

**ANIMAL RESEARCH REQUIREMENTS
COMPARISON TABLE**
As of October 11, 2001

Requirement	Animal Welfare Act - USDA	Public Health Service Policy - PHS (DHHS)
Regulatory Agency	US Department of Agriculture (USDA)	National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW)
Legislative Authority	Statute: 7 USC 2131-2156 Regulations: 9 CFR	Statute: Health Research Extension Act of 1985 (PL 99-158) ("Law") <ul style="list-style-type: none"> • Policies: PHS Policy on Humane Care and Use of Laboratory Animals, ("Policy") which includes the "Guide for the Care and Use of Laboratory Animals" (the "Guide")
Animals Covered	Any live or dead warm-blooded animals used in research, teaching, testing, experimentation, except rats, mice, and birds used in research. 9 CFR 1.1	Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes. Policy III.A.
Assurance/Registration	Registration - updated every 3 years; signed by an official who has the legal authority to bind the University and submitted to the APHIS, REAC Supervisor (on agency forms) 9 CFR 2.30	Assurance - typed on institution's letterhead and signed by the IO. Valid for a specified time, no longer than 5 years. The most recent semi-annual report (below) must be submitted with the Assurance. Policy, IV.A.
Institutional Official (IO)	An individual authorized to legally commit on behalf of the facility that regulatory requirements will be met. 9 CFR 1.1	An individual who signs, and has the authority to sign the institution's Assurance, stating that it will meet the requirements of the PHS Policy. Policy, III.F.
Animal Care Committee (IACUC)		
Appointed by	CEO	CEO
Members	Three (3) or more <ul style="list-style-type: none"> • 1 Veterinarian • 1 member not affiliated with the institution (or related to a person affiliated with the institution) representing general community interests in proper care and treatment of animals. • Where there are more than 3, not more than 3 shall be from the same administrative unit of the institution. 7 USC §2143(b) & 9 CFR §2.31	Five (5) or more <ul style="list-style-type: none"> • 1 Veterinarian • 1 individual who is not affiliated with the institution or related to a person affiliated with the institution. • 1 practicing scientist • 1 non scientist • An individual may meet more than one category of membership. Policy, IV.A.3
Quorum	A majority of the Committee members. 7 USC §2132(m); 9 CFR 1.1 A quorum is required for all formal actions, including semi-annual inspections. 7 USC §2143(b)(2)	A majority of members of the Committee. Policy, III.I
Chair	No statement/policy	Strongly recommends against having the IO or Veterinarian or anyone else with a potential conflict of interest serve as Chair. PHS FAQ

Animal Care Committee (IACUC), continued	Animal Welfare Act - USDA	Public Health Service Policy - PHS
Semi-Annual Report	<ul style="list-style-type: none"> • Review every 6 months the institution's program for humane care and use of animals using Title 9, as a basis. • Inspect every 6 months all of the institution's animal facilities using Title 9 as a basis. <p>NOTE: May use subcommittees composed of at least 2 members to conduct the above reviews and inspections.</p> <ul style="list-style-type: none"> • Submit written report of semi-annual reviews & inspections to IO; such report must describe the institution's adherence to Title 9 and identify any significant departures from Title 9, to include a reasonable and specific plan and schedule, with dates, for correcting deficiencies. • Report reviewed and signed by majority of Committee members, including minority views. • Report within 15 business days to APHIS and any federal funding agencies any failures to adhere to corrective plan and schedule that results in a significant deficiency remaining uncorrected. <p>9 CFR 2.31(c)(1)-(3)</p>	<ul style="list-style-type: none"> • Review every 6 months the institution's program for humane care and use of animals using the "Guide" and USDA regulations. • Inspect every 6 months all of the institution's animal facilities using the "Guide" and USDA regulations <p>USDA regulations override conflicting Guide policy.</p> <ul style="list-style-type: none"> • Submit written report to IO, describing the institution's adherence to the Guide and any significant departures from the Guide, to include a reasonable and specific plan and schedule for correcting each deficiency. • Report reviewed and signed by a majority of the members, including any minority views. <p>Policy IV.B.</p>
Annual Report	<ul style="list-style-type: none"> • Written report, signed by IO or CEO, to the AC Regional Director for the State on or before 12/1 of each calendar year covering the previous federal fiscal year (10/1 - 9/30); assuring compliance with the Act, location of all facilities where animals are housed/used, and specific animal information. <p>9 CFR 2.36</p>	<ul style="list-style-type: none"> • Written report to OLAW, including minority views, describing any changes to the institution's program or facilities that would place it in a different category; changes in IACUC membership (or stating that there are no changes) and dates that the Committee conducted its semi-annual evaluations. Policy IV.F <p>Annually file with Director of NIH a certification that the semi-annual reviews have been conducted, reporting any violations involving care and treatment of animals or assurances that have continued after notice to the institution of such violation(s).</p> <p>Law §495(a)(3)</p>

Animal Care Committee (IACUC), continued	Animal Welfare Act - USDA	Public Health Service Policy - PHS
Other Reports	<ul style="list-style-type: none"> • Report to APHIS and any federal funding agency any suspension of an activity involving animal and appropriate corrective action taken. <p>9 CFR 2.31(d)(7)</p>	<ul style="list-style-type: none"> • Prompt written notice to OLAW of circumstances and actions re: <ul style="list-style-type: none"> - Any serious or continuing noncompliance with this Policy - Any serious deviation from the Guide - Any suspension of an activity by the Committee <p>Policy IV.F.3</p> <ul style="list-style-type: none"> • Report to OLAW any suspension of an activity involving animal and appropriate corrective action taken. <p>Policy IV.C.7</p>
Suspension of Protocols	<ul style="list-style-type: none"> • IACUC may suspend any previously approved activity if it determines that the activity is not being conducted in accordance with the protocol approved by the IACUC. • Suspension requires a review at a convened meeting of a quorum with a majority vote of the quorum. <p>9 CFR 2.31(d)(6)</p>	<ul style="list-style-type: none"> • IACUC may suspend previously approved activity upon determination that the activity is not conducted in accordance with the Animal Welfare Act (7 USC2131-2156 and Title 9), the Guide, the Institution's Assurance or the Policy. • Suspension requires a review at a convened meeting of a quorum with a majority vote of the quorum. <p>Policy, IV.C.6</p>
Animal Care Committee (IACUC), continued		
IACUC Review Criteria	<ul style="list-style-type: none"> • Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals. • The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources. • The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments. • Procedures that may cause more than momentary or slight pain or distress to the animals will: <ul style="list-style-type: none"> - Be performed with appropriate sedatives, analgesics or anesthetics, unless the PI justifies in writing the scientific reasons for withholding such agents and that such withholding will continue only for the necessary period of time. - Involve, in their planning, consultation with the attending veterinarian or his/her designee. - Not include the use of paralytics without anesthesia. • Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure. 	<ul style="list-style-type: none"> • Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design. • Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, unless the PI justifies in writing the scientific reasons for withholding such agents and that such withholding will continue only for the necessary period of time. • Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

Animal Care Committee (IACUC), continued		
IACUC Review Criteria	<ul style="list-style-type: none"> • The animals' living conditions will be appropriate for their species. The housing, feeding and nonmedical care of animals will 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. • Medical care for animals will be available and provided as necessary by a qualified veterinarian. • Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures. • Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance • No animal will be used in more than one major operative procedure from which it is allowed to recover, unless: <ul style="list-style-type: none"> - the PI provides written justification of the scientific reasons, or - Routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or - In other special circumstances as determined by the USDA after written request. • Methods of euthanasia used must be in accordance with the definition set forth in the regulations unless the PI provides written justification for a deviation based on scientific reasons. <p>9 CFR §2.31(d)(1)</p>	<ul style="list-style-type: none"> • The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and nonmedical care of animals will 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. • Medical care for animals will be available and provided as necessary by a qualified veterinarian. • Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures. • Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator. <p>Policy IV.C.1</p>

Animal Care Committee (IACUC), continued	Animal Welfare Act - USDA	Public Health Service Policy - PHS
Other Duties and Responsibilities	<ul style="list-style-type: none"> • Review and investigate noncompliance • Recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training. • Review and approve, require modifications in or withhold approval of proposals or proposed changes in ongoing activities. • Have authority to suspend any activity involving animals. (Only after review at a convened meeting of a quorum with the suspension vote of a majority of the quorum) • Conduct continuing reviews of activities not less than annually. <p>9 CFR 2.31(c) and (d)(5)</p>	<ul style="list-style-type: none"> • Review concerns involving care and use of animals at the institution • Recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training. • Review and approve, require modifications in or withhold approval of proposals or proposed significant changes in ongoing activities. • Authority to suspend activity if not in compliance. (Only after review at a convened meeting of a quorum with the suspension of vote a majority of the quorum) • Conduct continuing review of each previously approved, ongoing activity at appropriate intervals, including a complete review ("de novo") at least once every 3 years. <p>Policy IV.B.4-8 and C.5-6</p>
Method of IACUC Review of Proposals	<ul style="list-style-type: none"> • Each member, prior to review, must be provided with a list of proposed activities for review • Written descriptions of all proposed activities shall be available to members • Any member may, upon request, obtain full Committee review of any proposal • If full Committee review is not requested, at least 1 member, designated by the Chairman and qualified to conduct the review, shall review the proposed activity, with authority to approve, require modifications in or request full Committee review. • If full Committee review is requested, approval may only be granted after review at a convened meeting of a quorum, with approval by a majority of the quorum. • No member may participate or be counted for purposes of a quorum if the member has a conflicting interest (i.e. personally involved in the activity). <p>9 CFR 2.31(d)(2)</p>	<ul style="list-style-type: none"> • Each member, prior to review, must be provided with a list of proposed activities for review • Written descriptions of all proposed activities shall be available to members • Any member may, upon request, obtain full Committee review of any proposal • If full Committee review is not requested, at least 1 member, designated by the Chairman and qualified to conduct the review, shall review the proposed activity, with authority to approve, require modifications in or request full Committee review. (a/k/a "Expedited Review") • If full Committee review is requested, approval may only be granted after review at a convened meeting of a quorum, with approval by a majority of the quorum. • No member may participate or be counted for purposes of a quorum if the member has a conflicting interest (i.e. personally involved in the activity) <p>Policy IV.C</p>
Approval/Non-approval	<ul style="list-style-type: none"> • Written notice to PI and research facility of decision to approval or not approve an activity. • If not approved, it shall include a statement of the reasons and give the PI an opportunity to respond in person or in writing. <p>9 CFR 2.31(d)(3)</p>	<ul style="list-style-type: none"> • Written notice to PI and research facility of decision to approval or not approve an activity. • If not approved, it shall include a statement of the reasons and give the PI an opportunity to respond in person or in writing. • Applications and proposals for change approved by IACUC may be subject to further review and approval by institutional officials; however those officials may not approve an activity if it has not been approved by the IACUC. <p>Policy IV.C.4 and 8</p>

Animal Care Committee (IACUC), continued	Animal Welfare Act - USDA	Public Health Service Policy - PHS
Records		
Recordkeeping Requirements	<ul style="list-style-type: none"> • Minutes of IACUC meetings, including attendance, activities of the Committee and deliberations. • Records of activities and proposed changes in activities involving animals, and whether IACUC approval was given or withheld. • Records of semi-annual IACUC reports and recommendations • Records of animals. <p>9 CFR 2.35</p>	<ul style="list-style-type: none"> • Copy of Assurance • Minutes of IACUC meetings, including attendance, activities of the Committee and deliberations • Records of applications, proposals and proposed significant changes in care and use of animals and whether IACUC approval was given or withheld. • Records of semi-annual IACUC reports and recommendations (including minority views) given to the IO. • Records of accrediting body determination. <p>Policy IV.E</p>
Record Retention	<ul style="list-style-type: none"> • At least 3 years for most records • Records relating to proposed activities and significant changes in on going activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and 3 years after the end of the activity. <p>9 CFR 2.35(f)</p>	<ul style="list-style-type: none"> • At least 3 years for most record. • Records relating to proposed activities and significant changes in on going activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and 3 years after the end of the activity. <p>Policy IV.E.2</p>
Training		
	<ul style="list-style-type: none"> • Responsible to ensure that all scientists, research techs, animal techs and other personnel involved with animals are qualified to perform their duties; to be fulfilled in part by the provision of training and instruction. • Make training and instruction available • Review qualifications of personnel with sufficient frequency. • Training and instruction must address specific areas <ul style="list-style-type: none"> - Humane use of animals - Alternative methods of research/testing methods - Proper use of anesthetics, etc. - Reporting non-compliance. <p>7 USC §2143(d) and (e) 9 CFR 2.32</p>	<ul style="list-style-type: none"> • Follow AWA requirements • Personnel caring for animals should be appropriately trained and the institution should provide formal "on-the-job" training to facilitate effective implementation of the program and humane care and use of animals. At a minimum it should include: <ul style="list-style-type: none"> - Appropriate, species-specific housing methods. - Husbandry procedures - Handling techniques. • Ensure that research staff performing experimental manipulation, including anesthesia and surgery are qualified through training or experience to do so in a humanely and scientifically acceptable fashion. • Ensure that staff whose work involves hazardous biological, chemical, or physical agents have training or experience to assess potential dangers and select and oversee appropriate safeguards. • Employee health program for all personnel working in laboratory animal facilities. <p>Guide, page 5</p>