

**Policy: Scientific Merit Review**

**Policy Number:** POL-013

**Version Number:** 00

**Category:** Administrative

**Subject:** Requirements and mechanisms for ensuring scientific merit review for Animal Use Protocols involving basic and applied research

**Approving Authority:** University Council on Animal Care

**Responsible Office:** Vice President (Research) Office

**Related Procedures:**

**Approval Date:** May 30, 2018

**Effective Date:** June 30, 2018

**Revised:**

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**Purpose**

The purpose of this policy is to outline CCAC’s requirements as well as outline an institutional mechanism 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*.

**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.*”<sup>1</sup> 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.

**Scope**

This policy pertains to basic and applied research associated with Animal Use Protocols within Western’s Research Community. As per CCAC’s FAQ document, 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

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<sup>1</sup> 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](https://www.ccac.ca/Documents/Standards/Policies/Scientific_merit_and_ethical_review_of_animal-based_research.pdf) 23 February, 2018

animals or biologics for scientific purposes – except where that production is part of a research project.<sup>2</sup>

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## **Policy**

Basic and applied research involving live animals must undergo two distinct and separate reviews before receiving institutional approval to proceed:

- peer review of the project’s scientific merit, followed by
- ethical review by the institution’s Animal Care Committee (ACC), as per *the Animal Use Protocols Policy (POL-002)*.

Scientific merit reviewers must

- possess the expertise to adequately review the science, and
- be independent from the research under review.

### ***Projects with Independent, Expert Scientific Merit Review from Funding Agencies***

A list of funding sources having independent scientific merit review processes involving appropriate expertise must be maintained by the Vice President (Research) Office and made available to the ACC.

For projects funded by external agencies that undertake scientific merit review by arms-length experts, the Principal Investigator must provide the funding agency grant number.

In situations where funding has not been awarded, yet the grant proposal received above average ratings during the peer review process, and the PI wishes this rating to be considered as evidence of scientific merit review for the related project, the PI must submit the funding agency rating outline to the Merit Review Committee for consideration.

Scientific merit reviews remain valid for the entire four-year life of an Animal Use Protocol.

### ***Mechanism for Internal Scientific Merit Reviews***

The Vice President (Research) Office must establish and maintain the Merit Review Committee (MRC) for ensuring scientific merit review has been undertaken in accordance with CCAC policy.

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<sup>2</sup> 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](https://www.ccac.ca/Documents/Standards/Policies/FAQ-Scientific_merit_and_ethical_review_of_animal-based_research.pdf) 23 February, 2018

The Merit Review Committee must maintain a list of potential scientific merit reviewers with expertise appropriate for the basic and applied research undertaken within Western's Research Community, as per its Terms of Reference and this policy.

***Projects without Independent, Expert Scientific Merit Review from Funding Agencies***

For projects not funded by external agencies that undertake scientific merit review by arms-length experts, scientific merit review must be undertaken by a minimum of two expert peers who are:

- independent from the research project or program under review,
- external to the ACC, and
- selected by the Merit Review Committee

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

Principal Investigators must submit the Scientific Merit Form to the Merit Review Committee in advance of submitting the Animal Use Protocol to the ACC.

Scientific merit reviewers must promptly submit their reviews to the Merit Review Committee using the Scientific Merit Reviewer Form.

Principal Investigators must be provided with the written Scientific Merit Reviewer feedback, and must address any concerns or questions via the Merit Review Committee.

***Animal Care Committee Involvement***

Scientific merit reviews must be completed in advance of final ethics review of the Animal Use Protocol (AUP) by the ACC.

The Animal Care Committee must receive confirmation from the Merit Review Committee that the AUP is part of a project or program deemed to have scientific merit by reviewers, as outlined above.

The ACC must respect the scientific merit reviewers' feedback provided by the Merit Review Committee; any concerns must be forwarded to the MRC for consideration.

***Pilot Studies***

Pilot studies used to explore 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.

Where uncertainty exists regarding whether a new study should be considered part of a research program, the Merit Review Committee must work with the PI in order to make the determination.

### ***Collaborative Projects***

Regardless of where the research is undertaken, each organization associated with a basic or applied research project involving live animals must ensure that the project has undergone scientific merit review, as defined within this policy.

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## **Roles and Responsibilities**

### **The Vice President (Research) Office is responsible to**

- Ensure a mechanism is in place to undertake scientific merit reviews in alignment with this policy, e.g. maintain a Merit Review Committee

### **Merit Review Committee is responsible to**

- Maintain a list of external funding agencies that undertake scientific merit reviews in alignment with CCAC policy
- Maintain a list of potential scientific merit reviewers that encompasses the types of basic and applied research associated with ACC-approved AUPs
- Make available to the research community the Scientific Merit Form and Scientific Merit Reviewer Form
- Where uncertainty exists regarding whether a new study should be considered part of a research program, this committee must work with the PI in order to make the determination
- Assign scientific merit reviewers to each PI request for review
  - If none are available within Western's Research Community, identify external independent experts willing to perform reviews
- Act as liaison between the PI, scientific merit reviewers and the ACC to resolve any outstanding questions or concerns arising from scientific merit reviews
- Provide the PI with the results of the scientific merit review; forward reviewer comments and questions
- Provide the ACC Coordinator with feedback regarding the outcome of scientific merit reviews
- Maintain a record of all scientific merit reviews undertaken by members of this committee; provide the record to internal and external regulators, as requested

### **Scientific Merit Reviewers are responsible to**

- Within two weeks of form receipt, perform and submit to the Merit Review Committee reviews using the Scientific Merit Reviewer Form
  - If the review timeline is not possible, immediately inform the Merit Review Committee
- As applicable, immediately upon request for review identify themselves as not meeting CCAC's requirements for 'independent' 'expert' peer reviewers, as defined within this policy

**Principal Investigators (PIs) are responsible to**

- Disclose the funding source in the AUP and indicate if it has received independent, expert scientific peer review
- For projects funded by external agencies that undertake scientific merit review by arms-length experts, the Principal Investigator must provide the Merit Review Committee approval identifier within the AUP.
- In situations where funding has not been awarded, yet the grant proposal received above average ratings during the peer review process, and the PI wishes this rating to be considered as evidence of scientific merit review for the related project, the PI must submit the funding agency rating outline to the Merit Review Committee for consideration.
- As required by this policy, complete the Scientific Merit Form and submit to the Merit Review Committee
  - As desired, append the funding
- Respond to scientific peer reviewer questions in a timely manner
- Forward any concerns associated with feedback or the related review process to the Merit Review Committee

**The ACC Coordinator is responsible to**

- Make available to the research community the Scientific Merit Form and Scientific Merit Reviewer Form
- Confirm with the Merit Review Committee the status of reviews
- Identify AUPs requiring outstanding Scientific Merit Reviews
- Inform Western's Grants office upon AUP approval

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**References**

MAPP 7.12 – Policy and Procedures for the Use of Animals in Research, Testing and Teaching  
University Council on Animal Care.

Animal Use Protocols Policy (POL-002) and Procedures (PROC-002)



## **University Council on Animal Care**

APP2-Scientific Merit Reviewer Form

Scientific Merit Policy POL-013-00

Approval Date: 30MAY2018

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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**

<b>Version</b>	<b>Date</b>	<b>Description of Changes</b>	<b>Author</b>
00	05-30-18	New policy	LT