Michigan Technological University

IACUC

Additional Policies

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Administrative Approvals of Amendments

Background

The Assurance between Michigan Tech and the Public Health Services for the IACUC allows administrative approval, by the IACUC chair or their designee, for protocol amendments that are solely to:

1. Add, delete, or change a title of a study;
2. Add, delete, or change personnel other than the Principal Investigator;
3. Add or delete location(s);
4. Add laboratory animals (rats and mice only) to an approved protocol when the increase is no greater than 10% of the original number of animals bred for use in research only;
5. Add, delete, or change a funding source.

The Principal Investigator (PI) is responsible for the submission of the completed and signed amendment form to the IACUC staff. Final approval of an amendment for addition of personnel will not be given until all personnel have received appropriate training and have enrolled in the Occupational Health and Safety Program (OHSP).

The above reviews will be designated as "Administrative Reviews" in the online submission management system. "Approval" may be listed as either "approved" or "acknowledged" in the system.

Addition of Personnel (other than PI)

When the IACUC receives an amendment that includes addition of new personnel:

A. Personnel **shall not work** with animals until they have completed the required online training course(s) at citiprogram.org and this has been verified by the IACUC Administrator. Required training includes completing the Investigators, Staff and Students courses and the appropriate species-specific modules (dependent upon each individual protocol) which include, but may not be limited to the following:
   - Working with the IACUC
   - Working with Mice in Research Settings
   - Working with Rats in Research Settings
   - Working with Rabbits in Research Settings
   - Animal Biosafety
   - Post Procedure Care

B. Personnel also **shall not work** with animals until they have enrolled in the Occupational Health Program.

Addition of Location

Addition of new location(s) for the use of animals may be administratively approved after the PI has submitted an amendment indicating a request for location change. All locations where animals are housed, or procedures take place, are subject to IACUC approval and must be inspected by the IACUC before animal work may commence. The Attending

Veterinarian (or designee) shall have 24/7 access to all locations where animal work is carried out.

Addition of Animal Numbers

An increase of up to 10% in the number of laboratory rats and/or mice bred for use in research only (but not other species) approved in the **original** protocol may be approved administratively after the PI has submitted an amendment indicating a request for additional animals. This number **must be verified** by the IACUC Chair or designee as allowable before additional animals may be put on the protocol by purchase or transfer.

Addition of Funding Source

Addition of a new or different funding source may be administratively approved. However, if the funding source requires a grant/protocol comparison, then the change may be administratively approved only after the assigned reviewer **provides written verification** that the comparison is satisfactory.

Reporting to IACUC

All administratively approved amendments will be placed on the agenda for the next scheduled meeting of the IACUC for informational purposes. All administrative approvals take effect when verification of all requirements is completed and written notification from the IACUC or their designee is sent to the PI.

Adoption of Laboratory Rabbits

Personnel Responsible

Personnel responsible are the Attending Veterinarian, the Animal Care Facility Director, and the IACUC.

Additional Training Required

1. None

Background or Explanation

1. The Guide for the Care and Use of Laboratory Animals (1) and the Guide for the Care and Use of Agricultural Animals in Research and Teaching (3) discuss the termination of research animals at the conclusion of the research project.
2. However, the Guide for the Care and Use of Laboratory Animals (1),the Guide for the Care and Use of Agricultural Animals in Research and Teaching (3), the PHS Policy (2), and the Animal Welfare Act (4) are silent on the issue of private adoption of rabbits for pets after a study has been completed or the animals are no longer required for research. The 9 CFR recordkeeping regulations and official policies offer institutions the option of developing and implementing an adoption policy. The Office of Laboratory Animal Welfare (OLAW) is supportive of the concept of adoption. This policy is also in congruence with the 2019 position statement issued by the American Veterinary Medical Association.

Adoption of Rabbits Upon Conclusion of Research Project

1. In certain cases of non-terminal research use of animals, adoption into a private home shall be encouraged by the Michigan Tech IACUC. Adoption is done in consultation with the principal investigator and orchestrated through the Animal Care Facility Adoption is at the discretion of the Principal Investigator (PI) and Attending Veterinarian. Due to sensitivity of animal research, no direct inquiries concerning adoption from the general public will be considered. Only employees or students of Michigan Tech are eligible to adopt rabbits.

Eligibility

For a rabbit to be eligible for adoption the following conditions must be met:

1. The animal must have not been subjected to a research major surgical procedure. Routine veterinary surgeries are exempted.
2. The animal must not have been administered any drugs other than FDA-approved human or veterinary drugs or food supplements or pharmaceutically compounded veterinary drugs. If any FDA approved drugs have been administered to the animal the drug should be disclosed to the potential adopter.
3. Transgenic or immunosuppressed animals cannot be adopted.
4. In cases where animals require specialized permits, it is the responsibility of the adoptee to obtain the permit.
5. Animals which have been exposed to infectious agents in course of the study protocol are

not eligible for adoption.
6. Animals must be adopted as personal or family pets only and may not be sold.
7. Animals must not be used for food (human or animal consumption).
8. The animal must be in good health and of acceptable behavior.
9. The adopter is responsible for any future medical care/support as may be required.

Procedures

The following set of procedures must be followed:

1. The PI must first indicate that the animal is not needed for research at Michigan Tech, state that they have no knowledge of any fact that would make the animal inappropriate for adoption, and recommend the animal be offered for adoption. If the PI is aware of any conditions that may have an impact on the animal's suitability as a pet, this must be communicated to the potential adopter.
2. If applicable, the animal may be offered for transfer to other PIs with an IACUC approved research protocol. If after 10 days no researcher indicates a desire to use the animal, the animal will be considered for the adoption program.
3. If an individual indicates an interest in adopting an animal, the Facility Director, IACUC Chair, or Attending Veterinarian will meet with that individual and conduct an interview to determine the reasons for the adoption and the person's willingness and ability to provide for the animal's welfare (See Appendix I). Potential adopters will be screened by the AV for their suitability, knowledge of the care of the type of animal, and qualifications. The AV has the discretion and authority to deny any adoption requests.
4. An Animal Adoption Agreement should be filled out by the PI transferring animal ownership to the new owner. A copy of the adoption agreement should be kept by the PI, the AV, and submitted to the IACUC.
5. The animal will be vaccinated (as appropriate) and sterilized prior to adoption at the expense of the Investigator. The adopter will be educated about the animal's health status, and will be provided a written record of the animal's health history.
6. For the transfer of rabbits, USDA transfer Form 7020 ("Record of Disposition of Animals other than Dogs and Cats") must be completed. Forms can be found at http://www.aphis.usda.gov/library/forms/pdf/aph7020.pdf
7. On the day the Animal Adoption Agreement is signed, the animal should be removed from the Michigan Tech facility. Once the animal leaves the facility it is the possession of its new owner; the University will no longer be responsible for the animal, its care or any damage it may cause.

Contacts

1. IACUC – iacuc@mtu.edu
2. Contact information for ACF Staff and the ACF Director: acf-l@mtu.edu or 906-487-2878

Related Information

a. PHS Policy on Humane Care and Use of Laboratory Animals
b. The Guide for the Care and Use of Laboratory Animals, 8th Edition
c. USDA Policy Veterinary Care

References

1. Institute of Laboratory Animal Resources (U.S.). 2011. Guide for the Care and Use of Laboratory Animals. Washington, D.C.: National Academy Press.
2. National Institutes of Health (U.S.). Office of Laboratory Animal Welfare., United States. Public Health Service. 2002.
3. Public Health Service policy on humane care and use of laboratory animals. Bethesda, MD (6705 Rockledge Dr., Bethesda 20892‑7982): Office of Laboratory Animal Welfare, National Institutes of Health, Dept. of Health and Human Services.
4. United States., United States. Animal and Plant Health Inspection Service. 2005. Animal Welfare Act and animal welfare regulations. Washington, D.C.: U.S. Dept. of Agriculture, Animal and Plant Health Inspection Service.
5. Emory University Policy 376 Adoption

Controlled Substances, Drugs, and Chemicals in Animal Subjects

1. Personnel Responsible
    a. This policy applies to the use of any controlled substances, drug formulations, or chemicals in all research, teaching, and biological testing projects using vertebrate animals conducted by anyone at Michigan Tech regardless of the source of funding.
    b. The Attending Veterinarian, Animal Care Facility Director, Institutional Official, and individual IACUC members have the authority to enforce this policy, and if necessary, temporarily stop any activity they believe is in violation of this policy.
2. Additional Training Required
    a. Training for using these substances is generally documented in IACUC protocols and can be gained through a variety of sources (instruction, mentorship, etc.). The IACUC may require additional specific training and documentation.
3. Background or Explanation
    a. The selection, authorization, use, and disposal of drugs is governed by multiple Federal and State rules and regulations, outlined in the "Guide," and covered by OLAW, the USDA and IACUC policies.
4. Drug selection
    a. Researchers are encouraged to review IACUC Animal Procedure: Rodent Survival_Surgery when selecting routine surgery anesthetics and analgesics. For additional questions on drug selection, dosage, or applicability, researchers should consult with the Attending Veterinarian.
5. Requirements for substances that require a State or Federal license
    a. Drug licenses (Controlled Substances)
        i. The PI or Co-PI must acquire appropriate State and Federal licenses when they are required - the university does NOT hold a blanket license.
            1. See the University's Controlled Substances program for details.
        ii. The license holder is ultimately responsible for managing regulated drugs including dispensing, inventory, and DEA visits.
6. Requirements for using pharmaceutical grade drugs
    a. Pharmaceutical grade drugs must be used, when available unless scientific justification for non-pharmaceutical drugs is provided. Justification must include:
        i. How the animal's welfare will be addressed
        ii. What grade or formulations will be used; in general the protocol must specify "purer" chemical formulations when they are available; see "Definitions" below for additional information.
        iii. How the drug's purity will be evaluated, especially for pyrogens.
    b. Drugs must be discarded after their expiration date (see below). The use of expired drugs is not allowed.
7. Requirements for procurement and disposal of controlled substances and other drugs
    a. Drug purchasing
        i. Drug purchases must be approved by ACF director or their designee
            1. Contact the ACF director for details
            2. Non-pharmaceutical grade drugs and all other chemicals, unavailable through the ACF, must be purchased through University Chemical Stores.
    b. Drug disposal

i. When possible, the ACF director will work with the local veterinary clinic to dispose of drugs through their Reverse Distribution procedures.
ii. For alternate disposal options contact Research Integrity Staff

8. Exceptions
    a. Exceptions to this policy must be approved by the IACUC. Exceptions should be based on sound scientific principles or the availability (or non-availability) of pharmaceutical grade formulations. Note that cost alone is not considered scientific justification.
9. ACF actions or ACF staff responsibilities
    a. The ACF director is the primary source for procuring pharmaceutical grade substances and is also the initial contact for disposing of expired drugs.
10. Sanctions
    a. Failure to follow this policy may be considered an animal welfare issue. Sanctions may include temporarily stopping the activity or possibly the suspension of the protocol.
11. Contacts
    a. IACUC – iacuc@mtu.edu
    b. Contact information for ACF Staff and the ACF Director: acf-l@mtu.edu or 906-487-2878
12. Related Information
    a. PHS Policy on Humane Care and Use of Laboratory Animals
    b. The Guide for the Care and Use of Laboratory Animals, 8th Edition
    c. USDA Policy Veterinary Care
13. Definitions
    a. Pharmaceutical grade compound:
        i. OLAW: 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 Pharmacopeia-National Formulary (USP NF), or British Pharmacopeia (BP).
        ii. USDA: Pharmaceutical-grade compound is any active or inactive drug, biologic, reagent, et cetera, which is approved by the FDA for which a chemical purity standard has been written or established by any recognized pharmacopeia, which is a book or a compendia, such as the US Pharmacopeia [USP], the National Formulary [NF], the British Pharmacopeia [BP], the Pharmacopoeia of the Council of Europe [EP]. Note the USP and the NF have combined their standards into one compendia... [http://www.usp.org/usp-nf].
    b. Analytical Standards: “Certificate of Analysis” a document that goes with each product run. This certificate lists the formula for the ingredients as well as the amount of each raw material/ingredient. The product name and lot number are listed to avoid confusion with other batches. The Certificate of Analysis also may contain results of tests for contaminants.
    c. Analytical Grade: ~99% purity; Certificate of Analysis usually available; appropriate preparation is imperative.
    d. Reagent ACS: This designates the highest quality commercial chemical. The “ACS” means the American Chemical Society. A Certificate of Analysis is available upon request.
    e. Reagent Grade: The highest quality commercial chemical; however, ACS has not set specifications for materials. A Certificate of Analysis is usually not available.

Documentation of Research Staff Training

Training verification is an institutional responsibility to ensure that all personnel working with laboratory animals are properly qualified. The Animal Welfare Act states: "Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facilities responsibilities." Further, the *Guide for the Care and Use of Laboratory Animals* notes: "Investigators, technical personnel, trainees, and visiting investigators who perform animal anesthesia, surgery or other experimental manipulations must be qualified through training or experience to accomplish these tasks in a humane and scientifically acceptable manner." Thus, to satisfy the training requirement of Michigan Tech, we have adopted CITI as our online training platform. Additionally, the online protocol submission software has entries for submitting CITI certificates, as well as additional training. The online submission software also has places to indicate which Personnel are working with which species, as well as which task. Additional training can be delivered through the ACF Director or Attending Veterinarian as described in Section 8 of the IACUC Policies and Procedures document.

Contacts

a. IACUC - iacuc@mtu.edu
b. Contact information for ACF Staff and the ACF Director: acf-l@mtu.edu or 906- 487-2878

Related Information

a. PHS Policy on Humane Care and Use of Laboratory Animals
b. The Guide for the Care and Use of Laboratory Animals, 8th Edition
c. USDA Policy Veterinary Care
d. CITI Platform

References

The University of Mississippi Medical Center Research Personnel Training Record

Field Study Policy

1. Background or Explanation
    a. This policy defines a "field study" for which IACUC review and approval is not required. Specifically OLAW states in PHS Policy on Humane Care and Use of Laboratory Animals FAQ: "If the IACUC determines that the proposed activity is likely to alter or influence the biology, behavior or ecology of the study animals or other species, then protocol review and approval is required. **However, if the IACUC determines that the proposed activity is purely observational and will not alter or influence the biology, behavior or ecology of the study animals or other species, IACUC review and approval is not required.**
    b. The IACUC is also responsible for assuring that all Federal and State permits or other landowner permissions are obtained and that personnel are not exposed to, or take the proper precautions to protect themselves from, animal derived zoonotic agents.
2. An exempt field study must meet ALL the conditions below:
    a. The study of wild and free living animals that are not threatened or endangered.
    b. Observational studies only, such as those:
        i. that do not disturb the animals more than briefly (e.g simple observation, video/audio recordings and still photography; examining animal scat, tracks and other animal signs; viewing, but not disturbing, dens/nests); or
        ii. that may cause minor disturbance to an animal or its habitat (picking up and replacing rocks, logs, etc.; potentially flushing animals so they fly/run away; using "hair traps" that remove a small amount of hair when the animal rubs up against it); or
        iii. that use temporary food sources to attract animals for viewing (birdfeeders, short-term food attracts) but are not intended to change animal behaviors or test feeding hypotheses, etc.
    c. Limited to areas where personnel will not be exposed to zoonosis dangers from the animals being observed (rabies, Huanta virus, etc.), to venomous animals, or to potential wildlife attacks.
3. Procedure
    a. The researcher/instructor completes a questionnaire that describes the field study and explains how it meets the definition of an exempted field study, and it is then sent to the IACUC Chair and/or administrator for evaluation.
    b. The IACUC administration or the Chair determines if the explanation meets the requirements for an exempt field study.
        i. If "yes" they inform the PI that it is indeed exempt
        ii. If "no" they inform the PI/Instructor to submit a full protocol for review.
4. Contacts
    a. IACUC – iacuc@mtu.edu
    b. Contact information for ACF Staff and the ACF Director: acf-l@mtu.edu or 906- 487-2878
5. Related Information
    a. PHS Policy on Humane Care and Use of Laboratory Animals

b. The Guide for the Care and Use of Laboratory Animals, 8th Edition
c. USDA Policy Veterinary Care
d. USDA Animal Care Tech Note: Research With Free-Living Wild Animals in Their Natural Habitat and the Animal Welfare Act

Field Study Questionnaire

Some field studies could be exempt from IACUC Review. An online form is available on the IACUC website for researchers to submit. The IACUC Chair (or their designee) will review the submission, and contact the PI with a determination. Results could be either a determination of exemption, that a protocol is needed, or that additional information is necessary to make an accurate determination. The Google Form listing the questionnaire can be found here.

Veterinary Verification and Consultation

Policy Intent: The intent of this policy is to describe the use of Veterinary Verification and Consultation, or VVC, at Michigan Tech.

1. Purpose
    a. Significant changes to a protocol must be approved either by a majority vote of a convened quorum of the IACUC (full committee review) or by designated member review. However, in the following specific circumstances (a-c below), administrative approval may be obtained by consultation with and approval of the Attending Veterinarian.
2. IACUC Policy
    a. It is the policy of the IACUC that the certain specific significant protocol changes (outlined in OLAW Guidance #NOT-OD-14-126 and further specified in this policy) may be approved by the Attending Veterinarian, with proper consultation and review of the approved protocol (including appropriate amendments).
3. Defined Changes
    a. Changes in Dose, Route, Concentration, Volume, and/or Duration: Modifying these parameters of an approved anesthetic, analgesic, antimicrobial, or sedative drug, provided it aligns with published veterinary formulates and doesn't increase pain or distress to the animal.
    b. Replacing or Adding Clinically Relevant Drugs of the Same Class: This might be needed due to drug shortages or non-availability (i.e. replacing a pharmaceutical grade drug with a non pharmaceutical grade drug).
    c. Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals.
    d. Duration, frequency, type, or number of procedures to be performed on an animal as long as those procedures are already approved in the protocol.
4. The VVC CANNOT be used to:
    a. Change a surgery from a nonsurvival to a survival
    b. Increase pain, distress, or degree of invasiveness
    c. Change housing or use of animals to a non-ACF location
    d. Change species
    e. Change study objectives
    f. Change Primary Investigator
    g. Make changes that will impact personnel safety.
    h. Add new procedures to a protocol.
5. Veterinary Accountability
    a. The Attending Veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance.
    b. Consultation with the Attending Veterinarian will be documented by having the AV send an email (or appropriate documentation) approving the change to the IACUC Chair (or their designee) within 2 business days of the change.
    c. The protocol will be updated by the Principal Investigator within 5 business days of the change.
    d. The Attending Veterinarian may refer any request to the IACUC for review for any reason and must refer all requests that do not meet the parameters of the IACUC reviewed and approved policies and/or procedures.

e. The IACUC will be informed of all VVC reviews at the next convened committee meeting.

6. References
   a. NIH Guide Notice NOT-OD-14-126
      i. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html
   b. OLAW Webpage Significant Changes
      i. http://grants.nih.gov/grants/olaw/significant_changes.htm
   c. OLAW Special Seminars: Guidance on Significant Changes to Animal Activities: Recording, transcripts and resources
   d. AVMA Euthanasia Guidelines
      i. https://www.avma.org/KB/Policies/Documents/euthanasia.pdf