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OLAW welcomes comments on any of its policy guidance, click here for more information.

OLAW develops and monitors, as well as exercises compliance oversight relative to the Public Health Service Policy on Humane Care and Use of Laboratory Animals (the "PHS Policy"). One of OLAW's primary functions is to advise awarding units and awardee institutions concerning the implementation of the PHS Policy. OLAW often provides this advice by responding to policy-related questions submitted by such units and institutions. The following FAQs provide guidance that represents OLAW's current thinking on these topics. This guidance is based on OLAW's experience with the subject matter and draws on best practices followed by the biomedical community regarding the use of research animals. Unless specific statutory or regulatory requirements are cited, the FAQs should be viewed as recommendations in that an institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy.

The USDA Animal and Plant Health Inspection Service (APHIS), Animal Care has reviewed and concurs with the guidance provided in these FAQs where applicable.

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A. Applicability of the PHS Policy

1. Should institutions apply the PHS Policy to all animal activities regardless of the source of funding?

There are many valid reasons for institutions to perform program oversight institution-wide using uniform and consistent standards for animal care and use. Likewise, it is generally impractical to separate activities based on the source of funding. Institutions must implement the PHS Policy for all PHS supported activities involving animals, and must ensure that any standards that might not be consistent with PHS Policy do not affect or pose risks to PHS supported activities.

It is permissible for institutions to delineate animal areas that are programmatically and functionally separate and that do not support PHS animal activities such as a herd of beef cattle used for food production or a stable of riding horses. The Assurance should explicitly reflect the exclusion of any specific area or activity. [A7, A11, DS]

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

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.

Similar guidance applies to surgical procedures. Surgery conducted in response to a specific, custom request is covered by the PHS Policy. An organization conducting custom surgery 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 conducting the surgery. When both organizations hold Assurances, some latitude is allowed in determining which IACUC will review the proposal. However, the awardee always retains primary responsibility for ensuring compliance with PHS Policy. [D6, A11]

See also OLAW FAQ F8: Is the mouse ascites method an acceptable method of monoclonal antibody production?

See also OLAW FAQ D8: When institutions collaborate, or when the performance site is not the awardee institution, which IACUC is responsible for review of the research activity?

3. 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. If either circumstance is applicable to the acquisition of dead animals, body parts or tissues, prior IACUC protocol review and approval are required.

4. 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.

5. Does the PHS Policy apply to larval forms of amphibians and fish? [UPDATED: 11/19/2012]

Yes, larval forms of fish and amphibians have vertebrae and are covered by the PHS Policy. As noted in FAQ A4, the PHS Policy applies to the offspring of egg-laying vertebrates only after hatching. Zebrafish larvae, for example, typically hatch 3 days post-fertilization.

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

If the activities are PHS-supported and involve vertebrate animals, the IACUC is responsible for oversight in accord with PHS Policy. IACUCs must know where field studies will be located, what procedures will be involved, and be sufficiently familiar with the nature of the habitat to assess the potential impact on the animal subjects. 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).

Investigators are encouraged to consult relevant professional societies, available guidelines, wildlife biologists, and veterinarians, as applicable, in the design of the field studies (Guide page 32, Appendix A) Studies with the potential to impact the health or safety of personnel (Guide page 18) or the animal’s environment may need IACUC oversight, even if described as purely observational or behavioral. When capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures are involved, the IACUC must ensure that proposed studies are in accord with the Guide (page 32). The IACUC must also ensure compliance with the regulations and permit requirements of pertinent local, state, national, and international wildlife regulations. A study on free-living wild USDA-covered species that involves invasive procedures, harms or materially alters the behavior of an animal under study is covered by USDA animal welfare regulations and requires IACUC review and approval.

See also OLAW FAQ E4: Is the IACUC required to inspect field study sites?

7. Does the IACUC need to approve research studies that use privately owned animals, such as pets?

The PHS Policy (PHS Policy I) covers live vertebrate animals used or intended for use in research, research training, and biological testing activities conducted or supported by the PHS. The PHS Policy and the Animal Welfare Act and Regulations (AWAR) do not distinguish between animals owned by the institution and privately owned animals. Pets used in research must be covered under an IACUC-approved protocol. The institution must have an OLAW-approved Animal Welfare Assurance covering all performance sites.
The institution should ensure that the informed consent of the owner is obtained prior to the conduct of the research. The institution may want to involve their legal counsel in the development of informed consent documents.

8. How can the IACUC determine if activities involving privately owned animals constitute veterinary clinical care or research activities?

When a privately owned animal is recruited, with the owner’s consent, for participation in a research study or veterinary clinical trial and the activity includes collection or generation of data for research purposes, such activities are considered research and are subject to IACUC oversight.

Veterinary research activities are typically supported by a grant or contract. The data are collected for the advancement of animal and/or human health. If the study is PHS funded, the institution must have an OLAW-approved Animal Welfare Assurance covering all performance sites and IACUC approval for the research activity. If the study is being conducted in collaboration with a private clinical veterinary practice, the operational components of the practice associated with the research activity should be a covered component of an Assured institution.

When doing research on a pet, the institution is responsible for obtaining informed consent for the research activity. If the research activity is being conducted in collaboration with a private veterinary practice, the institution should consider the use of a memorandum of understanding agreement. The institutional legal counsel may be involved in the development of the document.

The veterinary clinical care of a privately owned animal is not a research activity and does not require IACUC approval. Veterinary clinical care is typically offered as a fee-for-service activity and is regulated by state veterinary licensing boards.

B. IACUC Composition, Functions and Authority

1. What are the IACUC membership criteria?

The IACUC must consist of at least 5 members who are appointed by the institution’s chief executive officer (CEO). If the CEO delegates appointment authority, the delegation must be specific and in writing.

The appointed members must be qualified through experience and expertise to provide oversight for the institution’s animal programs, facilities, and procedures. At a minimum the IACUC must include a veterinarian, a practicing scientist experienced in animal research, a person whose primary concerns are in a nonscientific area, and a person who is unaffiliated with the institution except as a member of the IACUC (sometimes referred to as a public member). An individual who qualifies to fill more than one of the specified categories may be appointed to do so, but the committee must still consist of at least 5 members. The unaffiliated member should have no discernible ties or ongoing affiliation with the institution, and may not be a member of the immediate family of a person who is affiliated with the institution. Immediate family includes parent, spouse, child and sibling. Appointment of an individual who is unambiguously unaffiliated is the best way to fulfill the letter and spirit of this provision. PHS Policy incorporates the Guide which specifies that public members should not be laboratory animal users (Guide page 24) [A1]. The veterinarian on the IACUC must have direct or delegated program authority and responsibility for animal-related activities and therefore is always considered to be affiliated with the institution.

If an appointed member who fulfills one of the required specified positions (i.e., scientist, nonscientist, veterinarian, or unaffiliated) leaves the committee so that that position is no longer filled, the IACUC is not properly constituted and may not conduct official business until a member who fulfills the required position is appointed by the CEO (or designee).

2. May the IACUC have alternate members?


NOT-OD-11-053 does not preclude designation of one alternate for multiple regular members, provided the alternate for a member fulfilling a specific membership requirement (e.g., nonscientist) also fulfills that requirement. An alternate may not represent more than one member at any one time. Conversely, it is permissible to appoint more than one alternate to represent a particular member, but again, if the member fulfills a specific membership requirement then the alternate must also fulfill that requirement.

3. 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. [A1]

4. Is a certain level of meeting attendance required of IACUC members?

Attention should be paid to attendance at IACUC meetings to ensure that an appropriate mix of members attends meetings. Chronic nonattendance by IACUC members, especially those explicitly required by PHS Policy or USDA regulations, implies a lack of participation in the oversight responsibilities of the IACUC. [A1]

5. What is a quorum and when is a quorum required?

A quorum is a majority of the total number of voting members of the IACUC. A quorum must be convened, and there must be a vote of the members present, in order for the IACUC to (1) conduct full committee review and approval of a proposed project or of a significant change to a project, and (2) suspend an activity. Members may not participate in the review or approval of a project in which they have a conflict of interest, except to provide information, and may not contribute to the quorum for the vote on that project.

Abstentions from voting (for reasons other than conflict of interest) do not alter the quorum and do not change the number of votes required for approval. Recusal of a member due to a conflict of interest does alter the quorum and IACUCs must ensure that the necessary number of members are present if a quorum is required.

6. Does the IACUC have authority over activities not supported by PHS?

Institutions have discretion to subject animal activities to IACUC oversight regardless of the source of funding. This practice ensures uniform standards, appropriate oversight and accountability, and therefore is often in the best interest of the institution. (See also...
FAQ A1).

USDA requires IACUC oversight of any covered animal activity where (1) the animal has been acquired or transported by the facility, or (2) the research is being supported by any Federal funding source.

7. What information should be in IACUC minutes?
PHS Policy requires that minutes of IACUC meetings, records of attendance, activities of the Committee, and Committee deliberations, be maintained by the institution. Accordingly there should be documentation of major issues discussed by the IACUC and the outcome of the discussions in sufficient detail for an outsider to ascertain the nature of the discussion and the conclusions reached. Written transcripts or tape recordings of meetings are not required.

8. May an IACUC conduct business on a teleconference call?
Provisions for conducting convened meetings via tele- or videoconferencing are addressed in the NIH Guide for Grants and Contracts NOT-OD-06-052.

9. May an IACUC suspend (stop) animal activities that it did not initially approve?
Yes. The PHS Policy, Guide, and the USDA Animal Welfare Regulations presume that all ongoing animal activities have received the required prospective review and approval. An activity that has been undertaken without prior approval should be halted and subsequently reported to OLAW because it constitutes serious noncompliance.

10. Does the Institutional Official 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.

11. May the institution pay or reimburse expenses incurred by nonaffiliated members?
Nominal compensation for service on the IACUC, or reimbursement for expenses such as parking and travel costs, is generally not viewed as jeopardizing the nonaffiliated status of a member. Any compensation for participation should not be so substantial as to influence voting or reflect an important source of income. It is acceptable for the institution pay for IACUC training of nonaffiliated members (e.g., attendance at IACUC 101). [A1]

12. How does OLAW define nonscientific and nonaffiliated IACUC members?
The PHS Policy specifies that the IACUC “must include one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy)” in PHS Policy IV.A.3b3 and “one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution” in PHS Policy IV.A.3b4.

- **Nonscientific member**: an IACUC member who is not a practicing scientist experienced in research involving animals.
- **Nonaffiliated member**: an IACUC member who represents the general community interests in the proper care and use of animals. The nonaffiliated member is (1) not a laboratory animal user, (2) not affiliated with the institution, or (3) not an immediate family member of an individual affiliated with the institution. **Public member** is another term for nonaffiliated member.

It is possible for one individual to fulfill the requirement for both a nonaffiliated and a nonscientific member as long as that individual meets the requirements for each position. The PHS Policy states, “An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b. (1)-(4) of this Policy may fulfill more than one requirement. However, no committee may consist of less than five members.”

13. Does OLAW expect the IACUC to notify NIH when there is a change in an animal activity supported by PHS funds?
The terms “significant change” and “change in scope” have different meanings. According to NIH Grants Policy Statement (GPS), change in scope refers to a change in the direction, type of research or training from the aims, objectives, or purposes of the approved project. A change in an animal activity can be both a significant change requiring IACUC review and a change in scope requiring notification to the NIH funding component. However, a significant change is not necessarily a change in scope.

For a review of significant changes that require IACUC approval see OLAW FAQ D9 of Protocol Review. The investigator is responsible for submitting a proposed significant change in an animal activity to the IACUC for review and approval prior to implementing the change. As described in the PHS Policy IV.B.7, the IACUC is responsible for reviewing the significant change and approving, requiring modifications (to secure approval), or disapproving the proposed change. The IACUC is not required to notify OLAW or the NIH funding component of this type of change. However, conducting procedures that constitute a significant change in approved animal activities without prior IACUC approval is serious noncompliance that must be reported to OLAW. Additional information may be found at FAQ B9 of IACUC Composition, Functions and Authority and Notice NOT-OD-05-034.

Prior approval of a change in the scope of the research is required by GPS, which provides examples of potential indicators of changes in scope. These examples are not intended to imply that any change in animal model or in approved use of animals always represents a change in scope.

The **IACUC** is not responsible for notifying the NIH of changes in scope; rather the **Principal Investigator (PI) and the Authorized Organizational Official (AOO)** are responsible for requesting approval of a change in scope. The request for a change in scope must be made in writing to the Grants Management Officer (GMO) of the NIH Institute or Center (IC) that funds the grant (the funding component). The request must be made no less than 30 days before the proposed change and must be signed by both the PI and the AOO.

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C. Institutional Reporting to OLAW

1. What is the annual report to OLAW and when is it due?

The annual report is a document prepared by the IACUC and submitted to OLAW through the Institutional Official. It describes any changes in the institution's program of animal care and use, AAALAC accreditation status, changes of Institutional Official and in IACUC membership, the dates that the IACUC conducted its semiannual evaluations of the program and facilities, and any minority views.

Descriptions of program changes should be comprehensive and in sufficient detail to replace information in the currently approved Assurance. If there are no changes then a statement to that effect must be provided. Annual reports must represent the consensus of the Committee, and include any minority views filed by members of the IACUC.

The report covers a 12 month time period, and is due at the end of the month immediately following the end of the institution’s reporting period. OLAW encourages institutions to use the calendar year as the reporting period (January 1 – December 31) with the report due to OLAW January 31 for the preceding calendar year. Institutions that prefer a different 12 month reporting period may do so by indicating the preferred period in their Assurance or by notifying OLAW. Institutions that do not select a specific reporting period will be defaulted to the calendar year and their annual report will be due January 31.


2. What kinds of situations should be reported to OLAW under IV.F.3. of the PHS Policy, and when, where, and how should they be reported?


3. Should the IACUC report sanctions other than suspensions that are imposed by the Committee or by other institutional officials?

Sanctions imposed by the IACUC or by an institutional official due to serious or continuing noncompliance or serious deviations from the Guide must be reported to OLAW. Guidance on reporting noncompliance is in the NIH Guide for Grants and Contracts NOT-OD-05-034.

4. Are all documents submitted to OLAW subject to the Freedom of Information Act?

The Freedom of Information Act (FOIA), 5 U.S.C. 552, provides individuals with a right of access to records in the possession of the federal government. All documents submitted to OLAW are subject to the FOIA. However, the government may withhold information pursuant to the exemptions and exclusions contained in FOIA.

In a ruling by the US District Court for the District of Columbia Div. No 99-3024, In Defense of Animals v. Department of Health and Human Services (HHS), 9/28/2001, the Court ruled that HHS (NIH’s parent organization) may withhold IACUC members’ names. NIH does release the names of the IACUC Chairperson, veterinarian, and Institutional Official as reported in Assurances.

Note also that footnote 6 in the PHS Policy allows institutions to represent the name of IACUC members other than the chair and veterinarian by using numbers or other symbols, provided there is sufficient information to allow OLAW to determine that appointees are appropriately qualified. Identities of members must be readily ascertainable by the institution and available to OLAW upon request.

In providing the facility and species inventory as part of the Assurance submitted to OLAW, institutions may identify animal areas in any manner, e.g., initials, ID number. It is not necessary to provide OLAW with detailed diagrams of facilities or room numbers, unless specifically requested by OLAW.

Institutions are also advised to consult the Guidance on Prompt Reporting to OLAW under the PHS Policy (NIH Guide for Grants and Contracts NOT-OD-05-034) with respect to what information is expected to be reported when reporting noncompliance. Disciplinary documents (e.g., letters of reprimand) and correspondence between the IACUC and investigators are generally not required by OLAW, although they may be requested.

Additional information about the FOIA, including guidelines for submitting FOIA requests, is available at:

5. Are institutions required by FOIA to release information about their research, animal care programs, and IACUCs?

The Freedom of Information Act (FOIA) is a federal law that provides individuals with a right of access to records in the possession or control of the federal government. That means that OLAW is required to release information in its possession or control unless specifically requested by OLAW.

Both protocol approval and suspension of animal study protocols by the IACUC require a majority vote of a quorum of the IACUC. Although an IACUC member’s dissenting vote on these issues 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. Whether OLAW receives a minority view as part of an annual report, renewal Assurance document
materials, or directly from the dissenting IACUC member, it carefully reviews the information provided in accordance with requirements of the PHS Policy and provisions of the Guide.

7. What are PHS Policy reporting requirements for departures from the Guide? Updated: (10/05/2012)
The IACUC must review and approve departures from the Guide® IACUC approval of departures from the Guide must be based on scientific, veterinary medical, or animal welfare issues. Semiannual reports from the IACUC to the Institutional Official (IO) must identify specifically any departures from the Guide. (PHS Policy IV.B.3) Read the Guide carefully; it establishes exceptions in specific situations; these are not departures from the Guide and are not required to be reported to the IO.

Guidance in the Eighth Edition of the Guide is stated in terms of standards that must be met, standards that should be met and standards that may be met.

OLAW defines must as a minimum standard required of all Assured institutions. Deviation from these standards with IACUC approval is a departure from the Guide and must be reported in the semiannual report. Deviation from a must statement without IACUC approval is a noncompliance that must be reported to OLAW through the IO.

Reporting requirements for should statements in the Guide vary. Should statements often involve performance standards. Well-established performance standards are not departures from the Guide and need not be reported in the semiannual report. Deviation from a should statement with IACUC approval is a departure from the Guide and must be reported in the semiannual report to the IO. Deviation from a should statement without IACUC approval is a noncompliance that must be reported to OLAW through the IO.

May statements in the Guide are suggestions that institutions can choose to implement if suitable for their program and deviations are not included in the semiannual report to the IO. For examples of reporting requirements in varying circumstances and additional information, see Departures from the Guide.

D. Protocol Review

1. How frequently should the IACUC review research protocols?
Under PHS Policy the maximum interval between IACUC review and approval is three years, i.e., a complete de novo review is required at least every three years. The review must encompass all of the criteria in the Policy at IV.C.1.a.-g. See references at A2 and A6 for detailed guidance in how to satisfy this Policy requirement and the USDA requirement for annual review. [A2, A6]

2. May the IACUC administratively extend approval of a project that has expired?
No. IACUCs do not have authority to administratively extend approval beyond three years. When IACUC approval expires the protocol lacks valid approval. Continuation of animal activities in the absence of valid approval is a serious and reportable violation of PHS Policy (see NOT-OD-05-034). [A6, A11]

3. What are the possible methods of IACUC approval?
There are only two valid methods of IACUC review allowed by the PHS Policy: (1) full-committee review by a convened quorum of the members of the IACUC, or (2) designated member review by one or more members, employed only after all voting members have been provided an opportunity to call for full-committee review.

Full IACUC review may result in approval, a requirement for modifications (to secure approval), or withholding of approval. Full committee review must occur during a convened meeting of a quorum of the IACUC members, and with a formal vote. It is insufficient to poll each member individually in lieu of a convened quorum when using the full committee method of review. See NIH Guide for Grants and Contracts NOT-OD-06-052 regarding use of tele- or videoconferencing when a convened meeting is required.

Designated member review may be utilized only after all members have been provided the opportunity to call for full-committee review. If any member requests full committee review then that method must be used. If not, the IACUC Chairperson may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). Designated review may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. Designated review may not result in withholding of approval.

If a protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications.

The specific method of review for a given protocol must be documented, along with the outcome of the review. [D1, A2, A5, A10, A11]

4. May the IACUC grant conditional or provisional approval?
The PHS Policy recognizes that the IACUC may approve, require modifications, or withhold approval. If the IACUC determines that a protocol is approvable, contingent on receipt of a very specific administrative modification or clarification (e.g., a contact telephone number), the Committee may handle the issue as an administrative detail that an individual (e.g., IACUC Chair or Administrator) may verify. Requests for substantive modifications should result in the protocol coming back to the Committee. Protocols that lack substantive information necessary for the IACUC to make a judgment (e.g., justification for withholding analgesics in a painful procedure) should be considered incomplete and the IACUC should defer review until the requisite information is provided by the investigator. Applying descriptors, such as conditional, provisional or interim, when referring to IACUC approval is unclear, confusing, and should be avoided. [A2, A11]

5. May the investigator begin animal work before receiving IACUC approval?
No.

6. What criteria should the IACUC consider when reviewing protocols?

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IACUCs must confirm that:

- the protocol is consistent with the Guide unless a scientific justification for a departure is presented and is acceptable to the IACUC;
- the protocol conforms with the institution's Assurance;
- the protocol will be conducted in accordance with the USDA Animal Welfare Regulations if applicable; and
- the protocol meets the requirements of the PHS Policy at IV.C.1.a.-g.

For further guidance, the IACUC should refer to the U.S. Government Principles.

7. Should the IACUC consider the three “Rs” of alternatives when reviewing protocols? (Refinements to research, Reduction of animal numbers, and Replacement with non-animal models)

The federal mandate in U.S. Government Principle IV to avoid or minimize discomfort, distress, and pain in experimental animals consistent with sound scientific practices, is synonymous with a requirement to implement refinements (e.g., less invasive procedures or use of analgesia). Similarly, the mandate in U.S. Government Principle III to use the minimum number of animals necessary to obtain valid results is synonymous with a requirement to reduce animal numbers. U.S. Government Principle III further states that mathematical models, computer simulation, and in vitro biological systems should be considered, and is synonymous with a requirement to replace non-animal models wherever possible. Thus, 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). [D6]

8. When institutions collaborate, or when the performance site is not the awardee institution, which IACUC is responsible for review of the research activity?

There are many circumstances that involve partnerships between collaborating institutions or relationships between institutional animal care programs. Interinstitutional collaborations have the potential to create ambiguities. Therefore it is imperative that institutions define their respective responsibilities. OLAW and APHIS agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement. Institutions should have a formal written understanding (e.g., memorandum of understanding) that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight (Guide page 15). [D6]

PHS Policy requires that all awardees and performance sites hold an approved Animal Welfare Assurance. If an institution does not have an animal care and use program, facilities to house animals, and an IACUC, the awardee institution will conduct the animal activity at an Assured institution (performance site). Assured institutions also have the option to amend their Assurance to cover performance sites that do not have an approved Assurance with OLAW, which effectively subjugates the performance site to the Assured institution and makes the Assured institution responsible for the performance site.

If both the awardee institution and the performance site institution have Domestic Assurances, they may exercise discretion in determining which IACUC reviews animal activities and under which institutional program the research will be performed. There is no requirement for dual review; IACUCs may choose which IACUC will review protocols for the animal activities being conducted. It is recommended that if an IACUC defers protocol review to another IACUC, documentation of the review should be maintained by both committees. Additionally, the IACUC conducting the review should notify the other IACUC of significant questions or issues raised during a semiannual program inspection of a facility housing a research activity for which that IACUC bears some oversight responsibility.

NIH Grants Policy Statement on Written Agreements (15.2.1.) requires that awardees have a formal written agreement with consortium participants that addresses the negotiated scientific, administrative, financial, and reporting requirements of the grant. This written agreement must include incorporation of applicable public policy requirements, including agreement for meeting the PHS Policy requirement for review and approval of proposed animal activities, significant changes to animal activities, and semiannual facilities review by an IACUC (IV.B.2.).

9. What is considered a significant change to a project that would require IACUC review?

Examples of changes considered to be significant include, but are not limited to, changes:

- in the objectives of a study
- from non survival to survival surgery;
- resulting in greater discomfort or in a greater degree of invasiveness;
- in the species or in approximate number of animals used;
- in Principal Investigator;
- in anesthetic agent(s) or the use or withholding of analgesics;
- in the method of euthanasia; and
- in the duration, frequency, or number of procedures performed on an animal. [A4, A7, A13]

Changes in personnel other than the Principal Investigator need not be considered significant provided that an appropriate administrative review mechanism is in place to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC. See NIH Guide for Grants and Contracts NOT-OD-03-046. The IACUC has some discretion to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis. Because significant changes require IACUC approval (using one of the valid methods described in FAQ D3, and using the criteria described in FAQ D6) it is critical that the IACUC clearly define and communicate its policy and mechanism for determining significance.

10. Is the IACUC required to review the grant application?

PHS Policy and the NIH Grants Policy Statement (Part II, Terms and Conditions) require the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. This is not an explicit requirement for the IACUC to do a side-by-side comparison of an application/proposal and the IACUC protocol. However, institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with what is in the application/proposal. Institutions are free to devise a workable mechanism to accomplish this end. One method to prevent inconsistencies between the information submitted to PHS and that on the IACUC protocol is to implement a procedure for

http://grants.nih.gov/grants/olaw/faqs.htm

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11. **May the IACUC approve pilot studies?**
Yes. Pilot studies may be appropriate to determine the technical feasibility of larger studies or to make initial assessments of the effect of procedures on animals (Guide pages 26, 28). Whether proposed by investigators or required by the IACUC, pilot studies require review and approval by the IACUC in accordance with the PHS Policy.

12. **Is the IACUC responsible for judging the scientific merit of proposals?**
Peer review of the scientific and technical merit of an application is considered the purview of the NIH Scientific Review Groups (SRGs), which are composed of scientific experts from the extramural research community in a particular area of expertise. However, SRGs also have authority to raise specific animal welfare concerns that can require resolution prior to a grant award.

Although not intended to conduct peer review of research proposals, the IACUC is expected to include consideration of the U.S. Government Principles in its review of protocols. Principle II calls for an evaluation of the relevance of a procedure to human or animal health, the advancement of knowledge, or the good of society. Other PHS Policy review criteria refer to sound research design, rationale for involving animals, and scientifically valuable research. Presumably a study that could not meet these basic criteria is inherently unnecessary and wasteful and, therefore, not justifiable.

The primary focus of the SRG is scientific merit and the primary focus of the IACUC is animal welfare. The two bodies have differing constitutions, mandates and functions. However, since it is not entirely possible to separate scientific value from animal welfare some overlap is inevitable. SRGs may raise concerns about animal welfare and IACUCs may question the scientific rationale or necessity for a procedure. [A1]

13. **If an animal activity will be performed outside of the US (either by a foreign awardee or by a foreign institution as a subproject for a domestic awardee), is the awardee's IACUC required to review and approve that activity?**
When the awardee is a domestic institution (i.e., domestic award with a foreign component), PHS animal welfare requirements are applicable. Accordingly, the awardee remains responsible for animal activity conducted at a foreign site and must provide verification of IACUC approval. That approval certifies that the activity, as conducted at the foreign performance site, is acceptable to the awardee. The awardee IACUC may accept, as its own, the approval of a foreign entity's IACUC; however, the awardee IACUC remains responsible for the review. Additionally, the foreign institution must complete the Animal Welfare Assurance for Foreign Institutions (Foreign Assurance) available from OLAW. This document certifies that the institution will comply with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and that the institution will be guided by the International Guiding Principles for Biomedical Research Involving Animals. OLAW encourages, but does not require, foreign institutions to use the standards in the Guide. If the prime awardee is a foreign institution, IACUC approval is not required.

14. **May standard operating procedures (SOPs) or blanket protocols that cover a number of procedures be utilized in lieu of repeating descriptions of identical procedures in multiple protocols?**
The IACUC must review and approve activities on a project-specific basis, taking into account a number of factors, e.g., the aims of the study, consideration of alternatives, minimization of pain and distress. For routine aspects of research (e.g., species specific techniques for immunization and titer determinations during antibody production), IACUCs may approve SOPs that can be cited by investigators in their protocols in order to avoid needless repetition. SOPs should be reviewed by the IACUC at appropriate intervals (at least once every three years) to ensure they are up-to-date and accurate.

15. **Is IACUC approval required for the collection of samples in foreign countries from captive wild animals or research colonies?**
Collection of biological samples from any live vertebrate animal for the purpose of a PHS-supported activity is covered by the PHS Policy. If the awardee is a domestic institution, the IACUC should consider the species involved, nature of the specimens, invasiveness of the procedure, risks to personnel, and qualifications of the individual(s) taking the sample(s). (For further information concerning foreign performance sites see FAQ D13.)

Awardee institutions should also consult with other agencies of the federal government as appropriate, e.g., US Fish and Wildlife Service, USDA-APHIS-Veterinary Services, and the CDC for specimen importation requirements. [A7]

16. **Is IACUC approval required for the use of animals in breeding programs, as blood donors, as sentinels in disease surveillance programs, or for other non-research purposes?**
Although animals used as sentinels, breeding stock, blood and blood product donors, or for other similar purposes may not be part of specific research protocols, their use is part of the institutional research program and directly supports research activities. Consequently, the IACUC should review protocols and SOPs that involve animals for such purposes, initially and at appropriate intervals (at least once every three years). [A4]

17. **What guidelines should IACUCs follow for fishies, amphibians, reptiles, birds, and other nontraditional species used in research?**
PHS Policy is intentionally broad in scope and does not prescribe specifics about the care and use of any species, assigning that task to the IACUC and allowing for professional judgment. Many of the principles embodied in the Guide can generally be adapted to the care and use of various kinds of nontraditional research animals. IACUCs may seek the advice of experts when necessary, and refer to scientific-based publications prepared by professional organizations with interest in various species. Appendix A of the Guide references many such publications. [A7]

18. **Is it acceptable to have different individuals named as PI on the grant application and the IACUC protocol?**
Yes.

19. **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?**
When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

1. 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.
2. 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:

   a. 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.

   b. In order to conduct reviews by DMR subsequent to FCR, the institution should specify its intention to conduct reviews in this manner in its Assurance with OLAW. (IACUCs that newly elect to utilize a standard operating procedure for DMR subsequent to FCR should provide information about this program change to OLAW in the next Annual Report.)

3. 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 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. (PHS Policy IV.C.2)

If a protocol is reviewed and approved by DMR, the IACUC may use the date that the designated reviewer(s) approved the protocol as the date of approval. To facilitate efficient business practice, the IACUC also has the option of selecting a reasonable later approval date as described in NOT-OD-11-053. The approval date will appear in the written notification of approval to the principal investigator. If animal work is conducted before the approval date, as stated in the written notification of approval, this is to be reported to OLAW as a serious noncompliance with the PHS Policy. (PHS Policy IV.F.3)

In response to questions from the community regarding this guidance, OLAW offers the following clarifications:

To avoid temporal delays associated with the PHS Policy requirement that all members of the IACUC must be provided the opportunity to call for FCR for a proposal requiring modifications to proceed to DMR (PHS Policy IV.C.2.), OLAW formally recognized an alternative practice in NOT-OD-09-035 (Guidance to IACUCs Regarding the Use of DMR for Animal Study Proposal Review Subsequent to FCR) issued on January 8, 2009. USDA concurred with this practice.

What is “substantive information”?  
"Substantive information" is the information the IACUC needs to evaluate the proposal in accordance with the requirements of the PHS Policy. IACUCs are required to evaluate proposals to ensure that they conform with the institution's Animal Welfare Assurance and meet the requirements specified in the PHS Policy at IV.C.1., provide the information described in the PHS Policy at IV.D.1., and adhere to provisions of the Guide for the Care and Use of Laboratory Animals. Should a proposal fail to address any of these items to the IACUC's satisfaction, the Committee may determine that the proposal lacks substantive information and require modifications to secure its approval. Typographical or arithmetic errors, misspellings, incorrect room or telephone numbers, etc., are not considered substantive. While these corrections must be made, additional IACUC review is not required.

Can a quorum of the IACUC decide to establish the DMR subsequent to FCR policy?  
No. A DMR subsequent to FCR policy, along with appropriate implementing procedures, may be established only by unanimous consent of all members of the IACUC. While all members need not be physically present at the meeting where the policy is proposed, each individual must be given the opportunity to provide their input in person or via facsimile, email, or memorandum prior to its approval.

What does "in advance, in writing" mean?  
"In advance" means that the IACUC-approved policy must be in place prior to the first meeting at which it is used. "In writing" means that the policy and procedures must be written down and documented in the IACUC's permanent records as having been established by unanimous agreement of all Committee members. Members are not required to physically sign the DMR subsequent to FCR policy.

Does there have to be a written statement for every meeting?  
No. The IACUC-approved DMR subsequent to FCR policy allows an appropriately constituted Committee, by unanimous consent, to implement the policy, whenever appropriate, to evaluate revised proposals using DMR. The outcomes of DMRs must then be appropriately documented in the IACUC minutes or elsewhere.

When can the IACUC start using DMR subsequent to FCR?  
As soon as all members agree to the process and the IACUC-approved, written DMR subsequent to FCR policy and procedures are in place. In addition, when an IACUC establishes the new policy and procedures, OLAW must be notified in the next institutional Annual Report, and the policy must be documented in the institution’s Assurance renewal.

What happens to the DMR subsequent to FCR policy as the membership of the IACUC changes?  
OLAW expects IACUCs to have appropriate standing mechanisms in place to 1) inform new members of all its policies and procedures, and 2) review all IACUC policies and procedures regularly.

20. Does the IACUC have to review proposed animal research activities at the time of grant award if the animal research activities will not be conducted until year 4 or 5 of a grant?  
Yes, with rare exception.

Information about use of research animal subjects is required by PHS in the Vertebrate Animal Section (VAS) of the Research Plan of grant applications and in contract proposals:

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the veterinary care of the animals involved.

4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association Guidelines on Euthanasia. If not, present a justification for not following the recommendations.

The IACUC must approve the proposed use of animals described in the grant application or contract proposal. This is required to comply with the PHS Policy on Humane Care and Use of Laboratory Animals as stated in Section V.B.:

PHS awarding units may not make an award for an activity involving animals unless the prospective awardee institution and all other participating institutions have approved Assurances on file with OLAW, and the awardee institution has provided verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals....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. [emphasis added]

The IACUC review must be performed prior to the conduct of any PHS-supported animal activity. Approval is valid for a maximum of three years. Because the scientific enterprise is not static, the need for changes to animal protocols is anticipated and can occur at any time during the life of the protocol. If the changes are significant, PHS Policy, Section IV.B.7. requires prior IACUC approval of the proposed change(s). OLAW provides examples of the kinds of changes it considers to be significant in FAQ D9.

In rare cases, IACUC review of animal activities is conducted later in the life cycle of a grant or contract. This occurs if a delayed onset of animal activities is a component of the experimental research design described in the VAS of the grant application or contract proposal (e.g., the initial development of a drug or device with subsequent animal testing projected into the future). In these circumstances, the funding component will issue a Notice of Award with a special term and condition indicating that no funds may be drawn from the grant or contract for animal activities until a valid IACUC approval date has been provided to the funding component.

Additional OLAW Guidance regarding IACUC review of grant applications can be found at FAQ D10 and previous OLAW Commentary.

E. Program Review and Inspection of Facilities

1. 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. [A1, A7]

2. How does the IACUC distinguish between significant and minor deficiencies?

PHS Policy requires the IACUC to make this distinction in its semiannual reports to the Institutional Official. A significant deficiency is defined as one which is or may be a threat to the health or safety of animals. Examples include inoperable HVAC, electrical or watering systems, failure of such systems sufficient to affect critical housing and operational areas, and situations such as natural disasters that cause injury, death, or severe distress to animals. Significant program deficiencies can result from an institution's failure to fully understand or implement some aspect of its animal care and use program required by the PHS Policy, or failure to function according to commitments made in its Assurance, and may reach the level of reportable noncompliance. Generally, a minor deficiency refers to a problem for which an immediate solution is not necessary to protect life or prevent distress (e.g., peeling or chipped paint). Ongoing inattention to a minor deficiency may result in a chronic problem indicative of a programmatic failure and may constitute a significant deficiency. [A7]

3. May the IACUC use an AAALAC International site visit as its semiannual evaluation?


4. Is the IACUC required to inspect field study sites?

While semiannual IACUC inspections of field study sites are not required and in many circumstances are impractical, IACUCs should be apprised of the circumstances under which studies are conducted so that they can consider risks to personnel and impact on study subjects. This may be partially accomplished by written descriptions, photographs, or videos that document specified aspects of the study site. The IACUC should also ensure that appropriate permits are in place. USDA animal welfare regulations exempt areas containing free-living wild animals in their natural habitat from inspection [See 9 CFR, Part 2, Section 2.31(c)(2)].

See also OLAW FAQ A6: Does the PHS Policy apply to research that is conducted in the field?

F. Animal Use and Management

1. Is the use of carbon dioxide an acceptable euthanasia agent?

Although CO2 is generally considered an acceptable euthanasia agent for small animals when properly administered, its acceptability is predicated on a number of critical factors that are delineated in the NIH Guide for Grants and Contracts NOT-OD-02-062. The Guide states that because neonatal rodents are resistant to the hypoxia-inducing effects of CO2 and require longer exposure times to the agent, alternative methods should be considered such as injection with chemical agents, cervical dislocation, or decapitation.

http://grants.nih.gov/grants/olaw/faqs.htm

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2. **Is the IACUC responsible for tracking animal usage?**

   Although the PHS Policy does not explicitly require a mechanism to track animal usage by investigators, it does require that proposals specify a rationale for the approximate number of animals to be used and be limited to the appropriate number necessary to obtain valid results. This implicitly requires that institutions establish mechanisms to document and monitor numbers of animals acquired and used, including any animals that are euthanatized because they are not needed. Monitoring should not exclude the disposition of animals inadvertently or necessarily produced in excess of the number needed or which do not meet criteria (e.g., genetic) established for the specific study proposal. Institutions have adopted a variety of administrative, electronic, and manual mechanisms to meet institutional needs and PHS Policy requirements. [A7]

3. **May an investigator transfer animals and research to an institution different than the grantee institution?**

   The transfer of PHS-supported research to a different institution requires the prior approval of the funding component. The proposed new grantee institution must have or obtain an Animal Welfare Assurance and possess all the resources necessary to fulfill the conditions of the grant, and its IACUC must review and approve the animal activities. The original IACUC approval is void when the original grantee formally relinquishes the award. The receiving institution must provide verification of IACUC approval prior to receiving funding. Note that the conditions of approval by the IACUC at the receiving institution may differ from those required by the original grantee's IACUC.

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

   OLAW and USDA agree that pharmaceutical-grade1 chemicals and other substances, when available, must be used to avoid toxicity or side effects that may threaten the health and welfare of vertebrate animals and / or interfere with the interpretation of research results2. However, it is frequently necessary to use investigational compounds, veterinarian- or pharmacy-compounded3 drugs, and / or Schedule I4 controlled substances to meet scientific and research goals.

   The IACUC is responsible for evaluating the potential adverse consequences of such agents when used for research. In making its evaluation, the IACUC may consider factors including, for example:

   - grade,
   - purity,
   - sterility,
   - acid-base balance,
   - pyrogenicity,
   - osmolality,
   - stability,
   - site and route of administration,
   - compatibility of components,
   - side effects and adverse reactions,
   - storage, and
   - pharmacokinetics.

   The IACUC may use a variety of administrative methods to review and approve the use of such non-pharmaceutical-grade agents. For example, the IACUC may establish acceptable scientific criteria for use of these agents within the institution, rather than on a case-by-case basis. Investigators and IACUCs should consider relevant animal welfare and scientific issues including safety, efficacy, availability of pharmaceutical-grade compounds, and the inadvertent introduction of new variables. Cost savings alone are not an adequate justification for the use of non-pharmaceutical-grade or compounded drugs in animals.

   Although the potential animal welfare consequences of complications are less evident in non-survival studies, the scientific issues remain the same. The principles and need for professional judgment outlined above apply to non-survival studies.

   Procedures that may cause more than momentary or slight pain or distress to animals must be relieved by sedation, analgesia, or anesthesia using veterinary or human pharmaceutical-grade compounds, unless the use of an investigational chemical or formulation is scientifically necessary, appropriately justified, and approved by the IACUC. The use of a non-pharmaceutical-grade euthanasia agent must meet the same criteria.

   On March 1, 2012, OLAW, with USDA and AAALAC, offered additional guidance through a webinar on the "Use of Non-Pharmaceutical -Grade Chemicals and Other Compounds in Research with Animals". Here you will find a recording of the webinar, a transcript that includes answers to numerous questions, plus examples of situations for the use of non-pharmaceutical-grade substances.

1 A pharmaceutical grade compound is a drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the United States Pharmacopoeia-National Formulary (USP-NF) or British Pharmacopoeia (BP). According to guidance from the FDA, "pharmaceutical secondary standards" are acceptable for use in clinical animal studies if obtained from a reputable source and comply with compendia standards.

2 A listing of pharmaceutical-grade drugs and biologics is available through the FDA database. The Orange Book is the reference for FDA-approved veterinary drugs. The *Green Book* is the reference for FDA-approved human drugs. The *Green Book* is the reference for FDA-approved veterinary drugs.

3 Veterinary compounding is the customized manipulation of an approved drug by a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a research study. IACUCs considering the use of veterinary compounding for research purposes are advised to consult: [http://www.avma.org/issues/drugs/compounding/veterinary_compounding_brochure.asp](http://www.avma.org/issues/drugs/compounding/veterinary_compounding_brochure.asp) for more information about federal regulations.

4 United States Department of Justice Drug Enforcement Agency controlled substances Schedule I and II-IV drugs may be used in biomedical research according to the standards of the Code of Federal Regulations 1301.13.

5. **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.

6. How can institutions assure animal welfare when HVAC systems malfunction or fail?

Institutions that conduct PHS-supported research, testing, or training have a responsibility to ensure animal welfare and an obligation to protect the federal investments in these activities. The Guide provides recommendations regarding temperature, humidity, and ventilation for common laboratory animals and discusses parameters regarding heating, ventilating, and air conditioning (HVAC) that must be considered. It also states, "In the event of an HVAC system or component failure, systems should, at a minimum, supply facility needs at a reduced level, address the adverse effects of loss of temperature control, and, where necessary, maintain critical pressurization gradients. It is essential that life-threatening heat accumulation or loss be prevented during mechanical failure." (Guide page 140) Monitoring HVAC equipment performance is important to ensure timely identification of local or regional power disruptions or system malfunctions. Institutions are strongly encouraged to consider using available electronic technology to measure temperature in each animal room on a continuous basis. Appropriately installed and powered sensors and electronic alarm systems can rapidly notify maintenance and animal care staff of the need to take immediate action to prevent harm to animals (Guide page 143). Reliance on employees to identify changes in animal room conditions or the use of high-low thermometers to track changes in temperature may not be sufficient to allow timely intervention and prevent catastrophic loss.

Institutions are also responsible to ensure the welfare of fishes, amphibians, and other vertebrates whose environment is aquatic, with the emphasis on water temperature and quality, including oxygenation, circulation and filtration. (Guide pages 77-88) The Guide requires that institutions develop a plan that can be instituted if a disaster occurs. (Guide pages 35, 74-75) The disaster plan must include a scheme for relocating or euthanizing animals when power cannot be restored or repairs effected promptly. HVAC alarm malfunctions, failures in primary and emergency power sources, mechanisms for maintaining appropriate temperatures and ventilation are important issues that must be considered and included in the disaster plan. OLAW provides a Disaster Planning and Response Resources web page to assist institutions in planning and responding to natural and other disasters affecting animal facilities.

See also OLAW FAQ G3: Do awardee institutions need animal facility disaster plans?

7. What are the requirements for conducting rodent survival surgery?

The Guide requires that aseptic technique be followed for all survival surgical procedures. The manner in which asepsis is achieved varies by species. Modification of standard techniques may be desirable or even required, but should not compromise the well-being of the animals. "The design of a surgical facility should accommodate the species to be operated on and the complexity of the procedure to be performed." (Guide page 144) For most rodent survival surgery, "an animal procedure laboratory is recommended; the space should be dedicated to surgery...and appropriately managed to minimize contamination from other activities conducted in the room at other times." (Guide page 144)

8. Is the mouse ascites method an acceptable method of monoclonal antibody production?

The NIH concurs with the findings and recommendations in the 1999 report of the National Research Council Monoclonal Antibody Production (PDF) which indicates that during the accumulation of ascites there is likely to be pain and distress, particularly when some cell lines that are tissue-invasive are used and in situations of significant ascites development. The Report concluded that there is and will continue to be scientific necessity for this method, but that as tissue-culture systems are further developed, tissue-culture methods for the production of monoclonal antibodies should be adopted as the routine method unless there is a clear reason why they cannot be used.

Accordingly, IACUCs are expected to critically evaluate the proposed uses of the mouse ascites method. Prior to approval of such protocols, IACUCs must determine that (i) the proposed use is scientifically justified, (ii) methods that avoid or minimize discomfort, distress, and pain (including in vitro methods) have been considered, and (iii) the latter have been found unsuitable. [D6]

9. Are multiple major survival surgical procedures permitted on a single animal?

Surgical procedures should be defined as major or minor on a case-by-case basis and evaluated by the veterinarian and IACUC to determine their impact on the animal's well-being. (Guide pages 30, 117) Multiple procedures that may induce substantial post-procedural pain or impairment may be conducted on a single animal only if justified by the PI, and reviewed and approved by the IACUC. Multiple major surgical procedures on a single animal are acceptable only if they are:

- included in and essential components of a single research project or proposal;
- scientifically justified by investigator;
- or necessary for clinical reasons. (Note, clinically necessary procedures do not necessarily require review and approval by the IACUC in advance of the procedure.)

Cost savings alone are not an adequate justification for performing multiple major survival surgical procedures. (Guide page 30)

Note that under USDA regulations (AWR 2.31 (x) A-C), "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless: (A) Justified for scientific reasons by the principal investigator, in writing; (B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or (C) In other special circumstances as determined by the [Animal Care] Administrator on an individual basis. Written requests and supporting data should be sent to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale MD 20737-1234".

See also OLAW FAQ F13: Are laparoscopic procedures considered major surgery?

10. Can performance standards be used in determining rodent housing practices including management of rodent breeding colonies?

Performance standards are to be applied to rodent housing issues. (See Guide pages 56-58.) While the Guide's space recommendations are accepted reference points for addressing space needs, performance standards allow flexibility to improve animal welfare and scientific research. Adjustments to recommendations for primary enclosures may be made at the institutional level by the IACUC. The IACUC should critically evaluate objective measures of outcome-based performance. The Guide identifies examples of performance indices to assess adequacy of housing including:

http://grants.nih.gov/grants/olaw/faqs.htm
Rodent cages of the size commonly used in the United States may be appropriate for pair or trio breeding. The Guide does not add specific, additional engineering standards for breeding configurations. This empowers institutions to determine appropriate housing. The IACUC must consider relevant factors when assessing the adequacy of cage space according to performance standards. Examples of these factors may include:

- average litter size of the strain(s) of rodents;
- whether multiple litters are present in the cage;
- difference in the age of the pups of different litters;
- growth rate;
- need for cross-fostering;
- cage dimensions; and
- overall management and husbandry practices such as cage sanitation or bedding change.

Blanket, program-wide departures from the Guide for reasons of convenience, cost, or other non-animal welfare considerations are not acceptable. Cages that might be acceptable when litters are born may have insufficient space as pups grow. Whatever parameters are used to establish breeding configurations and weaning procedures, the IACUC must ensure that cage population does not negatively impact animal well-being and overcrowding does not occur.

11. Can IACUCs authorize the adoption of research animals as pets after the animals are no longer needed for study?
   
   The PHS Policy, the Guide and the Animal Welfare Act are silent on the issue of private adoption of research animals for pets after a study has been completed and the animals are no longer required. The 9 CFR recordkeeping regulations and official policies offer institutions the option of developing and implementing an adoption policy. OLAW is supportive of the concept of adoption but reminds institutions that NIH grant funds may not be used to support the cost of the program. The PHS will not assume legal or financial responsibility for any adoption program or any results of adoption. The institution should ensure that its policy meets pertinent state and local regulations for transfer of animal ownership and is encouraged to coordinate with local animal shelters.

12. What are the institution's responsibilities in ensuring that animals are shipped safely and in reporting adverse events that occur in shipment of animals to or from the institution?

   Animals should be transported according to international, federal, state and local regulations summarized in the Guide (page 107). Needs of the animals and protection of personnel should be considered in advance of transportation and met during loading, transportation and unloading, as described in the Guide (pages 107-109). OLAW expects all parties involved in the transportation of animals to apply due diligence in assuring that animals are shipped under appropriate conditions to prevent morbidity or mortality due to temperature extremes or other adverse events. When animals are shipped from an institution, that institution should consider and address all relevant factors to ensure safe transport of the animals. OLAW expects shipping institutions to report adverse events that occur to animals in transit. Receiving institutions should notify the shipping institution when animals are received in extremis or dead.

13. Are laparoscopic procedures considered major surgery?

   Surgical procedures can be categorized as major or minor. (See Guide page 117.) Major survival surgery penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection (e.g., laparotomy, thoracotomy, joint replacement, and limb amputation). Minor survival surgery does not expose a body cavity and causes little or no physical impairment (e.g., wound suturing, peripheral vessel cannulation, percutaneous biopsy, and most procedures routinely done on an outpatient basis in veterinary clinical practice). Animals undergoing a minor survival surgical procedure typically do not show significant signs of postoperative pain, have minimal complications, and quickly return to normal function.

   OLAW recognizes the authority of the IACUC to determine whether specific manipulations used in research are major operative procedures. The IACUC's determination must be based on a detailed description of the procedure and the anticipated or actual consequences, as characterized by the investigator. In some cases, the classification by the IACUC of a procedure as major or minor may be readjusted post-procedurally depending on clinical outcome. If the IACUC, after thorough review, determines that the surgical procedure only penetrates but does not expose a body cavity and that the procedure does not produce substantial impairment, the IACUC may conclude that it is not a major operative procedure. Any laparoscopic surgery that produces substantial impairment of physical or physiological function must be considered a major operative procedure. Whether the laparoscopic procedure is classified as major or minor, the IACUC must ensure that the appropriate analgesia, sterile technique, and perioperative monitoring is employed.

   Multiple major survival surgical procedures on a single animal are discouraged but may be permitted if they are related components of a research project, are scientifically justified by the investigator, or if they are needed for clinical reasons. Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures.

   See also OLAW FAQ F9: Are multiple major surgical procedures permitted on a single animal?

14. Is social housing required for nonhuman primates when housed in a research setting?

   There is universal agreement among oversight agencies that nonhuman primates should be socially housed. (See U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training Principle VII.) The Guide endorses social housing as the default for nonhuman primates. (Guide page xviii) The USDA requires regulated facilities to address the social needs of nonhuman primates known to exist in social groups in nature [See 9 CFR 3.81(a)], with certain specified

http://grants.nih.gov/grants/olaw/faqs.htm
exceptions [See 9 CFR 3.81(a)(1),(2), and (3) and 3.81(e)(1) and (2)]. Single housing of social primates is considered an exception to the standards under 9 CFR and must be reported as such in a research facility’s annual report [See 9 CFR 2.36(b)(3)].

Staff performing nonhuman primate socialization should be trained and competent in the procedure and knowledgeable about the animals. Behaviorally compatible animals should be used whenever possible in socialization attempts. Group composition is critical and numerous species-specific factors should be taken into consideration when forming a group. Due to conformational differences of animals within groups, more space or height may be required to meet the animals’ physical and behavioral needs. Determination of the appropriate cage size is not based on body weight alone. Professional judgment is paramount in making such determinations. (See Guide pages 58-61.)

Exemptions to the social housing requirement must be based on strong scientific justification approved by the IACUC or for a specific veterinary or behavioral reason. Lack of appropriate caging does not constitute an acceptable justification for exemption. When necessary, single housing of social animals should be limited to the minimum period necessary. When single housing is necessary, visual, auditory, olfactory, and (depending on the species) protected tactile contact with compatible conspecifics should be provided, if possible. (Protected tactile contact is considered single housing by USDA, with rare exceptions.) In the absence of other animals, additional enrichment should be offered (as appropriate to the species or individual animal), such as safe and positive interaction with the animal care staff, periodic release into larger enclosures, supplemental enrichment items, and/or the addition of a companion animal in the room or housing area.

Institutions are encouraged to consult the Animal Welfare Act and Regulations on primate housing requirements. Compliance with the USDA regulations is an absolute requirement of this [PHS] Policy. (Footnote 2, page 9) OLAW and USDA positions are further defined at the Nonhuman Primate Enrichment and Social Housing resource on the OLAW website.

15. Should positive reinforcement training be used for nonhuman primates?
In situations where it is safe and feasible, nonhuman primates should be given positive reinforcement training to perform desired cooperative activities involved with research and husbandry. This type of training may also aid in reducing stress from capture and restraint and the need for chemical darts. The Guide comments on procedural habitation and training on pages 64-65.

16. May performance standards determine housing issues?
Performance standards are to be applied to housing issues. Outcome-based performance standards are paramount when evaluating cage or pen space for housing animals used for research, research training, and biological testing. While the Guide's space recommendations are accepted reference points for addressing space needs (Guide pages 50-63), performance standards allow flexibility to improve animal welfare and scientific research. (Guide pages 6-7) An institution’s animal housing practices must be species-specific, appropriate for the animals, and in compliance with all applicable federal and local regulatory requirements. Compliance with the applicable regulations (9 CFR Subchapter A) issued by the U.S. Department of Agriculture under the Animal Welfare Act are an absolute requirement of the PHS Policy (Footnote 2, page 9).

17. May performance standards determine environmental enrichment issues?
An institution’s environmental enrichment practices must be species-specific and appropriate for the animals. Devices that animals climb on or through, perch on, or nest in contribute to, rather than detract from, the animal’s living space and need not be subtracted from the floor dimensions. Some species are upset by the introduction of novel items. Animals should not be subjected to the presence of items that they find distressing. (See Guide pages 52-54.) Compliance with the applicable regulations (9 CFR Subchapter A) issued by the U.S. Department of Agriculture under the Animal Welfare Act are an absolute requirement of the PHS Policy (Footnote 2, page 9).

18. Can performance standards be used in determining rabbit housing practices?
OLAW concurs with the Guide that animals “should be housed under conditions that provide sufficient space...to meet physical, physiologic, and behavioral needs.” (Guide pages 50-51) “The height of an enclosure can be important to allow for expression of species-specific behaviors and postural adjustments. Cage height should take into account the animals’ typical posture and provide adequate clearance for the animal from cage structures, such as feeders and water devices.” (Guide page 56) Space allocations should be assessed, reviewed, and modified as necessary by the IACUC considering the performance indices and special needs determined by the characteristics of the animal (Guide page 56). IACUCs may consider the use of a rabbit cage that is 14 inches in height, if appropriate for specific animals. The IACUC should establish, through performance indices related to animal well-being, that the cage provides sufficient space to meet the physical, physiologic and behavioral needs of the animal. For example, the rabbit must be able to hold its ears in an upright position (if this is natural for the breed) and ears must not be forced to fold over by contact with the cage ceiling.

19. May investigators restrict animals’ food and fluid?
Ingestion of food and fluid are requirements for proper nutrition. When food or fluid is restricted, the amount of the regulated item earned during testing and the amount of the regulated item freely given should be recorded to ensure each animal receives its minimum daily requirements. (NRC 2003, Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research, Washington: National Academies Press) The IACUC must evaluate the level of restriction and potential adverse consequences in regulating food or fluid. The IACUC must also evaluate the methods for assessing the health and well-being of animals involved in activities that regulate food or fluid consumption. The IACUC has the authority to approve scientific justifications for departures from the recommendations in the Guide. For instance, using scheduled access to food or fluid sources may be justified by describing the animal’s access to food or fluid. The IACUC may also approve longer periods to obtain the regulated item during social housing situations. The Guide discusses food and fluid restriction on pages 30-31.

G. Institutional Responsibilities

1. What kind of training is necessary to comply with PHS Policy, and how frequently should it be provided?
The U.S. Government Principles, Health Research Extension Act of 1985 and the PHS Policy repeatedly refer to appropriately trained, qualified, and experienced personnel, and availability of instruction and training. The institution is responsible for the training of its staff. The size and nature of institutional research programs varies significantly and accounts for the corresponding variation in the scope and depth of instructional programs and the frequency at which they are offered.

http://grants.nih.gov/grants/olaw/faqs.htm
Discussion of appropriate training is found throughout the five chapters of the Guide. At a minimum, the PHS Policy and the Guide (page 15) require institutions to:

- ensure that individuals who use or provide care for animals are trained and qualified in the appropriate species-specific housing methods, husbandry procedures, and handling techniques;
- ensure that research staff members performing experimental manipulation, including anesthesia and surgery, are qualified through training or experience to accomplish such procedures humanely and in a scientifically acceptable fashion;
- provide training or instruction in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress;
- ensure that professional staff whose work involves hazardous biological, chemical, or physical agents have training or experience to assess potential dangers and select and oversee the implementation of appropriate safeguards; and
- ensure compliance with any initial and continuing education regarding State requirements for the licensing of veterinary or animal health technicians.

1 The U.S. Government Principles direct that, "...housing, care, and feeding...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" (VII) and that, "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” (VIII).

2 The Health Research Extension Act of 1985 requires that, "scientists, animal technicians, and other personnel involved with animal care, treatment, and use...have available to them instruction or training in the humane practice of animal maintenance and experimentation..." (Sec. 495.(c) (1) (B)).

3 The PHS Policy requires that institutions seeking an Assurance provide "a synopsis of training or instruction in the humane practice of animal care, treatment, and use, as well as training or instruction in research or testing methods that minimize the number or animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care, treatment or use" (IV.A.1.g.); that medical care for animals will be provided by "qualified" veterinarians (IV.C.1.e.) and that, "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures" (IV.C.1.f.).

2. What is required for an occupational health and safety program?

The PHS Policy requires a "health program for personnel who work in laboratory animal facilities or have frequent contact with animals" (IV.A.1.f.). The Guide states that, "Each institution must establish and maintain an occupational health and safety program as an essential part of the overall Program of animal care and use...The nature of the OHSP will depend on the facility, research activities, hazards, and animal species involved.” (Guide pages 1-19)

"A comprehensive OHSP should include a hierarchy of control and prevention strategies that begins with the identification of hazards and the assessment of hazards associated with those risks.” (Guide page 18) An effective occupational health and safety program must encompass all personnel that have contact with animals. Depending on the species of animal or the amount of animal exposure, the program may not affect all personnel equally. Minimally, the program should include:

- pre-placement medical evaluation;
- identification of hazards to personnel and safeguards appropriate to the risks associated with the hazards;
- appropriate testing and vaccinations;
- training of personnel regarding their duties, any hazards, and necessary safeguards;
- policies and facilities that promote cleanliness;
- provisions for treating and documenting job-related injuries and illnesses;
- facilities, equipment, and procedures should be designed, selected, and developed to reduce the possibility of physical injury or health risk to personnel;
- good personal hygiene practices, prohibiting eating and drinking, use of tobacco products, and application of cosmetics and/or contact lenses in animal rooms and laboratories; and
- personal protective equipment (PPE).

Occupational Health and Safety in the Care and Use of Research Animals, published in 1997 by the National Research Council, includes helpful guidelines and references for establishing and maintaining an effective and comprehensive program.

3. Do awardee institutions need animal facility disaster plans?

The Guide requires that institutions develop disaster plans that take into account both the well-being of animals and consideration of personnel during unexpected events that compromise ongoing animal care. (Guide pages 35, 74-75) The plan should define the actions necessary to prevent animal pain, distress and deaths. Such plans should consider failure of critical systems including HVAC and alarm malfunctions, as well as failures in primary and emergency power sources, mechanisms for maintaining appropriate temperatures and ventilation, and a scheme for relocating or euthanizing animals when power cannot be restored or repairs effected promptly. Designations of responsibilities and personnel training in the disaster response, consideration of significant personnel absences, training, and institutional policies and procedures are important aspects of a disaster plan.

OLAW provides a Disaster Planning and Response Resources webpage to assist institutions in planning and responding to natural and other disasters affecting animal facilities.

4. What kind of administrative organization works best for ensuring compliance?

Direct, clear and straightforward lines of responsibility and corresponding authority function well and allow organizations to respond quickly and effectively when necessary. Key components in such organizations are the Institutional Official (IO), the IACUC, and the attending veterinarian. The IO should have the authority to allocate organizational resources needed to maintain a smoothly functioning animal care and use program based on recommendations and advice received from the IACUC and the veterinarian. The IO should also clearly define and assign responsibilities and reporting channels for other essential program elements such as training.
and occupational health. The IACUC, appointed by the organization’s chief executive officer, reports directly to the IO and is empowered to perform its duties without undue interference. It is recommended that the veterinarian report directly to the IO in connection with his or her responsibilities for implementing those parts of the animal care and use program that are set forth in the PHS Policy, the Animal Welfare Act, and the Guide. [A2]

5. What is the difference between the Institutional Official and the Chief Executive Officer? The Institutional Official (IO) signs the Assurance and is the person in the organization with the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with the requirements of the PHS Policy. The PHS Policy requires the chief executive officer (CEO) to appoint the IACUC in accord with specified qualifications and membership criteria, although the CEO may delegate this authority in writing. In some institutions, the IO and the CEO may be one and the same, whereas in other institutions, particularly large ones, the CEO may be further removed from the day-to-day program oversight. [A7]

6. Is post approval monitoring required? Continuing IACUC oversight of animal activities is required and can be accomplished through a variety of mechanisms. (Guide pages 33-34) Monitoring animal care and use is required by the PHS Policy, but the Policy does not explicitly require specific post approval monitoring (PAM) procedures to compare approved protocols and SOPs against the manner in which they are actually conducted. IACUCs are charged, however, with program oversight and as such are responsible for program evaluations, reviews of protocols, reporting noncompliance, ensuring that individuals who work with animals are appropriately trained and qualified, and addressing concerns involving the care and use of animals at the institution. The veterinarian with program authority and responsibility for animal activities along with the animal care and technical staff, add another important level of program supervision.

Related components of institutional programs provide monitoring by a multi-disciplinary team of individuals. Examples of such components include daily observation of animals by trained animal care personnel and communication to the veterinary staff for follow-up, facility monitoring by facility maintenance personnel, post operative care by trained personnel, evaluation of outcomes of animal procedures by investigators and staff, hands-on training in animal procedures, and appropriate reporting of incidents involving occupational health and safety. All of these functions and responsibilities imply a level of monitoring. Ultimately the institution has flexibility in how it achieves compliance.

Some institutions have developed PAM programs with dedicated staff that physically monitor procedures and practices associated with approved protocols. This is an acceptable method that institutions may elect to adopt, but it is not a federally mandated requirement. Whatever methods an institution incorporates, it is important that the authority and responsibility of the IACUC not be contravened by a PAM program, institutional compliance officials, or other mechanism established to monitor animal care and use.

7. May institutions utilize the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Ag Guide) if their programs include traditional farm animals? PHS Policy mandates that institutions use the Guide for the Care and Use of Laboratory Animals (Guide) as a basis for developing and implementing a program for activities involving animals. The Guide states that it “applies to agricultural animals used in biomedical research, including those maintained in typical farm settings.” It further emphasizes that the use of farm animals in research should be subject to the same ethical considerations as the use of other animals in research. (Guide, page 32)

The Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide) primarily refers to agricultural animals used in agricultural research for which the scientific objectives are to improve understanding of the animals’ use in production agriculture. It is therefore inappropriate to substitute the Ag Guide for the Guide based on the species of animal. However, there may be circumstances where it is appropriate to follow the standards of the Ag Guide in biomedical research (e.g., transmission studies of avian influenza under poultry production conditions). Information about environmental enrichment, transport, and handling in the Ag Guide may be helpful in both agricultural and biomedical research settings. Proposals to conduct such activities should be reviewed on a case-by-case basis and any approval to depart from provisions of the Guide must be based on scientific justifications acceptable to the IACUC.

8. What are the institution’s responsibilities in preparing for targeting by animal rights activists? Acts of vandalism and the threat or use of violence are tactics used by some animal rights extremist groups. Such actions endanger lives, cause millions of dollars in damage and destruction, and jeopardize biomedical research, training and biological testing. These actions are considered domestic terrorism by the FBI and are a source of serious concern for NIH and the awardee community. The Guide requires that institutions develop a plan that can be instituted if a disaster occurs. (Guide pages 35, 74-75) Additional detailed guidance on how IACUCs and Institutional Officials can prepare and protect their institution can be found in the ARENA OLAW Institutional Animal Care and Use Committee Guidebook (page 71):

"Since the IACUC has responsibility for the welfare of animals at its facility, it shares responsibility for the security of the animals and associated personnel with other groups within the institution, including the units responsible for security, public information, and governmental relations. Institutions receiving federal funds have an obligation to protect the federal investment in research by exercising due diligence in this area. The IACUC can serve a key role in advancing the institution’s vulnerability, and in developing a plan for responding to potential or real threats. In all cases the IACUC must consider allegations of noncompliance or animal welfare issues as concerns that must be addressed in accordance with relevant PHS Policy provisions and Animal Welfare Regulations (AWRs). There are four key elements to an institution’s preparedness:

- An animal care and use program of impeccable integrity;
- A security program based on risk assessment;
- An integrated communication plan with descriptions of research projects in lay terminology, spokespersons, and a telephone tree; and
- An internal and external community outreach program that includes legislators and funding agencies."

The ARENA OLAW Institutional Animal Care and Use Committee Guidebook goes on to describe in more detail the elements of a crisis management plan and how the institution should best prepare to respond to allegations in an honest and forthcoming fashion. OLAW encourages IOs and IACUCs to evaluate their institution’s readiness to deal with potential threats in accordance with the Guidebook’s recommendations. OLAW shares the concerns of Institutional Officials and IACUC members about the threats and intimidation their institutions may face and strongly encourages each institution, if it has not already done so, to: [A8]
Frequently Asked Questions - PHS Policy on Humane Care and Use of Laboratory Animals -...

9. How can institutions and their IACUCs best prepare for a pandemic?
Institutions must adhere to provisions of the PHS Policy, the Guide, and the commitments detailed in their Animal Welfare Assurance with OLAW. This includes advance planning for conditions that could arise as a result of a human pandemic (e.g., influenza) that could jeopardize the health and wellbeing of animals because of a lack of personnel to care for the animals and/or to conduct IACUC official business.

Pandemic plans developed by institutions and IACUCs should include consideration of the following:

- Animal facilities must be maintained at a level to ensure animal welfare. Plans should consider appropriate staffing levels, cross-training to cover critical operations, and adequate inventories of essential supplies (e.g., feed, bedding, personal protective equipment, cagewash supplies).

- The IACUC should develop a plan for conducting official business during a pandemic event, taking into account the following:
  ■ The IACUC must continue to be properly constituted.
  ■ A quorum is required to conduct official business at a convened meeting.
  ■ The IACUC must ensure that protocol approvals are not allowed to expire or if they do expire, that no further animal activities (e.g., data collection) are conducted.
  ■ Appointment and training of IACUC members (including nonscientific members and alternates) should be considered as a part of the plan. See NOT-OD-01-017.

In devising a pandemic plan, the institution may wish to consider using options provided in the PHS Policy that it does not choose to use in the normal operation of its animal care and use program. Social distancing means focused measures to reduce contact among people. The PHS Policy contains some provisions that can be instituted as social distancing measures to prevent the spread of disease, including:

- The IACUC may institute alternatives to face-to-face meetings such as teleconference or video conferencing (NOT-OD-06-052).
- The number of IACUC meetings may be reduced to as few as one every six months, the minimum allowed by the Guide.
- The IACUC may choose to expand their use of designated member review.


The following links may be helpful in developing an institutional pandemic plan:
http://pandemicflu.gov/index.html
http://www.pandemicflu.gov/index.html
http://www.iacuc.org/disaster.htm and

Additional guidance will be developed and posted on the OLAW website if an emergency situation is sufficiently severe and long-lasting that OLAW determines that the above suggestions do not meet the needs of the research community and funding components. OLAW is the only entity authorized to make determinations regarding waivers to provisions of the PHS Policy.

10. What is OLAW's position on performance standards?
OLAW encourages the cooperative application of diverse expertise to develop outcome-based performance standards that enhance the quality of animal care and use programs. OLAW does not consider a performance standard to be a departure from the Guide. A well-developed performance standard meets the following criteria:

- supports scientific objectives;
- supports the health and welfare of the animal;
- includes a justified performance index; and
- has associated outcome criteria.

IACUCs are able to meet their responsibility to ensure humane animal care and use while advancing quality scientific research through the use of performance standards.

11. May cost be used as justification for not implementing animal welfare standards?
Animal welfare and the integrity of research findings, rather than cost alone, should be the primary factors in decisions related to assuring compliance with the recommendations in the Guide in PHS-funded research. (See U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training Principle II.) The PHS Policy and the Guide define the minimum standards ("musts") and performance standards ("shoulds") that OLAW expects of Assured institutions. In many
instances, institutions and IACUCs elect to exceed the standards described in the Guide. This is not required and can add expense to the program. OLAW does not discourage or encourage institutions from exceeding the standards.

More Information About Comments

Grantee adherence to the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) is a term and condition of all PHS grant or contract awards that include use of live, vertebrate animals. These questions and answers provide guidance for institutions and IACUCs as they implement the PHS Policy. Institutions with species regulated by the USDA must also comply with the Animal Welfare Act and Regulations. Institutions have the discretion to establish more stringent requirements as matters of institutional policy.

References are to previously published guidance or commentary in Dear Colleague Letters, Lab Animal Magazine, Contemporary Topics, and ILAR News which may provide additional elaboration or commentary. The information in this document is updated and supersedes previous guidance or commentary.

OLAW will update this page with new FAQs as necessary.

OLAW welcomes comments on any of its policy guidance. Comments may be submitted to OLAW by email at: olaw@od.nih.gov (please insert the title of the specific guidance document in the subject field), or by mail to:

Division of Policy and Education
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

All relevant comments will be considered in OLAW decisions on timing and content of revisions to guidance documents, or development of new guidance documents. Comments generally will not result in direct responses from OLAW.

For questions about Assurances, email olawdoa@mail.nih.gov.
For questions about Compliance Oversight, email olawdco@mail.nih.gov
For general questions, email olaw@od.nih.gov

Comments or Questions?
• Please send email to olaw@od.nih.gov.