

Institutional Animal Care and Use Committee		UNTHSC
Title: Amendments to Approved Protocols		
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Approved by IACUC Date: October 26, 2021		

A. BACKGROUND INFORMATION

- a. The Institutional Animal Care and Use Committee (IACUC) at the University of North Texas Health Science Center (UNTHSC) has the responsibility to assure that all animal use activity meets federal law mandates, Public Health Service policy, the Guide recommendations and all accreditation expectations. Any change needed to an already approved protocol must be approved by the IACUC before the change can occur.

B. DEFINITIONS

- a. Amendment – A proposed change to an active and currently approved animal use protocol. The proposed change(s) must fit with the objectives, purpose, or aims stated in the original protocol to qualify as an amendment. Proposals not qualifying as an amendment will require submission of a new protocol. An Amendment is to be used to gain acceptance for a variation in the conduct of a protocol. In general, an amendment is used to correct problems that arise during the conduct of a study or to continue a study where the goal has not changed but the methods and procedures have been modified to better achieve the goals.
- b. Administrative Review (AR) – a review process only allowed for minor amendments.
- c. Veterinary Verification and Consultation (VVC) – a review process in accordance to OLAW Guidance #NOT-OD-14-126, in which an amendment may be reviewed according to the IACUC reviewed and approved policies in consultation with a veterinarian authorized by the IACUC.
- d. Designated Member Review (DMR) – a review process allowed by the regulations, in which each IACUC member is provided with at least a list of the proposed submission (i.e. amendment), and given a specified period to call for Full Committee Review. If no one calls for Full Committee Review, the submission is assigned to at least one IACUC Member as the Designated Reviewer. The Designated Reviewer may approve the submission, require modifications, or call for Full Committee Review.
- e. Full Committee Review (FCR) – a review process in which the proposal is reviewed at a fully convened IACUC meeting, attended by a quorum of IACUC members. The proposal must receive a majority vote of members present in order to receive full approval.

C. RESPONSIBILITIES

- a. It is the responsibility of the Principal Investigator (PI) to submit an amendment when a change is needed to an approved protocol. The PI cannot implement the change until the amendment is approved.

D. PROCEDURES

- a. If a change is needed to a protocol, the PI shall submit an amendment before implementing the change. The amendment must be approved before the change can take place.
- b. The PI will create the amendment in the electronic system and complete all appropriate fields as necessary. Any new procedures will require an updated or new flow chart.
- c. The PI shall submit the amendment via the electronic system (the amendment will automatically route to the IACUC office for review). If an amendment is submitted outside of the system, it will be returned to the PI with instructions on how to submit the amendment through the electronic system. .
- d. The Administrator will review to assure the application is complete. If revisions are needed, the Administrator will contact the PI with necessary revisions requested.
- e. After all revisions are received, the amendment will be triaged to determine which review process it qualifies for, i.e., Administrative Review (AR), Veterinary Verification and Consultation (VVC), Designated Member Review (DMR), or Full Committee Review (FCR). It will follow the review process as detailed below.

i. ADMINISTRATIVE REVIEW AMENDMENTS

1. Minor amendments may qualify for administrative review and assigned to the Chair. Administrative changes include changes that do not affect the welfare of the animals. Examples are provided below.
2. Administrative review amendments will be reviewed by the IACUC Administrator assigned to it, who will then route it to the Veterinarian for a veterinary review. Once the Veterinarian accepts the amendment, the Chair may then review the amendment for approval. The Veterinarian or Chair may refer any request to the IACUC for DRM or FCR for any reason.
3. The committee is provided a list of the amendments approved by AR each month.
4. Examples of AR amendments include:
 - a. Personnel changes, other than investigator
 - b. Changes/additions of lab locations (that have already been approved for animal use)
 - c. Title Changes/Funding Changes
 - d. Additional procedures during terminal surgery or post euthanasia.

ii. VETERINARIAN VERIFICATION & CONSULTATION AMENDMENTS

1. VVC Amendments falls within the NIH notice/ OLAW Guidance #NOT-OD-14-123, which allows for flexibility in the evaluation of certain proposed changes to animal protocols which may be handled in consultation by the Attending Veterinarian. The consultation with the Veterinarian must be documented. The Veterinarian may refer any amendment to the IACUC for review by DMR or FCR for a ny reason,

and must refer any amendment that does not meet the parameters of the IACUC approved policies, which are appropriate for the animal protocol and its circumstances.

2. Amendments that qualify for VVC review will be routed to the Veterinarian through the VVC feature in the electronic system. The Veterinarian will then have the opportunity to request clarifications, or request for the amendment to be reviewed by the IACUC (either through DMR or FCR), or mark that it meets the institution's policies while certifying their acceptance and marking of the approval date.
3. An approval letter is then prepared by the IACUC Administrator, and sent by the IACUC Chair.
4. The Committee is provided with a list of amendments approved by VVC each month.
5. Examples of VVC amendments include:
 - a. Additional test drugs if procedures are the same and drugs are not used to induce toxicity.
 - b. Increase in duration of experiment if not a post-surgical protocol:
 - i. Ex. Follow animals for effects of drug from 2 weeks to 4 weeks.
 - ii. Ex. Monitor spontaneous tumor development from 4 months to 8 months.
 - c. Method of bleeding, if an IACUC approved method.
 - d. Change in duration, frequency, type or number of procedures performed on an animal that do not cause additional pain or distress.
 - e. Changes in behavioral/observational procedures
 - i. Ex. Increasing observation period for a locomotor activity from 5 to 10 minutes.
 - f. Change/Addition of strain of animals within a species
 - i. Ex. Different knockouts or Sprague-Dawley to Wistar
 - g. Change of euthanasia to any approved in the AVMA Guidelines for the Euthanasia of Animals.
 - h. Change of anesthetic agent if switch is to an approved regimen for the species.
 - i. Additional procedures during a terminal surgery.
 - j. Change in number of animals less than or equal to 10% of the approved number (for that year). For USDA covered species, the amendment for additional animals would need to go to designated review.
 - k. Additional non-invasive sampling.
 - l. Change of age, sex, or source of animals to be used.

iii. DESIGNATED MEMBER REVIEW AMENDMENTS

1. Amendments that qualify for DMR include a select list of amendments involving significant changes. Examples of amendments that qualify for this review type are provided below.
2. Amendments undergoing DMR are generally assigned to the Chair or Vice-Chair; however, the Chair may designate any IACUC member to serve as the Designated Reviewer.
3. Committee members are given five business days grace period to call for full committee review. Committee members may provide comments of the document for the Designated Reviewer to consider.
4. Examples of DMR amendments include:
 - a. Amendment involving additional prolonged restraint.
 - b. Investigator transfers, only between faculty members in good standing.
 - c. Use of analgesics.
 - d. Changes in duration, frequency, or number of procedures performed on an animal that results in greater pain, distress, or degree of invasiveness.
 - e. Change in number of animals over 10% of the approved number (for that year, rodents only).
 - f. Change/addition of species (mice and rats only).
 - g. Change in housing or use of animals in a location that is not part of the animal program overseen by the IACUC.
 - h. Changes that impact personnel safety.

iv. FULL COMMITTEE REVIEW AMENDMENTS

1. Full Committee Review amendments are amendments that have significant changes, and may only be reviewed at a convened meeting with a quorum (simple majority) of members present. Examples of amendments that qualify for FCR are provided below.
2. Amendments that qualify for FCR, are placed on the next month's meeting agenda. The PI is notified of the meeting date in which the amendment will be reviewed.
3. Two Committee Members will be assigned as reviewers for the amendment, and will present the amendment at the IACUC meeting. A majority vote of the quorum present is needed to approve, require modifications (to secure approval), or withhold approval of an amendment.
4. Examples of amendments that require FCR include:
 - a. Change/Addition of USDA covered-animal species.
 - b. Changes in objectives of a study
 - c. Addition of survival surgeries (when no survival surgeries are described in original application). A change from non-surgery to surgery; from minor to major surgery; or from non-survival to survival surgery.

- d. Addition of animals to which invasive procedures will be performed (i.e. stroke surgery)
- e. Move to pain category E (withholding analgesics, painful procedures added, etc.).

v. NEW PROTOCOL APPLICATION

- 1. There are times in which the amendment exceeds the purpose of the protocol. In such instances, a new protocol may be requested at any given point during the review process of an amendment.

E. REFERENCES:

- a. [Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.](#)
- b. [PHS Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised 2015.](#)
- c. [NOT-OD-14-126 Guidance on Significant Changes to Animal Activities](#)
- d. [Guide for the Care and Use of Laboratory Animals, Eighth Edition. National Academy Press, Washington, D.C. 2011.](#)

Please refer to this chart for details on which of the amendment requests are eligible for Administrative Review (AR), Veterinary Verification & Consultation (VVC), Designated Member Review (DMR) or Full Committee Review (FCR).

AR	VVC	DMR	FCR
Personnel changes, other than Investigator	Additional test drugs if procedures are the same and drugs are not used to induce toxicity.	Amendment involving additional prolonged restraint.	Change/Addition of USDA covered-animal species.
Changes/Additions of lab locations (that have already been approved for animal use)	Increase in duration of experiment if not a post-surgical protocol: a. Ex. Follow animals for effects of drug from 2 weeks to 4 weeks. b. Ex. Monitor spontaneous tumor development from 4 months to 8 months.	Investigator transfers, only between faculty members in good standing.	Changes in objectives of a study
Study Title Changes/ Funding Changes	Method of bleeding, if an IACUC approved method.	Use of analgesics	Addition of survival surgeries (when no survival surgeries are described in original application). A change from non-surgery to surgery; from minor to major surgery; or from non-survival to survival surgery.
Additional procedures during terminal surgery or post euthanasia.	Change in duration, frequency, type or number of procedures performed on an animal that do not cause additional pain or distress.	Changes in duration, frequency, or number of procedures performed on an animal that results in greater pain, distress, or degree of invasiveness.	Addition of animals to which invasive procedures will be performed (i.e stroke surgery)
	Minor changes in behavioral/observational procedures. a. Ex. Increasing observation period for a locomotor activity from 5 to 10 minutes	Change in number of animals over 10% of the approved number (for that year, rodents only).	Move to pain category E (withholding analgesics, painful procedures added, etc.)
	Change/Addition of strain of animals within a species. a. Ex. Different knockouts or Sprague-Dawley to Wistar	Change/Addition of species (mice and rats only)	
	Change of euthanasia to any approved in the AVMA Guidelines for the Euthanasia of Animals	Change in housing or use of animals in a location that is not part of the animal program overseen by the IACUC. (IACUC inspection is required)	
	Change of anesthetic agent if switch is to an approved regimen for the species.	Changes that impact personnel safety	
	Additional procedures during a terminal surgery.	Breeding of animals over 10%	
	Change in number of animals less than or equal to 10% of the approved number (for that year). For USDA covered species, the amendment for additional animals would need to go to designated review.		
	Additional non-invasive sampling.		
	Change of age, sex, or source of animals to be used.		
	Breeding of animals less than 10%		