of Animals

The transportation of animals on CDC property, between buildings or facilities, to or from commercial carriers, or in any other manner shall be in accordance with all published federal, state, or local laws, and applicable SOPs or respective IACUC policies.

VI. PROCEDURE FOR SUBMITTING ANIMAL USE PROTOCOLS

A. Internal Protocols

The PI will complete a CDC Animal Use Protocol form. A separate form must be provided for each animal species to be used, unless waived by the local IACUC.

All protocols must be reviewed and approved by all of the following:

1. IACUC of the appropriate facility
2. AV
3. Member of the Office of Health and Safety or the Authorized Safety Official of the appropriate facility
4. Director of the Division in which the PI works.

B. External Protocols

All animal research supported by PHS funds through CDC and carried out at an external (non-CDC) site must have a protocol approved by both the local institution's IACUC and by a CDC IACUC if the protocol involves non-human primates, companion animals (cats, dogs, horses) or USDA class E pain[2].

If the institution to be funded does not have a PHS Assurance, then their protocols must also be approved by a CDC IACUC. If approval by a CDC IACUC is not required because the protocol does not involve companion animals or USDA class E pain and the external site has a PHS Assurance, then approval of external protocols may be deferred to a local IACUC.

[2] Pain level description provided on USDA Form 7023, Annual Report of Research Facility.

Documentation of the local IACUC approval must be maintained by both committees. The CDC animal use protocol for work to be performed at an external institution should list a CDC point of contact to act as a liaison for any questions the CDC IACUC may have on the protocol.

C. Protocol Modification

Significant changes to approved protocols must be reviewed and approved by the IACUC. Protocols may be modified by amendment or by submission of a new protocol. The separate IACUCs at each CDC site have established local policies for what kinds of changes require approval and procedures by which the changes and approvals are made – all within guidelines provided by the Animal Research Advisory Committee. If it is not clear to the investigator whether a protocol amendment or new protocol submission is appropriate for obtaining IACUC approval of proposed protocol changes, the AV and, if necessary, the IACUC chair should be consulted.

VII. PROCEDURE FOR REVIEW BY THE IACUC

All animal use protocols involving non-human primates, companion animals (cats, dogs, horses), or that involve USDA Class E pain, must undergo a full IACUC review.

Other animal use protocols may be eligible for designated review according to local IACUC policy. However, any member of the committee may request a full committee review of any animal use protocol. Approval via full committee review may only be granted by a majority vote of a quorum (greater than 50% of the members) of the committee.

The PI will be notified in writing of the decision of the committee to approve, require modifications in an animal use protocol, or withhold approval of the protocol. If the decision is to withhold approval, the committee will:

- Include in its written notification a statement of the reasons for its decision, and
- Give the principal investigator an opportunity to respond.

A committee member who has a conflicting interest (e.g., is personally involved in the project) may not:

- Participate in the committee review or approval of the protocol except to provide information requested by the committee, or
- Contribute to the constitution of a quorum of the committee.

The committee may invite consultants to assist in the review of complex issues. However, consultants are not ad hoc members of the IACUC and, thus, are not permitted to cast a vote.

The IACUC may suspend an activity that it previously had approved if it determines that the activity is not being conducted in accordance with established policies. A committee may suspend an activity only after review of the matter at a convened meeting of a quorum of the committee and with the suspension vote of a majority of the quorum present. However, if a protocol lapses, then that protocol is automatically suspended without the need for IACUC review.

VIII. PROCEDURE FOR REPORTING ANIMAL MISTREATMENT AND PROTOCOL NONCOMPLIANCE (DEVIATIONS FROM THE PHS GUIDE)

All instances of animal mistreatment or protocol noncompliance should be reported to the chair of the appropriate IACUC immediately. The chair should notify the IO of the incident within 48 hours, either orally or by e-mail. It is the responsibility of the chair to inform the IACUC and work with the committee to determine what actions should be taken. All decisions should be recorded as part of the IACUC records. The IACUC must review and, if warranted, investigate concerns involving the care and use of animals at its research facility.

The IO should be notified of the IACUC's response to the incident no later than two weeks following the initial report. The IO will notify OLAW as required. All facilities are required to have signs posted with contacts for reporting any concerns regarding animal care and use. This must include, but is not limited to, the IO and the IACUC chair for that facility.

IX. PROCEDURES RELATED TO OCCUPATIONAL HEALTH

Records for each individual employee who is involved in the care and use of animals, including contract personnel, will be maintained by the occupational health clinic or by the occupational safety and health officer. At a minimum, these records shall include:

- Physical examinations for all animal caretakers prior to beginning work in the facility.
- Collection and maintenance of serum samples from researchers, animal caretakers, and related personnel who work in facilities where infectious agents are handled, as required by CDC Policy, CDC-SM-1998-01, Baseline Serum Storage Program, or local IACUC policy.
- Administration or documentation of a tetanus booster for all staff who work directly with animals.
- Appropriate pre-exposure immunizations to all persons who handle animals at substantial risk of infection with agents such as rabies virus or hepatitis A and hepatitis B viruses.
- Maintenance of surveillance for potential exposure to zoonotic diseases by:

  Keeping records of bite wounds and other unintentional exposures and/or unusual illnesses, and

  Filing appropriate form (Form CDC 0.304 CDC/ATSDR Incident Report) or appropriate contract documentation of potential exposures.

- Tuberculin skin tests for persons working with non-human primates, which will initially be given prior to working with the animals, then biannually thereafter. Persons with positive tuberculin skin tests will undergo appropriate diagnostic testing and treatment, as indicated by the designated employee health service facility. These persons may be assigned to other work areas as deemed necessary.

X. RESPONSIBILITIES

A. Office of the Chief Science Officer, Institutional Official responsibilities regarding animal care and use

The Chief Science Officer serves as the CDC IO. The IO is responsible for administering all aspects of CDC activities involving laboratory animals. This includes the development and implementation of CDC-wide policies concerned with animal care and use. CDC animal facilities are currently located in:

Atlanta, GA - Roybal Campus, Chamblee, and Lawrenceville
Fort Collins, CO
Morgantown, WV

B. CDC Animal Research Advisory Committee (ARAC) responsibilities regarding animal care and use

The composition of the CDC ARAC is as follows:

1. Chief Science Officer, CDC – Chair, ARAC
2. Chairs from each IACUC
   a. Atlanta, GA
   b. Fort Collins, CO
   c. Morgantown, WV
3. Manager, Animal Care and Use Program Office
4. Director, Office of Health and Safety
5. Director, Division of Scientific Resources, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID) (proposed)
6. Chief, Animal Resources Branch, Division of Scientific Resources, NCPDCID (proposed)
7. Attending veterinarians from each of the animal facilities

   a. Roybal Campus
   b. Chamblee
   c. Lawrenceville
   d. Fort Collins, CO
   e. Morgantown, WV

The responsibilities of the advisory committee include, but are not limited to:

1. Advising the IO on appropriate guidelines for laboratory animal care and use in all facilities.
2. Advising the IO on appropriate standards for using laboratory animals in research, biologic and toxicologic testing, reagent production and training.
3. Serving as the focus for inquiries coming to CDC concerning animals and their use.
4. Reviewing and updating this policy as needed.

C. Institutional Animal Care and Use Committee (IACUC) responsibilities regarding animal care and use

CDC has separate IACUCs in Atlanta, Fort Collins, and Morgantown. Each IACUC is composed of at least five voting members, qualified through experience and expertise, to oversee and review activities involving animals. At a minimum, each committee includes the following:

1. One veterinarian with training or experience in laboratory animal science and medicine, who has responsibility for activities involving animals at CDC.
2. One practicing scientist experienced in research involving animals.
3. One member whose primary concern is in a nonscientific area.
4. One individual who is not otherwise affiliated with CDC and is not a member of the immediate family of a person who is affiliated with CDC.
5. A member of the Office of Health and Safety or the authorized safety official from that location.
6. An individual who meets the requirements of more than one of the categories above may fulfill more than one requirement. However, no IACUC may consist of less than five voting members.

The IO (or their designee at locations outside Atlanta) appoints members of the IACUC from nominees submitted by the IACUC executive secretary or appropriate designee. A list of IACUC members must be sent to the IO and kept current. Nominees and/or persons interested in serving as a member of the IACUC may voice interest via e-mail, memorandum, or letter to the IACUC executive secretary or appropriate designee.

The responsibilities of the IACUC include, but are not limited to:

1. Implementing local IACUC policies within the guidelines established by this policy.
2. Conducting initial and subsequent reviews of protocols and protocol modifications submitted for approval.
3. Inspecting facilities and reviewing the overall program at least twice per year.
4. Advising on upkeep and maintenance of animal facilities and recommending renovations, expansions, and new equipment as required.
5. Ensuring adequate training for all CDC personnel who deal with laboratory animals and for IACUC members. The IACUC is responsible for assuring that principal investigators and research technicians have received adequate training.
6. Reviewing the training program for animal care personnel.
7. Assuring adherence to standard guidelines for animal care and use as stated in this policy and all referenced materials.

D. Principal investigator (PI) responsibilities regarding animal care and use.

PIs are responsible for understanding and applying established policies and guidelines for animal use. Other responsibilities include, but are not limited to:

1. Submitting appropriate information on the animal use protocol form used by their facility.
2. Submitting a modification form requesting changes in procedures described in the existing protocol to the appropriate IACUC.
3. Ensuring all individuals listed on the animal use protocol receive training in the proper care and use of the species.
4. Submitting documentation of animal usage and protocol review for each approved protocol on an annual basis.

5. Ensuring that all personnel on their protocol have appropriate medical clearance for their facility, including any recommended immunizations.
6. Ensuring personnel wear appropriate PPE.
7. Adhering to all CDC policies and practices concerning handling and disposing of infectious materials or toxic substances and decontaminating all animal areas.
8. Adhering to all requirements imposed by their IACUC.
9. Adhering to the CDC Director's December 15, 2005 Memorandum of Veterinary Authority over Animals Being Used for Research and/or Training at CDC. This memorandum gives the veterinary staff of the Division of Scientific Resources, NCPDCID (proposed), authority that includes, but is not limited to, independent right of access to all spaces where animals are housed; supervision of husbandry and care; and oversight for purposes of ensuring adequacy of all other aspects of care, use, and handling of animals. Equivalent authority is given to the veterinary staff assigned laboratory animal responsibilities at each CDC site.

XI. REFERENCES AND RELATED RESOURCES

A. American Association for Laboratory Animal Science (http://www.aalas.org/)

B. Animal and Plant Health Inspection Service (http://www.aphis.usda.gov/ac/)

C. Animal and Plant Health Inspection Service, Title 9 CFR, Chapter 1, Parts1–199, January 2006.

D. Animal Welfare Act as amended, 7 U.S.C. §§ 2131 et. seq. October,1990.

E. Association for Assessment and Accreditation of Laboratory Animal Care International (http://www.aaalac.org/)

F. CDC "Biosafety in Microbiological and Biomedical Laboratories Manual", 4th Edition, 1999. (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

G. Information resource for Institutional Animal Care and Use Committees (http://www.iacuc.org/)

H. Institute for Laboratory Animal Research (http://dels.nas.edu/ilar_n/ilarhome/index.shtml)

I. ILAR. Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research. Washington, D. C.: National Academies Press. 2003. http://www.nap.edu/books/0309089034/html/

J. ILAR. Occupational Health and Safety in the Care of Nonhuman Primates. Washington, D.C.: National Academies Press, 2003. http://www.nap.edu/catalog/10713.html

K. NRC "Guide for the Care and Use of Laboratory Animals" revised 1996. (http://books.nap.edu/books/0309053773/html/index.html)

L. Office of Laboratory Animal Welfare (http://grants.nih.gov/grants/olaw/)

M. Office of Laboratory Animal Welfare, PHS, Policy on Humane Care and Use of Laboratory Animals" reprinted 2000.
(http://grants.nih.gov/grants/olaw/references/phspol.htm)

N. Tutorial for new IACUC members, investigators, etc.
(http://grants.nih.gov/grants/olaw/tutorial/index.htm)