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SCIENTIFIC MERIT REVIEW – GUIDELINES AND PROCESS FOR ANIMAL-BASED RESEARCH

Background

The use of animals for research demands that the research meet high standards of scientific integrity and review. The Canadian Council on Animal Care (CCAC) policy statement on: scientific merit and ethical review of animal-based research states that animal use research must only be undertaken if expert, independent opinion has attested to the probable scientific value of the research within its field.

Yukon University (YukonU) is responsible to have a mechanism in place to ensure that proposed animal use for research is independently peer-reviewed for its scientific merit prior to the animal use protocol review by the YukonU Animal Care Committee (ACC). These review and approvals must be complete before there is any use of animals.

Animal use for research purposes must have two equally important levels of review:

- 1. An independent expert peer review of the of the research program or project
- 2. A review by the ACC of whether the proposed animal use, as described within an animal use protocol is acceptable, and whether the proposed animal-based methods are appropriate.

This document outlines the requirements for scientific merit review and details the procedures that should be followed to ensure that all proposed research involving animals has undergone an independent peer review.

Scope

The University's Vice-Provost, Academic and Research (VPAR) is responsible for ensuring that YukonU research involving animals has had an independent review for scientific merit and ensuring that:

- Peer reviewers are identified for each project that has not already been peer reviewed; and
- Any concerns raised by the reviews are addressed before scientific merit is confirmed.

The Research Services Office and ACC Coordinator may assist in the administrative role, to facilitate the process. The YukonU Research Ethics Coordinator works out of the YukonU Research Office and is delegated to provide to the ACC solicited confirmation that each animal-based research protocol has been found to have scientific merit according to the formal process (detailed in this document) before it is subjected to ethics review by the ACC.



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The YukonU Research Office shall receive confirmation of protocol approval from the ACC before releasing funds for animal-based work for any projects.

Summary table of scientific merit review requirements and exemptions

Scientific Merit Review required	Exemption
When no scientific peer review has been	Research project's where a funding agency
done	employs a peer-review process that is
	acceptable to YukonU ACC (e.g. NSERC or
	CIHR).
If students are being taught/trained as	Regulatory testing or to teaching/training
partners in research projects- including	
honours projects, undergraduate and	
graduate level research	
Pilot studies	A proposed pilot study that is an extension
	of peer-reviewed research previously done
	by the researcher.
Start up fund projects	Start-up fund projects associated with a
	previous project that has undergone
	scientific peer review
	A proposed project that is deemed to be a
	minor extension of, or supplementary to, a
Collaborative animal based prejects	peer reviewed project.
Collaborative animal-based projects Examples include:	
•	
 protocol of a lead PI at another institution includes collaborative 	
work by a listed YukonU researcher	
 protocol of a lead PI at YukonU 	
includes collaborative work by a	
non-YukonU research collaborator	

Projects with Exemptions

If the protocol fits any of these exemptions, the researcher must provide to the YukonU ACC documentation that clearly supports the exemption request. For projects funded by external agencies that have scientific merit review the PI should provide the funding agency letter of award that includes the grant number to the ACC. Where the funding has not been awarded yet the grant proposal received scientific review and the researcher 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.



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In cases where a project is funded from smaller foundations (local, national or international), or an industrial source where peer-review for scientific merit has been conducted, documentation should include

- dates of review
- composition of the scientific panel
- brief description of the review process

If the proposed research has recently undergone external peer-review for scientific merit, the Vice-Provost, Academic and Research (VPAR) will determine whether the existing external peer review is sufficient and meets the peer review requirements. For the protocol to be considered for exemption, the researcher must provide the Research Proposal section of the grant, along with the external reviews and the evaluation details. The submitted documents will be considered by all Committee members.

The Chair of the Animal Care Committee (ACC) does have the option to request additional peer review on any submitted protocol, regardless of the agency funding and the status of peer review. This option only used if there is a serious concern by the majority of the members of the ACC regarding the particulars of the animal model or experimental design not related to the merit of the general scientific content.

Scientific Merit Review Process

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 determined by the YukonU Research Services office. Expert peer-reviewers must not be directly involved in the protocol design or implementation, and they should have appropriate experience and/or knowledge in the relevant field, discipline or sub-discipline to adequately review protocol content. There should also not be any conflict of interest in relation to the PI.

The researcher (PI) is responsible for initiating an appropriate Scientific Merit Peer review process with the Research Services Office. Researchers should provide:

- a research proposal
- the research summary form (see attached template).

The research proposal may be in the format of the existing proposal that was submitted to the sponsor, or it may require additional information if requested by those designated to serve on a Peer Review Committee. The researcher should also provide the researcher's name, title of the project and animal care protocol title with the proposal (if different title). The proposal should also include the objectives, hypothesis, methods and contributions of the project. If you have recommendations for prospective peer reviewers these may also be provided for consideration.

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Research that is to be conducted as part of an undergraduate student-research project will undergo internal review by a YukonU Peer Review Committee, whereas research that is to be done by a faculty/staff member may be required to be reviewed externally by peers.

All reviews must be documented and must contain sufficient information to support the reviewer's conclusions.

Internal Peer Review

In the case of student research projects, the Vice-Provost, Academic and Research (VPAR) in consultation with the Research Ethics Coordinator will identify two University faculty to review the Animal Use Protocol as part of the internal review process. However, these reviewers must not collaborate on research with the student researcher or have other conflicts-of-interest.

The requirements for internal review will be presented to students during the course information sessions for their respective programs to ensure that they are aware of the appropriate requirements and procedures. One reviewer can be current members of the ACC. However, as a minimum, one reviewer must be a faculty member who is external the ACC. The Animal Use Protocol will be forwarded to the reviewers who will then complete all sections of the **peer review form.**

Upon completion of the internal review process,

- 1. Peer reviews are returned to the VPAR for collation and appropriate action, based on the suggestions made by the peer reviewers.
- 2. Reviews will be documented and kept on file with at the Research Ethics Office for future reference.
- 3. The VPAR will notify the Chair of the ACC if the Animal Use Protocol application can then be considered by the ACC.
- 4. Should the research proposal be rejected on scientific merit by the reviewers, the student researcher may be asked by a member of the Peer Review Committee to clarify or modify the proposal for resubmission to the internal reviewers.
- 5. Should the proposal be deemed to NOT have scientific merit, the ACC will be notified by VPAR of the Peer Review Committee decision that the protocol cannot be approved.

External Peer Review

Yukon University is a small institution with few faculty that might have the necessary background or expertise to provide peer review of specific animal based research. All Yukon University faculty members who are using animals for any research project, and for whom a

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peer-review exemption does not apply, will be required to submit their research proposals for external review of scientific merit. This review must occur prior to any Animal Use Protocol application review by the ACC.

The Research Services office will seek recommendations and identify two external researchers to review the proposal. These people could include individuals suggested

- by other YukonU faculty or other senior administration
- through supports of the ACC Coordinator by the provision of email contacts of the ACC Coordinators at select Canadian Universities. ACC Coordinators from selected Canadian Universities that are contacted to request names of potential appropriate merit reviewers should only be given the title of Protocol. Upon receiving names of potential reviewers from these Coordinators, these should be reviewed with online research profiles to ensure appropriateness for the review.

They may not be people who collaborate on research with the researcher or have other conflicts-of interest. No member of the YukonU ACC may act as an external reviewer. Once the reviewers are selected, the remainder of the process is the same as that for internal peer reviews.

Conflict of Interest Guidelines for Selection of Reviewers Excludes individuals who:

- 1. have collaborated, published or been a co-applicant on a research or training grant with the applicant in the last 5 years.
- 2. been a student or supervisor of the applicant within the last 5 years.
- 3. are a close personal friend or relative of the applicant
- 4. have a long-standing scientific or personal difference with the applicant, are deemed to be in a conflict of interest and should not be part of the review process.

Process Summary

- The Researcher (PI) will provide to the Research Service Office the required information for the Peer Review including the Summary form with description of the project including sufficient information to allow the reviewer to comment on the following points:
 - Background and explanation of scientific objectives and goals for proposed work;
 - justification of the animal model proposed
 - description of the experimental design (including time lines if applicable)
- 2. The Animal Care Committee (ACC) Coordinator will send out the request to reviewers as selected by the RSO and VPAR. Individuals contacted to request assistance in providing the review (providing only protocol name at this point).

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- 3. Once reviewers are identified, they are sent the researchers summary form, the AUP and supporting documents to allow them to conduct the review.
- 4. The reviewers must comment on the points mentioned in the Scientific Merit Review Form which serves as the documentation of the review.
- 5. Questions or concerns raised by reviewers will be communicated to the researcher for comment which in turn will be forwarded to the respective reviewer.
- 6. The VPAR will provide the results of the review to the ACC Chair and Coordinator. The researcher will be provided de-attributed comments from the reviewers, in case they may want to do adjustments to the protocols before review by the ACC.
- 7. The complete reviews will be kept on file in the Research Ethics Office for record keeping purposes.
- 8. The peer review process should be started prior to submission of the protocol to the ACC. Final protocol approval will not be grated until such scientific merit assessment has taken place.
- 9. Should the research proposal be rejected on scientific merit by the reviewers, the Principal Researcher may be asked by the Chair of the Scientific Merit Review Committee to clarify or appropriately modify the proposal for resubmission to the reviewers.
- 10. Should the proposal be deemed to NOT have scientific merit, the ACC will be notified by the Chair of the Scientific Merit Review Committee that the protocol cannot be approved.

References and Acknowledgments Canadian Council on Animal Care

- CCAC Policy Statement on: scientific merit and ethical review of animal-based research
- <u>CCAC Frequently Asked Questions: Scientific Merit and Ethical Review of Animal-Based</u> <u>Research (March 2019)</u>
- CCAC Scientific Merit Review Form Template (October 2019)

YukonU would like to acknowledge that this policy has been adapted from the following:

- Mount Saint Vincent Animal Care Committee Policy on Scientific Merit Review of Animal Use Protocols for Teaching, Testing and Monitoring (Nov. 2020).
- Queens University. University Animal Care Committee Policy on Peer Review for Scientific Merit (Feb 2020)
- Western Research. Animal Care Committee Scientific Merit Review Policy. (November 2020)
- Lethbridge College. Scientific Merit Assessment Committee Procedures

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