

PUBLIC HEALTH SERVICE POLICY

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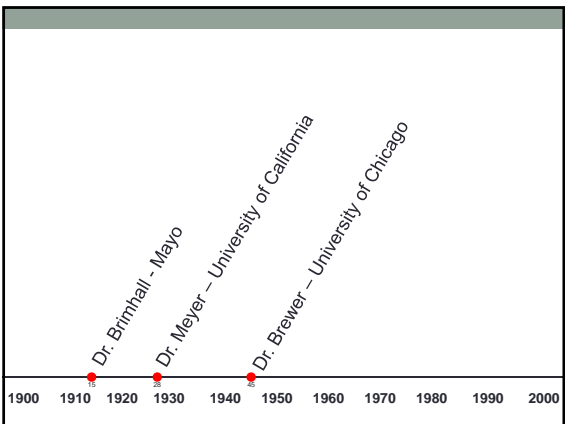
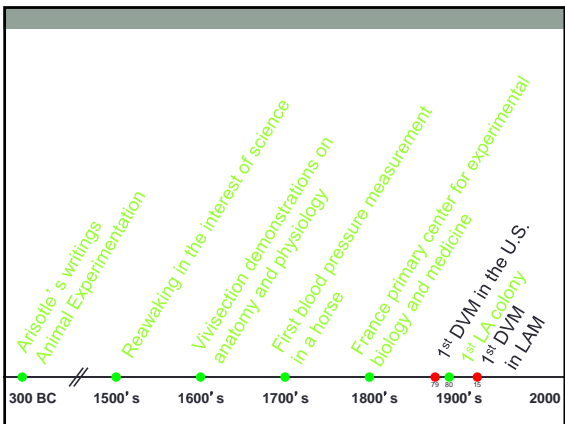
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- This presentation is not endorsed by PHS or OLAW
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 - No warranty for accuracy
- No information presented is known to be specifically included in the ACLAM Board examinations
- I do not remember what was on the boards
- I do not know what will be on the boards

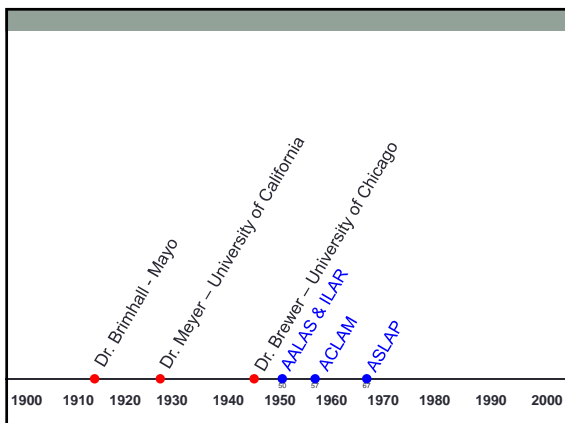
Thank you

- Julie Sharp, Associate Director, Duke University OAWA
- Ron Banks, Director, Duke University OAWA

Things I wish I did sooner

- Organize my study material
- Assemble a loose plan or routine assembled
- Don't be too strict






History

- 1963 - Guide for the Care and Use of Laboratory Animals
 - Guideline
- 1965 – AAALAC
 - Self-regulation
- Milestone – first time standards became available for institutions to evaluate the quality of their animal care program
- Still no Federal regulations

History

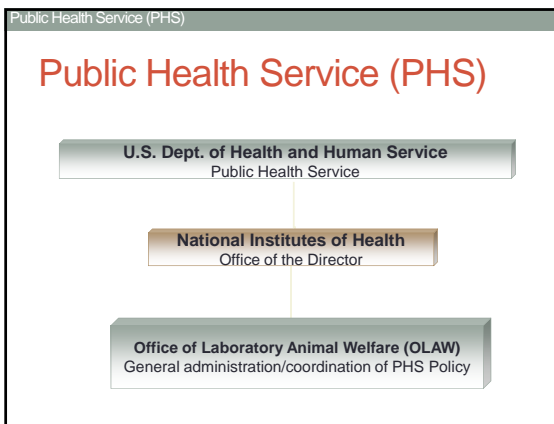
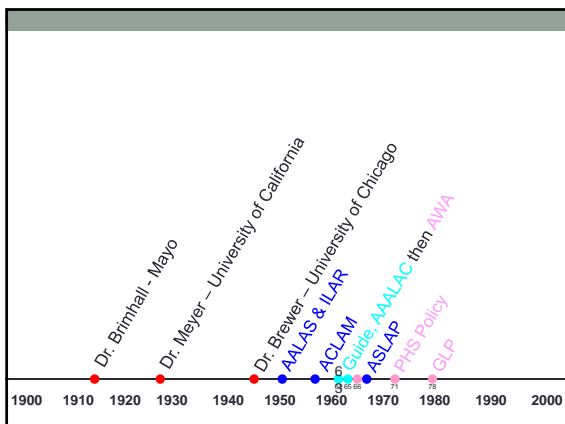
- Objective - stop animal research
- Increasing pressure on medical scientist, public, and government
- Contributed to medical research institutions to employing veterinarians



History

1971


- NIH policy on the Care and Treatment of Laboratory Animals
 - Law (OLAW)
 - Covers all vertebrates which research procedures are performed by or funded by U.S. Government agencies
 - “Guide for the Care and Use of Laboratory Animals”
 - Now named Public Health Service policies



Public Health Service (PHS)

Public Health Service (PHS)


- Federal Law:
 - Public Health Service Act
- Implementing Documents:
 - PHS Policy
 - The Guide
 - OHSP Guide
- The Statutory Authority:
 - Health Research Ext. Act 1985
- Administering Agency:
 - NIH: OD: OLAW
- Required for:
 - Federal projects
- FAQs: <http://grants.nih.gov/grants/olaw/faqs.htm>



Public Health Service (PHS)

Publication Components

- The [Health Research Extension Act of 1985 \(Public Law 99-158\)](#); November 20, 1985, "Animals in Research"
- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training
- Public Health Service Policy on Humane Care and Use of Laboratory Animals



Public Health Service (PHS)

Health Research Extension Act

- Provides the statutory mandate for the PHS Policy
- The Secretary, acting through the Director of the NIH, establishes guidelines for:
 - Proper care and treatment of animals used in biomedical and behavioral research
 - Proper use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia
 - Appropriate pre-survival and post-surgical vet care and nursing

Public Health Service (PHS)

Health Research Extension Act

- Animal Care Committees
 - Appointed by CEO
 - No fewer than 3 members
 - At least 1 individual who has no association with entity and at least 1 DVM
 - IACUC shall:
 - Review program at least semiannually
 - Keep appropriate records
 - File with the Director of NIH at least annually; certification that the review has been conducted, report violations to guidelines, assurances
 - Reports shall include minority views

Public Health Service (PHS)

Health Research Extension Act

- Director of NIH requires assurance that
 - Applicant meets the requirements of this Act
 - Facility has a animal care committee
 - Personnel have training available to them

Public Health Service (PHS)

Health Research Extension Act

- Director of NIH can
 - Suspend or revoke grants or contracts
 - If animal care, treatment, and use does not meet guidelines, the entity has been notified and does not correct problems
- No guidelines or regulations may require disclosure of publicly trade secrets or commercial or financial information which is privileged or confidential

Public Health Service (PHS)

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.

- Promulgated in 1985 by the Interagency Research Animal Committee (IRAC)
- Incorporated into PHS Policy in 1986 & provide a framework for conducting research
- Principles I - IX

Public Health Service (PHS)

U.S. Government Principles

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

Public Health Service (PHS)

U.S. Government Principles

- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number (*REDUCE*) required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered (*REPLACE*).
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals. (*REFINE*)
- **FAQ:** The 3R's - consideration of the three "Rs" should be incorporated into IACUC review, as well as other aspects of the institution's program (e.g., investigator training)

Public Health Service (PHS)

U.S. Government Principles

- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

Public Health Service (PHS)

U.S. Government Principles

- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

Public Health Service (PHS)

U.S. Government Principles

- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

Public Health Service (PHS)

PHS Policy

- I. Introduction
- II. Applicability
- III. Definitions
- IV. Implementation by Institutions
 - Animal Welfare Assurance
 - Functions of the IACUC
 - Review of PHS-Conducted or Supported Research Projects
 - Information Required in Applications and Proposals for Awards Submitted to PHS
 - Recordkeeping Requirements
 - Reporting Requirements
- V. Implementation by PHS

Public Health Service (PHS)

II. Applicability of the PHS Policy

- Applicable to all PHS-supported activities involving animals, conducted in any US territory.
- Foreign institutions: comply with policy OR provide evidence to PHS that standards will be met.
- Individuals: affiliated or sponsored by institutions, or should make other arrangements with PHS
- Policy does not affect applicable states or local laws that are more stringent.
- Must comply with the AWA and other federal laws.

Public Health Service (PHS)

II. Applicability of the PHS Policy

The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the Public Health Service (PHS). PHS agencies include:

- Agency for Health Care Research and Quality (AHRQ);
- Agency for Toxic Substances and Disease Registry;
- Centers for Disease Control and Prevention;
- Food and Drug Administration;
- Health Resources and Services Administration;
- Indian Health Service;
- National Institutes of Health; and
- Substance Abuse and Mental Health Services Administration.

Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to the production of custom antibodies or to the purchase of surgically modified animals?

Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to the production of custom antibodies or to the purchase of surgically modified animals?

❖ Yes: The generation of custom antibodies is an activity involving vertebrate animals and covered by PHS Policy. Antibodies are considered customized if produced using antigen(s) provided by or at the request of the investigator (i.e., not purchased off-the-shelf). An organization producing custom antibodies for an awardee must have or obtain an Assurance, or be included as a component of the awardee's Assurance. In addition, the awardee must provide verification of project-specific IACUC approval for the production of the antibodies.

Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to use of animal tissue or materials obtained from dead animals?

Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to use of animal tissue or materials obtained from dead animals?

- ❖ The use of dead animals or parts of animals is not covered by the PHS Policy unless the activity involves:
 - (1) killing animals for the purpose of obtaining or using their tissues or other materials, or
 - (2) project-specific antemortem manipulation of animals prior to killing them.

Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to live embryonated eggs?



Q. Does the PHS Policy apply to larval forms of amphibians and fish?



Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to live embryonated eggs?



- ❖ Although avian and other egg-laying vertebrate species develop backbones prior to hatching, OLAW interprets the PHS Policy as applicable to their offspring only after hatching. The egg-laying adult animal is covered by the Policy. OLAW expects Assured institutions to have policies and procedures in place that address the care or euthanasia of animals that hatch unexpectedly.

Q. Does the PHS Policy apply to larval forms of amphibians and fish?

- ❖ Yes, larval forms of fish and amphibians have vertebrae and are covered.



Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to animal research that is conducted in the field?

Q. Does the PHS Policy apply to privately owned animals/pets?

Public Health Service (PHS)

FAQs

Q. Does the PHS Policy apply to animal research that is conducted in the field?

- ❖ If the activities are PHS-supported and involve vertebrate animals and if the activity alters or influences the activities of the animal(s) that are being studied, the activity must be reviewed and approved by the IACUC (e.g., capture and release, banding). If the activity does not alter or influence the activity of the animal(s), IACUC review and approval is not required (observational, photographs, collection of feces).

Q. Does the PHS Policy apply to privately owned animals/pets?

- ❖ Yes, PHS does not distinguish between animals owned by the institution and privately owned animals.

Public Health Service (PHS)

III. Definitions

- **Animal:** any live, vertebrate animal used or intended for use in research,....
- **Animal facility:** any and all buildings, rooms, areas,...used for animal confinement, maintenance... Satellite Facility: area outside of the core where animals are kept for >24 hours.
- **Animal Welfare Act:** and the implementing regulations published in 9CFR
- **Animal Welfare Assurance or Assurance:** the documentation from the institution assuring compliance with PHS Policy
- **Guide:** Guide for the Care & Use of Laboratory Animals
- **Institution:** Any public or private organization, business...
- **Institutional Official:** Signs the institution's Assurance, making a commitment that the requirements will be met.
- **Public Health Service:** Includes all the agencies on the previous slide
- **Quorum:** A majority of the members of the IACUC

Public Health Service (PHS)

IV. Implementation by Institutions

A. Animal Welfare Assurance

- The Institution's written assurance must be acceptable to PHS
- Without it, there can be no PHS-supported activity with animals
- Assurances are submitted to OLAW
- Assurances shall be signed by IO
- OLAW: approve, disapprove or negotiate approval
- Approval will be for a specified period of time (no longer than 5 years).

Public Health Service (PHS)

IV. A. Animal Welfare Assurance

- Fully describe the Institution's program for the care and use of animals using the Guide as reference.
- The program description must include the following:
 - a list of every branch and major component of the institution,
 - the lines of authority and responsibility for administering the program,
 - the qualifications, authority, and responsibility of the veterinarian(s) and the percent of time each will contribute to the program;
 - the membership list of the Institutional Animal Care and Use Committee(s) (IACUC)
 - the procedures which the IACUC will follow to fulfill the requirements
 - the health program for personnel who work in laboratory animal
 - a synopsis of training or instruction in the humane practice of animal care and use
 - the gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species
 - any other pertinent information requested by OLAW.


Public Health Service (PHS)

IV. A. Animal Welfare Assurance

- Institutional Status: Must assure that program and programs fall into one of the following:

Category 1 - Accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All of the institution's programs and facilities have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months.

Category 2 - Evaluated by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months.



Public Health Service (PHS)


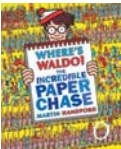
IV. A. Animal Welfare Assurance IACUC

- Appointed by CEO
- Assurance must include names, position titles, and credentials of IACUC members (can use numbers/symbols for everyone's name except for the chairperson and veterinarian with program authority)
- Shall consist of at least:
 - DVM with training or experience in LAM, has program authority for the animals at the institution
 - Practicing scientist experienced in animal research
 - A member whose concerns are non-scientific
 - A member who is not affiliated with the institution directly or whose immediate family member is not affiliated with the institution
- An individual may fulfill more than one IACUC requirement but committee must still be at least 5.

Public Health Service (PHS)

FAQs

Q. Must certain members be present in order to conduct official business?


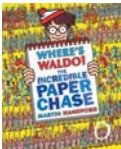



Public Health Service (PHS)

FAQs

Q. Must certain members be present in order to conduct official business?

❖ The presence of any one specific member is not necessary in order to conduct official business or to meet the quorum requirement.

Public Health Service (PHS)

IV. B. Functions of the IACUC

1. Review at least once every six months the institution's program (using the Guide as a basis for evaluation);
2. Inspect animal facilities (including satellite facilities) at least once every 6 months (using the Guide as a basis for evaluation);
3. Prepare reports of the IACUC evaluations conducted, and submit the reports to the IO;
4. Review concerns involving the care and use of animals;
5. Make recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training;
6. Review and approve, require modifications in (to secure approval) or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals;
7. ...and of proposed significant changes to ongoing animal use activities;
8. Be authorized to suspend an activity involving animals.

Public Health Service (PHS)

IV. B. Functions of the IACUC, Reports

- Prepare reports of the IACUC evaluations conducted, and submit the reports to the IO,
- Updated at least once every six months after the semiannual evaluations,
- Maintained by the Institution and made available to OLAW upon request,
- Must contain description of the nature and extent of the institution's adherence to the Guide and this Policy and identify any departures and reasons for each departure,
- Must distinguish significant deficiencies from minor deficiencies,
 - A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the IO, is or may be a threat to the health or safety of the animals.
- Must contain a reasonable and specific plan and schedule for correcting each deficiency.
- Must identify AAALAC accreditation (or another accrediting body recognized by PHS)

Public Health Service (PHS)

FAQs

Q. Should the IACUC inspect laboratories or other sites where investigators use animals?

Public Health Service (PHS)

FAQs

Q. Should the IACUC inspect laboratories or other sites where investigators use animals?

- Institutions are responsible for oversight of all animal-related activities regardless of how long or where the activity occurs.
- Satellite facilities (defined by PHS Policy as a containment outside a core or centrally managed area in which animals are housed for more than 24 hours) and areas where any form of surgical manipulations (minor, major, survival, non-survival) are performed must be inspected at least once every six months by the IACUC as part of the semiannual evaluation.
- Institutions have discretion with regard to how they oversee areas used for routine weighing, dosing, immunization, or imaging, but should monitor such areas on a random or fixed schedule to effectively oversee activities at the institution.
- USDA requires semi-annual inspection of "animal study areas" defined as areas where USDA covered animals are housed for more than 12 hours.

Public Health Service (PHS)

Q. Do awardee institutions need animal facility disaster plans?

Public Health Service (PHS)

Q. Do awardee institutions need animal facility disaster plans?

- ❖ The *Guide* requires that institutions develop disaster plans that take into account the well-being of animals and personnel during unexpected events... Location-based risk should be accounted for in the disaster plan with mitigation strategies to address all known vulnerabilities.
- ❖ The disaster plan "should define the actions necessary to prevent animal pain, distress, and deaths"
- ❖ Institutions should periodically review and update the plan to adapt to program changes, evolving risk, and lessons learned from drills and actual disasters.

Public Health Service (PHS)

IV. C. Research Project Review

- Review components related to care and use of animals (accordance to the Policy, AWA, Guide and institution's Assurance)
 - Avoid/minimize pain & distress
 - Use appropriate anesthesia/analgesia for procedures that produce more than momentary pain & distress
 - Animals will be humanely euthanized if experiencing unrelieved pain & distress
 - Living conditions will be species appropriate; husbandry will be under the direction of a trained individual
 - Medical care is available as needed by a qualified veterinarian
 - Personnel will be appropriately qualified and trained to perform procedures
 - Euthanasia will be as described in the AVMA Panel on Euthanasia unless scientifically justified
- Protocols shall be available to all members. Any member may call for FCR, but if not then at least 1 member of the IACUC is designated by Chair to review the proposal. FCR actions must be by a majority vote of the convened quorum (members with a conflict of interest do not contribute to the quorum).
- May invite consultants to assist reviews; cannot vote unless also members of the IACUC.

Public Health Service (PHS)

IV. C. Research Project Review

- The IACUC shall notify investigators and the institution, in writing, of IACUC decisions (reasons for withholding approval and give opportunity to respond). If approval is withheld, the reasons will be stated and the investigator will have the opportunity to respond.
- The IACUC shall conduct continuing reviews of ongoing work. A complete review will be performed at least every 3 years.
- The IACUC may suspend activity if it is not being conducted accordingly. The matter is reviewed at a convened meeting (quorum present), and a majority of the quorum in favor of suspension.
- If the IACUC votes to suspend an activity, the IO in consultation with the IACUC shall review the reasons for suspension, take corrective actions and report to the details to OLAW.
- IACUC approved proposals may be subject to further review and approval by officials from the Institution. BUT, those officials may not approve an animal activity that is not IACUC approved.

Public Health Service (PHS)

FAQs

Q. May an IACUC use designated member review (DMR) to review an animal study protocol subsequent to full committee review (FCR) when modifications are needed to secure approval?

Public Health Service (PHS)

FAQs

Q. May an IACUC use designated member review (DMR) to review an animal study protocol subsequent to full committee review (FCR) when modifications are needed to secure approval?

- If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review, or returned for FCR at a convened meeting.
- If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:
 - All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
- If all members are not present and the IACUC lacks written standard procedures as described above, the committee has the option to vote to return the protocol for FCR at a convened meeting or to employ DMR. If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so.

Public Health Service (PHS)

FAQs

Q. Does the IO have authority to suspend an activity that was previously approved by the IACUC, or to approve one that was not initially approved by the IACUC?

Public Health Service (PHS)

FAQs

Q. Does the IO have authority to suspend an activity that was previously approved by the IACUC, or to approve one that was not initially approved by the IACUC?

- Nothing in the PHS Policy precludes the Institutional Official or another authorized official from unilaterally suspending, terminating, or imposing sanctions on any activity involving animals, regardless of whether it was previously approved by the IACUC.
- However, no institutional official may approve animal activities or reinstate animal activities that were suspended by the IACUC.

Public Health Service (PHS)

FAQs

Q. May investigators use non-pharmaceutical-grade compounds in animals?

Public Health Service (PHS)

FAQs

Q. May investigators use non-pharmaceutical-grade compounds in animals?

- ❖ OLAW and USDA agree that pharmaceutical-grade chemicals/substances, when available, must be used to avoid toxicity, side effects, and prevent interference with research results.
- ❖ However, it is frequently necessary to use investigational compounds, veterinarian- or pharmacy-compounded drugs, and / or Schedule I controlled substances to meet scientific and research goals.
- ❖ Cost savings alone are not an adequate justification for the use of non-pharmaceutical-grade or compounded drugs in animals.

Public Health Service (PHS)

FAQs

Q. May investigators use expired pharmaceuticals, biologics, and supplies in animals?

Public Health Service (PHS)

FAQs

Q. May investigators use expired pharmaceuticals, biologics, and supplies in animals?

- ❖ The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care.
- ❖ Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal.
- ❖ Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study.
- ❖ The veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals.

Public Health Service (PHS)

IV. D. Information Required for PHS Awards

- All Institutions:
 - Species and number to be used
 - Rational for using animals, appropriateness of species and number
 - Description of proposed use
 - Description of procedures to limit pain
 - Euthanasia
- Institutions with Approved Assurance
 - Applications or proposals (competing and non-competing), verification of Assurance approval.
 - For competing applications or proposals only, verification may be filed at any time prior to an award. If it is subsequent to the submission of the proposal, the verification shall state any modifications required by IACUC. No need for IO signature.
- Without Approved Assurance
 - The signature of the official signing for the applicant organization shall constitute a declaration that the institution will submit an Assurance when requested by OLAW.

Public Health Service (PHS)

IV. E. Recordkeeping Requirements

- Institution shall Maintain:
 - A copy of the approved Assurance;
 - Minutes of IACUC meetings, including attendance, activities and deliberations;
 - Records of applications, proposals, and proposed significant changes and whether IACUC approval was given or withheld;
 - Records of semiannual inspections and recommendations (including minority reports) as forwarded to IO;
 - Records of accrediting body determinations.
- Keep 3 years or for the duration of activity plus 3 years after completion of the study.

Public Health Service (PHS)

IV. F. Reporting Requirements

- At least once every 12 months, the IACUC, through the IO, shall report in writing to OLAW:
 - any change in category (1 or 2 based upon AAALAC accreditation status) than specified in its Assurance
 - any change in the description of the institution's program for animal care
 - any changes in the IACUC membership
 - notice of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the Institutional Official.
- Report as above, noting no changes.
- The IACUC, through the IO, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to :
 - any serious or continuing noncompliance with this Policy
 - any serious deviation from the provisions of the Guide
 - any suspension of an activity by the IACUC
- Minority Opinions

Public Health Service (PHS)

FAQs

Q. What are PHS requirements for recording and reporting minority views?

Public Health Service (PHS)

FAQs

Q. What are PHS requirements for recording and reporting minority views?

- ❖ Institutions must maintain records of minority views expressed (1) as recommendations to the Institutional Official and/or (2) during semiannual inspections. These minority views must be included in the Annual Report to OLAW.
- ❖ Some IACUCs have expressed confusion about the difference between a minority view and a dissenting vote.
 - An IACUC member's dissenting vote on protocol approval/suspension must be recorded in the minutes, this does not constitute a minority view for reporting purposes.
 - Any IACUC member may submit a minority view to OLAW addressing any aspect of the institution's animal program, facilities, or personnel training.

Public Health Service (PHS)

V. A. OLAW Responsibilities

- General administration and coordination of the Policy and will:
- Request and negotiate, approve or disapprove, and, as necessary, restrict or withdraw approval of Assurances;
- Distribute to Scientific Review Administrators of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions [domestic and foreign] that have an approved Assurance;
- Advise awarding units and awardee institutions concerning the implementation of this Policy;
- Evaluate allegations of noncompliance with this Policy;
- Have the authority to review and approve or disapprove waivers to this Policy;
- Conduct site visits to selected institutions.

Public Health Service (PHS)

V. B. Responsibilities of the PHS Awarding Unit

- No award shall be made until all required Assurances have been submitted by the institution(s), been approved by OLAW, and the institution(s) have provided verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals.
- If institution does not have an approved Assurance on file with OLAW, the awarding unit will ask OLAW to negotiate an Assurance with the institution(s) before an award is made.

Public Health Service (PHS)

V. C. Conduct of Special Reviews/Site Visits

- Each awardee institution is subject to review at any time by PHS staff and advisors, which may include a site visit.

V. D. Waiver

- Institutions may request a waiver of a provision or provisions to OLAW. It will not be granted unless sufficient justification is provided in writing.

Questions?



Questions
are
guaranteed in
life;
Answers
aren't.