

PROTOCOL AMENDMENTS

1 Policy statement

Under the NACLAR Guidelines, changes/amendments to an IACUC-approved protocol must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) before they occur.

The intent of this policy is to outline the IACUC requirements for the review of protocol amendments for species covered under the NACLAR Guidelines and the Animals and Birds (Care and Use of Animals for Scientific Purposes) Rules 2004.

2 Definitions

Animal	All live fish, amphibians, reptiles, birds, non-human mammals and cephalopods.
Approved Protocol	Any project that involves the use of any animal for any scientific purpose and that is approved by an IACUC.
Designated Member Review (DMR)	Review of both new protocols and significant amendments that meet DMR criteria, and minor amendments by two Designated IACUC Reviewers (DRs) outside of a Full Committee/Quorate meeting.
Housing Facilities	Buildings, yards, paddocks, grounds in which animals are kept.
Institutional Animal Care and Use Committee (IACUC)	The Committee, constituted by an institution, responsible for the oversight and evaluation of all aspects of the institution's animal care and use programme.
Minor Amendments	A change to an approved protocol that does not alter the study objectives and does not increase pain, distress, or risk to animal welfare.
Principal Investigator (PI)	A person who proposes and/or has IACUC approval to conduct a protocol involving the use of animals, and has overall responsibility of a protocol.
Procedure areas	Locations where animals undergo any procedure and/or are held for less than 24 hours.
Protocol	A written description of a project put forward by a PI for review by the IACUC.
Scientific Purposes	Any purpose for which activities (including breeding of animals integral to a research or teaching project) are performed for the acquisition, development or demonstration of knowledge or techniques in any scientific discipline, including the purpose of research, teaching, diagnosis, field trials, product testing, production of biological products and environmental studies.

Significant Amendment	A change to an approved protocol that may affect animal welfare, alter the scientific objectives, or impact regulatory compliance.
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3 Scope

This policy applies to all animal work covered under NUS Animal Care and Use Programme.

4 Guidelines

4.1 Amendment Submission and Approval Requirements

- 4.1.1 The IACUC should develop a policy on the types of changes/amendments that are considered significant or minor, and how to review these changes to avoid ambiguity.
- 4.1.2 PI must submit an amendment for any modification in an approved protocol during the project. No work on an amendment may begin prior to obtaining IACUC approval.
- 4.1.3 PIs are responsible for timely submission and compliance.

4.2 Classification and Review of Amendments

- 4.2.1 Amendments are classified as Significant, Minor and Administrative Amendments. Please refer to Annex A for details on the classification.
- 4.2.2 Review of significant changes to previously approved protocols should, with few exceptions, receive Full Committee/Quorate Review in a convened meeting of the IACUC. The IACUC may allow Designated Member Review (DMR) of protocols in lieu of a Full Committee/Quorate Review. In this regard, the IACUC must develop a policy on what can be approved by DMR. A DMR should be conducted by the AV, or the AV alternate, and at least one other member of the IACUC.
- 4.2.3 Changes considered as Minor Amendments do not require IACUC review at a quorate meeting and can be approved by DMR upon submission to IACUC. Nevertheless, IACUC reserves the right to review the changes at a Full Committee/Quorate meeting should circumstances warrant it.
- 4.2.4 A DMR will be conducted by the AV, or an AV designate, in conjunction with at least one additional member of the IACUC. Representatives from Comparative Medicine (CM) Operations, CM Imaging Facilities (CMIF), CM Training, and the Office of Risk Management and Compliance (ORMC) will also review the amendment and provide input as part of the review process.
- 4.2.5 Administrative Amendments are amendments that can be processed administratively without IACUC review and approval. These include changes which IACUC gives the authority to designated reviewers to perform administrative review to ensure all requirements are met for approval.

4.3 Record Retention

All amendment requests and decisions must be retained for at least three years after protocol completion, in accordance with NAELAR requirements.

5. References

1. [Guidelines on the Care and Use of Animals for Scientific Purposes. National Advisory Committee for Laboratory Animal Research. 2022](#)
2. [Animals and Birds \(Care and Use of Animals for Scientific Purposes\) Rules 2004](#)

6 Related documents/SOPs

1. [P101 Animal Use that Requires IACUC Review and Application Form Requirements](#)
2. [P106 Animal Use Location and IACUC Review Requirement](#)
3. [P210 Visual and Audio Documentation of Animal Use](#)

Revision	Author	IACUC approval date
Last reviewed	Dr Foo Tet Wei, John	31 March 2015
P201.01. Reviewed to: 1. ensure policies are in compliance with the NAELAR Guidelines 2022 and the updated Animals and Birds (Care and Use of Animals for Scientific Purposes) Rules 2004; and 2. up-to-date with current practices Changes made: 1. to add "The IACUC should develop a policy on the types of changes/amendments that are considered significant or minor, and how to review these changes to avoid ambiguity" and "changes/amendments to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur."; and 2. update to "Review of significant changes or amendments to approved protocols should be conducted by Full Committee Review."; and 3. add administrative review to be up-to-date with current practices; and 4. collate the various types of amendments under Annex A to ensure the policy is up-to-date with current practices	Dr Chew Li Li IACUC	16 January 2023
P201.02. Reviewed to: 1. rename policy to "Protocol Amendments" 2. revise Section 4.1.2 3. include Designated Member Review (DMR) of significant amendments in Section 4.2.2 4. include the designated members conducting the DMR in Section 4.2.4 and 4.3 Record retention 5. update policy format and Annex A	IACUC Designated Reviewers Dr Chew Li Li Ms Keh Lee Hwei	19 February 2026



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Annex A: Classification and Review of Amendments

1. Any submissions not listed in the table will be reviewed by IACUC members at a Full Committee/Quorate meeting.
2. Regardless of the processing stage (e.g after triage by office for DMR or already under review by DRs), reviewer had the option to escalate any of the submission(s) below for quorate review.

Review Type	DMR		Admin Review
Protocols	Full protocols		
	1. All protocols using small number of animals i.e. ≤ 100 for small animals and ≤ 500 for fishes. These protocols should be either a. pain cat C; or b. non-survival surgery e.g perfusion. Note: <i>a. Use of NHP, except for point 3 below, will require quorate review.</i> <i>b. use of pigs, except for point 2 and 3 below, will require quorate review.</i> 2. Teaching protocol using all animals for workshop where CM vet(s) will be stationed to support the whole procedure e.g. ASTC. 3. Review of procedures to be performed in NUS based on MOU requirements. Procedures to be performed as approved in service protocols such as NMPC, Transgenic and Gene Targeting Facility (TGTF) and CMIF service protocols. 4. Research (euthanasia and tissue harvest only) 5. Simple breeding ¹		1. Biodiversity (Observation only, see checklist in Annex A of P210 Visual and Audio Documentation of Research Animals and Animal Use Areas for details) 2. Notice of Intent (NOI) to use: a. zebrafish ≤5dpf. b. medaka ≤ 3 days post-hatching. c. chick embryos < embryonic day 16 (ED16).
	Amendments		
	Significant Amendments	Minor Amendments	Changes for Admin Review
Changes in procedures	1. Addition of: a. cell line(s) ² with change in species of origin, ABSL or route of administration and not requiring rHBR approval b. new experiment(s) with all procedures, strains and substances previously approved within the same protocol Note: <i>i. Exclude use of death as an endpoint and re-use of animals. Addition of new experiments involving the two will require quorate review even if it had been previously approved in the protocol.</i> <i>ii. Addition of up to 2 experiments and a total of 2 changes per amendment will be reviewed by DMR. Anything more will require quorate review.</i> 2. Increase in number of experimental time points, frequency, duration and/or number of approved non-surgical procedures e.g. IVIS, blood collection etc 3. Change in use of pharmaceutical grade substances to non-pharmaceutical grade or from higher purity/grade to lower purity/grade. Refer to IACUC policy P215 section 4.1.5). Note: for change from PGs to NPGs, DMR if reason(s) for change fits the acceptable justification stated in P215, Annex B, FAQ question 5. If not, quorate review will be required.	1. Changes in surgical plan, anaesthesia and/or analgesia and/or antibiotics with CM vet consultation and in accordance with CM SOP(s) ³ 2. Refinement or minor change of approved procedures (i.e. similar or less invasive) without increasing pain or distress to animals; 3. Change to a method of euthanasia that is approved under CM SOP(s) ³ 4. Change in procedures in accordance with CM SOPs ³ 5. Addition of: a. procedures in accordance with CM SOPs ³ b. cell lines ² with no change in species of origin, ABSL or route of administration and not requiring rHBR approval c. new procedures done in accordance with already approved procedures described in service protocols such as NPC, TGTF and CMIF service protocols. 6. Decrease in number of experimental time points, frequency, duration and number of procedures with no change in monitoring 7. Change in use of non-pharmaceutical grade substances to pharmaceutical grade or to one that is equivalent (e.g. change in vendor), or preferred (e.g. from analytical grade bulk chemical to USP reference standard). Refer to IACUC policy P215 section 4.1.5).	Nil
Change in animal no.	Increase in number of animals by > 20% of the approved number.	Increase in number of animals by ≤20% of the approved number assuming there are no changes that require quorate review	
Change in animal use location	Nil	Nil	Change from one procedure room to another procedure room: 1. both rooms are IACUC approved and AVS licensed for the same procedures; and 2. PI will be performing the same procedures as approved in the original procedure room. Note: ORMC recommendation required for approval.
Change in species, strains, types and sources	Addition of new strains to breeding protocol ¹	1. Inclusion of nursing mothers for approved pups or change in the sex, age, weight provided the change will not have any adverse effects on the animals; 2. Change in animal source as long as it is not self-acquisition	1. Updating “Animal Sources” field in an approved protocol to the new approved protocol number if mice are being obtained from an expired breeding protocol. Note: No change in procedures or animal numbers. 2. Amendment to supply surplus naïve animals to other PIs and/or protocols in NUS. Note: No increase in animal number and animals are not bred specifically for the purpose.
Others	1. Change of PI 2. Re-review of application not approved within 6 months after IACUC quorate review	1. Amendment to include photography and video-recording ⁴ 2. Removal of special husbandry arrangement with CM vet consultation 3. Change in personnel status i.e. personnel working in/ with Non-NUS facilities/ animals to be reviewed by ≥ DRs (one to be CM vet) and CM ops.	1. Change(s) in funding source and/or project title 2. Change in personnel including Co-PI and PI designate/Emergency contact. 3. Administrative correction in the wordings of approved information e.g. typos to make consistent with reviewers’ approval. 4. Contact information, userid, staff no., OH programme no., RCULA certificate no and other administrative updates.

¹ Simple breeding protocol or amendments to add new strains with:

- a. Simple corresponding research applications (submitted or approved) i.e strain added served small no. of research protocols (≤3), small animal no. (≤500) and strains (≤5) added.
Note: ≤500 refers to the total number of animals, including offspring to be produced, for the whole application. It is not applicable to the use of zebrafish ≤5dpf and medaka ≤3 days post-hatching]
- b. No adverse phenotype for strains added
- c. Strains not available commercially (locally)
- d. No multiple crosses with intermediate strains
- e. no special requirements such as. extended weaning, co-rearing etc

² Cell lines must satisfy BMT requirements.

³ In accordance with CM SOP, only straight forward procedures not requiring special justification/conditional approval

⁴ Applications to display research animals such as fluorescent zebrafish during technofest, NUS open house etc to be reviewed by IACUC quorate via email.

- email only primary members;
- quorate responses needed. Out of the quorum, majority votes needed for approval; and
- IACUC approve the application subjected to AVS license. Researcher to provide the license for office documentation when available