



<b>SUBJECT:</b> Protocol and Amendment Review	<b>Effective Date:</b> 1/29/2021	<b>Policy Number:</b> 10.4.1c				
	<b>Supersedes:</b> 3/6/2020 9/28/2018 6/30/2017 10.4.1 FAU policies and Procedures Manual	<table border="1"> <tr> <td><b>Page</b></td> <td><b>Of</b></td> </tr> <tr> <td>1</td> <td>8</td> </tr> </table>	<b>Page</b>	<b>Of</b>	1	8
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<b>Responsible Authorities:</b> Vice President, Research Institutional Animal Care and Use Committee Assistant Vice President for Research, Research Integrity Assistant Vice President for Research, Comparative Medicine						

- I. Background  
 FAU and its Institutional Animal Care and Use Committee are committed to the humane care and use of animals in research, teaching or testing activities. In accordance with the [PHS Policy on Humane Care and Use of Laboratory Animals](#) and the [Animal Welfare Act](#) the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of those components related to the care and use of animals in order to approve proposed research projects or proposed significant changes in ongoing research projects.
  
- II. Purpose  
 FAU's IACUC has developed a strategic review process for IACUC protocol and amendment submissions. The purpose of this policy is to provide guidance to Research Personnel regarding the administrative process for IACUC protocol and amendment review once submitted to the IACUC Office.
  
- III. General Statement  
 FAU's IACUC is responsible for ensuring that all animal activities are in compliance with the federal regulations, including the Animal Welfare Act, the Public Health Service Policy (PHS) and are consistent with the *Guide for the Care and Use of Laboratory Animals*.

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#### IV. Policy

1. All protocol and amendment applications must be submitted directly to the IACUC Office. If research personnel require assistance with protocol development, the Attending or Clinical Veterinarian may be contacted prior to submitting to the IACUC Office, however Veterinary review will be coordinated by the IACUC office.
2. All protocol and amendment applications using USDA pain categories D and E procedures (see [Guidelines for Determining USDA Pain/Distress Levels](#)) require Full Committee Review (FCR) and must be submitted to the IACUC Office by the application deadline for the monthly meeting (see [IACUC Meeting Dates and Application Deadlines](#)). Applications requiring FCR review submitted after the application deadline will be reviewed at the next scheduled monthly meeting.

Only completed applications submitted by the application deadline will be reviewed at the monthly meeting. Any application that is missing documentation (e.g. signatures, appendices, Section G: Personnel Qualification Forms) will not be eligible for review until all documents are received by the application deadline prior to the next scheduled monthly meeting.

3. All protocol and amendment applications eligible for Designated Member Review (DMR) using USDA pain categories B and C procedures (see [Guidelines for Determining USDA Pain/Distress Levels](#)) may be submitted at any time.
4. The Principal Investigator will have 90 days to submit a revised protocol or amendment application requested from any of the following reviews; **Pre-Review**, **DMR** or **FCR**. An email reminder will be sent to the PI within 8 weeks. Failure to submit the revised application within 90 days of notification from the IACUC/RI office request will result in withdrawal of the protocol or amendment application.
5. The IACUC Office will confirm that all research personnel have completed any required training. The IACUC Office will approve the protocol or amendment when all required trainings have been completed.
6. Protocols or amendment applications describing the use of hazards in their procedures and requiring Institutional Biosafety Committee (IBC) review and approval will not receive final approval from the IACUC until IBC approval is granted. A copy of the IBC approval letter must be submitted to the IACUC office for confirmation of the approval. A copy of the IBC approval letter will be kept on file with the associated IACUC protocol.
7. Pilot studies may be described either in a new protocol or amendment application to an existing protocol. The IACUC must be able to determine preliminary assessments of the effect of procedures on animals (*Guide* pages 26, 28). The results of the pilot study must be provided to the IACUC in a written report. The Principal Investigator will have 90 days to submit the written report from the approval date of the protocol or amendment application. An email reminder will be sent to the PI within 8 weeks.

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If a pilot study has not concluded within the 90-day deadline, the PI must notify the IACUC office with an estimated timeframe of when the study is expected to be completed. The written report must be submitted to the IACUC once the study has concluded.

The written report will be reviewed at a convened meeting of a quorum of the IACUC members with a formal vote to determine whether the results of the pilot study are acceptable to continue as a larger study. A written notification will be sent to the PI indicating the IACUCs decision.

8. Three-year renewal protocols must be submitted to the IACUC Office 8 weeks prior to the expiration date of the protocol. Failure to submit the three-year renewal protocol by the deadline date will result in the protocol being expired ([Institutional Policy 10.4.19](#)).
9. Annual renewal protocols involving USDA covered species must submit the [USDA Annual Renewal Form](#) to the IACUC Office at least 2 weeks prior to the one year anniversary date of the protocol. Failure to submit the form by the deadline date will result in the expiration of the protocol and inability to order animals through Comparative Medicine (see [Institutional Policy 10.4.19](#)).

V. Accountability

**The Principal Investigator (PI) will be responsible for:**

- § Assuring that all Animal Care and Use protocols and/or amendments are submitted to the IACUC Office by the deadline dates and are renewed at appropriate intervals to avoid expiration of a protocol.
- § Assuring that procedures are performed as described in the corresponding approved IACUC protocol and if necessary submitting an amendment to the protocol and awaiting approval before new method(s) will be introduced.
- § Ensuring that all personnel have completed required training.
- § Ensuring compliance to all applicable Federal, State and University regulations and policies pertaining to the care and use of animals in research, teaching or testing.
- § Completing all required institutional training.
- § Reviewing and adhering all institutional policies as applicable to their research.

**The IACUC will be responsible for:**

- § Providing oversight for all animal care and use procedures conducted.
- § Reviewing and approving, requiring modifications in (to secure approval) or withholding approval of IACUC protocols and/or amendments.
- § Assuring that all personnel conducting work with animals are appropriately trained.

**The Research Integrity (RI) / IACUC office will be responsible for:**

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- § Administrative support of the IACUC members to facilitate their regulatory function.
- § Maintaining policy and assure regular review and update as necessary by the IACUC.
- § Confirmation that all research personnel have completed all required IACUC training.

**The Office of Comparative Medicine (CM) will be responsible for:**

- § Veterinary review of IACUC protocol and amendments.
- § Providing veterinary care and husbandry as described in all IACUC approved protocols.

VI. Procedures

**1. Pre-Review**

The RI / IACUC Office will perform a pre-review of all protocol or amendment submissions to determine if the application is complete and all applicable sections are addressed. Comments may be directed back to the Principal Investigator requesting modifications prior to submitting for IACUC review. The PI will submit the revised protocol to the IACUC Office. The IACUC Office will assign the revised protocol for Veterinary review and IACUC review.

**2. Veterinary Review**

The protocol or amendment will receive Veterinary review from either the Attending Veterinarian (AV) or Clinical Veterinarian. If the Veterinarian requests for modifications the PI will be notified by email from the IACUC Office. The PI will submit the revised protocol and the IACUC Office will review the protocol for completeness of response.

**3. Full Committee Review (FCR)**

Full Committee review (FCR) will only occur at a convened meeting of a quorum of the IACUC members and with a formal vote. A lead reviewer is assigned to facilitate the review of the protocol or amendment at the meeting. Following the presentation of the protocol or amendment by the lead reviewer, discussion is held and a motion is made from the members to approve, require modifications in (to secure approval), request for DMR review, table or withhold approval. All motions must be seconded and approved by the majority of the members to pass.

If the committee votes to request modifications in (to secure approval) the PI will be notified by email from the IACUC Office. The PI will submit the revised protocol or amendment and the IACUC Office will review for completeness of response prior to further committee review.

If the committee votes to request for DMR review following FCR review, the protocol or amendment will be assigned to at least one IACUC member for review. A list of required modifications will be sent to the PI and the PI will be required to submit the revised application to the IACUC office within 90 days or the application will be

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withdrawn for consideration. The application will then be routed for DMR as described below.

If the committee votes to table, the protocol or amendment will be reviewed at the next convened IACUC meeting. A list of required modifications will be sent to the PI and the PI will be required to submit the revised application to the IACUC office according to the application deadline for the next convened IACUC meeting (see [IACUC Meeting Dates and Application Deadlines](#)).

If the committee votes to withhold approval a written notification will be sent to the PI indicating the reasons justifying such an action. The PI is invited to meet with the IACUC committee and address the IACUC's concerns in writing.

#### **4. Designated Member Review (DMR)**

Designated Member Review (DMR) will only occur after all members have been provided the opportunity to call for full committee review. If any member requests full committee review (FCR) then that method is used. All IACUC members must receive the protocol or amendment and are given five business days to review and make a decision if the protocol or amendment should go to full committee. If DMR is selected, then the IACUC Chairperson will appoint one appropriately qualified IACUC member to serve as the designated reviewer. Designated review may result in approval, require modifications in (to secure approval) or request for full committee review. Designated review cannot result in withholding of approval.

If the designated reviewer requests for modifications in (to secure approval) the PI will be notified by email from the IACUC Office. The PI will submit the revised protocol or amendment and the IACUC Office will review for completeness of response or refer back to the designated reviewer for approval. The revised application must be received by the IACUC office within 90 days of the notice or the application will be withdrawn for consideration.

If the designated reviewer requests for FCR review the protocol or amendment will be deferred to the next scheduled IACUC meeting.

#### **5. Three-Year Renewal**

In accordance with the PHS regulations, IACUC protocols that involve non-USDA covered species are required to be renewed every three years. The PI must submit a new IACUC protocol application for review and approval as part of the renewal process every three years if the research is to continue. The PI must provide in the protocol a summary of animal care and use over the past three years of the project as well as the proposed use of animals for the upcoming three years. The PI must submit the three-year renewal protocol to the IACUC Office 6 weeks prior to the expiration date of the protocol. Failure to submit the three-year renewal protocol by the deadline date will result in the protocol being expired. All experimental animal activity conducted under that expired protocol must cease and animals transferred to the holding protocol to be maintained by Comparative Medicine (CM) until such time

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that an active, approved IACUC protocol is in place again to transfer the animals back to the PI (see [Institutional Policy 10.4.19](#)).

## 6. Annual Renewal

In accordance with USDA regulations, IACUC protocols that involve USDA covered animal species require an annual renewal. The PI must submit the [USDA Annual Renewal Form](#) describing the status of the project and assure that activities are being conducted in accordance with the approved protocol. Significant changes to the protocol must be reviewed and approved by the IACUC. The USDA Annual Renewal form must be submitted to the IACUC Office at least 2 weeks prior to the one year anniversary date of the protocol. Failure to complete and return the form by the deadline date will result in the expiration of the protocol and inability to order animals through Comparative Medicine (see [Institutional Policy 10.4.19](#)).

## 7. Amendments

Amendments can be any significant or minor change requested to an approved IACUC protocol. Significant changes are reviewed and approved through DMR, FCR or Veterinary Verification and Consultation (VVC) and minor changes are reviewed and approved through Administrative Review.

### A. DMR/FCR

In accordance with the [PHS Policy: NOT-OD-14-126](#), significant changes to previously approved animal activities include changes that have, or have the potential to have, a negative impact on animal welfare. Significant changes listed below must be reviewed and approved through DMR or FCR review.

- Change from non-survival to survival surgery
- Change resulting in greater pain, distress or degree of invasiveness
- Change in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- Change in species
- Change in study objectives
- Change in Principal Investigator
- Change that impacts personnel safety
- A requested addition of  $\geq 10\%$  of the total number of animals on the approved protocol must be reviewed and approved through FCR.
- A requested addition  $\leq 10\%$  of the total number of animals on the approved protocol may be reviewed and approved through DMR.

### B. VVC (Veterinary Verification and Consultation)

In accordance with the [PHS Policy: NOT-OD-14-126](#), some activities that may not have a direct impact on animal welfare are also considered to be significant. Significant changes listed below may be reviewed and approved administratively, but require consultation with the Veterinarian. The Veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and –approved policy is appropriate for the animals in this circumstance.

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Consultation with the Veterinarian will be documented through the Veterinary review. The Veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and –approved policies, SOPs and Guidelines. Other sources of adequate documentation for the verification of proposed changes to anesthesia, analgesia, or sedative substances may include published veterinary formularies and peer reviewed publications.

- Change in anesthesia, analgesia, or sedation
- Change in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
- Change in duration, frequency, type or number of already approved procedures including behavioral tests performed on an animal as long as it doesn't result in greater pain or distress
- Change in volume, administration route of already approved experimental substances
- Change in frequencies, volume and site of already approved blood collection
- Change in identification method

### **C. Administrative Review**

In accordance with the [PHS Policy: NOT-OD-14-126](#), minor changes listed below do not require IACUC review and may be reviewed and approved administratively.

- Correction of typographical errors
- Correction of grammar
- Change in contact information
- Change in personnel; other than PI. All personnel must complete required trainings and enroll in the Occupational Health and Safety Program.

VII. Policy Renewal Date  
1/29/2024

### VIII. References

1. USDA. 2013. Animal Welfare Act and Animal Welfare Regulations.  
[https://www.aphis.usda.gov/animal\\_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf](https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf)
2. Office of Laboratory Animal Welfare. 2015. Public Health Service Policy on Humane Care and Use of Laboratory Animals.  
<https://grants.nih.gov/grants/olaw/references/phspol.htm#ReviewofPHS-ConductedorSupportedResearchProjectshttps://grants.nih.gov/grants/olaw/references/phspol.htm>

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3. Office of Laboratory Animal Welfare. 2014. Guidance on Significant Changes to Animal Activities. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>
4. Office of Laboratory Animal Welfare. 2008. Correct Conduct of Full-Committee and Designated-Member Protocol Reviews. <http://grants.nih.gov/grants/olaw/references/laba02v31n9.htm>
5. Office of Laboratory Animal Welfare. 2008. Model for Performing Institutional Animal Care and Use Committee: Continuing Review of Animal Research. <http://grants.nih.gov/grants/olaw/references/contop96.htm>
6. Guide for the Care and Use of Laboratory Animals, 8<sup>th</sup> edition, 2011

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POLICY APPROVAL

*Initiating Authority*

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Name: Daniel C. Flynn, Ph.D., Vice President for Research

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**Executed signature pages are available in the Initiating Authority Office(s)**