



## **IACUC Policies and Procedures**

*Rosalind Franklin  
University  
of  
Medicine & Science*

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**Policy Title:** The IACUC and its General Procedures

**Category:** Animal Care and Use

**Policy Number:** 110

**Sponsor:** Executive Vice President for Research

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## **POLICY 110: “THE IACUC AND ITS GENERAL PROCEDURES”**

**INTRODUCTION AND PURPOSE.** This document describes the Institutional Animal Care and Use Committee (IACUC) and its general procedures.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

**POLICY STATEMENTS.** The University is committed to ensure institutional compliance with relevant laws and government policies regarding the care and use of animals.

The Executive Vice President for Research is the Institutional Official responsible for institutional compliance with relevant laws and government policies regarding the care and use of animals, including those relating to the IACUC.

The IACUC is an administrative body established by the University to oversee and promote the humane care and use of animals at the University.

### **DEFINITIONS**

***Animal.*** The term “animal” means any live vertebrate animal used or intended for use in research, research training, teaching, testing, or exhibition.

### **PROCEDURES.**

1. **Members.** The IACUC membership, including the Chair, is appointed annually in writing by the Executive Vice President for Research (pursuant to delegated authority from the President/Chief Executive Office of the University) and normally serves for three years or more. Membership consists of those whose experience and expertise will promote the functions of the IACUC. The IACUC will:

a. have at least one member who is a Doctor of Veterinary Medicine (this person must have training or experience in laboratory animal science and medicine and have direct or delegated program responsibility for activities involving animals at the University);

b. have at least one member who is a practicing scientist experienced in research involving animals;



- c. have at least one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy);
  - d. have at least one member who is a person not otherwise affiliated with the University and who is not part of the immediate family of a person affiliated with the University (this person is intended to represent the general community interests in the proper care and treatment of animals); and
  - e. have at least a total of five members, but not more than three members may be from the same administrative unit of the University.
2. Functions. With respect to activities involving animals, the IACUC, as an agent of the University, shall:
- a. Review Program. Review, at least once every six months, the University's program for humane care and use of animals (see the Animal Care and Use policy entitled "Review Program" for specifics about this function);
  - b. Inspect Animal Facilities. Inspect, at least once every six months, all of the University's animal facilities, including animal study areas (see the Animal Care and Use policy entitled "Inspect Animal Facilities" for specifics about this function);
  - c. Prepare and Submit Semi Annual Reports. Prepare reports of its evaluations conducted as required by the above two subparagraphs and submit the reports to the Executive Vice President for Research (see the Animal Care and Use policy entitled "Prepare and Submit Semi Annual Reports" for specifics about this function);
  - d. Review and Investigate Concerns. Review and, if warranted, investigate concerns involving the care and use of animals at the University resulting from public complaints received and from reports of noncompliance received from laboratory or University personnel or employees (see the Animal Care and Use policy entitled "Review and Investigate Concerns" for specifics about this function);
  - e. Make Recommendations. Make recommendations to the Executive Vice President for Research regarding any aspect of the University's animal program, facilities, or personnel training (see the Animal Care and Use policy entitled "Make Recommendations" for specifics about this function);
  - f. Review Proposed Activities. Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals (see the Animal Care and Use policy entitled "Review Proposed Activities" for specifics about this function);



g. Review Proposed Significant Changes. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities (see the Animal Care and Use policy entitled “Review Proposed Significant Changes” for specifics about this function); and

h. Be Authorized to Suspend Activities. Be authorized to suspend an activity involving animals (see the Animal Care and Use policy entitled “Be Authorized to Suspend Activities” for specifics about this function).

3. Education and Training. Each member of the IACUC shall complete an initial education and training program before participating as an IACUC member. Furthermore, each member of the IACUC shall maintain currency with annual refresher education and training in order to continue to participate as an IACUC member. The content of the initial and refresher education and training will be as determined by the Executive Vice President for Research, but will include at least the information relating to the laws and University policies regarding animal care and use.

4. Disclosure Reports. Each member of the IACUC shall submit a disclosure report (as described in the University conflict of interest policies on disclosure reports) and ensure a copy of a fully completed disclosure report is forwarded to the IACUC Coordinator before participating as a member of the IACUC.

5. Meetings and Minutes. The IACUC shall meet periodically, at the call of the Chair, to fulfill its functions, normally on a monthly basis. Written minutes for each full IACUC convened meeting will be prepared and presented at the next meeting for approval. The minutes will contain at least the following information:

- a. date and times of the IACUC meeting;
- b. names of members present to establish quorum (and, reflect whether any members enter or depart the meeting while in session);
- c. names of guests present and when, in relation to deliberation and voting, those guests departed the meeting;
- d. specifics of significant matters raised and discussed; and
- e. voting results for each determination (number voting for, against, and abstaining).

6. Record Retention.

- a. The following records shall be maintained by the IACUC Coordinator for three years from its creation or, in the case of records relating to the review of activities involving animal protocols, the termination of the relevant protocol:



- (1) copies of the IACUC minutes;
- (2) copies of all documents and correspondence submitted to the IACUC for review or consideration (including those relating to periodic reviews and inspections, activities reviews, and concerns and complaints); and
- (3) copies of all documents and correspondence generated by the IACUC (including signed review and inspection reports, determination letters).

b. The following records shall be maintained for two years by the IACUC Coordinator after the record ceases to be in effect (e.g. cancelled due to the implementation of another document):

- (1) A list of IACUC members and sufficient information to reflect fulfillment of IACUC membership criteria listed under paragraph 1 above entitled "Members" (i.e. name, education and other relevant credentials, experience, affiliation status with the University, and, if employed by the University, the position title and administrative unit assigned);
- (2) Records reflecting IACUC members' status regarding education and training and disclosure reports submission; and
- (3) University policies regarding IACUC.

## REFERENCES

United States Department of Agriculture (USDA) Animal Welfare Regulations (9 C.F.R. Parts 1 and 2).  
Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.  
*Guide for the Care and Use of Laboratory Animals*, National Research Council, 2011.



**Policy Title:** Review Program  
**Category:** Animal Care and Use  
**Policy Number:** 111  
**Sponsor:** Executive Vice President for Research  
**Date:** 01-02-2006; updated 09-21-2016

## **POLICY 111: “REVIEW PROGRAM”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of reviewing the University’s program for the humane care and use of animals.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

The IACUC will review, at least once every six months, the University’s program for humane care and use of animals, using USDA regulations and the Guide as a basis for this evaluation.

### **DEFINITIONS.**

*Animal.* The term “animal” means any live vertebrate animal used or intended for use in research, research training, experimentation, teaching, testing, or exhibition.

*Guide.* The “Guide” refers to the *Guide for the Care and Use of Laboratory Animals*, National Research Council, 2011, Washington D.C., or succeeding revised editions.

### **PROCEDURES.**

1. **Timing of Review.** The reviews will be semi-annual and shall be conducted during the month of February and again during the month of August of each year, unless an exception is granted by the Executive Vice President for Research based on extraordinary circumstances. This review will normally coincide with the semi-annual animal facilities inspection.

2. **Subcommittee to Conduct Review.**

a. During the month that precedes the month in which the review must be conducted (i.e. January and July), the Chair of the IACUC shall create a subcommittee of at least two current members of the IACUC to conduct this review. Any member of the IACUC who wishes to participate in the subcommittee to conduct a particular semi-annual review must so inform the Chair of the IACUC prior to the first day of the month in which that review is to be conducted; upon which that member will be allowed to participate.



- b. Upon the approval of the Chair of the IACUC and the Executive Vice President for Research, ad hoc consultants may be utilized to assist in conducting the review.
  - c. The subcommittee designated to conduct this review also may conduct the semi-annual animal facilities inspection.
3. Basis for Review. This review shall consist of comparing the existing program (i.e. the University's policies and practices) with the federal requirements (i.e. the relevant USDA regulations and the Guide), as they relate to the care and use of animals. A checklist will be used as a tool to assist in conducting this review.
4. Report of Program Review. Upon completion of the review, the subcommittee will prepare a written report as described in the Animal Care and Use Policy entitled "Prepare and Submit Reports."



**Policy Title:** Inspect Animal Facilities  
**Category:** Animal Care and Use  
**Policy Number:** 112  
**Sponsor:** Executive Vice President for Research  
**Date:** 01-02-2006; updated 09-21-2016

## **POLICY 112: “INSPECT FACILITIES”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of inspecting the University’s animal facilities.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

The IACUC will inspect, at least once every six months, the University’s animal facilities, using USDA regulations and the Guide as a basis for this evaluation.

### **DEFINITIONS.**

*Animal.* The term “animal” means any live vertebrate animal used or intended for use in research, research training, experimentation, teaching, testing, or exhibition.

*Animal facilities.* Animal facilities are the buildings, rooms, areas, enclosures, and/or vehicles used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation.

*Guide.* The “Guide” refers to the *Guide for the Care and Use of Laboratory Animals*, The National Academies Press 2011, Washington D.C., or succeeding revised editions.

### **PROCEDURES.**

1. **Timing of Review.** The reviews will be semi-annual and shall be conducted during the month of February and again during the month of August of each year, unless an exception is granted by the Executive Vice President for Research based on extraordinary circumstances. This review will normally coincide with the semi-annual program review.

2. **Subcommittee to Conduct Review.**

a. During the month that precedes the month in which the review must be conducted (i.e. January and July), the Chair of the IACUC shall create a subcommittee of at least two current members of the IACUC to conduct this inspection. Any member of the IACUC who wishes to participate in the subcommittee to conduct a particular semi-annual





inspection must so inform the Chair of the IACUC prior to the first day of the month in which that inspection is to be conducted; upon which that member will be allowed to participate.

b. Upon the approval of the Chair of the IACUC and the Executive Vice President for Research, ad hoc consultants may be utilized to assist in conducting the inspection.

c. The subcommittee designated to conduct this inspection also may conduct the semi-annual program review.

3. Basis for Review. This inspection shall consist of comparing the existing animal facility and relevant policies with the federal requirements (i.e. the relevant USDA regulations and the Guide). A checklist will be used as a tool to assist in conducting this inspection.

4. Report of Animal Facilities Inspection. Upon completion of the inspection, the subcommittee will prepare a written report as described in the Animal Care and Use Policy entitled "Prepare and Submit Reports."



**Policy Title: Prepare and Submit Reports**  
**Category: Animal Care and Use**  
**Policy Number: 113**  
**Sponsor: Executive Vice President for Research**  
**Date: 01-02-2006; updated 09-21-2016**

## **POLICY 113: “PREPARE AND SUBMIT REPORTS”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of making and submitting reports of the semi-annual program review and animal facilities inspection.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

The IACUC will submit written reports of each semi-annual program review and animal facilities inspection to the Executive Vice President for Research.

### **PROCEDURES.**

1. **Preparation of Draft Report(s).** During the month following the semi-annual program review and semi-annual animal facilities inspection (i.e. during March and during September), the subcommittee(s) that conducted those evaluations shall prepare a draft written report of that evaluation. The draft report must:
  - a. Contain a description of the nature and extent of the University’s adherence to the USDA regulations;
  - b. Specifically identify any departures from those regulations;
  - c. State the reasons for any such departure;
  - d. Distinguish significant deficiencies from minor deficiencies (a significant deficiency is one which, with reference to the USDA regulations and, in the judgment of the IACUC and the Executive Vice President for Research, is or may be a threat to the health or safety of the animals); and
  - e. If any deficiencies are noted, contain a reasonable and specific plan and schedule with dates for correcting each deficiency.



*Note:* Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Executive Vice President for Research, to APHIS, PHS and any Federal agency funding that activity.

2. Approval of the Draft Report(s).

- a. The draft report(s) must be presented to all members of the IACUC who are reasonably available to review the draft report(s) and the subcommittee will respond to questions from members regarding the evaluation(s) and/or draft report(s).
- b. The draft(s) will become the approved written report(s) upon receiving concurrence through a signature of a majority of all members of the IACUC. Those members of the IACUC who reviewed the draft(s) but did not sign in concurrence shall prepare and submit written minority views, which must be attached to the written report.

3. Delivery of Approved Written Report(s). The Chair of the IACUC shall deliver the approved written report(s) to the Executive Vice President for Research and respond to questions regarding the evaluation(s) and/or written report(s). The Chair of the IACUC shall retain a copy of each written report for three years.



**Policy Title:** Review and Investigate Concerns  
**Category:** Animal Care and Use  
**Policy Number:** 114  
**Sponsor:** Executive Vice President for Research  
**Date:** 01-02-2006; updated 09-21-2016

## **POLICY 114: “REVIEW AND INVESTIGATE CONCERNS”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of reviewing and investigating, if warranted, concerns involving the care and use of animals.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

The University encourages the reporting of concerns involving the care and use of animals at the University, including reports of noncompliance with the applicable laws or policies.

Knowingly making a false report is prohibited.

### **PROCEDURES.**

1. **Reporting Systems.** The Chair shall publish, in an effective manner (e.g. electronically post on its webpage), the University mailing address and telephone number of the IACUC office that may be used by anyone (including members of the general public) to report concerns involving the care and use of animals at the University. The Chair may publish additional methods to report these concerns, including making reference to the reporting systems maintained by the Office of Compliance.

2. **IACUC Review of Concerns.** All concerns involving the care and use of animals at the University that were reported will be reviewed by the Chair of the IACUC to determine whether the concern includes an allegation of noncompliance with the law or policies.

a. If the concern includes an allegation of noncompliance with the law or policies, the Chair of the IACUC shall designate one or more members of the IACUC to investigate the allegation and brief the IACUC at the next convened meeting. The IACUC may, if warranted, require the matter be investigated further. The IACUC shall take action as deemed appropriate and, if a finding of noncompliance is made, the IACUC will consider various responses as described in Compliance Policy 140 (entitled “Responding to



Noncompliance”) and Animal Care and Use Policy 118 (entitled “Be Authorized to Suspend Activities”).

b. If the concern does not include an allegation of noncompliance with the law or policies, the Chair of the IACUC shall brief the IACUC at a convened meeting of the concern and take action as deemed appropriate (e.g. see Animal Care and Use Policy 115 entitled “Make Recommendations”).

3. Documentation. The minutes of the convened IACUC meeting shall include an accurate summary of the concern received, investigation conducted (if any), and action taken by the IACUC. Written reports (such as investigation reports) should be created for matters that would be burdensome to be accurately summarized in IACUC minutes (in which case the IACUC minutes will make reference to and include a copy of such report).



**Policy Title: Make Recommendations**  
**Category: Animal Care and Use**  
**Policy Number: 115**  
**Sponsor: Executive Vice President for Research**  
**Date: 01-02-2006; updated 09-21-2016**

## **POLICY 115: “MAKE RECOMMENDATIONS”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of making recommendations to the Executive Vice President for Research regarding any aspect of the University’s animal program, animal facilities, or personnel training.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

The IACUC will make, as appropriate, recommendations to the Institutional Official regarding any aspect of the University's animal program, animal facilities, or personnel training.

### **PROCEDURES.**

1. Any member of the IACUC may ask the Chair to include on the agenda for the next IACUC meeting a particular recommendation regarding any aspect of the University's animal program, animal facilities, or personnel training.
2. Absent extraordinary circumstances, the Chair shall include such recommendation on the agenda for the next IACUC meeting.
3. After appropriate discussion and obtaining additional useful information, the IACUC, during a convened meeting with quorum present, may determine to make a particular recommendation to the Executive Vice President for Research regarding any aspect of the University’s animal program, animal facilities, or personnel training. The IACUC’s determination is made upon such a vote of a majority of the quorum present.
  - a. A quorum exists when a majority of IACUC members are present and qualified to participate (“qualified to participate” means the member is current in education and training, is current in filing the conflicting interest report, and has no conflicting interest in the particular matter under review).
  - b. The Chair may invite guests to the IACUC meeting to provide information to the IACUC. These guests may be subject-matter experts or others with information helpful to the IACUC. All guests will depart the meeting upon direction of the Chair and in no case may any guest with a conflicting interest be present for deliberations and voting.



- c. A person providing administrative support to the IACUC is not considered a guest or a member; the Chair may permit that person to remain throughout the IACUC meeting to perform administrative support duties.
- 4. The IACUC's recommendation is communicated to the Executive Vice President by the Chair of the IACUC in writing.



**Policy Title:** Review Proposed Activities  
**Category:** Animal Care and Use  
**Policy Number:** 116  
**Sponsor:** Executive Vice President for Research  
**Date:** 01-02-2006; updated 09-21-2016, 04-13-2018

## **POLICY 116: “REVIEW PROPOSED ACTIVITIES”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of reviewing proposed activities involving the care and use of animals, including research and teaching.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

All proposed activities involving animals (including research and teaching) shall undergo a review to protect and promote the humane care and use of animals consistent with applicable laws and University policies.

### **DEFINITIONS.**

*Animal.* The term “animal” means any live vertebrate animal used or intended for use in research, research training, experimentation, teaching, testing, or exhibition.

*Principal Investigator.* All protocols involving the care and use of animals (including research and teaching) must designate an individual as the Principal Investigator (PI). The PI is the individual responsible and accountable for the appropriate design, conduct, and monitoring of a particular protocol. The PI must:

1. Have a faculty appointment at the University with the title of Professor, Associate Professor, Assistant Professor, or Instructor (regardless of suffix or prefix, but not those with only a title of Lecturer);
2. Have the experience, expertise, and skill sets appropriate for the particular research project;
3. Have received training regarding the humane care and use of animals within the last three (3) years, the content of which is determined by the Executive Vice President for Research; and
4. Not have a conflicting interest relating to the duties and responsibilities of PI, unless that conflicting interest is disclosed and effectively managed.





*Co-Investigators (also termed Collaborative Investigators)*. Protocols involving the care and use of animals may designate one or more co-investigators or collaborative investigators to assist the PI in the design, conduct, and monitoring of that protocol. These investigators must:

1. Have the experience, expertise, and skill sets appropriate for their role;
2. Have received training regarding the humane care and use of animals within the last three (3) years, the content of which is determined by the Executive Vice President for Research; and
3. Not have a conflicting interest relating to their duties and responsibilities of investigator, unless that conflicting interest is disclosed and effectively managed.

### **PROCEDURES.**

1. Application. For each proposed activity involving the care and use of animals (including research and teaching), the PI shall complete, sign, and submit to the IACUC Chair an application for review using the applicable form developed by the IACUC. Applications that are incomplete may be returned to the PI, prior to review, as an incomplete submission.

a. Supporting Documents. In addition to and with the application, the PI shall submit:

(1) Protocol. The protocol shall include:

- (a) Identification of the species and the approximate number of animals to be used;
- (b) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;
- (c) A complete description of the proposed use of the animals;
- (d) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and
- (e) A description of any euthanasia method to be used.



- (2) Conflict of Interest Management Plan. The Conflict of Interest management plan, if applicable, shall be included.
  - (3) Letters from Other Committees. When applicable, written approval letters from other committees, such as:
    - (a) The Radiation Safety Officer (when the activities involve the use of radioactive material, such as radioisotopes, in animals); and
    - (b) The Biosafety Committee (when the activities involve the use of carcinogens, infectious agents, and other potentially hazardous materials not covered by another committee in animals, or involve the use of recombinant DNA in animals).
- b. Timing. Applications and supporting documents should normally be submitted three (3) weeks prior to the scheduled IACUC meeting date on which the PI desires the protocol to be reviewed. Earlier submission is encouraged and PIs should consider the possibility of IACUC requiring additional information or modifications to the proposal.
2. Action by the IACUC Chair.
- a. Return Incomplete Submissions to PI. Applications that are incomplete (including when the required supporting documents are lacking) may be returned to the PI, prior to review, as an incomplete submission.
  - b. Advance Review by Attending Veterinarian. Once considered complete, a copy of the application with its supporting documents will be forwarded to an Attending Veterinarian for advance review. The purpose of this review is to identify problems or deficiencies relating to the function of the Attending Veterinarian. The Attending Veterinarian may communicate directly with the PI to resolve problems or deficiencies. The Attending Veterinarian shall communicate in writing to the IACUC Chair any identified problems or deficiencies.
  - c. List and Notice to Members. Normally no later than two (2) weeks prior to the scheduled IACUC meeting, the IACUC Chair will distribute to each member of the IACUC a list of proposed activities to be reviewed (note: more detailed written descriptions of all of those proposed activities shall be made available at the IACUC Coordinator's Office) along with a notification stating that:
    - (1) any member may request a full IACUC meeting on any proposed activity (any such request must be granted); and



(2) if no member requests a full IACUC meeting, the proposed activity will be reviewed by one or more members of the IACUC, as designated by the Chair.

3. Determination Authority.

a. Full IACUC. If any member requested a full IACUC meeting to review the proposed activity, then the determination authority for that proposed activity is a convened meeting of the IACUC during which a quorum is present.

(1) A quorum exists when a majority of IACUC members are present and are qualified to participate (“qualified to participate” means the member is current in education and training, is current in filing the conflicting interest report, and has no conflicting interest in the particular matter under review).

(2) The Chair may invite guests to the IACUC meeting to provide information to the IACUC. These guests may be subject-matter experts or others with information helpful to the IACUC. All guests will depart the meeting upon direction of the Chair and in no case may any guest with a conflicting interest be present for deliberations and voting.

(3) A person providing administrative support to the IACUC is not considered a guest or a member; the Chair may permit that person to remain throughout the IACUC meeting to perform administrative support duties.

b. Designated Member(s). If no member requested a full IACUC meeting to review the proposed activity, the Chair shall designate one or more members qualified to conduct the review (“qualified to conduct the review” means the member(s) are knowledgeable and able to apply the applicable University policies, are current in education and training, are current in filing the conflicting interest report, and have no conflicting interest in the particular matter under review). The designated member(s) may seek and obtain useful information from others, such as subject-matter experts; however, those others may not vote.

4. Determination Options. The determining authority will make one of three determinations, as described below:

a. Approval. A determination of “*Approval*” may be made only as follows:

(1) Vote.

(a) In cases of full IACUC review: A majority of members comprising the quorum at a meeting vote for “*Approval*” after determining that all “Required Criteria” (listed below) are fulfilled. A mere plurality, even in



cases of a member or members abstaining, is not sufficient for a determination of Approval. Voting by proxy is not permitted.

(b) In cases of designated members(s) review: All designated members vote for “*Approval*” after determining that all “Required Criteria” (listed below) are fulfilled.

(2) Required Criteria. All of the following must be fulfilled for approval:

(a) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.

(b) The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.

(c) The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments.

(d) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(i) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the PI and will continue for only the necessary period of time;

(ii) Involve, in their planning, consultation with the attending veterinarian or his or her designee; and

(iii) Not include the use of paralytics without anesthesia.

(e) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

(f) The animals' living conditions will be appropriate for their species in accordance with federal regulations and policies, and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the Attending Veterinarian or other scientist



trained and experienced in the proper care, handling, and use of the species being maintained or studied.

(g) Medical care for animals will be available and provided as necessary by a qualified veterinarian.

(h) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

(i) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on vertebrate animals higher than rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents or lower vertebrates do not require a dedicated facility, but must be performed using aseptic procedures.

(j) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:

(i) Justified for scientific reasons by the PI, in writing; or

(ii) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian.

(k) Methods of euthanasia used must be consistent with the current AVMA Guidelines for the Euthanasia of Animals, unless a deviation is justified for scientific reasons, in writing, by the PI, and approved by the IACUC.

b. Modifications Required To Obtain Approval. A determination of “*Modifications required to obtain approval*” may be made only as follows:

(1) In cases of full IACUC review: A majority of members comprising the quorum at a meeting vote for “*Modifications required to obtain approval*” after determining that the protocol would fulfill the criteria for “*Approval*” upon implementing a specified list of modifications and the PI would be required to show implementation of those modifications and receive written final approval from the IACUC Chair before initiation of the protocol. A mere plurality, even in



cases of a member or members abstaining, is not sufficient for a determination of “Modifications required to obtain approval”. Voting by proxy is not permitted.

(a) When the list of modifications includes any requirement to provide “substantive information” then there must be a review of that information to evaluate whether the criteria for approval have been fulfilled before a determination of that final approval may be made. That review must be made by the full IACUC unless the following are fulfilled and, in such instances, the review and final approval may be made by designated review:

(i) Either the full IACUC voted to permit the subsequent review to be made by a designated reviewer assigned by the Chair, or all of the IACUC members have agreed in advance, in writing, that the quorum of members present at a convened meeting may decide by unanimous vote to use designated review subsequent to full committee review when additional modifications are needed to secure approval.

(ii) upon receipt of the modified protocol by the designated reviewer, all members of the IACUC are notified of receipt of that modified protocol and are provided an opportunity to view that protocol for a reasonable period of time (normally 7 days);

(iii) all members of the IACUC are provided the opportunity, for a reasonable period of time (normally 7 days), to call for a full IACUC review of the modified protocol and none have done so.

*Note: “Substantive information” means information that needs to be evaluated to ensure whether the protocol, as modified with that new information, conforms to this policy relating to required criteria for approval.*

(b) When the list of modifications does not include any requirement to provide “substantive information” then the final approval may be made by the Chair (or designated reviewer) upon determining the list of modifications have been implemented in the protocol. Examples of modifications that do not include “substantive information” are typographical or arithmetic errors, misspellings, incorrect room or telephone numbers, etc. While those corrections must be made, additional evaluative review is not required.

(2) In cases of designated members(s) review: All designated members vote for “Modifications required to obtain approval” after determining that the protocol would fulfill the criteria for “Approval” upon implementing a specified list of



modifications and the PI would be required to show implementation of those modifications to the Chair of the IACUC and receive written final approval from the IACUC Chair before initiation of the protocol.

c. Withhold Approval or Refer to Full IACUC. The consequence of the determination authority NOT making the determination of “*Approval*” or “*Modifications required to obtain approval*” is as follows:

(1) In cases of full IACUC review (Withhold approval): When the full IACUC has determined that the PI has fulfilled neither the criteria for “*Approval*” nor “*Modifications required to obtain approval*”, then the consequence is a determination of “*Withhold approval*”.

(2) In cases of designated member(s) review (referral to full IACUC): When the designated member(s) have determined that the PI has fulfilled neither the criteria for “*Approval*” nor “*Modifications required to obtain approval*”, then the consequence is a determination of “*Referral to full IACUC*.”

Note: An exception to this consequence is when the IACUC intentionally delays making a determination and holds the case for further deliberation and vote until the next scheduled meeting. The PI should be notified of this delay.

## 5. Announcing Determinations.

### a. Announcing Decision to PI.

(1) In cases of *Approval*, the Chair will issue a letter to the PI indicating the determination along with any requirements and constraints imposed. The letter will include a statement that approval does not alleviate the PI from complying with other laws and regulations that are beyond the scope of IACUC review.

(2) In cases of *Modifications required to obtain approval*, the Chair will issue a letter to the PI indicating the determination and the list of the required modifications. The letter will include a statement that initiation of the protocol may not commence until a final approval letter is issued by the Chair. That final letter of approval by the Chair would include a statement that approval does not alleviate the PI from complying with other laws and regulations that are beyond the scope of IACUC review.

(3) In cases of *Withhold approval*, the Chair will issue a letter to the PI indicating the determination, the reasons for its determination, and the circumstances in which the PI may seek or provide additional information regarding the determination. The PI may respond in writing and seek reconsideration of the





protocol after submitting additional information and/or modifications that address the reasons for the IACUC's determination of *Withhold approval*.

(4) In cases of *referral to full IACUC*, no announcement of the decision need be made but the Chair or IACUC Coordinator may so inform the PI.

b. Announcing Decision to University. Copies of all determination letters will be forwarded to the Executive Vice President for Research, who will brief the President as appropriate. Although the Executive Vice President for Research is not required to conduct an additional level of review, the Executive Vice President for Research may decide to do so and disapprove any activity involving the care and use of animals even though that activity may have been approved by the IACUC. However, the Executive Vice President for Research may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

6. Renewal of Approval. All IACUC approvals will expire at a pre-determined date that is no longer than one year from the date of that approval. The PI shall apply for a renewal of the approval in a timely fashion so that the action by the IACUC will occur prior to expiration of the existing approval. There are two types of review associated with a continuing project: annual and triennial.

a. Annual (Short-Form) Renewal. Annual review follows a process similar to that described above in paragraphs 1-5, except that pre-review by an Attending Veterinarian and some supporting documents may not be required. Additional scrutiny may apply for annual renewal applications involving USDA covered species but typically designated review is used, unless any member of the IACUC refers the annual renewal to full committee review.

b. Triennial (Long-Form) Renewal. A review following the exact procedures described for new protocols above in paragraphs 1-5 is required at least once every three years.

7. Lapse of Approval. The failure to obtain a renewal of approval prior to the expiration date will result in a lapse in approval. In such cases all activities that require IACUC approval must cease during the period of lapse of approval (except those activities that are necessary for the humane care of animals).





**Policy Title:** Review Proposed Activities  
**Category:** Animal Care and Use  
**Policy Number:** 117  
**Sponsor:** Executive Vice President for Research  
**Date:** 01-02-2006; updated 09-21-2016

## **POLICY 117: “REVIEW SIGNIFICANT CHANGES”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of reviewing proposed significant changes in ongoing activities involving the care and use of animals, including research and teaching.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

A proposed significant change regarding the care and use of animals in ongoing activities (including research and teaching) may not be initiated until that proposal is reviewed and approved in order to protect and promote the humane care and use of animals consistent with applicable laws and University policies. Notwithstanding the previous statement, a change may be made without prior review and approval when necessary to eliminate apparent and immediate hazards to the animals or to humans, in which case the PI shall notify the IACUC and the Attending Veterinarian promptly of the change.

### **DEFINITIONS.**

**Significant change.** A significant change, as it relates ongoing activities involving animals, is one that involves a change:

1. In the objectives of a study;
2. From non-survival to survival surgery;
3. In the degree of invasiveness of a procedure or discomfort to an animal;
4. In the species;
5. Addition of a new strain (unless the additional strain does not increase the original approved number of animals, in which case it would then be a minor amendment). Please indicate whether the increase is in keeping with the original rationale for the number of animals approved. In addition, provide attestation that the change will not result in a “change of scope”.



6. An increase in any number of animals (ie., 1 or more). Please indicate whether the increase is in keeping with the original rationale for the number of animals approved. In addition, provide attestation that the change will not result in a “change of scope”.
7. If the change results in a negative impact on animal welfare such as if the new strain has any pain or distress associated with it.
8. Of the PI (note: a change in other personnel who are involved in animal procedures is not considered a "significant change" if the PI ensures that those individuals are appropriately identified, adequately trained and qualified, and meet other criteria as required by the IACUC);
9. In anesthetic agent(s), the use or withholding of analgesics, or methods of euthanasia;
10. In the duration, frequency, or number of procedures performed on an animal; or
11. That is similar in nature or effect to the above list.

## **PROCEDURES.**

**1. Application.** For each proposed significant change in ongoing activities involving animals (including research and teaching), the PI shall complete, sign, and submit to the IACUC Chair an application for review using the applicable form developed by the IACUC. Applications that are incomplete may be returned to the PI, prior to review, as an incomplete submission.

**a. Supporting Documents.** In addition to and with the application, the PI shall submit:

(1) Protocol of Significant Change(s). The protocol of significant change(s) shall include the following items (as they relate to the proposed significant change(s)):

- (a) Identification of the species and the number of animals to be used;
- (b) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;
- (c) A complete description of the proposed use of the animals;
- (d) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and



(e) A description of any euthanasia method to be used.

(2) Letters from Other Committees. When applicable, written approval letters from other committees, (as they relate to the proposed significant change(s)) such as:

(a) the Radiation Safety Officer (when the activities involve the use of radioactive material, such as radioisotopes, in animals); and

(b) the Biosafety Committee (when the activities involve the use of carcinogens, infectious agents, and other potentially hazardous materials not covered by another committee in animals or involve the use of recombinant DNA in animals).

b. Timing. Applications and supporting documents should normally be submitted three (3) weeks prior to the scheduled IACUC meeting date on which the PI desires the proposed change(s) to be reviewed. Earlier submission is encouraged and PIs should consider the possibility of IACUC requiring additional information or modifications to the proposal.

## 2. Action by the IACUC Chair.

a. Return Incomplete Submissions to PI. Applications that are incomplete (including when the required supporting documents are lacking) may be returned to the PI, prior to review, as an incomplete submission.

b. Advance Review by Attending Veterinarian. Once considered complete, a copy of the application with its supporting documents will be forwarded to an Attending Veterinarian for advance review. The purpose of this review is to identify problems or deficiencies relating to the function of the Attending Veterinarian. The Attending Veterinarian may communicate directly with the PI to resolve problems or deficiencies. The Attending Veterinarian shall communicate in writing to the IACUC Chair any identified problems or deficiencies.

c. List and Notice to Members. Normally no later than two (2) weeks prior to the scheduled IACUC meeting, the IACUC Chair will distribute to each member of the IACUC a list of proposed activities to be reviewed (note: more detailed written descriptions of all of those proposed activities shall be made available at the IACUC Coordinator's Office) along with a notification stating that:

(1) any member may request a full IACUC meeting on any proposed activity (any such request must be granted); and



(2) if no member requests a full IACUC meeting, the proposed activity will be reviewed by one or more members of the IACUC, as designated by the Chair.

### 3. Determination Authority.

a. Full IACUC. If any member requested a full IACUC meeting to review the proposed activity, then the determination authority for that proposed activity is a convened meeting of the IACUC during which a quorum is present.

(1) A quorum exists when a majority of IACUC members are present and are qualified to participate ("qualified to participate" means the member is current in education and training, is current in filing the conflicting interest report, and has no conflicting interest in the particular matter under review).

(2) The Chair may invite guests to the IACUC meeting to provide information to the IACUC. These guests may be subject-matter experts or others with information helpful to the IACUC. All guests will depart the meeting upon direction of the Chair and in no case may any guest with a conflicting interest be present for deliberations and voting.

(3) A person providing administrative support to the IACUC is not considered a guest or a member; the Chair may permit that person to remain throughout the IACUC meeting to perform administrative support duties.

b. Designated Member(s). If no member requested a full IACUC meeting to review the proposed activity, the Chair shall designate one or more members qualified to conduct the review ("qualified to conduct the review" means the member(s) are knowledgeable and to able apply the applicable University policies, are current in education and training, are current in filing the conflicting interest report, and have no conflicting interest in the particular matter under review). The designated member(s) may seek and obtain useful information from others, such as subject-matter experts; however, those others may not vote.

For changes involving increase in any number of animals, the significant amendment may undergo administrative approval (ie, approval by the IACUC Chair, co-Chair, or BRF veterinarian).

4. Determination Options. The determining authority will make one of three determinations, as described below:

a. Approval. A determination of "Approval" may be made only as follows:



(1) Vote.

a) In cases of full IACUC review: A majority of members comprising the quorum at a meeting vote for "Approval" after determining that all "Required Criteria" (listed below) are fulfilled. A mere plurality, even in cases of a member or members abstaining, is not sufficient for a determination of approval. Voting by proxy is not permitted.

(b) In cases of designated members(s) review: All designated members vote for "Approval" after determining that all "Required Criteria" (listed below) are fulfilled.

(2) Required Criteria. All of the following must be fulfilled for approval:

(a) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.

(b) The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available.

(c) The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments.

(d) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(i) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

(ii) Involve, in their planning, consultation with the attending veterinarian or his or her designee; and

(iii) Not include the use of paralytics without anesthesia.

(e) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.



(f) The animals' living conditions will be appropriate for their species in accordance with federal regulations and policies, and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the Attending Veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

(g) Medical care for animals will be available and provided as necessary by a qualified veterinarian.

(h) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

(i) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on vertebrate animals higher than rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents or lower vertebrates do not require a dedicated facility, but must be performed using aseptic procedures.

(j) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:

- (i) Justified for scientific reasons by the PI, in writing; or
- (ii) Required as routine veterinary procedure or to protect the health or well being of the animal as determined by the attending veterinarian.

(k) Methods of euthanasia used must be consistent with the current AVMA Guidelines for the Euthanasia of Animals, unless a deviation is justified for scientific reasons, in writing, by the PI.

**b. Modifications Required To Obtain Approval.** A determination of "Modifications required to obtain approval" may be made only as follows:

(1) In cases of full IACUC review: A majority of members comprising the quorum at a meeting vote for "Modifications required to obtain approval" after determining that the protocol would fulfill the criteria for "approval" upon implementing a specified list of modifications and the PI would be required to



show implementation of those modifications and receive written final approval from the IACUC Chair before initiation of the protocol. A mere plurality, even in cases of a member or members abstaining, is not sufficient for a determination of "Modifications required to obtain approval". Voting by proxy is not permitted.

(a) When the list of modifications includes any requirement to provide "substantive information" then there must be a review of that information to evaluate whether the criteria for approval have been fulfilled before a determination of that final approval may be made. That review must be made by the full IACUC unless all of the following are fulfilled (and, in such instances, the review and final approval may be made by a designated reviewer):

(a) When the list of modifications includes any requirement to provide "substantive information" then there must be a review of that information to evaluate whether the criteria for approval have been fulfilled before a determination of that final approval may be made. That review must be made by the full IACUC unless the following are fulfilled and, in such instances, the review and final approval may be made by designated review:

(i) Either the full IACUC voted to permit the subsequent review to be made by a designated reviewer assigned by the Chair, or all of the IACUC members have agreed in advance, in writing, that the quorum of members present at a convened meeting may decide by unanimous vote to use designated review subsequent to full committee review when additional modifications are needed to secure approval.

(ii) upon receipt of the modified protocol by the designated reviewer, all members of the IACUC are notified of receipt of that modified protocol and are provided an opportunity to view that protocol for a reasonable period of time (normally 7 days);

(iii) all members of the IACUC are provided the opportunity, for a reasonable period of time (normally 7 days), to call for a full IACUC review of the modified protocol and none have done so.

Note: "Substantive information" means information that needs to be evaluated to ensure whether the protocol, as modified with that new information, conforms to this policy relating to required criteria for approval.

(b) When the list of modifications does not include any requirement to provide "substantive information" then the final approval may be made by





the Chair (or designated reviewer) upon determining the list of modifications have been implemented in the protocol. Examples of modifications that do not include "substantive information" are typographical or arithmetic errors, misspellings, incorrect room or telephone numbers, etc. While those corrections must be made, additional evaluative review is not required.

(2) In cases of designated member(s) review: All designated members vote for "Modifications required to obtain approval" after determining that the protocol would fulfill the criteria for "approval" upon implementing a specified list of modifications and the PI would be required to show implementation of those modifications to the Chair of the IACUC and receive written final approval from the IACUC Chair before initiation of the protocol.

c. Withhold Approval or Refer to Full IACUC. The consequence of the determination authority NOT making the determination of "Approval" and "Modifications required to obtain approval" is as follows:

(1) In cases of full IACUC review (withhold approval): When the full IACUC has determined that the PI has fulfilled neither the criteria for "Approval" nor "Modifications required to obtain approval", then the consequence is a determination of "Withhold Approval."

(2) In cases of designated member(s) review (referral to full IACUC): When the designated member(s) have determined that the PI has fulfilled neither the criteria for "Approval" nor "Modifications required to obtain approval", then the consequence is a determination of "Referral to Full IACUC."

Note: An exception to this automatic consequence is when the IACUC intentionally delays making a determination and holds the case for further deliberation and vote until the next scheduled meeting. The PI should be notified of this delay.

## 5. Announcing Determinations.

### a. Announcing Decision to PI.

(1) In cases of Approval, the Chair will issue a letter to the PI indicating the determination along with any requirements and constraints imposed. The letter will include a statement that approval does not alleviate the PI from complying with other laws and regulations that are beyond the scope of IACUC review.

(2) In cases of Modifications required to obtain approval, the Chair will issue a letter to the PI indicating the determination and the list of the required modifications. The letter will include a statement that initiation of the protocol





may not commence until a final approval letter is issued by the Chair. That final letter of approval by the Chair would include a statement that approval does not alleviate the PI from complying with other laws and regulations that are beyond the scope of IACUC review.

(3) In cases of Withhold Approval, the Chair will issue a letter to the PI indicating the determination, the reasons for its determination, and the circumstances in which the PI may seek or provide additional information regarding the determination. The PI may seek reconsideration of the protocol after submitting additional information and/or modifications that address the reasons for the IACUC's determination of withhold approval.

(4) In cases of Referral to Full IACUC, no announcement of the decision need be made, but the Chair or IACUC Coordinator may so inform the PI.

b. Announcing Decision to University. Copies of all determination letters will be forwarded to the Executive Vice President for Research, who will brief the President as appropriate. Although the Executive Vice President for Research is not required to conduct an additional level of review, the Executive Vice President for Research may decide to do so and disapprove any activity involving the care and use of animals even though that activity may have been approved by the IACUC. However, the Executive Vice President for Research may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

6. Annual and Triennial Renewal of Approval. The review and approval (or any other determination) of a significant change in ongoing activities involving the care and use of animals does not alter the previously established date relating to the annual and triennial renewal of approval.



**Policy Title: Be Authorized to Suspend Activities**

**Category: Animal Care and Use**

**Policy Number: 118**

**Sponsor: Executive Vice President for Research**

**Date: 01-02-2006; updated 09-21-2016**

## **POLICY 118: “BE AUTHORIZED TO SUSPEND ACTIVITIES”**

**INTRODUCTION AND PURPOSE.** This document describes the specific IACUC function of being authorized to suspend an activity involving animals, including research and teaching.

**SCOPE AND APPLICABILITY.** This document applies to all employees and others who are authorized to conduct activities involving animals at the University.

### **POLICY STATEMENTS.**

The IACUC has the authority to suspend activities involving animals (including research and teaching) if it determines that the activity is not being conducted in accordance with the description of that activity provided by the PI and approved by the IACUC.

### **PROCEDURES.**

1. After appropriate review and investigation, if warranted, the IACUC, during a convened meeting with quorum present, has authority to suspend an activity involving animals if it determines that the activity is not being conducted in accordance with the proposal as previously approved by the IACUC. The IACUC determination to suspend may be made only upon such a vote of a majority of the quorum present.
  - a. A quorum exists when a majority of IACUC members are present and qualified to participate (“qualified to participate” means the member is current in education and training, is current in filing the conflicting interest report, and has no conflicting interest in the particular matter under review).
  - b. The Chair may invite guests to the IACUC meeting to provide information to the IACUC. These guests may be subject-matter experts or others with information helpful to the IACUC. All guests will depart the meeting upon direction of the Chair and in no case may any guest with a conflicting interest be present for deliberations and voting.
  - c. A person providing administrative support to the IACUC is not considered a guest or a member; the Chair may permit that person to remain throughout the IACUC meeting to perform administrative support duties.



2. If the IACUC determines to suspend an activity involving animals:
  - a. The Chair of the IACUC shall so inform the PI in order to implement the suspension (verbal notification will normally be made by the end of the next business day followed by written notification within 3 business days).
  - b. The Chair of the IACUC shall consult with the Executive Vice President for Research, normally within one week, to discuss the IACUC's determination to suspend and IACUC's reasons for that determination.
  - c. The Executive Vice President for Research, after such consultation with the Chair of the IACUC:
    - (1) shall review the reasons for suspension,
    - (2) take appropriate corrective action (which may include actions affecting the particular animals, actions that permanently cease activities under that protocol, actions that affect the PI and/or the noncompliant person, and/or actions that modify written procedures), and
    - (3) report the determination to suspend along with corrective action taken with a full explanation to APHIS, PHS, and any Federal agency funding that activity.