

Institutional Animal Care and Use Committee Policy on the Humane Care and Use of Laboratory Animals

John Carroll University is committed to the humane treatment of animals used in teaching and research. To justify the ethical costs of using live animals in research, teaching, or testing, there must be a reasonable expectation that such usage will contribute to the advancement of knowledge that may eventually benefit humankind and/or animals. John Carroll University's policy is to provide the best possible care for animals used in research or teaching, thereby meeting or exceeding accepted guidelines and all applicable federal, state, and local legislation.

The university follows the guidelines established by the Public Health Service in its publications, *Public Health Service Policy on Humane Care and Use of Laboratory Animals* and the *Guide for Care and Use of Laboratory Animals*. The latest editions of these publications are available on the university's IACUC website at https://jcu.edu/research/iacuc or from the IACUC Administrator or the Chair. All university employees and students are responsible for adherence to this policy. All animals owned and cared for by the university with university funds are covered by this policy and all research proposing to use animals for which funding is received from or through the university is subject to this policy.

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I. Institutional Policy

- A. This institution shall comply with all applicable provisions of the Animal Welfare Act and other federal statutes and regulations relating to animals including the Office of Laboratory Animal Welfare (formerly the Office for Protection from Research Risks Division of Animal Welfare) and the National Institutes of Health's Public Health Service Policy (PHS). Reporting will be done following the Office of Laboratory Animal Welfare's (OLAW) Guidelines.
- B. This institution is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, a copy of which is attached as Appendix A.
- C. This institution acknowledges and accepts responsibility for the care and use of animals involved in research and teaching. As partial fulfillment of this responsibility, this institution will make all possible efforts to ensure that all individuals involved in the care and use of animals understand their individual and collective responsibilities for compliance with all applicable laws and regulations pertaining to animal care and use.
- D. This institution has established and will maintain a program of activities involving animals in accordance with the *Guide for the Care and Use of Laboratory Animals (Guide)*.
- E. This institution has established an Institutional Animal Care and Use Committee (IACUC) that is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.
- F. The ex officio Institutional Official (IO) of the IACUC is the Provost and Academic Vice President of John Carroll University.
- II. Institutional Animal Care and Use Committee (IACUC)
 - A. Members
 - 1. The Institutional Official (IO) appoints members nominated by the chair of the IACUC. The IACUC consists of at least five members who are ordinarily appointed for a three-year term. Membership meets the minimum composition requirements set forth in the PHS Policy and Animal Welfare Act:
 - a. One veterinarian with training or experience in laboratory animal science and medicine;
 - b. One practicing scientist experienced in research with animals;
 - c. One member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy); and
 - d. One member who is not affiliated with the institution other than as a member of the IACUC.

In addition to following PHS Policy and the Animal Welfare Act composition requirements, the Committee must also be comprised of at least two members from the Department of Biology.

- 2. The IACUC reports directly to the Institutional Official through the ex officio Chair of the committee, the Associate Academic Vice President. The ex officio Co-Chair of the IACUC is the Chair of the Department of Biology.
- 3. Duties of the IACUC Administrator include scheduling meetings, notifying members of meetings, writing and distributing minutes of the meetings, typing and distributing IACUC documents, receiving and distributing *Protocol Review Forms*, serving as the contact person for members' questions and investigators' responses regarding protocols, and recording approved or disapproved protocols. The Administrator also schedules the semiannual inspection and writes the report based on the subcommittee's comments.
- 4. An IACUC member shall be recused from reviewing an IACUC protocol from a principal investigator or co-investigator with whom the member has an unresolved personal, professional, or financial conflict of interest. For example, an IACUC member cannot review an IACUC protocol submitted by a student advisee. If an IACUC member is involved in a protocol, that member may not count toward the quorum, may not be present during deliberations, and may not vote on the protocol.
- B. The functions of the IACUC are:
 - 1. Program Review: The IACUC must review at least once every six months the institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC shall review policies and procedures outlined herein, veterinary care, the qualifications of personnel responsible for animal care and use, training programs, and measures related to personal hygiene and occupational health for employees and students working with animals. The IACUC Administrator will generate the inspection report to be reviewed and signed by a majority of the IACUC members. Electronic signatures or email approvals will be accepted. In addition, the IACUC Administrator and/or committee members will work to correct program deficiencies in a timely manner.
 - 2. Facilities Inspection: The IACUC must inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the *Guide* as a basis for evaluation. The IACUC shall appoint a subcommittee of at least two voting members to inspect and evaluate both the physical plant and the animal husbandry associated with each facility. The IACUC Administrator will assist the subcommittee in the inspection process and will generate the inspection report. The inspection report will then be reviewed and signed by a majority of the IACUC members. Electronic signatures or email approvals will be accepted. In addition, the IACUC Administrator and/or a

subcommittee member will notify Facilities Management and the Principal Investigators of any deficiencies and will follow up with them to ensure that deficiencies are corrected in a timely manner.

- 3. Prepare reports of the IACUC evaluations required above and submit the reports to the Institutional Official (IO).
- 4. Review and investigate any concerns involving the care and use of animals at the institution. Deficiencies in animal care and treatment may be reported to any IACUC member or directly to the IACUC Chair. No individual may be discriminated against or be subject to any reprisal for reporting violations of any regulations or standards. Methods for reporting deficiencies in animal care and treatment must be included in the training program for all individuals receiving training on animal care and use through John Carroll University.
- 5. Make written recommendations to the Institutional Official (IO) regarding any aspect of the institution's animal program, facilities, or personnel training.
- 6. Review and approve, require modifications in, or withhold approval of activities related to the care and use of animals in research, teaching, training, or testing.
- 7. Review and approve, require modifications in, or withhold approval of proposed significant changes regarding the use of animals in ongoing research, teaching, training, or testing.
- 8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval.
- 9. Suspend ongoing activities if the activities are not being conducted in accordance with the description of that activity provided by the user and approved by the IACUC.
- III. Review of Protocols by the Institutional Animal Care and Use Committee
 - A. IACUC approval must be obtained before the start of any project using live vertebrates that involves invasive¹ procedures, potential harm to the animals, or materially alters the animals' behavior. This applies to teaching (including classroom demonstration/presentation of animals) and research projects that are conducted through or on the John Carroll University campus, associated with any teaching degree program at John Carroll University, or financed by any internal or external funding administered by John Carroll University.
 - B. IACUC approval must be obtained before the start of any field project using

¹ Invasive: relating to a technique in which the body is entered by puncture or incision.

live vertebrates that involves invasive¹ procedures, potential harm to the animals, or materially alters the animals' behavior. This applies to field research projects that are conducted through or on the John Carroll University campus, associated with any teaching degree program at John Carroll University, or financed by any internal or external funding administered by John Carroll University. In addition, applicable permits (i.e., Ohio Department of Natural Resources) must be obtained before a field project will be approved by the IACUC and a copy of the permit(s) must be submitted with the *Protocol Review Form*.

- C. A *Protocol Review Form* must be submitted by the Principal Investigator or instructor to the IACUC Administrator for each such project. Forms are available on the IACUC website at <u>https://jcu.edu/research/iacuc</u> or from the IACUC Administrator.
- D. New Protocol Review:

When a new protocol is received, the IACUC Administrator will send the protocol to all IACUC members. Each member will then have 5 working days to read the protocol and to make a determination if the full committee should review the protocol. Any member can make the decision to send the protocol to full committee review at any time during the initial 5-day period by notifying the IACUC Administrator or Chair.

- <u>Designated Member Review (DMR)</u>: If no member calls for a full committee review, the Chair will then select one or more qualified committee members to be the designated reviewer(s). The designated reviewer(s) will review the protocol following the "Criteria for Evaluation of the *Protocol Review Form*," a copy of which is attached as Appendix B. The designated reviewer(s) will act on behalf of the entire IACUC to approve the protocol, request additional information from the Principal Investigator to approve it, request revisions to the protocol, or refer it for full committee review. The designated reviewer(s) does not have the power to withhold approval and in such cases must refer the protocol for full committee review. If the Principal Investigator has concerns or disputes regarding the protocol review, he/she should contact the IACUC Chair. The IACUC Administrator will facilitate communications among the Principal Investigator, the designated reviewer(s), and the Chair.
- 2. <u>Full Committee Review (FCR)</u>: If a full committee review is requested, a quorum of the committee must be present at a convened meeting in order to vote. A quorum is a majority of those eligible to vote. A majority of members present at the meeting must vote to approve the protocol. The IACUC will review the protocol following the "Criteria for Evaluation of the *Protocol Review Form*," a copy of which is attached as Appendix B. After review of the protocol, the IACUC may request additional information from the Principal Investigator or revisions to be made to the protocol. If not all

committee members are present at the meeting, the quorum of members present may decide by unanimous vote to have the revised research protocol reviewed and approved by a designated reviewer. However, any IACUC member may request to see the response from the Principal Investigator prior to final approval. Members may request at any time that revisions be reviewed at a full board meeting. If the Principal Investigator has concerns or disputes regarding the protocol review, he/she should contact the IACUC Chair (see II.A.3 for information on conflict of interest).

- E. Once the protocol has been approved, a Notice of IACUC Protocol Approval is sent to the Principal Investigator and faculty instructor (if applicable), and a copy will be sent to the appropriate department chair(s). A copy of the approval notice, a copy of the *Protocol Review Form*, and any opposing minority opinions, are maintained in the IACUC files for three years after completion of the research project. A protocol may be approved for a time period of one to three years and this will be noted on the Notice of IACUC Protocol Approval. (See also L. Continuing Review, below.)
- F. If the IACUC decides to withhold approval of a project, it must send written notification to the instructor or investigator that includes a statement of the reasons for the decision, and give the user an opportunity to respond in writing. The IACUC may reconsider its decision, with documentation in IACUC minutes, in light of the information provided by the user.
- G. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, or the *Public Health Service Policy on Humane Care and Use of Laboratory Animals*. The IACUC may suspend an activity only after a review of the matter at a convened quorum of the IACUC and with a vote for suspension by a majority of the quorum present. If the IACUC suspends an activity involving animals, the Academic Vice President, in consultation with the Chair of the IACUC, shall review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation, as required by the circumstances, to any extramural agency sponsoring the activity.
- H. <u>Significant changes</u> to an active and previously approved protocol must be submitted to the IACUC as an addendum to the original *Protocol Review Form*. The changes must be approved by the IACUC before they may be implemented. Significant changes include, but are not limited to:
 - 1. Changes in the objectives of a study;
 - 2. Proposals to switch from nonsurvival to survival surgery;
 - 3. Changes in the degree of invasiveness of a procedure or discomfort to an animal;

- 4. Changes in species;
- 5. Changes in Principal Investigator (PI); and
- 6. Changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia.
- 7. Additional factors may involve changes in the duration, frequency, or number of procedures performed on an animal.
- I. Changes to an active and previously approved protocol that may be handled administratively by the IACUC Administrator include an increase in previously approved animal numbers as long as the study objectives and all other methodologies remain unchanged. At the discretion of the IACUC Administrator, this requested change may be referred to the IACUC for approval if the increase in number may negatively impact the welfare of the animals with respect to appropriate housing and care, availability of qualified personnel, and any other factor(s) that may be a concern.
- J. Any adverse events, such as the injury and death of an animal covered by an approved protocol, must be immediately reported by the Principal Investigator to the IACUC Chair. The IACUC Chair must then report the event to the Institutional Official (IO).
- K. The IACUC will maintain a list of animals housed on campus that are owned by the university but not covered under an approved research protocol. The list will be maintained with the assistance of the person in charge of the animal.
- L. Continuing Review:

The IACUC shall conduct continuing review of activities covered by these policies at appropriate intervals as determined by the IACUC, but at least once a year. The researcher should notify the IACUC by submitting an "IACUC Protocol Continuation Review" webform, found on the IACUC Forms & Policies webpage before the start of the second and third year that the project will continue. Any changes to the protocol and number or species of animal, and any problems, should be reported on this web form, if not reported earlier.

- 1. If there are no changes or adverse events reported by the PI on the continuation review form, the IACUC Administrator sends a copy of the form to the IACUC for their review. If after 5 working days, no members of the IACUC have any questions or objections to the continuation, the IACUC Administrator issues a Notice of Continuation Approval.
- 2. If a member of the IACUC has objections to the continuation of the protocol or if the PI reports significant changes (see item H. above) or adverse events on the continuation review form, the protocol must be reviewed by the IACUC according to the procedures described in D.

New Protocol Review.

- 3. If the project will continue for a fourth year, the researcher must submit a new protocol form and wait for approval before the start of the fourth year. The IACUC can request a new protocol any time prior to the three-year renewal if warranted.
- M. Faculty sponsors have the responsibility of ensuring that student projects are conducted in accordance with the *Protocol Review Form* and in accordance with federal regulations.
- N. Projects conducted by JCU faculty at an institution assured by PHS and receiving IACUC approval from that institution need not be reviewed by the IACUC at John Carroll University. However, a copy of the *Protocol Review Form* submitted to the other institution, along with a copy of the approval memorandum or letter, should be provided to the Chair of the IACUC and maintained by the IACUC Administrator in the files of the Committee.
- O. Projects conducted by JCU students at an institution assured by PHS and receiving IACUC approval from that institution need not be reviewed by the IACUC at John Carroll University. However, a copy of the approval memorandum or letter from the other institution should be provided to the Chair of the IACUC and maintained by the IACUC Administrator in the files of the Committee.
- P. Any project proposing the use of animals for which John Carroll University will provide partial or total funding should submit a *Protocol Review Form* for consideration by the IACUC.
- IV. Recordkeeping Requirements
 - A. The IACUC shall maintain:
 - 1. Minutes of its meetings, including records of attendance, activities of the committee, and committee deliberations.
 - 2. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
 - 3. Records of semiannual IACUC reports and recommendations, including minority views, as forwarded to the Provost/Academic Vice President.
 - B. All records shall be maintained for at least three years. Records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity.

Appendix A

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

The development of knowledge necessary for the improvement of the health and wellbeing of humans, as well as other animals, requires *in vivo* experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C.2131 et seq.) and other applicable federal laws, guidelines, and policies.²
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

² For guidance throughout these Principles, the reader is referred to the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute of Laboratory Animals Resources, National Academy of Sciences.

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

Appendix B

Criteria for Evaluation of the Protocol Review Form

- 1. The IACUC reviews those components of projects related to the care and use of animals.
- 2. Projects must avoid or minimize unnecessary discomfort, distress, or pain to animals.
- 3. Procedures that may cause more than momentary or slight pain or distress to animals must: be performed with appropriate sedatives, analgesics, or anesthetics unless withholding such agents is justified for scientific reasons; involve consultation with the attending veterinarian; not include the use of paralytics without anesthesia; allow euthanasia to avoid severe or chronic pain or distress.
- 4. Projects must not unnecessarily duplicate previous work.
- 5. Animals' living conditions must be appropriate.
- 6. Medical care for animals must be available.
- 7. Individuals conducting procedures on animals must be appropriately qualified and trained in those procedures.
- 8. Projects involving surgery must include provision for pre-operative and post-operative care of the animals in accordance with established veterinary practices.
- 9. No animal may be used in more than one major operative procedure from which it is allowed to recover, unless: it is justified for scientific reasons; it is required as routine veterinary procedure or to protect the health or well-being of the animal; or in other special circumstances.
- 10. Euthanasia must involve humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death. John Carroll University will use a method of euthanasia recommended by the American Veterinarian Medical Association (AVMA) Guidelines on Euthanasia. A copy of the current AVMA Guidelines on Euthanasia may be requested from IACUC Administrator or accessed from the AVMA website at www.avma.org/KB/Policies/Documents/euthanasia.pdf.