INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE STANDARD OPERATING PROCEDURES

Kansas City University

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Eugene Konorev **Date**

IACUC Chair

Edward R O'Connor — 11.19.2021

Edward O'Connor **Date**

KCU Institutional Official

1. General Policy

The Standard Operating Procedures Policy is in place to ensure appropriate care and use of all animals handled, cared for, or used by the University personnel or individuals otherwise subject to the University's policies. This policy applies to all research and teaching activities that involve animals regardless of funding source. Research activities taking place at the University shall be conducted in accordance with this policy as well as all applicable federal, state, and local laws, regulations, and policies including, but not limited to:

- Public Health Service {PHS) Policy on Humane Care and Use of Laboratory Animals at http://grants.nih.gov/grants/olaw/references/phspol.htm
- Health Research Extension Act of 1985, Public Law 99-158 "Animals in Research" (November 20, 1985) at http://grants.nih.gov/grants/olaw/references/hrea1985.htm
- U.S. Government Principles for the Utilization and care of Vertebrate Animals Used in Testing, Research and Training (promulgated in 1985 by the lnter-agency Research Animal Committee) at http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinci%20pies
- Animal Welfare Act, Public Law 89-544, 1966 (P.L. 91-579, P.L. 94- 279 and P.L. 99-198) 7 U.S.C. 2131 et. seq 222which implements regulations in the Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1-3 at https://www.gpo.gov/fdsys/pkg/CFR-2006-title9-vol1/pdf/CFR-2006-title9-vol1-chapI.pdf
- Animal Welfare Act and Regulations at: https://www.aphis.usda.gov/wcm/connect/APHIS_Content_Library/SA_Our_Focus/SA_Animal_Welfare/SA_AWA/CT_AWA_Program_Information?presentationtemplate=APHIS_Design_Library%2FPT_Print_Friendly
- Animal use and maintenance shall be in accordance with the Guide for the Care and Use of Laboratory Animals, National Academy Press, 2011, Washington, D.C. or succeeding revised versions at http://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf
- AVMA Guidelines on Euthanasia, 2020 Edition at: https://www.avma.org/sites/default/files/2020-01/2020-Euthanasia-Final-1-17-20.pdf
- CDC Manual or Biosafety Manual or BMBL: NIH and Center for Disease Control's (CDC), Biosafety in Microbiological and Biomedical Laboratories, Edition 6 at https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf

- International Guiding Principles for Biomedical Research Involving Animals, 2012 http://grants.nih.gov/grants/olaw/Guiding_Principles_2012.pdf

2. Definitions

- Animal - Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
- Animal Facility - Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.
- Animal Welfare Act - Public Law 89-544, 1966, as amended (P.L. 91-579, P.L. 94-279, and P.L. 99-198), 7 U.S.C. 2131 et seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3, and are administered by the U.S. Department of Agriculture.
- Animal Welfare Assurance or Assurance - The documentation from an institution assuring institutional compliance with the Public Health Services Policy.
- The Guide - Guide for the Care and Use of Laboratory Animals: Eighth Edition, National Academy Press, 2011, Washington, D.C., or succeeding revised editions.
- Change in scope: Change in direction, type of research or training from the aims, objectives, or purposes of the approved project. Change in scope requires notification to an NIH funding component. A change in an animal activity can be both a significant change requiring IACUC review and a change in scope. However, a significant change is not necessarily a change in scope.
- IACUC: The University's Institutional Animal Care and Use Committee.
- Immediate Family Member: Parent, spouse, children, siblings.
- Institution - Any public or private organization, business, or agency (including components of Federal, state, and local governments).
- Institutional Official – Appointed by the Chief Executive Officer of the University. An individual who signs, and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.
- Nonscientific member: Member whose primary concerns are in a nonscientific area(s) (e.g., ethicist, lawyer, member of the clergy). This member must not be a practicing scientist experienced in research involving animals.
- Official Business: The IACUC conducting full committee review and approval of a proposed project or significant change to a project, and/or suspending a research/teaching activity. There must be a quorum convened for an IACUC to conduct official business.
- PHS Policy: Current PHS Policy on Humane Care and Use of Laboratory Animals.

- Public Health Service - The Public Health Service (PHS), includes the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.
- Quorum - A majority of the members of the Institutional Animal Care and Use Committee (IACUC).
- Serious Noncompliance: Includes, but is not limited to, undertaking animal activities that have not received prior IACUC approval or have not timely received tri-annual re-approval (before the expiration date). Serious noncompliance must be reported to OLAW if the activity is federally funded, and if applicable, the NIH funding component.
- Significant Change: Requires IACUC approval before Principal Investigator implements change. The IACUC is not required to notify OLAW or an NIH funding component for significant changes. However, conducting significant changes without prior IACUC approval constitutes serious noncompliance that must be reported to OLAW if the activity is a result of federal funding.
- The University: The Kansas City University (KCU).
- Unaffiliated member: Member not affiliated with the University in any way other than as a member of the IACUC and who is not a member of the immediate family of a person who is affiliated with the institution. Unaffiliated member must represent general community interests in proper care and use of animals and cannot be a lab animal user.
- Ex Officio members may be appointed by the CEO and / or The IO as necessary to assist the IACUC.

3. Applicability

This policy applies to animals that have been acquired or transported by the University for Research and teaching activities involving animals regardless of the source of funding. All personnel responsible for handling animals, whether for care/maintenance, experimentation and/or teaching, or any other reason are subject to this policy - Such personnel may include faculty, staff and students. External institutions utilizing the services of the University's IACUC are subject to this University policy and procedures as well, and must agree in writing to abide by it before IACUC review will be rendered.

4. Responsibilities

- The University is responsible for ensuring adequate support and resources in place, so research and facilities involving animals at the University are compliant with all applicable laws and regulations, including the Guide. The University maintains an environment that emphasizes respect for the health, well-being and humane use of laboratory animals and

ensures a safe working environment for personnel involved in the animal care and use program as stated in the PHS Policy. The University is also responsible for ensuring all necessary external reporting obligations are fulfilled via the Institutional Official (IO). The Office of Research and Sponsored Programs is responsible for setting policy about the roles and responsibilities of the IACUC in accordance with federal regulations.

- Principal Investigators - The term "principal investigator" encompasses both lead investigators of research project and instructors/course supervisors in teaching labs. The responsibilities of principal investigators include, but are not necessarily limited to:

  - Being familiar with the applicable laws and regulations for care and use of animals, including those legal sources described in this policy.
  - Completely and accurately filling out the appropriate IACUC forms/applications to the IACUC within the deadlines described in this policy.
  - Reporting significant changes to previously approved protocols, changes in scope of the research, and adverse events/incidents to the IACUC in accordance with this policy.
  - Developing standard operating procedures and lab practices that are based on the recommendations in the Guide and the Biosafety Manual, and ensuring ongoing compliance with the practices and procedures outlined in those standard operating procedures, the Guide, and the Biosafety Manual.
  - Never beginning research activities until IACUC has approved the protocols and likewise not continuing approved research activities after the renewal deadline set by the IACUC expires.
  - Securing veterinary consultation when necessary for developing protocols that involve Pain, anesthesia, surgery, etc.
  - Submitting a Financial Conflict of Interest Disclosure Form.
  - Understanding the contents of the University's IACUC policies and procedures contained in this document as well as the regulations and laws it references. If a PI does not understand any of the content referenced in this section, the PI is responsible for contacting the Research Compliance Coordinator for clarification

- IACUC - The IACUC is charged with several responsibilities. Those responsibilities include, but are not necessarily limited to, the following:

  - Reviewing research and teaching protocols involving the use of animals and either approving, requiring modifications to secure approval, or withholding approval for applicable protocols.
  - Reviewing and either approving, requiring modification to secure approval, or withholding approval for proposed significant changes.

- Reviewing any concerns received internally or from the public regarding the care and use of animals at the University, including allegations of noncompliance with University and/or federal, state, local laws, rules, regulations, policies, and/or procedures.
- Preparing reports of the IACUC evaluations conducted as required by the PHS Policy and submitting such reports to the Institutional Official. The reports shall be updated at least once every six months upon completion of the required semi-annual evaluations.
- Making recommendations to the IO about any needed improvements to the animal program, facilities, or training.
- Suspending any research or teaching activity involving animals that is in noncompliance with University and/or federal, state, local laws, rules, regulations, policies, and/or procedures, including, but not limited to, applicable provisions of the Animal Welfare Act, the Guide, the University's Assurance, or the PHS policy. Generally, to suspend a research or teaching activity, except in the case of expiration of the allowed time for a Principal Investigator to obtain re-approval of a previously approved study, the IACUC must review the matter at a convened meeting and approve the suspension by a majority vote of the present quorum.

- Research Compliance Coordinator- the Research Compliance Coordinator is responsible for ensuring the information listed on protocols, the IACUC reviews and approves is congruent with the content of the corresponding grant application/proposal provided. The Research Compliance Coordinator is also responsible for oversight and development of animal care and use compliance education, serves as a liaison between Principal Investigator and the IACUC and between the University and government regulatory agencies, and provides clarification as to IACUC policy, procedures, and governing law and regulations. Further responsibilities include management of the protocol review process, committee meeting process, IACUC policy and procedure development, and educating constituents about animal protections and the IACUC process.

- The Vice President of Research / Institutional Official - The Vice President of Research/IO has broad ultimate oversight of the research compliance program and allocates organizational resources needed to maintain a smooth functioning animal care and use program, and meeting institution and federal requirements. The Vice President of Research/IO also defines and assigns responsibilities for other essential program elements such as personnel training; occupational health and safety, and maintenance of facilities The IO may disapprove an activity involving animals. However, the IO may not approve animal activities or reinstate animal activities that were suspended by the IACUC. The IO is responsible for submitting required external reports and assurance updates.

- Personnel Involved in the Care and Use of Animals - All personnel involved in the care and use of animals, including, but not limited to, professional, management and supervisory personnel; animal care personnel; and research investigators, instructors, technicians, trainees, and students, must ensure they are qualified for or supervised during conducting procedures on animals; fulfilling training requirements, enrolling in the occupational health program, and following/carrying out IACUC decisions.

- Veterinarian - The University's veterinarian shall be responsible for quality husbandry programs and veterinary medical services, as well as expert consulting for selection, care and use of animals at the University. The veterinarian shall provide guidance and oversight on handling, immobilization, sedation, analgesia, anesthesia, and euthanasia. He or she shall provide guidance and oversight on surgery programs and oversight of post-surgical care. The veterinarian has authority to oversee all aspects of animal care and use and shall have access to all areas where animals are housed or used.

5. IACUC Procedure

- Committee Composition
    - Appointment of Members - Institutional Animal Care and Use Committee (IACUC) members are appointed by the Vice President of Research/IO within the Office of Research and Sponsored Programs (ORSP).
    - Number of Members - The IACUC shall have at least five voting members. If one member possesses more than one of the PHS-required roles outlined below, there still must be at least 5 members on the committee.
    - Required Member Qualifications - The IACUC shall consist of members with at least the following expertise/qualifications. If a member possesses one or more of the following required criterion and leaves the committee, the IACUC cannot conduct official business until a replacement possessing similar qualifications of the leaving member is appointed by the IO or designee. One member may have more than one area of expertise, with the exceptions contained in the section below and:
        - One Doctor of Veterinary Medicine who has training and/or experience with lab animal science and medicine. This member shall have direct responsibility for research and teaching activities involving animals at the University. One practicing scientist experienced in research activities that involve animals.
        - One member with primarily nonscientific concerns (e.g., ethicist, attorney, clergy member).
        - One member who is not affiliated with the University in any way other than serving as a member of the IACUC and who is not an immediate family member of an individual who is affiliated with the University.

- Alternate Members - Alternate members may be appointed as necessary to attend meetings when regular voting members cannot attend. Alternate members shall have the same rights as regular members. An alternate member can be designated for multiple regular members, so long as the alternate fulfills the specific membership requirements (e.g., nonscientist) as the member(s) he or she replaces. However, an alternate is disallowed from representing more than one member at any one time. However, it is allowable to appoint multiple alternates to represent a particular member, again, so long as the alternates fulfill the specific membership requirement(s) as the regular member. All alternates cannot vote, if the regular member (s), he or she represents is in attendance.

- Meetings
  - Frequency - Meetings shall be held once a month unless there is no official business to conduct. At minimum, a meeting shall be held every six months.
  - Quorum Requirement for Conducting Official Business: The determining factor as to whether official business can be conducted is whether quorum is present. Official business, for which a quorum must be convened, includes but is not limited to, conducting full committee review and approval of a proposed project or significant change to a project, and/or other voting items.
  - A quorum shall consist of a majority of the voting members (at least 50% of the members plus one). Abstentions from voting do not alter quorum or change the number of votes required. No specific member need to be present at a convened meeting to conduct official business.

- Conflict of Interest
  - Members that have conflict of interest may be present at the meeting during questions, but they will recuse themselves during discussion and voting. Members with a conflict of interest shall not contribute to the quorum for the vote on the project for which they have a conflict of interest.
  - No compensation to voting members should be so substantial as to influence voting or constitute an important source of income; as such compensation may rise to the level of creating a conflict of interest.
  - Abstentions from Voting for reasons other than conflict of interest do not alter the quorum nor change the number of vote required for approval. However, a member's recusal due to conflict of interest alters quorum and the committee must ensure the necessary number of voting members are present to conduct official business.

- Attendance

Chronic nonattendance by members implies a lack of participation in oversight responsibilities of the IACUC and will be addressed appropriately. Such measures might include adding additional members or removal from the committee when necessary.

- Minutes

  The University shall maintain IACUC meeting minutes, records of attendance, activities of the committee and committee deliberations. Such records shall be kept for a minimum of three years. The minutes shall include documentation of major issues discussed by the committee and the outcomes of those discussions in sufficient detail for an outside person to ascertain the nature of the discussion and conclusions reached. Transcripts/tape recordings of meetings are not required.

- Compensation to Nonaffiliated Members

  Nominal compensation for serving on IACUC as well as reimbursement for expenses such as parking, travel, and paying for training does not jeopardize the nonaffiliated status of the member. For compensation and conflict of interest, please see the conflict of interest section of this policy.

- Teleconference/Videoconference Meetings

  Video/tele-conference meetings may be conducted in accordance with the guidance on NIH Guide for Grants and Contracts NOT-OD-06-052.

6. IACUC Review of Research Protocols

Before beginning research or teaching activities or submitting an IACUC approval date to NIH, the protocol must be reviewed and approved by the IACUC. All applications to the IACUC must be done through IRBNet at www.irbnet.org . The IACUC must approve protocols before animals are acquired. Prior to the IACUC meeting, each IACUC member shall be provided with a list of proposed research and/or teaching projects to be reviewed. Written descriptions of research projects involving the care and use of animals shall be available to all IACUC members.

- Protocols
  - All research and teaching protocols involving animals must be reviewed and approved by the IACUC before such activities take place.
  - Field Work/Collection of Samples Animal activities falling under the necessity of IACUC review are not limited to work within the lab, and include but are not limited to, field work and collection of biological samples from any live vertebrate

animals in captivity or in research colonies. This section encompasses such collection taking place in foreign countries. During review of such activities, IACUC shall consider the species involved, nature of specimens, invasiveness of procedure, risks to personnel, and qualifications of individual(s) taking sample(s). The University shall consult with other agencies as appropriate, e.g. US Fish and Wildlife Service, USDA-APHIS- Veterinary Services, and the CDC for specimen importation requirements.

- Breeding Programs/Blood Donors/Sentinels in Disease Surveillance Programs and other Non-Research Purposes Such activities involving animals at the University shall also require review and approval by the IACUC before they are commenced.

- New Protocol Application:

Before commencing research activities, the PI must submit a new IACUC protocol application along with other supporting documentation listed in the IRBNet to the IACUC for review and receive written IACUC approval.

- Annual Report:
  - As part of the IACUC's written approval of a PI's initial protocol, the IACUC shall give notice to the PI of when he or she must submit an Annual Report.
  - A report of the PI's activities must be submitted to the IACUC annually. Upon receipt of the annual report, the IACUC may ask for more information and may require modifications to the previously approved protocol if necessary to preserve the safety of the animals.
  - Annual review must be completed by the anniversary month of the protocol.

- Tri-Annual Renewal:

The An IACUC approval of a protocol must be renewed every three years. The IACUC shall conduct de novo review or tri-annual renewal by submitting all required forms as a new study.

- Significant Changes to Protocol

  Whenever a PI wishes to make a significant change to an IACUC- approved protocol, the Principal Investigator shall first submit a Protocol Amendment Form to the IACUC and secure IACUC approval before carrying out such a change.

  Examples of Events that Constitute Significant Change Requiring IACUC Review. Such examples include, but are not limited to, changes:

  1. Study objectives;
  2. Changes from non-survival to survival surgery;

3. Greater discomfort or greater degree of invasiveness for the animal.
4. Ten percent (10%) or greater increase of previously approved animal numbers;
5. Changes In the species;
6. Changes in the principal investigator;
7. Method of euthanasia;
8. Increased duration, frequency, or number of procedures to be performed on an animal;
9. Housing or use of animals in a location that is not part of the animal program overseen by KCU;
10. An impact to personnel or animal safety;
11. Changing or adding location of activities involving animals.
12. Whether or not a project is receiving federal funding, if the proposed change in scope is also a significant change that proposed change must be reviewed and approved by the IACUC.

Proposed changes that do not fit the category above, may or may not be determined to be significant, such determination will be made by the Chair or designee.

- Changes that are not deemed significant

Changes that are not deemed significant do not have the potential to impact substantially and directly on the health and well-being of animal subjects and may be approved by DMR. Whenever a PI wishes to make a change to an IACUC approved protocol, the principal investigator shall submit a Protocol Amendment Form to the IACUC.

Changes not deemed significant that may be administratively updated include:

1. The correction of typographical errors and/or grammar,
2. Contact information updates, or
3. Personnel addition or removal.

All changes will be approved for the duration of time remaining in the original approved protocol and will not begin a new three-year project period.

7. Noncompliance / Complaints /Adverse Events

- Individuals concerned with the welfare of an animal(s) involved with a research or teaching project or aware of non-compliance with this policy or any of the policies, rules, regulations, and laws regarding animal care and use for research and teaching, should contact the Research Compliance Coordinator, IACUC and / or the IO.

- Noncompliance and adverse events regarding research protocols should be submitted on an Adverse Event/Non-Compliance Form in the IRBNet and to be reported to the Office of Research and Sponsored Programs at 816-654-7602.
- For adverse events involving biohazardous spills, consult the University's Biosafety Policy.

8. Changing or Adding Location of Activities Involving Animals

- Before making any changes to the location of a research or teaching activity involving animals the PI must submit a Protocol Amendment Form and secure an approval letter from the IACUC after inspection of the new location.

- Before adding an additional location for activities involving animals, the PI must submit an Additional Location Form.

9. Ordering Animals

In order to have animals shipped to KCU; the submitted Animal Order Form request must be reviewed and approved by the Manager for Research Operations and Safety Compliance and the Vice President for Research before being approved by the Finance Department.

10. Financial Conflict of Interest Form

With every Annual Renewal of an animal use protocol the PI and all research personnel must submit a Financial Conflict of Interest Disclosure Form.

11. Review Forms for IACUC Committee Members

- Reviewer Forms/Checklists

IACUC reviewers may use the Reviewer Worksheet – Initial and Tri-Annual Renewal Review as reference for every initial and tri-annual IACUC application. If the review is reviewed by FCR, the Chair may complete the Reviewer Worksheet in a way that summarizes the options and votes of the members at a convened meeting which includes dissenting opinions. If the review is reviewed by DMR, the reviewer may complete the Reviewer Worksheet. If there is more than one reviewer, the reviewers must be unanimous in any decision. The Worksheet has been developed to aid members assessing protocols.

12. Timelines, Deadlines, and Expiration Date

- IACUC approvals for protocols are valid for three years from the date specified as the approval date in the IACUC's written approval. There are absolutely no extensions or grace periods. Please note that an annual report must be submitted.

- Consequences for Continuing Research Activities after IACUC Approval has lapsed are considered Serious Non-Compliance.

- Research activities that are part of expired protocols shall be suspended upon the protocol's expiration if IACUC approval has not been timely secured. If previously approved activities are continued past the expiration date of approval without timely renewed IACUC review and approval, such continuation is considered serious noncompliance and shall be reported to OLAW for applicable, federally funded studies. Serious noncompliance in any study, regardless of federal funding, will be externally reported as required and result in suspension of the research and/or teaching activity and subject the appropriate individuals to discipline under the University's disciplinary policy.

13. Types of IACUC Review

The following are the types of IACUC review of protocols. The specific method of review for any protocol, along with the outcome, must be documented in the IACUC records and minutes.

- Receipt & Pre-Review

  The Research study, Protocol, and any other supporting documentation must be submitted in the IRBNet online system. All the forms and templates are available for the researchers in the IRBNet system under forms and templates. All research study materials must be submitted at least two weeks prior to the IACUC meeting for proper pre-review. Meeting dates and deadlines can be found on the IACUC Webpage. Only submissions received two weeks prior to the IACUC meeting will be guaranteed review at the IACUC meeting.

  To assure timely approval, it is also recommended that researchers obtain any necessary veterinarian consultation review prior to the two week deadline. Once submissions are received, the Research Compliance Coordinator will notify the IACUC Chair and Veterinarian for pre-review. In consultation, the Chair, Veterinarian, and Research Compliance Coordinator will determine if the submission requires significant revision or can be considered further for review. Once approved for further consideration, the Research Compliance Coordinator will grant access of the submission to all members of the IACUC.

  For official business requiring a convened quorum for action, The Chair may also assign one or more other reviewers to conduct a pre-review. The primary or primary and secondary reviewers of a protocol are usually chosen for their expertise or familiarity with a given topic

and take responsibility for inputting a summary of their review in the electronic system before the full convened committee meeting. The reviewers also take responsibility for describing the proposal during review and discussion by the Committee which has also reviewed the protocol(s), for discussion at the convened meeting

- Full-committee review.

  Full Committee Review occurs during a convened meeting of a quorum of the IACUC members, and with a formal vote. Full IACUC review results in approval, designated Members Review, modifications required to secure approval, or withhold approval. A majority vote of the quorum members present at a convened meeting is required to approve, require modifications to secured approval, or non-approval. When using the Full Committee Review method, polling each member individually in lieu of a convened quorum is not allowed.

- Designated member review by one or more members (DMR).

  This type of review may only be employed after all voting members have been provided an opportunity to call for full-committee review and discussion. If any member requests full committee review, then full committee review must be utilized. DMR may be used for initial applications/protocols, referred significant and other changes/modifications, or annual continuing reviews.

  The IACUC chair may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). Designated review may result in approval (requires DMR approval or all designated DMRs approval, if more than one, assigned to review the protocol application), require modifications to secure approval, or referral to full committee review. Designated review may not result in a withholding of approval. Responses from investigators will be forwarded to the original designated reviewer(s), if available. The Chair can reassign reviewers if the original designated reviewer is not available.

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

  a. For submissions including the initial protocol application, a significant change/modification, annual continuing review, etc., all voting members of the committee receive an email one week in advance informing them of the study in order to review given the 3-business-day opportunity to request if the full committee be convened for discussion.

b. All protocols approved by DMR during the current month will be noted in the meeting minutes.

- Opportunity for Full Committee Review

  For any protocol submission to the IACUC by the Principal Investigator, including the initial protocol application, an amendment, a continuing review application, ~~etc.~~, all voting members of the committee must be given the opportunity to request that the full committee be convened for discussion. This requirement even applies to reviews that have been approved for designated member review.

- Administrative Review

  For any submission of personnel addition submitted by the principle investigator to the IACUC, the Chair and the Vice-chair will conduct the administrative review of the submitted package (except if there is a conflict of interest) and the outcome of the review will be communicated to the principle investigator. The outcomes of the administrative reviews are either approved, information requested, or modification required to secure approval or FCR. The administrative review could not be completed by the Ex-officio members.

14. Review Criteria

- The IACUC shall review the following elements of protocols. This list is not necessarily meant to be exhaustive:
  - Ensure proposals conform to University's Animal Welfare Assurance
  - Protocols meet the requirements specified in PHS Policy
  - The PI has provided the information described in PHS Policy
  - Protocols are consistent with the Guide unless there is a departure presented with scientific justification that is presented to and approved by the IACUC.
  - Consistency with the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. This requires, in part, analysis of the scientific merit of the project, justification for the number and type of animals, consideration of alternatives to live animals, refinements to research, reduction of animal numbers and replacement with non-animal models.
  - If applicable, the protocol will be conducted in accordance with the USDA Animal Welfare Regulations.
  - Potential for pain and distress to the animals associated with proposed experimental manipulations. This includes clinical and behavioral abnormalities known to be potentially present in spontaneous or induced animal models (e.g., mutant and transgenic mouse strains).

- Use and method of euthanasia and the endpoints. Methods of euthanasia used must be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia. PI must use appropriate pain and distress anesthetics / analgesics in painful procedures and conditions that to be distressful to the animals. These analgesics can only be withheld in a potentially painful or distressful procedure, that the PI has provided a specific, scientific justification. The IACUC must evaluate whether the scientific justification is adequate to approve the protocol by conducting a risk-benefit analysis.
- Fulfillment of training requirements by appropriate research personnel as specified online at the ORSP Compliance Website. IACUC approval shall be withheld until proof of satisfaction of training requirements is provided.
- When applicable, enrollment in the University's Occupational Health Program. IACUC approval shall be withheld until proof of satisfaction of training requirements is provided.
- Approval by other applicable research committees such as the Institutional Biosafety Committee and/or Institutional Review Board or other committees or University officials as needed.
- Adequate veterinary consultation has been obtained when necessary.
- Any other elements specified on any of the forms in the IRBNet IACUC documentation for Researchers that are submitted for IACUC review.
- Any and all applicable additional/updated federal, state or locally mandated review criterion not herein mentioned.

15. Outcomes of Review

- There are three possible outcomes of review of an initial protocol application, annual continuing report, or modification:
- Approval

  IACUC has determined that all review criteria have been adequately addressed by the investigator. The IACUC may approve the proposal, thus providing the investigator permission to perform the experiments or procedures as described in the protocol application.

  - Modifications Required to Secure Approval

  The IACUC may require modifications (revisions) to the proposal before granting approval. If the IACUC determines that a proposal is approvable contingent upon receipt of a very specific modification, or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details that an individual, such as the Chair or designee, could verify or by DMR.

- Withhold Approval

When the IACUC determines that a proposal has not adequately addressed all the requirements as applicable, the committee may withhold approval. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

The IO may not administratively overrule an IACUC decision to withhold approval of a proposal.

- Such actions require a vote by a convened quorum. It is insufficient to poll each member individually in lieu of a convened quorum when using the full committee method for review.

- PI Notification of Outcome - The IACUC shall notify the principal investigators and the University in writing of its decisions regarding protocols. If the IACUC withholds approval of an activity, it shall include in the written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond.

IACUC approvals for protocols are valid for three years from the date specified in the IACUC's written approval. Written approval will note the approval and expiration date of the protocol. There are absolutely no extensions or grace periods. Note that an annual review must be submitted each year and approved.

16. Veterinarian Consultation

- Federal regulations mandate that the veterinary be consulted when planning studies that involve the potential for pain or distress to animals. Therefore, the veterinarian shall be consulted when necessary for such protocol elements that include, but are not limited to:
    a) Regimens for anesthetics, analgesics and tranquilizers, including monitoring.
    b) Behavioral and other indicators of species-specific signs of pain and distress.
    c) Surgical approaches and aseptic technique.
    d) Post-procedural monitoring/intensive care. The veterinarian shall train a PI in pain/distress minimizing techniques when necessary.
    e) Euthanasia

17. Post Approval Monitoring

Post approval monitoring consists of annual continuing review or protocols, the Manager for Research Operations and Safety Compliance performing routine observations for any abnormalities, at least monthly veterinary walk-throughs of the facility, hands-on training in animal procedures, appropriate reporting of incidents

involving occupational health and safety and the IACUC semi-annual inspections for the facility and labs, in additional to the annual continuing review of protocols. IACUC members may, and are urged to, conduct walk-throughs of the facility at any time.

18. Suspension of Activity

The IACUC will be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

- The IACUC is empowered to suspend a protocol if it finds violations of the PHS Policy, Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with a vote for suspension from a majority of the quorum present. The IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action to correct the situation and prevent a recurrence, and report the action with a full explanation to OLAW and any federal agency funding that activity. At the time of suspension of the protocol, the IACUC will vote on terms of reactivation of the protocol.

- The Principal Investigator will be notified in writing of the suspension as well as of any actions that are required in order to lift the suspension.

- The Attending Veterinarian, or designee, may suspend animal-related protocol Activities prior to IACUC review, if warranted, because of serious and urgent animal welfare and safety concerns. The initial notification of suspension will be verbal followed by written documentation to the PI and IACUC.
- The IACUC may vote to reactivate (approve) the protocol after FCR at a convened quorum of IACUC by a vote of the majority vote of the quorum present. Protocols will be reactivated only after violations have been corrected.

19. Semi-Annual Review of Animal Care and Use Program and Animal Facilities

- Required Evaluations & Frequency of Evaluation
    - Review at least once every 6 months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
        - A subcommittee of at least three voting IACUC members and/or alternates, to include the Chair and veterinarian (or designees), shall conduct a review of the University's care and use of animal program, including the Animal Handlers' Occupational Health program. The IACUC shall conduct the review at a minimum, once every six months using the PHS Policy and the Guide for the Care and Use of Laboratory Animals: Eighth Edition in conjunction with the recommended Semiannual Program Review and

Facility Inspection Checklist, which may be modified so relevant topics are considered.

- All IACUC members are apprised of the review schedule and invited to participate; No IACUC member wishing to participate shall be excluded from any portion of the review. The review may include, but not necessarily be limited to, a review of the following: 1) IACUC Membership and Functions; 2) IACUC Records and Reporting Requirements; 3) Husbandry and Veterinary Care; 4) Assessment of Personnel Qualifications and Training; 5) Occupational Health and Safety; and 6) Emergency Preparedness and Disaster Plan. The university's Standard Operating Procedures and PHS Assurance will be reviewed.

- Inspect at least once every 6 months all of the Institution's animal facilities, lab where animals are used, including satellite facilities and animal surgical sites, using the Guide (8th ed.) as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

  - A subcommittee of at least three voting IACUC members and/or alternates, to include the Chair and veterinarian (or designees), shall conduct a separate review of the University's care and use of animal facilities. All IACUC members are apprised of the inspection schedule and invited to participate; No IACUC member wishing to participate shall be excluded from the inspection. The IACUC shall conduct a separate review at a minimum, once every six months using the PHS Policy and the Guide for the Care and Use of Laboratory Animals: Eight Edition in conjunction with the recommended Semiannual Program Review and Facility Inspection Checklist, which may be modified so relevant topics are considered.

  - All animal facilities will be visually inspected, to include any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is defined as any containment outside of a core facility or centrally designated or managed area in which animals are house for 24 or more hours.

  - The IACUC will have access to all investigators' animal laboratories for the purpose of verifying that activities involving animals are conducted in accordance with the proposal approved by that committee. The university's Standard Operating Procedures and PHS Assurance will be reviewed.

- Facilities Requiring Inspection
    - All campus animal facilities.
    - Satellite facilities: containment outside a core or centrally managed area in which animals are housed more than 12 hours.
    - Area where any form of surgical manipulations are performed: minor, major, survival, non-survival.
    - Field Studies: While semiannual IACUC inspections of field study sites are not required and in many circumstances are impractical, the IACUC 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 shall 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.
    - All areas where animals are taken for experimental manipulations.

- Inspection Reports

  The IACUC prepare reports of its evaluations according to PHS Policy IV.B.3. and submits the reports to the Institutional Official.

20. Reporting

- Internal Reporting Requirements

    - Contents of Report
        - Description of the nature and extent of the institutions adherence to the Guide of the Care and Use of Laboratory Animals, the PHS Policy, and the Animal Welfare Act.
        - The report(s) will identify specifically any departures from the provisions of the Guide, the PHS Policy, and AWA and must state the reasons for each departure.
        - The report(s) distinguishes between significant and minor deficiencies. If deficiencies are noted, there must be included a specific and reasonable corrective plan, responsible party (ies) and a schedule for making the corrections.
        - The reports will note minority views of the IACUC. If there are not minority views, the reports will state such. Any IACUC member may submit a minority view addressing any element of the University's animal program, facilities, or personnel training. The University shall maintain records of minority views when expressed 1) as recommendations to the IO and/or 2) during semiannual inspections. Such

minority views shall be included in an Annual Report to OLAW when such a report is required.

- Signature of a majority of the IACUC members

- The IACUC shall provide a copy of the final semiannual report to the Research Compliance Coordinator. The Coordinator shall monitor compliance with required corrective actions, as identified in the final semiannual report, and shall keep the IACUC abreast. If any deficiencies are not remedied within the time period set forth in the final semiannual report, the IACUC may take appropriate corrective action.

- "Deficiency" Definitions

  - Significant Deficiency: Deficiency that does or may be a threat to health or safety of animals or people. E.g., inoperable HVAC, electrical or watering systems, failure of systems that affects critical housing, operational areas, situations such as natural disasters that cause injury and death, or severe distress to animals. The University's failure to fully understand and/or implement some aspect of its animal care and use program required by PHS Policy or failure to uphold commitments made in the assurance may reach level of reportable noncompliance.
  - Minor deficiency: problem for which immediate solution is not necessary to protect life or prevent distress (e.g., peeling or chipped paint). But ongoing inattention to minor deficiency can lead to chronic problem that constitutes programmatic failure that is a significant deficiency.

- External Reporting

  - General

  The University has an assurance with OLAW; the IACUC is responsible for developing an annual report for the IO to submit to OLAW. The content that must be reported is specified in this policy and the PHS Policy. The IACUC and IO are responsible for being familiar with the PHS Policy that covers situations that must be reported to OLAW.

  - Timeframe for Reporting
    - Annual Report
      - Reports to OLAW shall cover a 12 month period. The report is due at the end of the month immediately following the end of the University's reporting period. The University shall use the following calendar year as a reporting period (October 1 – September 30). The report to OLAW is due December 1 for that calendar year.

- Noncompliance Report
  - The IACUC, through the IO shall promptly provide a report to OLAW with the full explanation of circumstances and actions taken with respect to any serious or continuing noncompliance, serious deviation from the provisions of the Guide and/or any suspension activity by the IACUC.
- Contents of Reports

  The OLAW annual report shall contain any changes in the University's program of animal care and use (changes to any elements of the program description outlined in PHS Policy, IV.A.1.a.-I must be reported), AAALAC accreditation status, changes of the IO and in IACUC membership, dates IACUC conducted semiannual evaluations of the program and facilities. Descriptions of program changes should be comprehensive and sufficiently detailed to replace information in the currently approved assurance. A full explanation of circumstances and actions taken with respect to any serious or continuing noncompliance, serious deviation from the provisions of the Guide and/or any suspension activity by the IACUC or IO shall be included in the report.

  If the IACUC finds no reportable changes have occurred, the IO must report such in writing to the funding component. Annual reports shall represent the consensus of the IACUC and include any minority views filed by IACUC members. Note, reports shall include, whether or not any reportable changes have occurred, notice of the dates that the IACUC conducted its required IACUC evaluations of the animal care program and facilities and dates such evaluations were submitted to the IO.

- All reports shall contain minority views.
- Clarification Regarding "Minority Views" that Must be Reported, the PHS Policy IV.E.1.d describes in detail the recording/reporting requirements for minority views. Any IACUC member may submit a minority view to OLAW addressing any element of the University's animal program, facilities, or personnel training. The University shall maintain records of minority views when expressed
  - As recommendations to the IO and/or
  - During semiannual inspections. Such minority views shall be included in an Annual Report to OLAW, when such a report is required.

  A minority view is not the same as a dissenting vote during an IACUC review of a protocol or suspension of a protocol. Such dissenting votes must be recorded in the meeting minutes, but do not constitute a minority view(s) subject to OLAW's reporting requirements.

21. Recordkeeping

- The Office of Research and Sponsored Programs shall maintain records of the following:
    - The Office of Research and Sponsored Programs shall maintain a copy of the University's PHS-approved assurance.
    - IACUC meeting minutes, including records of attendance, activities of the committee and committee deliberations.
    - Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or held.
    - Records of semi-annual IACUC reports and recommendations (including minority views) as forwarded to the IO.
    - Records of accrediting body determinations.
    - Reports of noncompliance/adverse events.

- Length of Time Records Shall Be Maintained
    - All records shall be maintained at least three years.
    - Records relating directly to applications, proposals, and proposed significant changes (amendments) 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.

- Accessibility of Records

All records regarding projects shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

22. Complaints Regarding Policy/Animal Welfare Violations

- Individuals concerned with the welfare of an animal(s) involved with a research or teaching project or aware of non-compliance with university policy or any of the policies, rules, regulations, and laws regarding animal care and use for research and teaching, should contact any of the following individuals: Attending Veterinarian, IACUC Chair, Institutional Official, Research Compliance Coordinator, Manager for Research Operations, Safety Compliance, or any IACUC member. Contact information may be found on the IACUC Compliance webpage, by searching the KCU website, or by postings throughout the animal facility.

  Allegations may be issued verbally or as a written document. Persons are not required to be identified for an allegation to be submitted; however, it is the responsibility of the person(s) receiving the complaint to fully document all communication regarding the allegation to prevent miscommunication or misunderstandings.

The IACUC will review all concerns in a timely and systematic manner and, when necessary, take prompt, appropriate corrective action(s). Action taken will be driven by the potential significance of the alleged situation. Requests of confidentiality will be honored to the extent possible and allowable by law. This includes protecting the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The policy of the university is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participant in an investigation pertaining to, allegations of wrongdoing. Reporting to external agencies, possibly to the NIH, may be necessary depending on type of event and funding agency requirements. Noncompliance complaints should be documented / submitted on the Adverse

- Whistleblower Protection

  Complaints are confidential and will remain anonymous to the largest extent possible. By law, such "whistleblowers" are protected from being retaliated/discriminated against. University policy further protects whistleblowers from retaliation.

- Complaint/Investigation Procedure

  The IACUC will review all concerns in a timely and systematic manner, then upon report to the Chair (or designee), in consultation with the AV, will determine if further review is needed. If it is warranted, an IACUC subcommittee of the Chair or designee and at least 2 IACUC members should conduct the information gathering investigation and report back to the IACUC by an imposed completion date. There shall be no actual or perceived conflicts of interest in this process. Information to be gathered depends on the circumstances, but often involves:

  a. Interviewing complainants, any persons against whom allegations were directed, and pertinent program officials;
  b. Observing the animal and their environment; and
  c. Reviewing any pertinent records (e.g., animal health records, protocol and other documents).

  The report to the IACUC should summarize the concern(s), the results of the interviews, the condition of animals and their environment, the results of records and other document reviews, any supporting documentation such as correspondence, reports and animal records, conclusions regarding the substance of the concerns, and recommended actions, if appropriate.

Upon receipt and evaluation of the report, the IACUC may request further information or find that:

a. There was no evidence to support the concern or complaint
b. The concern or complaint was not sustained, but conclusion is:
    i. Related aspects of the animal care and use program require further review Other institutional programs may require review
    ii. Concern or complaint was valid
d. Subsequent actions of the IACUC may include
    i. Implementing measures to prevent recurrence (such measures may include change in administration, management, IACUC policies and procedures, and recommended action to the IO for implementation);
    ii. Notifying the IO and the AV of its actions (written notice delivered by email and in person, if possible)
    iii. Notifying funding or regulatory agencies, as needed; and
    iv. Notifying the complainant, any persons against who allegations were directed, the pertinent program officials (appropriate supervisory and management staff, public relations office, institutional attorneys, etc.).

23. Guide for Animal Use and Management

All personnel involved in the care, maintenance or use of animals and subject to this University policy shall carry out activities involving animals in accordance to the Guide. Principal Investigators contemplating animal research activities shall develop standard operating procedures for their labs in accordance with the standards set forth with the Guide and when necessary veterinary consultation. If animal lab work also involves biologically hazardous materials an application to the Institutional Biosafety Committee and adherence to all the Biological Safety policies and procedures is required before work in the lab may begin.

24. Training

- Principal Investigator and Researchers

  Researchers, staff, and volunteers are trained and understand the hazards associated with their work area and job/research duties, and how those risks are mitigated through institutional policies, controls, work practices and personal protective equipment.

  - Institutional Training

Annual mandatory animal care and use training meets the needs of each type of personnel, as referenced in the Guide under General Training Objectives. Training is provided in Dybedal Research Center at various times and includes:

a) Use of animals in research briefing
b) Topics under the 3 R's (replacement, reduction and refinement), to include training on research or testing methods that minimize the number of animals required to obtain valid results and limit pain and distress,
c) Training in recognition and alleviation of animal pain, distress, and abnormalities,
d) Approved euthanasia techniques
e) Reporting noncompliance or adverse events
f) Occupational health and safety
g) Handling potential hazards (safety)
h) Zoonosis
i) Personal hygiene
j) Personal protection equipment
k) Limitation of protective equipment
l) Emergency preparedness
m) Accident procedures

Training on the following topics is provided via web-based training courses every 3 years to all researchers: Working with the IACUC, Animal Biosafety, and Conflicts of Interest. Additional courses may be required that are specific to their research, such as Working with Zebrafish, Working with Mice in Research, Reducing Pain and Distress in Lab Mice and Rats, Aseptic surgery, etc.

- Protocol specific training is provided by the principal investigator for persons working under his/her supervision. Specific protocol training includes potential hazards, personal protection equipment, and limitations of protective equipment, research responsibilities, and hands-on-experience with required techniques. Detailed procedural training of student researchers or research assistants may be conducted by the PI after the person has been added to a protocol and must be pre-approved by the IACUC.
- Enrolling in the Occupational Health and Safety Program

- IACUC Members

All personnel serving on the IACUC receive training to allow them to perform their duties.

- Orientation for new IACUC Members

a) Federal, state, local laws, regulations and policies, along with the Standard Operating Procedures, will be provided as required orientation reading. The pdf versions of PHS Policy, the Guide for the Care and Use of Laboratory Animals and the OLAW/ARENA IACUC Guidebook are provided to each member. Discussion concerning the syllabus information, operational procedures, records, semiannual reviews and roles, responsibilities, and relationships will take place during the first IACUC meetings. Questions from new members may be answered at any time during the meetings.

b) Web-based training courses for IACUC members are to be completed / current before becoming an active member: IACUC Chairs, Members and Coordinators (or IACUC Community Member for nonaffiliated members), Animal Biosafety, Conflicts of Interest. Animal specific courses may also be required. Alternative training may be substituted as approved by the IO or Chair (or designee). The Chair will complete the above courses, plus courses related to working with zebrafish and mice.

c) Orientation Objectives

- ✓ Use of animals in research briefing
- ✓ To introduce member to the role of the IACUC and its evolution
- ✓ To provide the basic information necessary for IACUC member to discharge their responsibilities (to include training on research or testing methods that minimize the number of animals required to obtain valid results and limit pain and distress)
- ✓ To provide a forum for response to, and discussion of, members' concerns and questions

- o Continuing Education and Training

Continuing education and training will be provided through various mediums including, but not limited to, publications, industry best practices, conferences, seminars, IACUC 101 workshops, webinars, in-house sessions, external speakers, etc. The objectives of providing ongoing training for IACUC members is to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It provides a regular forum for the IACUC to discuss concerns or questions brought forth by the faculty, staff or member of the community.

- o Enrolling in the Occupational Health and Safety Program

- Maintenance, Facilities, Security, and other Support Staff

Staff and contractors are trained and understand the hazards associated with their work area and how those risks are mitigated through institutional policies, controls, work practices and personal protective equipment.

  - Enroll in the Occupational Health and Safety Program

- Approved Visitors

Occasionally, non-employees may require access to KCU lab and animal facilities. These individuals may involve touring research collaborators, regulatory or accreditation site visitors, and vendor personnel (equipment and/or maintenance).

The non-employees request to access to animal facilities includes the following process:

1. The visitor's host must notify the Manager for Research Operations and Safety Compliance or designee, in writing, at least one (1) business day before the visit:
2. Name of visitor, his/her institution, agency, or company, purpose of the animal facility visit, date(s) involved, and email and phone number for visitor.
3. Visitors must sign an Animal Care and Use Medical Waiver before entrance into the land and animal facility.
4. An approved escort must accompany all visitors when in the animal facility.
5. A log of the visitors is kept with the Manager for Research Operations and Safety Compliance.