

Purpose / Scope

The purpose of this policy is to apply Canadian Council on Animal Care's (CCAC) requirements for ensuring scientific merit review of animal use for research purposes, as per *CCAC's policy statement on scientific merit and ethical review of animal-based research*. This policy pertains to basic and applied research associated with Animal Use Protocols (AUP) within Western's Research Community.

This policy does not apply to projects focused upon regulatory, teaching or training, except where individuals are being taught or trained as research partners – testing, animal health surveillance, or the production of animals or biologics for scientific purposes – except where that production is part of a research project.¹

Rationale

In its preamble to the policy statement on scientific merit and ethical review of animal-based research, CCAC states, "*animal use in research must only be undertaken if expert, independent opinion has attested to the probable scientific value of the research within its field.*"² As such each institution is responsible to develop and utilize a mechanism to ensure that all research involving animals has received independent review of its scientific value by expert peers.

Policy

Before an AUP is reviewed and approved by Western's ACC, the project must first undergo scientific merit review.

Scientific merit reviewers must

- possess the expertise to adequately review the science, and
- be independent from the research under review, as defined by Tri-Agency³.

¹ Canadian Council on Animal Care. Frequently Asked Questions on the CCAC policy statement on: scientific merit and ethical review of animal-based research. Retrieved from https://www.ccac.ca/Documents/Standards/Policies/FAQ-Scientific_merit_and_ethical_review_of_animal-based_research.pdf 23 February, 2018

² Canadian Council on Animal Care. CCAC policy statement on: scientific merit and ethical review of animal-based research. Retrieved from https://www.ccac.ca/Documents/Standards/Policies/Scientific_merit_and_ethical_review_of_animal-based_research.pdf 23 February, 2018

³ Government of Canada. Conflict of Interest and Confidentiality. 4.0. Definitions. Retrieved from http://www.science.gc.ca/eic/site/063.nsf/eng/h_90108244.html 15 July, 2019

Scientific merit reviews must be completed for all new AUPs and every subsequent Full Renewal.

Pilot studies used to explore a new research direction not covered within an existing peer-reviewed AUP must undergo scientific merit review.

- Pilot studies that develop or evaluate a new methodology within the context of an existing merit reviewed AUP do not require scientific merit review.

The ACC reserves the right to request a scientific merit review at any time when there are significant changes to an AUP being requested, e.g. the research goal.

Where uncertainty exists regarding whether a new study should be considered part of a research program, the Department / Research Institute must work with the AUP Holder (PI) in order to make the determination.

Projects with Independent, Expert Scientific Merit Review from Funding Agencies

For projects funded by external agencies that undertake scientific merit review by experts who are independent from the research, the AUP Holder must provide the funding agency grant number within the associated AUP.

In situations where funding has not been awarded yet the grant proposal received scientific review **and** the AUP Holder wishes the review to be considered as evidence of scientific merit for the related project, they must submit the corresponding documentation with the AUP form.

Projects without Independent, Expert Scientific Merit Review from Funding Agencies

For projects funded by external agencies or by internal funding sources that do not undertake scientific merit review by independent experts, scientific merit reviews must be undertaken by a minimum of two independent, expert peers who are selected by the Department or Research Institute.

Department / Research Institutes associated with the AUP must:

- determine appropriate scientific merit reviewers,
- maintain this membership list and provide it to the Office of Research Ethics, and
- coordinate communications about the merit reviews with the PIs.

Procedures for Undertaking Scientific Merit Reviews must be followed (PROC-013).

Once the scientific merit review has been completed and consensus is reached by the reviewers, the Department/Research Institute must notify the ACC of the decision.

References

Western University

- MAPP 7.12
- Animal Use Protocols Policy (POL-002-A,B,C) and Procedures (PROC-002-A,B)

Canadian Council on Animal Care.

- CCAC policy statement on: scientific merit and ethical review of animal-based research
 - Frequently Asked Questions on the CCAC policy statement on: scientific merit and ethical review of animal-based research
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Revision History

Version	Date	Description of Changes	Author
00	05-30-18	New policy	LT
01	09-09-19	Reallocate responsibilities for administering merit reviews to Faculties/Research Institutes, update terms and titles, remove Roles & Responsibilities section	LT/LC/EB /TR
02	10-11-20	Reformat; add ref. to the procedures doc.	LT