	UCSD INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POLICY MANUAL	POLICY # 39.02 Originally Issued: 02/28/19 Revised: 09/06/19
	IACUC Protocol Review Process	

I. Background and Purpose

The UCSD IACUC is responsible for overseeing and evaluating all aspects of animal care and use. All proposals involving animals are reviewed by the IACUC committee to ensure that the criteria established in the PHS Policy, the Animal Welfare Regulations (AWRs), and the Guide for the Care and Use of Laboratory Animals are implemented. In its review of proposals, the IACUC's primary goal is to facilitate compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

II. Who Should Read This Policy

All personnel listed on animal use protocols, particularly those responsible for submitting new protocols, third year rewrites and amendments to approved protocols.

III. Definitions

Term	Definition
Amendment	Any change to an IACUC approved protocol.
Full Committee Review (FCR)	Requires a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that for proposals reviewed by the full committee, a simple majority vote of the members present is required for approval. The Committee has the authority to approve, require modifications in (to secure approval), withhold approval, or defer until future meeting, any proposed activity.
Designated Member Review (DMR)	Mechanism by which one or more qualified IACUC members are assigned to review a protocol outside of FCR; this may only occur after the entire IACUC has been notified of the protocols eligible for DMR and has been given at least two business days to call for any of the protocols to be reviewed by FCR.
Administrative Designated Member Review (DMA)	Mechanism by which changes to a protocol may be approved administratively if they meet the criteria for an administrative approval.
Veterinary Verification and Consultation (VVC)	Mechanism by which an amendment to a protocol can be administratively approved in consultation with a veterinarian designated by the Attending Veterinarian, who is authorized by the IACUC to review and verify that the proposed amendment conforms to specific approved IACUC policies or documents.

IV. Policy

1. Every vertebrate animal used in research, teaching, or testing at UC San Diego must be included in an approved Animal Use Protocol (AUP).
2. Any change to a protocol (other than the addition/deletion of personnel or change in their protocol responsibilities) must be submitted as an amendment to the protocol.
3. None of the proposed changes may be implemented until the amendment is approved by the IACUC.
4. New protocols and Third Year Rewrites are generally reviewed by Full Committee Review (FCR).
5. Changes to an approved animal use protocol are processed by Full Committee Review (FCR), Designated Member Review (DMR), Veterinary Verification and Consultation (VVC), or administrative approval (DMA), depending on the nature of the proposed revision.
6. Protocols will be processed by Full Committee Review (FCR) when the amendment involves the following criteria:
 - a. A dog, cat or non-human primate,
 - b. Pain category E procedures,
 - c. Procedures that introduce a new higher-level pain category,
 - d. Addition of three or more experimental groups to Question 12,
 - e. Addition of a survival procedure to a previously non-survival protocol,
 - f. Addition of 20% or more of the total number of animals previously approved,
 - g. Request for an exception to IACUC Policy or the Guide for the Care and Use of Laboratory Animals (NRC, 2011), or
 - h. Addition of a new satellite facility (or use of an already approved SF).
7. Amendments will be reviewed administratively (DMA) if they meet the following criteria:
 - a. Correction of typographical errors;
 - b. Correction of grammar;
 - c. Contact information updates; and
 - d. Change in personnel, other than the PI. (There will be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)
 - e. Change in lab location;
 - f. Addition of a comparable breed/strain if no change in pain, distress, or biosafety is expected;
 - g. Minor clarification of an already approved procedure (i.e. adding already approved compound to Question 17 or VIII. Hazardous Agents);
 - h. Addition/change of a funding source;
 - i. Removal of a proposed experiment from a protocol;
 - j. Addition of training information for Teaching/Training protocols; or
 - k. Increase in animals does not exceed 10% of the number approved by the IACUC, for previously approved procedures (only for non-USDA-covered species and only once per year)

8. Amendments to protocols that do not involve a dog, cat or non-human primate that may be processed administratively after veterinary verification and consultation (VVC) are:
 - a. Addition of Buprenorphine SR as post-operative analgesia, with dosage and application schedule as recommended by the ACP veterinarian.
 - b. In cases of drug supply shortages, at the recommendation of an ACP veterinarian, an extension of an existing drug's expiration date for a specified period of time or use of a non-pharmaceutical grade equivalent of the approved drug for a specified time.
 - c. Addition or replacement of a euthanasia method that is acceptable (or conditionally acceptable when those conditions are met) according to the AVMA Guidelines for the Euthanasia of Animals.
 - d. Replacement of an existing blood collection method or addition of a blood collection method when performed as described in the Blood Collection policy. The new method must not increase the potential risk and/or pain and distress level and at least one method must already be approved in the protocol.
 - e. Addition or replacement of an approved experimental or therapeutic compound or agent for a similar compound or agent, or a change of dosage, frequency or application route for a compound or agent, only after ACP veterinary consultation, and if the expected drug action and possible adverse effects are comparable.
 - f. Requests for permission to photograph or video animals according to IACUC Policy 29, Video and Photography in Animal Use Areas.
9. All other amendments not covered by Points 6-8 are eligible to be processed by DMR.
10. For extraordinary cases, an investigator may petition for an Exceptional Designated Member Review (DMX) by following up with an email to iacuc@ucsd.edu to request the faster review and provide their compelling justification for the request. Investigators should note that this type of review is reserved for truly exceptional circumstances.
11. Any amendment that is eligible for DMR or for which a DMX has been requested may be sent to FCR by any IACUC member at any point in the review process consistent with federal regulations.
12. Annual reviews for USDA-covered species protocols and for Department of Defense (DOD) funded protocols are reviewed administratively (DMA).
13. No member will participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor will a member who has a conflicting interest contribute to the constitution of a quorum, in accordance with federal regulations.

V. Related Documents

UCSD Documents	IACUC Policy 26 Minimizing Pain and Distress IACUC Policy 13 Euthanasia IACUC Policy 29 Video and Photography in Animal Use Areas
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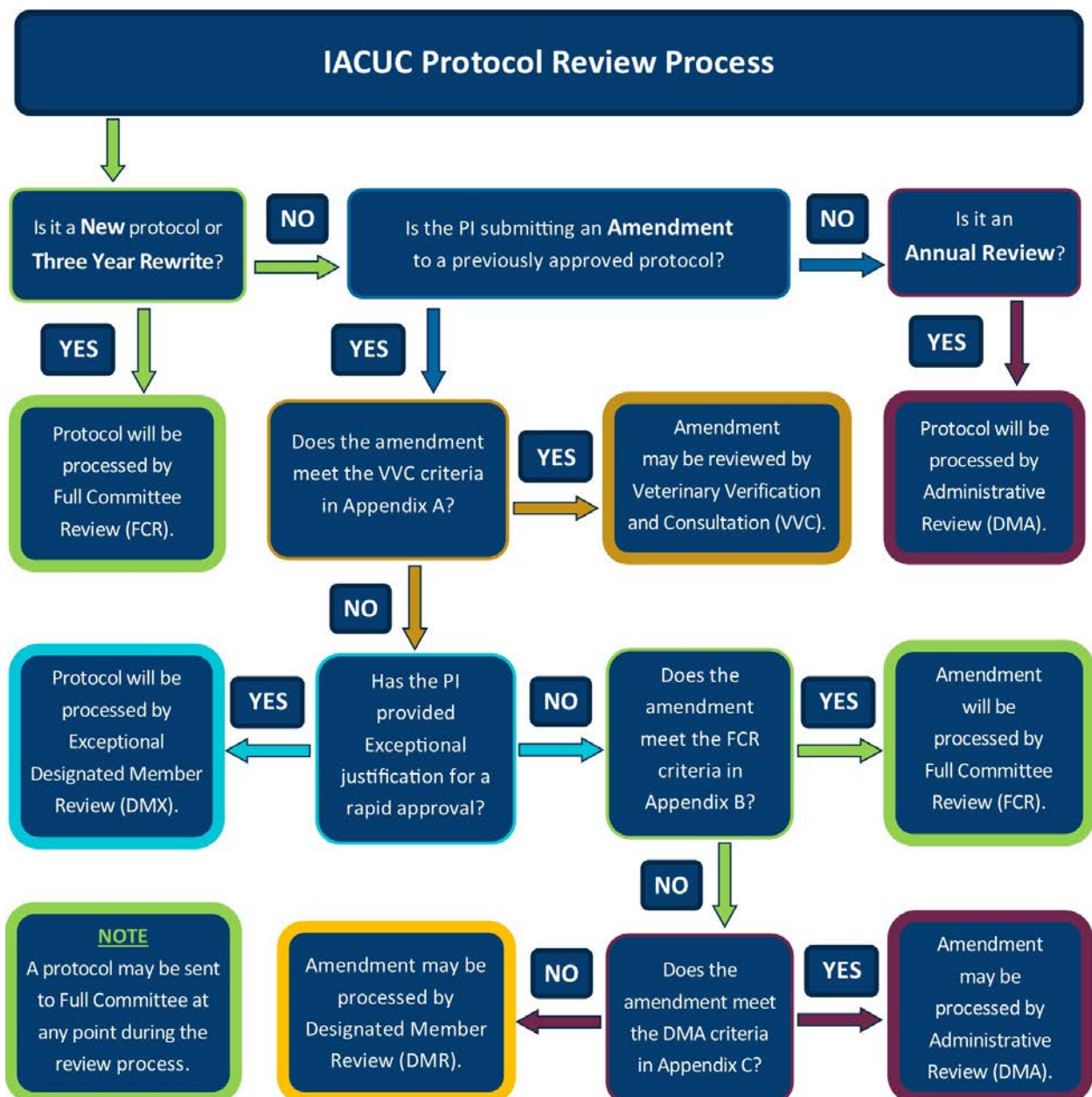
Other Documents and References	PHS Policy on Humane Care and Use of Laboratory Animals Animal Welfare Act and Regulations Animal Care Policy Manual Guide for the Care and Use of Laboratory Animals NOT-OD-14-126 NIH's Guidance on Significant Changes to Animal Activities
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VI. Additional information

Methods of IACUC Review

1. Full Committee Review (FCR):
 - a. Requires a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that for proposals reviewed by the full committee, a simple majority vote of the members present is required for approval.
 - b. The Committee has the authority to approve, require modifications in (to secure approval), withhold approval, or defer until future meeting, any proposed activity.
2. Designated Member Review (DMR):
 - a. Each IACUC member is provided a list of the protocols eligible for DMR and are given two business days to consider the request. If any member believes an amendment should be discussed at the full committee, DMR will not be granted and the amendment will be reviewed at the next meeting by FCR.
 - b. The IACUC Chair (or his/her designee) designates one or more qualified members to review the proposed amendment. If assigned by the designee, the IACUC Chair will be notified of the reviewer assignment and will reassign if deemed necessary.
 - c. The designated member(s) has authority to approve, require modifications in (to secure approval), or request full committee review. A designated reviewer may not withhold approval; this action may only be taken by the full committee.
3. Exceptional Designated Member Review (DMX):
 - a. While the UCSD IACUC has several efficient processes for review of proposed activities, there may be the rare occasion where a PI needs a review/approval more rapidly than can be accommodated by the standard processes. The process for an exceptional designated member review consists of the following:
 - i. The Principal Investigator or alternate contact sends an email to the IACUC office providing strong justification for the need for a faster review. This could include a "sudden" experiment to prevent the loss of data or wastage of an animal.
 - ii. Subsequent steps for IACUC review by DMX will follow standard DMR procedures as outlined above.
 - iii. New and 3-year rewrites are usually not eligible for DMX.
4. Administrative Designated Member Review (DMA):
 - a. While Federal regulations allow for two types of review of animal use protocols (FCR and DMR), recent guidance from the Office of Laboratory Animal Welfare (OLAW) granted authority for a small number of items to be administratively approved, i.e., Administrative Designated Member Review (DMA).

- b. Amendments processed by DMA will be reviewed by an IACUC member or official alternate.
- 5. Veterinary Verification and Consultation (VVC):
 - a. An ACP veterinarian designated by the Attending Veterinarian, is authorized by the IACUC to review and verify that the proposed amendment conforms to specific approved IACUC policies or documents.
 - b. If the ACP veterinarian verifies the changes, the amendment is administratively approved following the usual process, including sending the amendment approval letter to the PI.
 - c. If the ACP veterinarian indicates that FCR or DMR is needed, the amendment is routed accordingly.



Appendix A

Amendments to protocols that do not involve a dog, cat or non-human primate that may be processed administratively after veterinary verification and consultation (VVC) are:

- a. Addition of Buprenorphine SR as post-operative analgesia, with dosage and application schedule as recommended by the ACP veterinarian.
- b. In cases of drug supply shortages, at the recommendation of an ACP veterinarian, an extension of an existing drug's expiration date for a specified period of time or use of a non-pharmaceutical grade equivalent of the approved drug for a specified time.
- c. Addition or replacement of a euthanasia method that is acceptable (or conditionally acceptable when those conditions are met) according to the AVMA Guidelines for the Euthanasia of Animals.
- d. Replacement of an existing blood collection method or addition of a blood collection method when performed as described in the Blood Collection policy. The new method must not increase the potential risk and/or pain and distress level and at least one method must already be approved in the protocol.
- e. Addition or replacement of an approved experimental or therapeutic compound or agent for a similar compound or agent, or a change of dosage, frequency or application route for a compound or agent, only after ACP veterinary consultation, and if the expected drug action and possible adverse effects are comparable.
- f. Requests for permission to photograph or video animals according to IACUC Policy 29, Video and Photography in Animal Use Areas.

Appendix B

Protocols are processed by Full Committee Review (FCR) when the amendment involves the following criteria:

- a. A dog, cat or non-human primate,
- b. Pain category E procedures,
- c. Procedures that introduce a new higher-level pain category,
- d. Addition of three or more experimental groups to Question 12,
- e. Addition of a survival procedure to a previously non-survival protocol,
- f. Addition of 20% or more of the total number of animals previously approved,
- g. Request for an exception to IACUC Policy or the Guide for the Care and Use of Laboratory Animals (NRC, 2011), or
- h. Addition of a new satellite facility (or use of an already approved SF).

Appendix C

Amendments will be reviewed administratively (DMA) if they meet the following criteria:

- a. Correction of typographical errors;
- b. Correction of grammar;
- c. Contact information updates; and

- d. Change in personnel, other than the PI. (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)
- e. Change in lab location
- f. Addition of a comparable breed/strain if no change in pain, distress, or biosafety is expected
- g. Minor clarification of an already approved procedure (i.e. adding already approved compound to question 17 or VIII. Hazardous Agents)
- h. Addition/change of a funding source
- i. Removal of a proposed experiment from a protocol
- j. Addition of training information for Teaching/Training protocols
- k. Increase in animals does not exceed 10% of the number approved by the IACUC, for previously approved procedures (only for non-USDA-covered species and only once per year)