



ANIMAL CARE AND USE PROGRAM: STANDARD OPERATING PROCEDURES

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SECTION 1: OVERVIEW

1.1 Mission of the Animal Care and Use Program (ACUP) at Jacksonville University

The mission of the ACUP is to ensure the ethical and humane care and use of live vertebrate animals in research and teaching at Jacksonville University.

1.2 Scope of the Animal Care and Use Program

The ACUP is defined as the research, testing and teaching activities conducted by and at Jacksonville University which, irrespective of funding source, have a direct impact on the well-being of animals.

At present, JU's animal models include birds, reptiles, amphibians, fish, and invertebrates. JU does not currently participate in or conduct Public Health Service-supported projects involving live vertebrate animals. Individuals wishing to work with captive mammal models should consult the IACUC committee prior to submitting an application.

If, in the future, JU expands its animal models beyond the current scope of birds, reptiles, amphibians, fish, and invertebrates for research or teaching purposes, this Animal Use Policy will require revision, and JU will be required to register its Assurance with the U.S. Office for Laboratory Animal Welfare (OLAW).

1.3 Regulatory Authority (these should be linked)

The ACUP operates in accordance with the U.S. Department of Agriculture Animal Welfare Act (1966), Regulation (C.F.R., 2009) and policies, the Health Research Extension Act (1985), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS, 2002), the Guide for the Care and Use of Laboratory Animals (National Research Council, 2011), and other applicable federal, state, and local laws, regulations, policies, and guidelines.

1.4 Research Engagement

Jacksonville University is engaged in animal research when any of its agents are engaged in animal care and use activities. Agents can include Employees (Faculty, Staff, and Administration), Students, Contractors/Vendors and Volunteers.

SECTION 2: INSTITUTIONAL ROLES AND RESPONSIBILITIES FOR ANIMAL WELFARE

2.1 ACUP Components

The ACUP consists of three distinct components: the Institutional Official (IO), the Attending Veterinarian (AV), and the Institutional Animal Care and Use Committee (IACUC). The following outlines the roles, authorities, and responsibilities of each component.

a) Institutional Official (IO)

Federal law requires the highest operating official of the organization to appoint all members of the IACUC. The President has delegated this authority to appoint the IACUC if the delegation is specific and in writing. Once appointed, IACUCs report to a senior administrator known as the Institutional Official (IO). The IO has administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements.

Definition: The individual at Jacksonville University who is authorized to legally commit on behalf of the research facility that it will meet the requirements of the AWA. PHS policy defines the IO as the individual who signs and has the authority to sign the institution's Assurance, which commits the institution to meet the requirements of PHS policy. JU's Institutional Official is Dr. Sherri Jackson, Interim Provost & Senior Vice President.

Responsibilities of the Institutional Official:

1. Provides adequate resources to support the animal care and use program.
2. Has the authority to sign the University's Assurance and commit the institution to meet the requirements of AWA.
3. Commits the institution to meet the requirements of PHS policy.
4. Receives inspection reports and recommendations from the IACUC.
5. In consultation with the IACUC, determines whether deficiencies are minor or significant, determines corrective actions or suspensions and reports such actions to regulatory and funding agencies.
6. Receives notification of the IACUC's decision to approve or withhold its approval of animal activities.
7. Receives and transmits annual reports to the National Institutes of Health (NIH)/ Office of Laboratory Animal Welfare (OLAW) and to Animal and Plant Health Inspection Service (APHIS).
8. May subject protocols that have been approved by the IACUC to further review and approval, but may not approve an activity that has not been approved by the IACUC.
9. Ensures that all personnel involved in animal care, treatment and use are qualified to perform their duties and that specific training is provided to those personnel.

10. Ensures that training, instruction, and the qualifications of personnel are reviewed with sufficient frequency to fulfill the research facility's responsibilities.
11. Ensures the University has an attending veterinarian who provides adequate veterinary care to its animals in compliance with the AWA.
12. Ensures that the University maintains the required records for the specified time periods.

Note: JU does not currently participate in or conduct Public Health Service-supported projects involving live vertebrate animals, or projects involving warm-blooded animals. If, in the future, JU expands its animal models beyond the current scope of birds, reptiles, amphibians, fish, and invertebrates for research or teaching purposes, this Animal Use Policy will require revision, and JU will be required to register an Assurance with the U.S. Office for Laboratory Animal Welfare.

b) Attending Veterinarian (AV)

Definition: The Attending Veterinarian (appointed by the IO as the University Veterinarian with direct or delegated program authority and responsibility for activities involving animals at the institution as defined under the AWA and PHS policy) serves on the IACUC and shall have appropriate training or experience in laboratory animal medicine and science and have direct or delegated program responsibilities for activities involving animals at the institution. This individual should have graduated from an accredited veterinary school, have a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or have received the equivalent formal education as deemed appropriate by the Animal and Plant Health Inspection Service (APHIS) administrator, and must be licensed by the FL State Board of Veterinary Medicine. (PHS Policy (IV,A,3,b,1) and AWAR (2.31,b,3,i).

Responsibilities of the Attending Veterinarian:

13. Provide veterinary consultation on the recognition and palliation of pain.
14. Direct the animal care and use program.
15. Provide medical care.
16. Conduct aseptic surgery and post-operative care.
17. Provide oversight on multiple major survival surgery resulting from a veterinary condition in an animal that also had experimental surgery.
18. Advise the IACUC on new procedures or procedures with the potential to cause pain and distress that cannot be reliably controlled.
19. Ensure that veterinary care is available to mitigate the illnesses, lesions, or behavioral abnormalities associated with animal restraint.
20. Serve as Designated Reviewer for Observational Studies.
21. Serve as a resource for IACUC members, PIs, and students on issues related to animal welfare.

22. Assist with training and education of IACUC members, PIs, students, etc. as needed.
23. Provide expertise on matters of animal health and welfare, including, but not limited to: use of proper anesthesia and analgesia in laboratory animals in the relief of pain and distress, discussion of the possible complications related to procedures used or a disease model proposed, provide a review of the plans for appropriate and timely medical intervention.
24. Conduct initial review of protocols for completeness prior to submission to the full committee.
25. Serve as a member of the IACUC.

c) Institutional Animal Care and Use Committee

The Institutional Animal Care and Use Committee (IACUC) reviews all projects involving animals to ensure that they are justified by their benefits and minimize any animal pain or suffering that might occur. This includes all animals used in research and instruction/teaching.

2.2 Administrative Units Supporting the ACUP

Reporting to the Provost for Academic Affairs, the Office of Research and Sponsored Programs (ORSP) provides the administrative oversight and support for all animal research, teaching, and testing conducted at Jacksonville University. In cooperation with academic leadership and the IACUC, the ORSP has responsibility for the development of overall research policies and operating procedures for the ACUP.

ORSP Research Compliance Administrator - The Research Compliance Administrator is a non-faculty member that provides administrative support and guidance to the Committee; the position functions as a non-voting, non-member of the IACUC. Reporting to the Director of Research and Sponsored Programs, the Administrator serves as the liaison between Principal Investigators (PIs) and the IACUC. Primary responsibilities include but are not limited to screening protocols for completeness, scheduling review meetings, developing agendas, recording all actions in committee meetings for inclusion in the official minutes, and issuing determination letters to PIs.

2.3 Principal Investigator Expectations and Responsibilities

Investigators who utilize animals in their research or teaching are explicitly responsible for:

- a) Obtaining IACUC approval prior to conducting any animal use activities
- b) Adhering to the protocol as approved by the IACUC
- c) Ensuring all vertebrate animals utilized in their research are handled by individuals that have received appropriate training
- d) Ensuring all personnel involved in animal use are listed on the applicable IACUC protocol prior to initiating work with animals
- e) Promoting proper animal care and handling of animals in their studies

SECTION 3: IACUC FUNCTION AND MEMBERSHIP

3.1 IACUC Functions

Federal regulations mandate that the Chief Executive Officer of Jacksonville University appoint an Institutional Animal Care and Use Committee (IACUC) to provide guidance and oversee the Animal Care and Use Program (ACUP) and to maintain compliance with applicable laws, regulations, and policies. The IACUC is responsible for the following oversight functions:

- a) Review, at least once every 6 months, the research facility's program, using AWAR, USDA Regulations/*Guide* and the *AG Guide* as basis for evaluation.
- b) Inspect, at least once every 6 months, all of the animal facilities, including animal study areas/satellite facilities, using AWAR, USDA Regulations/*Guide* and the *AG Guide* as basis for evaluation.
- c) Prepare reports of IACUC evaluations and submit the reports to the Institutional Official.
- d) Review and investigate legitimate concerns involving the care and use of animals at the research facility resulting from public complaints and from reports of non-compliance received from facility personnel or employees.
- e) Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities, or personnel training.
- f) Review, require modifications, approve, or withhold approval of proposed activities related to the care and use of animals.
- g) Review, require modifications, approve, or withhold approval of proposed significant changes regarding care and use of animals in ongoing activities.
- h) Suspend activity involving animals when necessary; take corrective action and report to funding agencies and USDA, as applicable.

Activities approved by the IACUC may be subject to further appropriate review and approval by officials of Jacksonville University. **However, no officials of the institution may approve animal subjects use (i.e., authorize it to proceed) that has not been approved by the IACUC. The IACUC's decision-making must be independent from coercion or undue influence.**

3.2 Composition of Membership

The IACUC is appointed by the President of the University and is qualified through the experience and expertise of its members to oversee the University's animal program, facilities and procedures in accordance with the applicable regulations. Federal regulations require that the membership of the IACUC include at a minimum a veterinarian, a scientist experienced in research involving animals, a member whose principal expertise is in a nonscientific field of study, and an individual not affiliated with Jacksonville University. The President of the University has delegated authority to the Institutional Official (IO) to appoint the IACUC. The IO is the Associate Provost for Assessment & Academic Operations.

- a) **Federal regulations stipulate a minimum of five members. The JU IACUC is comprised of five members:**
 1. One Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine who has direct or delegated program authority and responsibility for activities involving animals at the institution (Affiliated Member, ex officio).
 2. Two practicing scientists experienced in research involving animals (Affiliated Members)
 3. One member whose primary concerns are in a nonscientific area (for example, administrator or faculty of non-scientific disciplines) (Affiliated Member).
 4. One member not affiliated in any way with the institution and not a member of the immediate family of a person who is affiliated with the institution; person who represents the general

community interests in the proper care and treatment of animals; and is not a laboratory animal user (Unaffiliated Member)

b) IACUC Chairperson

Definition: The chairperson should be knowledgeable and effective as a leader. This individual must have the full support of the Institutional Officer (IO) and sufficient stature to perform the functions of the position without jeopardy to career or position. The Chairperson is appointed by the Institutional Official. The chairperson plays an active role in the oversight of all IACUC activities. The Chairperson serves five constituent groups: Senior Administration (CEO and IO), the scientific community, other members of the IACUC, the federal government, and the public. It is not recommended that the Attending Veterinarian be the IACUC Chairperson, due to real or perceived conflicts of interest.

Responsibilities of the Chairperson

The IACUC Chairperson is responsible for overseeing the coordination and implementation of effective, efficient systems for protocol review and program review by the IACUC in compliance with the Public Health Service (PHS) policy and the Animal Welfare Act (AWA). Specifically the Chairperson should:

1. Ensure that the IACUC has a quorum present at all meetings
2. Declare the loss of a quorum resulting in the end of official business if a sufficient number of members depart
3. Prepare and/or oversee the preparation of meeting minutes, agendas, and reports and submit appropriate documents to the IO in accordance with PHS policy and the AWA
4. Report to the IO any activities which have been suspended by the IACUC for non-compliance as required by PHS policy
5. Ensure the establishment of a written system of communication for the IACUC with the investigators concerning the approval status of Animal Use Protocols (AUPs) and the steps necessary to secure approval.
6. Stay abreast of the most recent regulatory trends and interpretations
7. Assign designated reviewers for protocols
8. Advise Primary Investigators (PIs)
9. Educate and support IACUC members, PIs and others regarding the IACUC process
10. Participate in facility inspections
11. Communicate regularly with the IO, Attending Veterinarian, IACUC Administrator and staff
12. Serve as spokesperson for the IACUC

c) Non-Affiliated Member

Definition: Someone who is not affiliated with the University in any manner, intended to represent the general community interests in the proper care and treatment of animals. This person may not be the immediate family of a person affiliated with the institution. Non-Affiliated members should not be laboratory animal users. (AWAR 2.31,b,3,ii;PHS Policy IV, A, 3,b,4)

Responsibilities of the Non-Affiliated member

1. Play an active role in all IACUC activities.
2. Make persistent, straightforward inquiries about matters that are undetected by the institutional members of the IACUC.
3. Critically review protocols
4. Serve as designated reviewer when appropriate

5. Attend all IACUC meetings.
6. Participate in six month facility inspection and program reviews.

d) Non-Scientist Member

Definition: A person whose primary concern is in a non-scientific area having no obvious connections to any area of science. Individuals may have some scientific training, but clearly do not qualify as a practicing scientist with experience in research involving animals.

Responsibilities: The role of the Non-Scientist member is to:

1. Play an active role in all IACUC activities.
2. Make persistent, straightforward inquiries about matters that are undetected by the other members of the IACUC.
3. Critically review protocols
4. Serve as designated reviewer when appropriate
5. Attend all IACUC meetings.
6. Participate in six month facility inspection and program reviews.

e) Scientist Member

Definition: A practicing scientist knowledgeable about the types of research and teaching being reviewed and conducted; at least one with laboratory animal experience. Jacksonville University policy is to represent all areas having involvement with animal research. No more than two scientists from one department/administrative unit should serve on the IACUC.

Responsibilities of the Scientist members

1. Play an active role in all IACUC activities.
2. Make persistent, straightforward inquiries about matters that are undetected by the other members of the IACUC.
3. Critically review protocols
4. Serve as designated reviewer when appropriate
5. Attend all IACUC meetings.
6. Participate in six month facility inspection and program reviews.

3.3 Appointment of Members

The IACUC membership is comprised of faculty representatives from Jacksonville University departments or colleges. Members are nominated by their Department Heads or by current IACUC members and are appointed by the Provost as the Institutional Official. IACUCs are also required to have one community and one non-scientist member; these individuals may be nominated by faculty members and will be appointed by the Provost. All members serve for a period of three years and may serve additional terms. To maintain an adequate level of experience the membership terms may be staggered.

IACUC Chair – The Chair is elected by the IACUC members and is appointed by the Provost. The Chair is appointed for a period of one year and may be reappointed.

3.4 Failure to Achieve IACUC Member Expectations

Those members (primary or alternate) who are not able to meet the “Expectations of Committee Participation” may be encouraged to reconsider their role on the committee (attendance and participation will be monitored by the IACUC office):

- a) Members may choose to increase their participation or may choose to request removal from the IACUC
- b) The IACUC may request the Chairman to reconsider the recommendation of the individual to the committee.
- c) With continued disengagement, the IACUC may recommend the Institutional Official reconsider the appointment to the IACUC of the disengaged member.

3.5 Expectation of Member Confidentiality

IACUC members have the role of assessing the humane use of animals in research, teaching or training conducted at Jacksonville University. IACUC members ensure that the use of animals or testing on animals is conducted in a humane, ethical manner, with the highest standard of care according to applied Federal, State, local regulations and institutional policies and guidelines. To adequately evaluate the humane and ethical use of animals a free and open exchange of information is necessary. To protect the integrity of the institution and its researchers:

- a) Members must not disclose confidential or proprietary information (protocol or investigator specific information) to any non-IACUC member
- b) Members must not discuss, communicate, or disclose any details of IACUC business (e.g. protocol reviews, non-compliance discussion, subcommittee investigations or reviews, etc.) to third parties without the consent of the IACUC Chair or Institutional Official.

Note: Use of IACUC discussion concepts or issues in faculty and staff meetings are considered acceptable and encouraged uses of the member’s experience.

3.6 Mandatory Training Requirements

The Jacksonville University IACUC requires ALL persons participating in research and/or teaching involving animal subjects must be adequately educated, trained, and/or qualified in basic principles of animal science, as mandated by applicable regulations and guidelines. JU utilizes the Collaborative Institutional Training Initiative (CITI) which is a web-based training program that serves learners at academic institutions, government agencies and commercial organizations in order to meet research regulatory requirements.

SECTION 4: IACUC REVIEW PROCESS

4.1 Protocol Submission

All individuals proposing to use live vertebrate animals in their training, teaching or research at Jacksonville University must submit a complete application to the Institutional Animal Use and Care Committee (IACUC) for review and approval. Federal regulations and Jacksonville University Policy require that an investigator must receive a letter of approval of their application from the Institutional Animal Care and Use Committee before the investigator may begin the proposed activity involving the use of live vertebrate animals for research, teaching, or testing. The procedure for submitting an application appear below. However, before the IACUC reviews an application, those individuals whose studies involve live vertebrate animals must complete JU’s IACUC training in its entirety.

Applicants are strongly encouraged to learn about the guidelines IACUC follows to evaluate applications by reading the [National Research Council's publication Guide for the Care and Use of Laboratory Animals](#) (8th ed., 2011; hereafter, referred to as the Guide).

The IACUC Protocol Review Application and related submission materials are available through the Forms and Templates Library in [IRBNet](#). As forms are updated periodically, Principal Investigators (PIs) are advised to download and use the current versions directly from IRBNet. The application and all protocol-related documents must be submitted electronically through IRBNet by the established submission deadline. Applications received after the announced deadline will be reviewed in the next review cycle.

Upon receipt of an application, the ORSP Research Compliance Administrator will conduct an administrative review and return the package to the applicant if it is incomplete.

If the application is complete and clear upon first submission or upon re-submission, the Research Compliance Administrator will route the application through IRBNet for review by the IACUC members.

Proposals to the JU IACUC must include, at a minimum:

1. Completed JU IACUC Protocol Review Application.
2. CITI Training Credentials for all project personnel.

IACUC Submission and Review Cycle		
<i>For Research & Courses Occurring</i>	<i>Application Packets Must be Submitted No Later Than</i>	<i>Final Decisions Given on or Before</i>
Fall Semester	Last Week in March*	End of May
Spring Semester	Last Week in September*	End of November

*Note: Timelines are subject to change.

The Primary Investigator (PI) is the individual responsible for research project(s) using vertebrate animals, and it is the PI, as opposed to the IACUC, who is accountable for all aspects of animal care and welfare. If the PI is a JU student, a Faculty Mentor must co-sign the application.

To allow for adequate review by the IACUC, proposals should be submitted well in advance of the preferred start date. While every effort should be made to submit a proposal during the fall and spring review period, there are instances that may arise that make the above schedule un conducive to research and teaching. Special requests for proposal reviews outside of the above schedule will be considered on a case by case basis. PIs requesting a special review outside of the time parameters above should send the justifications for the request in an email to the IACUC Chair. Members of the IACUC cannot review their own proposal.

Classifications of Proposals

Protocols shall be categorized by Purpose, Setting and Method. Most protocols will fall under multiple categories and all categories must be identified. Below is a brief description of each category with examples where appropriate.

PURPOSE OF STUDY	
A. Faculty Research	- A Jacksonville University faculty member conducts research that utilizes vertebrate animals. This may be a lab or field study (see below) and may be observational or manipulative (see below). Students working with faculty will be covered under the faculty member's proposal.
B. Student Research	- An undergraduate or graduate student enrolled in Jacksonville University conducts research that utilizes vertebrate animals. This may be a lab or field study (see below) and may be observational or manipulative (see below). <u>All students must have a faculty mentor</u> and seek their mentor's permission in advance. Students working on a faculty project do not need to submit a separate proposal.
C. Instruction/Teaching	- A faculty teaches a course in which students will conduct projects that utilize vertebrate animals. This may be a lab or field study (see below) and may be observational or manipulative (see below). The proposal covers the entire course and faculty need only submit one proposal per course, not per lab. All students in the class for that semester will be covered; however, if the student continues the study beyond the semester, the faculty and/or student (whichever is most appropriate) must submit a new IACUC proposal. An example of when a teaching IACUC proposal would be required is a faculty teaching a marine science course having students perform research projects on wild-caught fish.
SETTING	
D. Lab Study	- A study conducted inside one of Jacksonville University's labs or facilities or of a partnering facility that does not have its own IACUC. If a partnering facility, research must obtain Site Authorization for Off-Campus Research (see forms library).
E. Field Study	- Any study conducted on free-living wild animals in their natural habitat. PIs are responsible for obtaining permission and permits for working at off campus sites as necessary. Investigators working off campus for a field study should inform their Department Head and the IACUC, as appropriate.
METHOD	
F. Manipulative	- A study that involves procedures that will directly affect a vertebrate through capture and release or by altering its ecology, physiology and/or behavior. For example, an independent-study student playing predator calls to elicit responses from birds or a faculty member capturing and marking turtles for a population study.
G. Observational	- A study that involves observations of vertebrates in the field. Certain studies are exempt from IACUC oversight; however, this does not mean that the research should not be conducted in a humane and ethical manner.

Only the IACUC can determine whether a project is exempt from oversight. The IACUC reserves the right to require that all projects go through the approval process prior to starting any research or teaching involving the use of animals. Regardless of whether or not the study meets the criteria for exemption, an application to the IACUC must be submitted.

4.2 Administrative Review

Upon submission through IRBNet, applications are logged and reviewed by the ORSP Research Compliance Administrator. Once the submission is accepted for processing, an IACUC protocol number is assigned within IRBNet.

The application then undergoes an Administrative Review, which typically takes 48-72 hours after initial receipt of the application. PIs may be contacted by the ORSP Research Compliance Administrator to provide clarifications, corrections, or with requests to submit missing appendices before IACUC review. Failure of a PI to respond to questions or queries within 30 calendar days of the reviewer's requests will result in Administrative Closure of the application, requiring a new application to be submitted for review.

Applications which have successfully passed Administrative Review are prepared for IACUC Member Review. IACUC members will conduct protocol reviews using IRBNet, which provides secure electronic access to protocol applications, supporting documentation, reviewer comments, and committee communications.

4.3 IACUC Review

The Jacksonville University IACUC uses both the Full Committee and the Designated Member Review methods for review of Animal Care and Use Protocols.

Protocols involving unalleviated pain or distress (USDA Category E), multiple major survival surgery, the use of paralytics, or prolonged restraint are automatically assigned to Full Committee Review (FCR) for final approval. All other protocols are assigned as eligible for Designated Member Review (DMR) by the ORSP staff. Exceptions to the Guide for the Care and Use of Laboratory Animals and the Animal Welfare Regulations, including the use of atypical caging (wire-floor, limited space, running wheels, etc.), single housing of social animals, limitations of environmental enrichment, and nonstandard environmental conditions (altered light cycles, complete darkness, etc.), may be reviewed by the Designated Member Review Process.

Full committee review of a research protocol and suspension of an activity requires a convened meeting of a quorum of the IACUC members. Each protocol must receive the approval vote of a majority (>50%) of the quorum present to receive official approval. Review of proposals by the full committee method invokes a deliberative process, and the minutes of IACUC meetings must reflect committee deliberations.

No proposed research may be approved prior to each member of the IACUC being notified and given the opportunity to request a Full Committee review. To utilize designated member review, each IACUC member must be provided with, at a minimum, a list of the proposed research protocols or proposed significant changes to previously approved protocols prior to the decision of approval. Written descriptions of the research proposals must be made available to IACUC members upon request.

All members must have the opportunity to request full committee review of any proposal. If no member requests full committee review, the Chair designates one or more qualified members to review the proposal (or proposed amendment). These designated members have authority to approve, require modifications (to secure approval), or request full committee review.

The IACUC reserves the right to deny any application for projects that lie beyond the scope of current JU resources.

a) Designated Member Review (DMR) Process:

Protocol submissions determined to be eligible for approval by the Designated Member Review method by the ORSP Research Compliance Administrator are initially routed to the full IACUC. These protocols are available to all IACUC members for review and comment for a minimum of 5 business days.

The IACUC Chairperson has delegated authority to assign the primary reviewer. The veterinary reviewer role is generally assigned to the veterinarian directly overseeing the facility involved. Both the primary and veterinary reviewers may request additional reviewers be assigned for specific expertise or assistance.

IACUC members review protocols in IRBNet and may request clarifications, additional information, revisions, or other modifications from the investigator. The Research Compliance

Administrator communicates review feedback to the investigator through IRBNet and facilitates the exchange of responses, revised documents, and other requested materials. If no IACUC member requests Full Committee Review during the period of IACUC review, the review is completed by a primary and veterinary reviewer as a Designated Member Review. Complex protocols may be exchanged between the reviewers and the investigator several times for changes and clarifications prior to approval by the Designated Reviewers.

Any Designated Reviewer can call for a Full Committee review of any protocol submitted for Designated Review at any time during the review process. Once requested, the protocol must be approved by Full Committee review which occurs during the regular convened meeting of the IACUC.

Any approval decision by the Designated Reviewers must be a consensus decision. If the Designated Reviewers cannot reach a consensus decision, the protocol is sent for Full Committee Review.

b) Full Committee Review (FCR) Process:

Protocol submissions received through IRBNet are assigned to a primary reviewer and a veterinary reviewer. The primary reviewer is designated by the ORSP Research Compliance Administrator or the IACUC Chairperson, while the veterinary reviewer is assigned to the veterinarian directly overseeing the facility involved. All IACUC members are granted access to the submission in IRBNet and are provided with a designated review period to review the protocol, submit comments, request clarifications, recommend modifications, or request Full Committee Review.

The ORSP Research Compliance Administrator then routes the protocol back to the investigator with all comments for consideration, responses, and changes listed. While there is no time limitation for the investigator to respond and resubmit the protocol, reminders are sent by the ORSP Research Compliance Administrator periodically. After responding to the written concerns, the investigator resubmits the protocol through IRBNet.

The protocol is then rerouted to the primary and veterinary reviewers for additional review and to ensure the investigator has responded to the questions, requested changes, clarifications, etc. If questions or concerns remain, the primary or veterinary reviewers may return the protocol to the investigator for additional responses, information, clarification, etc. Complex protocols may be exchanged between the reviewers and the investigator several times before the protocol is considered ready for Full Committee Review and it is placed on the meeting agenda.

At convened IACUC meetings, the primary reviewer presents a summary of the protocol, including any outstanding concerns or issues that remain unresolved at the time of the meeting. The IACUC discusses the protocol and related matters and determines whether sufficient information is available to make a review determination. Protocol discussions are considered potentially confidential and are conducted in an executive session. Final IACUC actions and recommendations are determined by committee vote and are communicated to the investigator by the Research Compliance Administrator through IRBNet.

4.4 Criteria for Review of Protocols

The IACUC is responsible for overseeing and evaluating all aspects of animal care and use, and is charged with reviewing proposals that involve animals to ensure that the criteria established in OLAW and the AWA are implemented. IACUC-approved animal use protocols represent a 'contract' between

the Principal Investigator (PI), the IACUC, and the federal government. The IACUC is considered the representative of the federal government within an institution, thus all applicable laws are binding and maintained through the IACUC. In its review of proposals, the Committee's primary goal is to facilitate compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

Table A (below) lists each review criterion of the PHS Policy and AWAs along with the applicable US Government Principles. If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal, it may bring in outside expert consultants to provide information. Such consultants may not vote. In all cases, the onus should be on the investigator to justify and explain his or her proposed experiments to the satisfaction of the IACUC.

Table A. Regulatory Criteria Applicable to Protocol Review
Principle I: The transportation, care and use of animals should be in accordance with applicable federal laws, guidelines, and policies.
Principle II: Procedures involving animals should be designed and performed with due consideration of their scientific relevance to human or animal health, the advancement of knowledge, or the good of society.
Principle III: The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
Principle IV: Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, PIs should consider that procedures that cause pain or distress in human beings might cause pain or distress in other animals.
Principle V: Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on non-anesthetized animals paralyzed by chemical agents.
Principle VI: Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly euthanatized at the end of the procedure or, if appropriate, during the procedure.
Principle VII: PIs and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
Principle VIII. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the PIs directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

4.5 Actions of the IACUC: (For New Animal Use Protocols and 3 year de novo Protocol reviews)

a) Approval

When the IACUC has determined that all review criteria, based on OLAW and AWA, 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. A formal Notice of Approval will be electronically submitted to the PI, along with an electronically stamped application verifying approval. A copy of the approved application should be kept readily available by the PI at all times. The IACUC recommends PIs keep a copy in their labs where work is performed, as well as a copy if and when work will be conducted in the field. A digital copy or photo of the approved documents is also acceptable.

An IACUC-approved proposal may be subject to further appropriate review and approval by institutional officials due to financial, policy, facility, or other institutional or administrative considerations. However, those officials may not approve an activity if it has not been approved by the IACUC.

The IACUC decision and any requested clarifications or changes are communicated to the investigator via IRBNet.

b) Approval with Explicit Changes

May also be referred to as “conditional approval,” “provisional approval” or “approved pending clarification.” The IACUC may determine by a majority vote that a proposal is approvable contingent upon 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, could verify. When substantive additional information is required by the IACUC and modifications are needed to secure approval, the Committee may allow DMR subsequent to FCR. DMR subsequent to FCR can only occur in these situations by the unanimous vote of the members present at a properly convened meeting. If this method is chosen, the IACUC Chairperson and Committee generally assign the designated reviewer during the discussion of the protocol.

If a study is unusually complex or involves untried or controversial procedures, the IACUC may wish to impose restrictions to the protocol (e.g., approval for the use of a limited number of animals as a pilot study with a written report of interim results, or close monitoring by veterinary or other qualified personnel.) If such modifications represent significant deviations from the original protocol, the IACUC can ask the investigator to revise the protocol to reflect the modifications imposed by the IACUC. If the proposal is missing substantive information necessary for the IACUC to make a judgment, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be revised and resubmitted. If the IACUC wishes to shift to the designated reviewer mode for the approval of the modified protocol, as described in the above paragraph, that shift should be explicitly noted in the minutes and the requirements for DMR must be met. Anything less than full IACUC approval via one of the accepted methods described above is not adequate for initiation of animal activities or for submission of an IACUC approval date.

c) Approval Withheld

A proposed study that does not fully comply with [the Guide](#) and with the [Animal Welfare Act](#), and that cannot be modified to meet compliance without substantially changing its integrity, will not be approved. A designated (individual) reviewer may not deny approval; this action may only be taken using the full committee method of review. The IACUC may, by a majority vote, withhold approval for a protocol. In these cases, the investigator is notified in writing of the IACUC's decision and the reasons for such a decision. The investigator is provided with the opportunity to respond to the IACUC's decision either in person or in writing. The IACUC may reconsider its decision following the investigator's response. As indicated in Section I, a higher institutional authority may not administratively overrule an IACUC decision to withhold approval of a protocol.

The IACUC decision and any requested clarifications or changes are communicated to the investigator via IRBNet.

d) Table Review

The IACUC reserves the right to table the review of any proposal during its scheduled meeting. Protocols with numerous or serious flaws requiring extensive rewriting may not be considered for review and may be deferred (tabled). Investigators are provided with a list of concerns, comments, and questions for response and guidance in resubmitting the protocol for consideration. Deferred protocols must be reviewed (FCR or DMR) before approval may be granted.

Examples of possible reasons for a tabled action include but are not limited to:

1. further clarification required by the PI,
2. committee members who possess a certain expertise are not present, or
3. the IACUC wishes to seek external consultation.

4.6 Annual Animal Use Protocol Reviews, aka Continuing Review:

The JU IACUC reviews all protocols, regardless of funding source, on an annual basis and requires a de novo review of every protocol at an interval not to exceed 3 years. Projects are approved for a maximum of three years. All PIs must submit an annual Continuing Review form within 60 days of the one-year anniversary date to provide a progress report on activities. After the three-year period, PIs must submit a new Protocol Review Application.

Jacksonville University uses the Designated Member Review method of protocol review for annual protocol reviews. The investigator completes a short questionnaire concerning any changes in the protocol and provides a brief progress report, which is distributed for review and consideration by all IACUC members. If no IACUC member requests Full Committee Review during the period of IACUC review, the review is completed by an IACUC reviewer as a Designated Member Review.

4.7 Amendments to Animal Use Protocols:

Amendments to approved protocols must be submitted through IRBNet. Based on the criteria listed below, amendments are classified as either minor or major (significant). Major amendments require IACUC review as detailed in PHS Policy (IV, B,7) and AWAR (2.31,c,7). Further clarification on significant changes to animal activities is delineated in NOT-OD-14-126.

Significant protocol amendments are reviewed by the Designated Member Review method. Amendments are completed by the investigator within the original protocol format with changes clearly delineated by changes in text color to the reviewer. After submission to the IACUC, the amendment request is available to all IACUC members for review and comment. If no IACUC member requests Full Committee Review during the period of IACUC review, the review is completed by an IACUC member and a veterinarian as a Designated Member Review.

Examples of major amendments requiring IACUC review and approval include the following:

1. Change in purpose or specific aim of study
2. Change of principal investigator and/or personnel involved in animal procedures
3. Change of species
4. 10% or more increase in animal numbers over the number approved on the initial protocol and any subsequent committee reviewed amendments
5. Changes in methodology (i.e. traps and equipment used)
6. Changes in duration, frequency, or number of procedures performed on an animal.
7. Change in methods of euthanasia;
8. Addition of a survival surgery
9. Change in degree of invasiveness of a procedure or discomfort in an animal
10. Unanticipated marked increase in clinical signs or proportion of animal deaths

Review of significant changes may be conducted using either the full committee review or the designated member review method described above.

b) Examples of specific significant changes that may be approved administratively after consultation with an IACUC authorized veterinarian* (Attending Veterinarian or designated alternate) include the following:

1. Change in anesthesia, analgesia, sedation or experimental substance
2. Change in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
3. Change to the duration, frequency, type or number of procedures performed on an animal
4. Addition of a strain or change of sex of the same species
5. <10% increase in animal number approved on the initial protocol and any subsequent committee reviewed amendments
6. Addition of sample collection times (if not exceeding standard limits)
7. Additional non-invasive sampling (if not exceeding standard limits)
8. Reducing or eliminating previously approved water or feed restrictions

c) Minor amendments are processed through the ORSP Research Compliance Administrator as administrative changes. Minor amendments include the following:

1. Correction of typographical or grammatical errors
2. Changes to contact information or training updates of the PI or study personnel
3. Addition or deletion of study personnel
4. Decrease in the number of animals used
5. Addition or deletion of animal usage location
6. Changing the title of a protocol

4.8 Recordkeeping and Reporting

Minutes of the IACUC meetings will reflect meeting attendance, activities of the Committee, and Committee deliberations.

Although members may arrive late or leave during a meeting, generally a member is marked as either present or absent. An exception would be when the IACUC member leaves the meeting room during discussion of a protocol on which that member is a participant. If the temporary absence of a member drops the number of members present below the quorum, this should be noted in the minutes. Certain official IACUC actions require a quorum.

Activities of the Committee include corrections or approval of previous minutes; presentation of program, policy, facility and compliance reports; and decisions on policies, protocols, and amendments. Deliberations refers to the discussion and reasons leading to particular IACUC decisions. The minutes should include as a minimum a summary of the key points discussed prior to a committee decision.

Animal applications and proposed significant changes are to be retained for the duration of the animal activity and for an additional three years after the end of the activity. Proposals submitted to the IACUC must be kept for three years even if approval was not granted or animals were not used. The records must show whether IACUC approval was given.