

UMKC IACUC Guide Book

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Revisions to the Guidebook:

This Guidebook is intended to be flexible and readily adaptable to changes with regulatory and UMKC institutional requirements and IACUC Policies. This document is intended to be only a Guide and does not supersede the IACUC policies. This Guidebook is reviewed as part of the semiannual program reviews to assess whether it is appropriate. It will be changed as experience shows that a certain approach is not effective or suggests a better alternative. The UMKC IACUC has the authority to amend this guidebook.

A. The Animal Care and Use Committee (IACUC)

Functions

The IACUC is the Chancellor's advisory committee responsible for oversight and evaluation of all the animal care and use on the UMKC campus. An IACUC is required by the federal Animal Welfare Act Regulations (9 CFR, Chapter 3), in the National Research Council's *Guide for the Care and Use of Laboratory Animals* (The Guide), and in the Public Health Service's *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy), as is an Institutional Official, who has the authority to commit the UMKC IACUC, to comply with AWA Regulations and PHS Policy.

The mandated functions of the IACUC include:

- Semiannual review of the institutional program for animal care and use;
- Semiannual inspection of animal facilities and animal-study areas;
- Submission of reports of the semiannual evaluations to the Institutional Official;
- Review and approve, require modifications to secure approval, review amendments, or withhold approval of proposed activities related to the care and use of animals;
- Make recommendations to the Institutional Official, Vice Provost of Research Support, regarding any aspect of the animal care program, facilities, or personnel training;
- Suspension of any animal care and use activity that does not comply with standards and approved protocols, and
- Review of concerns involving the care and use of animals at UMKC.

The Chancellor or Institutional Official may assign other responsibilities to the IACUC.

IACUC Membership and Chairman

Membership Criteria

The size of the committee is determined at the discretion of the IO, but should include the following:

- At least one scientific member from each academic unit that has more than three protocols approved for animal use; this currently includes:
 - Biological Sciences
 - Dentistry
 - Medicine
 - Pharmacy
- At least one librarian;
- At least one non-affiliated member that does not use laboratory animals;
- The Attending Veterinarian shall be a member of the IACUC in accordance with Federal policy and, because of specialized role and expertise, is excluded from the term limits below.
- Adhoc members: At least one person with expertise in biostatistics, one person with biosafety experience and one person with Occupational Health.

- A Chairperson will be appointed and charged with carrying out or designating the following responsibilities:
 - As a shared responsibility with the Institutional Official, Attending Veterinarian, ensuring compliance with IACUC-related USDA and PHS regulations, and AAALAC guidelines;
 - Recommending membership changes to the IO;
 - Convening/chairing meetings; designating acting chair if both the Chair and Vice Chair are unable to attend meetings; canceling meetings when appropriate;
 - Ensuring that a quorum is present to conduct meetings;
 - Ensuring that semiannual program reviews, facility and laboratory inspections are performed every six months and appropriately documented. Taking appropriate actions based on program review and facility inspection findings;
 - Ensuring adequate documentation of IACUC activities, such as meeting agendas, meeting minutes, inspection reports, and membership changes;
 - Acting as spokesperson on behalf of the IACUC, both internally and externally;
 - Representing the IACUC to USDA and FDA inspectors and AAALAC site visitors;
 - Coordinating the IACUC subcommittees;
 - Investigating cases of noncompliance and complaints about the care or use of laboratory animals. Aid in the preparation of the OLAW Assurance Statement and annual reports;
 - Reviewing and documenting approval of protocols, amendments, and protocol renewals/deletions.
- A Vice-Chair will be appointed to serve with the Chair. Vice-Chair responsibilities are to provide support to the Chair, serve as acting Chair in the Chair's absence or when the Chair has a conflict of interest. The Vice-Chair appointment does not imply that the incumbent will become the next chair.
- Ad Hoc non-voting attendees may be invited as needed. Examples of such attendee include, but are not limited to, representative(s) from Campus Facilities Management, Institutional or designee, and Past Chair (if no longer a member).

Membership Terms

Member Terms:

- Members, including the Chair, will serve on the IACUC for a term of three years.
- Members may be reappointed for one additional consecutive term. There are no lifetime term limitations; however, there must be at least one year between subsequent reappointments.
 - Under extraordinary and exceptional circumstances, the Institutional Official may waive the requirement for at least one year between subsequent reappointments.
 - The term for serving as Chair is 3 years. The term may be limited to 1 or 2 years if approved by the Institutional Official. The Chair may not serve for more than 4 consecutive years.
 - The term for serving as Vice Chair is 3 years. The term may be limited to 1 or 2 years if approved by the Institutional Official. The Vice Chair may not serve for more than 4 consecutive years.

Member Appointments:

The Chancellor, in consultation with the Institutional Official and IACUC Chair, has the authority to appoint members to the IACUC. Members will be solicited

from the University of Missouri - Kansas City and greater Kansas City communities.

Consultants

The Committee can invite internal or external consultants to assist the Committee in its duties; for example in the performance of protocol review. Such consultants cannot vote, but can provide their professional opinion. The IACUC remains responsible for its decisions that may be based on information provided by consultants.

IACUC Quorum

“Quorum” is defined as a majority (>50%) of the voting members of the IACUC. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

A quorum of the IACUC is required for full committee reviews of protocols and suspension of an activity. Convened IACUC protocol reviews can only be approved if a quorum is present and more than 50% of the quorum votes in favor. The IACUC uses the designated review process, but any IACUC member has the option to call for a full committee review.

IACUC Staff

The IACUC chair is typically the person who has the greatest impact on how an IACUC operates. UMKC, however, has created the Office of Research Protections, in which the IACUC Staff perform many of the supportive tasks normally associated with the Chair. This arrangement allows the freedom for the Chair to primarily run meetings and serve as a committee spokesperson. This also provides continuity for the IACUC during changes in Chair, Vice Chair, and individual members.

- The staff responsibilities include:
 - Preparing the USDA Annual Report for Research Facilities; submits reports to the USDA Animal Care Regional Director by December 1 of each calendar year;
 - Preparing and submitting reports to IO related to semiannual program reviews, facility and laboratory inspections;
 - Assisting investigators and IACUC representatives in obtaining current IACUC forms (e.g. protocols and amendment forms);
 - Screening new protocols for completeness and appropriate signatures;
 - Scheduling meeting times and locations for the entire year; sending a schedule to committee members, institutional officials, and principal investigators;
 - Drafting a meeting agenda and attachments prior to each meeting for approval by the Chair and subsequent distribution to the committee;
 - Recording meeting minutes that include, but are not limited to, attendance, review of protocols and amendments, and other committee decisions;
 - Drafting meeting minutes for Chair approval and subsequent distribution to the committee. The meeting minutes will be reviewed at the next IACUC meeting.
 - Assigning a protocol number to submitted protocols and entering them in the database following preliminary administrative review. Following IACUC review, approval,

- and final signature by the Chair, the coordinator sends a copy of the approval summary page to the PI, saves an electronic copy, and files the original copy;
- Maintaining files of IACUC documents; archiving inactive protocols files, destroying outdated documents greater than three years after the end of the protocol activity;
 - Initiating/tracking annual protocol renewal forms and protocol expiration forms;
 - Maintaining computerized database for tracking activity of protocols;
 - Notifying PIs when they reach 80 percent of the approved animal limit number; and
 - Distributing current list of approved, amended, and expired protocols at each IACUC meeting.
 - Maintaining a current principal investigator list;
 - On behalf of the Institution, ensure an evaluation of "scientific merit" has occurred for projects involving the use of animals. In most cases, the Institution will rely on the peer review process of submitted proposals used by scientific funding agencies (e.g. NIH and NSF). For projects not undergoing external peer review, the Institution will require a PI to obtain an external review for scientific merit. Documentation of scientific merit review will be maintained in the appropriate IACUC protocol files; and
 - Notifying PIs when 90, 60, and 30 days prior to the protocol expiration/renewal date.

B. Responsibilities of the IACUC

IACUC Policies and Procedures

The IACUC shall establish policies and procedures guiding the execution of its responsibilities. Major categories of IACUC policies and procedures are:

- Internal IACUC policies and procedures, including those for:
 - Protocol review;
 - Semiannual animal care and use program review;
 - Semiannual inspections of animal facilities and animal use areas;
 - Investigating concerns about animal care and use;
 - Suspending activities that do not comply with standards or approved protocols.
- External IACUC policies and procedures that guide researchers, animal care program staff and others in interacting with the IACUC, including those for:
 - Preparing and submitting an animal use protocol for IACUC review;
 - Protocol submission forms should include:
 - Justification for the numbers of animals proposed to be used;
 - Documentation of the search for potential duplicative procedures and procedures that may cause less pain and distress;
 - Scientific justification required for studies causing pain in which anesthetics and analgesics must be withheld;
 - Methods that avoid the use of death as an experimental endpoint;
 - Explanation of experimental methods.
 - Multiple survival surgeries
 - Prolonged restraint
 - Withholding food or water
 - Reporting concerns about the care and use of animals;

- Policy and procedure for responding to deficiencies cited by the IACUC in semiannual program review or facility inspection.
- The IACUC may approve policies and guidelines for animal care and use that are developed by the Laboratory Animal Center Staff and/or Attending Veterinarian. Examples include:
 - Sources and procedures for animal acquisition;
 - Quarantine and conditioning of animals;
 - Methods for anesthesia and analgesia;
 - Drugs and dosage regimens generally accepted as adequate for common laboratory species.
 - The Attending Veterinarian is consulted in planning studies that have the potential to cause more than momentary or slight pain or distress;
 - Guidelines for postoperative care consistent with current veterinary guidelines
 - Methods for Animal Euthanasia:
 - Methods for collection of biological samples;
 - Methods for administering materials to animals by various routes;
 - Animal handling and restraint;
 - Aseptic surgery methods in rodents;
 - Aseptic surgery methods in non-rodent mammals.

C. Review of Protocols

The IACUC shall:

- Review the animal care and use components of proposed research projects to ensure that procedures and practices are in compliance with the Guide, AWA regulations, NIH Assurance Statement, and any other regulations or policies which apply. When necessary, the IACUC will require further supportive information from the investigator or meet with the investigator to ensure that all members of the review committee understand the procedures to be used on the animal. If there is any variance from the guidelines noted above, the IACUC will require justification for the variance on scientific grounds.
- Ensure that the PI has submitted the “Grant Review Form” to Sponsored Programs and Research Support, or its designee, for review to verify the proposal related to the care and use of animals corresponds with grant application.

The IACUC may:

- Invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.
- No IACUC member may participate in review or approval of a research project in which that member has a conflicting interest. The conflicted member may provide information requested by the IACUC. A conflicted member may not contribute to the constitution of a quorum.

The IACUC shall:

- This review may be conducted by the Departmental Review Committee (DRC) of the Principal Investigator (PI), the NIH, or other funding agencies other than NIH listed on the “IACUC List of Funding Agencies That Conduct Acceptable Scientific Merit Review”.

- Proposed IACUC protocols must include documentation of current scientific merit review and/or approval from one of the listed agencies or from the appropriate DRC.

Use of Hazardous Agents

The IACUC must coordinate the review and approval of protocols with the appropriate safety committee. To that end, PIs must include prior approval notification from UMKC RSC and/or IBC with proposed animal use protocols when appropriate.

Actions Taken Prior to Protocol Review

After receiving a protocol submitted to the IACUC office, a member of the IACUC Staff conducts an administrative review followed by an assessment of veterinary care issues by the Attending Veterinarian. Questions raised during these reviews are resolved with the PI. Protocols passing administrative and veterinary review are subsequently submitted to the IACUC members for review.

Review by a Designated Reviewer

If full committee review is not requested, at least one member of the IACUC qualified to conduct the review will be designated by the IACUC or Chairperson. The assigned designated reviewer shall review the research projects and have the authority to approve, require modifications (to secure approval) or request full committee review of assigned research projects.

All IACUC members receive electronic copies of all protocols.

- Individual IACUC members are allowed one week to either request a full committee review or allow the protocol to be reviewed by a designated reviewer.
- If a member does not request convened IACUC review of a protocol, s/he may submit questions and/or comments for consideration by the designated reviewer during the review process.
- Members notify the IACUC Coordinator if they request a full committee review. The protocol is then reviewed at the next IACUC meeting, or a special meeting called for the review. If any member requests convened review, then any questions or comments that had been submitted about the protocol will be forwarded to the PI to provide an opportunity for him/her to provide answers or clarification prior to the convened review.

Designated Reviewer:

- If no member calls for a full-committee review, then the IACUC Staff or Chair can refer the protocol to a designated reviewer;
- The Chair may select one or more members thought to be qualified to review the protocol;
- The designated reviewer acts on behalf of the entire IACUC to approve the protocol.

The Designated Reviewer(s) may:

- Request additional information from the PI prior to approval;
- Require modifications in the protocol;
- Refer the protocol for full review;

Approve the protocol:

- The designated reviewer approval has the same validity as the full-committee approval;
- Once the designated reviewers approve the protocol, the Chair signs the approval form.

Acceptable Practices during the Designated Review:

- If there is no call for full-committee review, it is acceptable for members to share comments with a designated reviewer to use while conducting the designated review;
- IACUC may consider the lack of member replies within the prescribed time period as no requests for full review. If all members decline to request convened review prior to the end of the allocated time, the Chair may then implement the designated review process;
- If two designated reviewers are assigned to review a protocol, both have to agree for approval. If one does not agree on approval, the Chair cannot consider the protocol approved.

Full Committee Review

If full committee review of the protocol is requested, approval of those research projects may be granted only after completion of the review at a convened meeting of a quorum of the IACUC and with the approval vote of the majority present. If a member requests a convened review of a protocol either a special meeting is called to review the protocol or it is placed on the agenda for review at the next regularly scheduled meeting.

If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review, or returned for full committee review at a convened meeting.

If all members of the IACUC are not present at a meeting, the committee may use designated member review subsequent to full committee review, if all the IACUC members agree in advance in writing, that the quorum of members present at a convened meeting may decide by unanimous vote to use designated member review subsequent to the full committee review.

However, any member of the IACUC may, at any time, request to see the revised protocol and/or request full committee review of the protocol.

The IACUC members may vote to either continue the review a special meeting held via teleconferencing as per the “Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals” - Notice Number: NOT-OD-06-052.

Notification Approval of Protocol or Withholding Approval

- The IACUC Staff shall notify investigators and the institution in writing, via e-mail, 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.
 - If the IACUC decides to withhold approval of an activity, it shall include in its notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

There are two ways the Institution (IO) is notified of decisions regarding protocol review:

1. The IO is copied on all e-mailed agendas which indicate which protocols are to be reviewed at the upcoming full convened meeting.
2. The IO is copied on the e-mails with the meeting minutes attached. The meeting minutes include the results of the full committee reviews/decisions.

Modifications to a Protocol

The IACUC must review changes to a protocol that has animal welfare implications before the change is implemented. . Examples of animal care and use changes that require IACUC approval include changes in:

- The objectives of a study;
- Blood collection site, frequency, volume;
- Non-survival to survival surgery;
- Minor to major surgery;
- Increase from one to multiple survival surgeries;
- The degree of invasiveness of procedures or the level of discomfort, pain or distress to animals;
- Tumor being transplanted;
- The personnel involved in animal procedures;
- The species or approximate number of animals used in the protocol or in procedures within the protocol;
- Anesthetic or analgesic drugs or adding them if they were to be withheld, or withholding them if they were to have been administered;
- Methods of euthanasia;
- Duration, frequency, or number of procedures performed on individual animals.

The PI submits a description of the change to the IACUC; generally this is referred to as an amendment. Amendments are reviewed in the same manner as a new protocol.

Continuing Review of Protocols

The IACUC requires an annual update for its review for each approved protocol. The IACUC coordinator sends an “Annual Continuation Renewal of Animal Care and Use Protocol” form to PIs at least 60 days in advance of the anniversary of the protocol’s approval. The completed form must be received by the IACUC at least 30 day before the anniversary of the protocol’s approval to assure review prior to the anniversary date.

- Approved protocols are only good for three years. At the end of that period, a new protocol review form must be completed and submitted as a new protocol.
- Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. Those officials, however, may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

D. Facility Inspection and Program Review

The IACUC is required to inspect animal facilities, animal use areas (laboratories), and review the institutional animal care and use programs semiannually as detailed by Animal Welfare Act regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals. These “regulations,” as well as UMKC’s institutional policy, require compliance with two sets of standards - the [AWA Regulations](#) and the [Guide for the Care and Use of Laboratory Animals](#). The AWA Regulations and the *Guide* contain many specific requirements applicable to physical plant, environmental controls, husbandry procedures, and institutional programs such as personnel training, veterinary care, and occupational health. The IACUC's task is to confirm that UMKC's facilities and programs conform to the standards.

Responsibilities of IACUC include:

- Review the program for humane care and use of animals once every six month, using the *ILAR Guide for the Care and Use of Laboratory Animals* (Guide) and the *Animal Welfare Act* (Act) as bases for evaluation;
- Inspect all animal facilities (including satellite facilities) and animal study areas at least every six months using the Guide and Act as bases for evaluation;
- Review concerns involving the care and use of animals;
- Review and approve, require modifications in (to secure approval) or withhold approval of those components of activities related to the care and use of animals and modifications (amendments); and
- Make recommendations to the Institutional Official regarding any aspect of the animal care program, facilities, or personnel training.

Facility Inspection

The inspections of animal facilities and animal use areas (laboratories) are the best opportunity for the IACUC to review elements of institutional programs. Among these are IACUC approved protocols, verifying adequacy of personnel qualifications and training, and occupational health program.

Inspection of Animal Facilities and Animal Use Areas

The IACUC Staff will send out an e-mail to all IACUC members asking for volunteers to participate on the subcommittee for the upcoming inspection/program review. If none of the members respond or enough do not respond, members will be assigned to the subcommittee. The IACUC members are assigned to the subcommittee on a rotating basis. The subcommittee will be comprised of at least three members, but no less than two, one of whom must be the Chair or Vice-Chair.

IACUC subcommittee members must become familiar with the required standards and documents, but may find useful the condensed guidelines contained in the IACUC Policies/Guidelines and the LARC SOPs. In addition, members will use the IACUC’s checklists for facility inspections, which include general considerations for several typical animal resource functional areas: animal housing and support, cage wash, aseptic surgery, and procedure (laboratory) areas.

One feature of an inspection is the actual observation of animal and facility conditions at the time of the inspection visit, using the above referenced documents as the basis of comparison with acceptable standards. There are two other features that help significantly in making the visit the significant evaluation tool it is intended to be: examination of documentation and discussion with responsible animal care personnel.

Examples of documentation that members should consider include facility standard operating procedures, daily animal observations, animal room environmental monitoring, sanitation schedules, health records, and postoperative recovery records.

Discussions with facility animal care personnel can clarify the facility's operating procedures and policies, and provide information about the availability and quality of training and participation in the occupational health program.

Inspection subcommittee members should consider the following procedures to promote effective communication with inspected units:

- During the visit, ask questions and engage facility personnel in discussion regarding concerns and questions about standards as they arise.
- At the end of the inspection, give an exit briefing with the LARC Manager and other facility personnel, laboratory managers or PIs
- State facility areas and programs that are of concern to the other inspecting members, i.e., what the members think will be cited as deficiencies and suggestions in the report.
- Explain that the written report will be prepared by the inspecting members, and then reviewed and signed by the whole committee.
- Advise them that the draft report prepared by the members, for the particular facility will be distributed to LARC Manager when the members reach agreement, but that it is not “final” and “official” until it is signed by a majority of the IACUC. Advise that a plan for correction and timeline for correction - agree on both
- Ask the LARC Manager and facility personnel for their feedback or questions on the inspection process, or any other aspects of IACUC business.
- Remind facility personnel about the mechanism for reporting concerns about animal care and use.

Additional considerations for inspecting procedure areas outside the central housing facility:

- The major consideration is to confirm compliance of procedures being performed with those specified in approved protocols.
- Ask research personnel how they do things.
- If procedures appear inconsistent with those usually approved by the IACUC, make a note and check the approved protocol after the visit.
- Even if procedures appear consistent with those usually approved by the IACUC, check some of the approved protocols to confirm that they include the procedures.
- Ask for the names of personnel who do animal procedures associated with each protocol executed in the laboratory being inspected. Then confirm that the personnel involved are listed in the appropriate protocol review forms, that personnel are properly trained, and that they participate in the occupational health program.

- Any area that houses animals for more than 12 hours should be considered in the same way as the central animal housing facility. There may be adequate justification for this housing, but the standards should not be compromised. It is important to assess incidental health risks to personnel that may not be involved in the occupational health program.

Administrative details of facility and animal use area inspection:

- PHS and USDA are quite rigid about the interpretation of “semiannual” meaning not more than six months may elapse between inspections at any facility. The UMKC IACUC has committed to conduct inspections in February, May, August, and November. To date, the regulators have agreed to accept the resultant intervals.
- The IACUC Staff coordinates the subcommittee, as described above, for the inspection and prepares a schedule before each round of inspections begin.
- The IACUC Staff notifies all IACUC members of the schedule in accordance with AWA regulations and PHS policy, which require that all IACUC members must have the opportunity to participate in inspections.
- The IACUC Staff provides to each member of the IACUC subcommittee, a blank inspection checklist/form, a copy of the previous semiannual inspection report, and a list of animal use areas (e.g. laboratories) associated with each animal facility.
- During the inspection each IACUC subcommittee member should record observations that may lead to report deficiencies or suggestions for improvement. Ideally, each such observation will also be discussed with an appropriate representative during or after the inspection.

At the end of each inspection, each IACUC subcommittee member submits their comments and checklist to the IACUC Staff who enters it into the desired IACUC format. Then the formatted draft report is reviewed and signed by the IACUC subcommittee members. Once the report is approved by the full IACUC, per the process described above, notification of the results of the inspection will be sent to the appropriate PI. A summary of the inspections will be sent to the IO and other appropriate institutional representatives.

Program Review

IACUC subcommittee members reviewing animal care and use programs must become familiar with the standards documents (AWA Regulations and the *Guide*), but may find useful the condensed guidelines contained in the IACUC Policies/Guidelines and the LAC SOPs. Program review has been difficult for IACUC’s at many institutions because there has been widespread confusion about what is included in “Animal Care and Use Programs.” By way of explaining what is included in program review, below is a list of the items adapted from a checklist provided by OPRR to guide ACUC animal care and use program review.

Animal care and use program review at UMKC is conducted by the following mechanism. The subcommittee members meet with the IACUC Chair and/or IACUC Coordinator, Attending Veterinarian or the LAC Manager, during the program review for the purpose to review program specific material, inform the subcommittee members of the current practices, and to answer any questions. The IACUC Chair and/or IACUC Coordinator are heavily involved because they have broad general knowledge, although obviously not exhaustive knowledge, of the overall UMKC animal care and use programs. All IACUC members are notified of the schedule so that any who wish to participate may do so.

Administrative details of program inspection:

- PHS and USDA are quite rigid about the interpretation of “semiannual” meaning “not more than six months may elapse between program reviews.” The UMKC IACUC has committed to conduct inspections in May and November. To date the regulators have agreed to accept the resultant intervals.
- The IACUC Staff coordinates the subcommittee, as described above, for the program review.
- The IACUC Staff notifies all IACUC members of the schedule in accordance with AWA regulations and PHS policy, which require that all IACUC members must have the opportunity to participate in inspections.
- The IACUC Staff provides to each member of the subcommittee with a blank program review checklist/form and a copy of the previous semiannual program review report.
- During the program review, each IACUC subcommittee member should record observations that may lead to report deficiencies or suggestions for improvement. Ideally, each such observation will also be discussed with an appropriate representative during or after the inspection.

At the end of each program review, each IACUC subcommittee member submits their comments and checklist to the IACUC Staff who enters it into the desired IACUC format. Then the formatted draft report is reviewed and signed by the IACUC subcommittee members. Once the report is approved by the full IACUC, per the process described above, notification of the results of the program review will be sent to the IO and other appropriate institutional representatives.

E. Reports to Institutional Official

The IACUC shall:

- Prepare reports of the IACUC evaluations conducted as required and submit the reports to the Institutional Official. A majority of the IACUC members must sign the reports indicating their approval of the information submitted. Reports shall be maintained and made available to regulating agencies upon request. The same rigid requirement of reporting once every 6 months is expected.

The Reports must:

- Contain a description of the nature and extent of adherence to the Guide, Act, and identifies any departures from their provisions, and must state the reasons for each departure.
- Distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which is or may be a threat to the health or safety of the animals. If facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency including a timeline.

F. Training

It is an institutional responsibility to ensure availability of training in the humane practice of animal maintenance and experimentation to scientists, animal technicians and other personnel involved with animal care, treatment and use. It is an IACUC responsibility to determine that

scientists, animal technicians and other personnel involved with animal care, treatment and use are qualified by training or experience for their animal-related duties.

The IACUC shall:

- Ensure that scientists, animal technicians and other personnel involved with animal care, treatment and use are provided with training in the humane practice of animal maintenance and experimentation. Scientist should also be aware of concepts and procedures that minimize the use of animals or minimize animal distress.
- Ensure that all animal users have the opportunity to become familiar with all federal, state, city, and institutional requirements that may apply to their work.

Training of new IACUC members includes the following:

- Meeting with IACUC Chair and/or Coordinator - Introduction to overall policies and procedures by providing the necessary documents as resources to appropriate animal welfare rules and regulations and institutional policies and procedures necessary for institutional compliance.
- All IACUC members must complete a set of modules from the CITI (Collaborative Institutional Training Initiative) member training every 3 years.
- Depending upon the nature of the member, some additional materials will be provided. (i.e. – scientific, community, attending veterinarian, non-scientific.)
 - Attending Veterinarian (AV) – will outline the AV's responsibilities and the reporting line between the Institutional Official (IO), IACUC Chair, and the AV's responsibilities and authority related to proper maintain and management of the Animal Care and Use Program of adequate veterinary care, communication with investigators about proper agents necessary to minimize pain and distress of the animals, and proper surgical procedures including the proper use of euthanasia.
 - Non-Scientist and Community Members – (additional information may be necessary) will aid with medical and unfamiliar scientific terminology.
 - Meeting with current IACUC members – provide additional support and guidance outside of IACUC meetings and respond to questions until the new member is comfortable with the IACUC process.
 - Attendance at IACUC 101 courses is encouraged.

Training for Current Members:

- Due to the fact that few IACUC members have the opportunity and available time to review new or revised laws, regulations, and guidelines, it is necessary that continuing training and educational opportunities are offered to current IACUC members.
- IACUC members should be enrolled in the IACUC Forum, an online discussion list devoted to IACUC issues.
- Providing Resources at IACUC Meetings;
 - Set aside time at each IACUC meeting to distribute recent and relevant information that may aid in the discussions or topics to be addressed. These topics should be based on the needs of IACUC and the Animal Care and Use Program.

- Due to members' time constraints – a process can be initiated where there is a rotation of members to present material at the IACUC meetings.
 - Requirement of a yearly training for IACUC members to review policies and procedures.

Training for Principle Investigators and Research Personnel: Working with the IACUC on CITI (Collaborative Institutional Training Initiative) every 3 years.

Additional training is provided by the Attending Veterinarian and Veterinary Technician. They provide “hands on” training covering topics such as animal handling, proper injection techniques, anesthetic monitoring and surgical procedures. This training is available to IACUC members, investigators, and research staff who work with animals.

G. Suspension of Activities

The IACUC may:

- Suspend any activity if determined that the activity is not being conducted in accordance with applicable provisions of the Guide, Act, or NIH Assurance Statement. The IACUC may suspend an activity only after review at a convened meeting of a quorum of the IACUC and with the vote of suspension by a majority of the quorum present. This is based on requirements in the AWR and PHS policy.
- During a review, the IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the Principal Investigator and approved by the Committee. The Institutional Official, in consultation with the IACUC, will review the reasons for suspension and take appropriate corrective action.
- If, at any point during the investigation, the health and well being of animals is an immediate concern, the Attending Veterinarian, IACUC Chair, or a designee, will be notified and will assess the health status of the animals involved to ensure that animal health and welfare issues are resolved as soon as possible. The IACUC Chair and/or Attending Veterinarian have the authority to immediately suspend research activities if the health and well being of the animals are a concern.
- If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the NIH Office for Lab Animal Welfare (OLAW) and Western Regional Director of the USDA.

The IACUC shall:

- Ensure that no research, testing project, teaching program, or any other study (including field studies) involving animals be commenced without prior IACUC approval of a written Animal Protocol Review Form; further, no animals shall be acquired before such approval. This includes internally-funded projects.

Assurance of Protocol Adherence:

- The Principle Investigator must comply with a wide array of local, state, and federal laws, regulations by funding agencies, institutional policies, and contracts, along with their own animal-use protocol. Infraction to any of these may be accidental or intentional, and may range from oversight to neglect.

Protocol Noncompliance:

- Protocol Noncompliance is failure to follow terms and conditions of an approved protocol including, but not limited to:
 - Housing animals in unapproved facilities.
 - Beginning research projects without IACUC approval.
 - Wrongful or abusive physical or psychological treatment of an animal.
 - Involvement of personnel not listed in approved protocol.
 - Changing analgesics or anesthetics without approval.

Reporting Concerns:

UMKC intends for all aspects of animal care and use in research, teaching and testing to fully comply with applicable Federal animal welfare policies and regulations, and with the standards of the *Guide for the Care and Use of Laboratory Animals*. The UMKC Institutional Animal Care and Use Committee is responsible for monitoring all UMKC animal care and use activities for compliance with Federal mandates and standards, and with protocols and procedures approved by the IACUC for animal care and use. In addition, the University maintains accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care, an external peer review process that helps assure adherence to high standards.

The investigation of concerns about animal care and use is an important function of the IACUC in assuring compliance with standards. UMKC and the IACUC encourage reporting of concerns. It is UMKC's policy to prohibit discrimination or reprisal against anyone for reporting violations of standards or deviations from policies or approved protocols and procedures for animal care and use.

Procedure for Reporting Concerns:

The UMKC IACUC investigates all concerns regarding the care, treatment, and use of animals for research at the university. Reports can be made through the IACUC e-mail, umkciacuc@umkc.edu or reporting concerns to the IACUC Chair, IACUC Coordinator or any member of the IACUC.

IACUC would prefer any reports of concerns to be in writing, by either e-mail or memo in order to ensure accuracy and facilitate investigation. If possible, indicate times, dates, place and procedures of concern. The more specific information provided, the more effective is the IACUC evaluations. Reports can also be made verbally.

- Functions of the IACUC specified by the Federal Animal Welfare Act Regulations, 9 CFR Part 2, Subpart C include:

"Review and, if warranted, investigate concerns involving the care and use of animals at the facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees". In addition, institutions are required to train personnel in the "methods whereby deficiencies in animal care and treatment are reported including deficiencies in animal care and treatment reported by any employee of the facility."

H. Appropriate Care of Animals

The IACUC shall:

- Ensure appropriate care of vertebrate animals in all stages of their life according to current federal regulations and guidelines. Adequate veterinary care must be available at all times for all animal species used by the University.
- Ensure the living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and non-medical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

Care and Housing of Animals:

- Evaluation, measurement, maintenance and improvement for the well being, care and use of the animals should be done by the best professionally qualified researchers.
- An animal facility housing animals should meet current federal regulations and guidelines (USDA, 1990, 1991) and are required to be inspected twice a year (USDA, 1989).
 - All animal procedures must be reviewed by IACUC to ensure appropriate and humane treatment of the animals.
 - All animals must be provided with humane care and healthy conditions while housed at the laboratory facilities.
 - In every phase of the project, researchers need to make every effort to ensure that the animals are provided with adequate food, water, ventilation, space, and impose no unnecessary stress on the animals.
 - Any animals taken from the wild should be handled in a humane manner and in accordance with federal, state, and local regulations.
 - Endangered species or taxa are to be used only under the full attention of required permits and ethical concerns as obtained from the Fish and Wildlife Service.

Care and Use of Animals during Experimental Procedures:

- The design and conduct of all procedures must take into consideration the humane care and well being of the animals.
 - In all circumstances, experimental procedures should be adjusted to maintain the humane care and well being of the animal while maintaining the aims of the research.
- Only when the objectives of the research cannot be obtained by other means, is it acceptable to have procedures that cause momentarily aversive stimulation or discomfort to the animal that are not relieved. Detailed scientific justification is necessary in the protocol for such procedures.

- Animals must have the proper amounts of anesthetics to insure insensitiveness to more than slight momentary pain throughout the procedure and must be euthanized before regaining consciousness.
- In any case where the animal is caused severe distress or chronic pain that cannot be alleviated that is not related to the purpose of the research, the animal must be euthanized immediately.
- Procedures that require prolonged aversive conditions or use restraints must conform to federal regulations and require a detailed justification.
- If available and compatible with scientific aims, alternative procedures must be used to minimize animal discomfort.
- Procedures that use paralytic agents without reducing the pain and discomfort of the animal require extensive review and consideration. It is unacceptable to use muscle relaxants or paralytics without the use of anesthesia during these procedures.
- All surgical procedures are required to be supervised and detail attention to the humane care and use of the animals according to **Public Law 99-158 November 20, 1985, "Animals in Research"**
 - 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 might cause pain or distress in animals.
 - 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.
- The euthanasia of an animal at the conclusion of research must be in accordance with procedures outlined in the most recent publication of the American Veterinary Medical Association (AVMA) Panel on Euthanasia.

I. Meetings

- UMKC IACUC meetings are held at least quarterly. Meetings are scheduled in the months of February, May, August, and November.
- Other meetings are scheduled as necessary to fulfill the IACUC responsibilities.

Meeting Minutes:

- The meeting minutes should include an explanation of the major issues discussed by the IACUC and the outcomes of the discussions for each issue. A written transcript of the proceedings is not required. There should be enough information for an outsider to ascertain the nature of the discussion and the conclusions reached by the Committee.

Sunshine Law:

- Sunshine laws include both federal and state laws that require that the public have access to certain records and that certain meetings are open to the public. The Freedom of Information Act (FOIA, 5 USC 552) compels federal agencies to release official documents, except those containing information pertaining to national security, federal investigations, personnel information, and protected health information. The provisions of this Act apply to

both AWA and PHS policy, thus it applies to nearly all material pertaining to animal care and use programs that are associated with these agencies. This includes USDA and the IACUC's inspection reports, program review reports, and meeting minutes. The only exceptions are cases of ongoing investigations into alleged violations of the AWA or PHS policies in which case all relevant documents are protected until the investigation is completed.

J. General Requirements

The IACUC will regularly review:

- Its responsibilities to meet changing needs within the institution, the scientific community, and society as a whole and expand its responsibilities, as necessary, to meet the requirements of new regulations and policies;
- The concerns of the public within our own community;
- The security of the animals and research facilities;
- Standard operating procedures and ensure these are in place;
- Policies and procedures for monitoring animal care and experimental procedures within the institution.

The IACUC will:

- Maintain liaison with federal and state authorities where applicable.
- Develop and maintain liaison with the public and foster an "open door" policy, as appropriate.
- Sponsor from time to time seminars or workshops on research animal science and the ethics of animal experimentation.

The IACUC shall:

- Achieve and maintain a high profile within the institution and in the community in order to allay some public concerns regarding animal experimentation.
- Be responsive to the needs and concerns of the research and animal care community at the University and work toward a harmonious relationship with those it serves. At the same time, the Committee must, in all cases, retain its ability to be objective so that it fulfills its responsibilities as the overseer of the animal care and use program.