CCAC policy statement on: scientific merit and ethical review of animal-based research

This policy replaces:

- The CCAC policy statement on: the importance of independent peer review of the scientific merit of animal-based research projects (2000)
- Appendix II (Section A) and Appendix III of the CCAC policy statement for: senior administrators responsible for animal care and use programs (2008)
- The provisions on scientific merit included in Section 2 of the CCAC guidelines on: animal use protocol review (1997)

As explained in the core *CCAC policy statement on: ethics of animal investigation*, 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. Animal-based work can then proceed only if an institutional animal care committee (ACC) finds the use of animals acceptable ethically and in practice: the proposed animal-based methods should be appropriate for the work and meet institutional and CCAC guidance and standards. Animal use for research purposes must consequently be subject to two levels of review:

- 1) an independent, expert peer review of the scientific merit 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

Both levels of review are equally important, and it is also important that:

- the ACC respect the findings of the expert, independent peer review with regard to the scientific merit of the research and refer any questions on scientific merit to the research administration of the institution
- the researcher whose protocol is being examined by the ACC understands that the ACC will review the protocol with regard to animal-based methods, and collaborates with the ACC to determine the most appropriate methods to be used

1. Review of Scientific Merit: Research Administration

It is the institution's responsibility to develop and implement a mechanism to ensure that proposed research that will involve animals is independently reviewed for scientific merit by expert peers.

For a research program or project that has been examined through an independent and expert peer-review process (e.g. federal and provincial granting agencies and others), the institutional research administration can choose to accept the results of this review as evidence of scientific merit.



For projects that are either internally funded or that are funded by a source not using a peer review mechanism with appropriate independence and expertise, the research administration or a delegated scientific review committee must select at least two independent experts (both of whom should be external to the ACC) to review the scientific merit of each project. It is not appropriate for the ACC to select reviewers, nor is it appropriate for a principal investigator to select reviewers for his or her own project. The reviewers should be asked to produce written reviews that include comments on the objectives, hypotheses, methodological approach, and potential contribution(s) of the study to scientific knowledge. The principal investigator should be provided with the reviews, and should address any questions or concerns, working with the research administration, before the research administration can confirm to the ACC that the work has been found to have scientific merit.

2. Review of Animal-based Methods Within the Protocol Review Process: Animal Care Committee

When a principal investigator submits a research animal use protocol to the ACC for approval, the ACC must receive confirmation from the principal investigator and the research administration that the protocol is part of a research program or project that has been found to have scientific merit, as detailed above. Information provided within the animal use protocol should provide the ACC with context for the proposed study, and indicate the relationship between the proposed study and the overall research objectives.

The ACC must examine the protocol to determine whether the use of animals is acceptable ethically and in practice, and must decide whether the animal-based methods are appropriate for the proposed work, with careful consideration of the Three Rs (replacement, reduction and refinement of animal use).

The principal investigator must provide clear information on animal-based methods to the ACC. The investigator may choose to append information such as grant proposal excerpts or scientific reviewers' comments, where relevant, to facilitate the protocol review process.

Where ACCs are unfamiliar with the proposed type of work, they are encouraged to seek relevant expertise.

The ACC's review and approval procedures must be based on the CCAC policy statement on: terms of reference for animal care committees and the CCAC guidelines on: animal use protocol review. Any other institutional and CCAC guidance relevant to the nature of the study should also be used.

3. Release of Funds for Animal-Based Work: Research Administration

Once the ACC has approved a protocol, it must inform the research administration of this fact. Funds may then be released for the animal-based work. Institutions administering research granting agency funds should work with these agencies to have acceptable mechanisms in place to directly link animal use protocol approvals with the release of related research funds.

Approved by the CCAC Council on March 2, 2013