**Ensuring Scientific Merit of Animal Use Protocols**

**Background:**

The CCAC *Policy Statement for Senior Administrators Responsible for Animal Care and Use Programs (2008) and the CCAC policy statement on: scientific merit and ethical review of animal-based research (2013)* states that it is the institution’s responsibility to have in place a mechanism to ensure that proposed animal use for research is independently peer-reviewed for its scientific merit before it is given final approval by the Animal Care and Use Committee (ACUC). The University of Alberta is committed to the highest standards in research, teaching and testing. Its processes for scientific merit review of animal use are described below.

**Requirements:**

Animal Use Protocols (AUPs) submitted for review by the ACUC must indicate whether the project has been peer-reviewed.

In most cases, the funding agency performs this peer review before it grants funds to a project (such as CIHR, NSERC, NIH...). In general, funding agency review is considered acceptable if:

* peer review for scientific merit is done in the first stage of the competitive funding award process (and reference to this process is available on either the agency’s web site or with the application instructions), and funding is successful. Please indicate the full name of this funding agency in your documentation to the ACUC; OR
* an application to an agency with a competitive funding process is unsuccessful due to lack of funds, but the agency’s favourable peer review assessment is forwarded to the ACUC with the research proposal and AUP.

In cases where peer review has not been carried out by a granting agency, at least two independent experts who do not collaborate with the protocol author(s) are asked to review the objectives, hypotheses, methods and contributions of the project. These internally-managed peer reviews are valid for a maximum of 5 years but the ACUC has the right to request new peer review at any time, especially if the hypotheses, objectives, or methods change significantly.

**Process:**

Where the applicant confirms that an independent peer review as described above has not been undertaken, arrangements for arm’s length peer-review must be made and the review successfully completed before the protocol will be approved by a University of Alberta ACUC.

For the purposes of this process, an independent peer review is defined as the review of the research proposal by two or more researchers, who have the technical expertise to assess the science of the protocol and are at arm’s length from the research team and the ACUC. The peer reviewers will assess the scientific merit of the proposal and offer a recommendation as to whether or not the proposal has adequate scientific merit to justify the use of animals; however, reviewers will not be asked to consider the degree of compliance of the research methods with University of Alberta ACUC or animal facility procedures or processes.

**Recommending Appropriate Reviewers:**

In the AUP (Animal Use Protocol) application in ARISE, the Principal Investigator (PI) is asked to suggest two potential reviewers. The Research Ethics Office (REO) administrator will add the suggested reviewers to a list maintained by the office, and may choose reviewers with relevant expertise from the list or from the ones suggested by the PI.

To assure that the scientific review is at arm’s length from the Principal Investigator and the ACUC (Animal Care and Use Committee), the following conditions for peer reviewers will apply:

* Peer reviewers must be external to the research team and laboratory in which the protocol will be undertaken, and must not be directly involved in the protocol design or implementation.
* Reviewers should have appropriate experience and/or knowledge in the relevant field, discipline or sub-discipline to adequately review protocol content.
* Reviewers should not have collaborated, published or been a co-applicant with the applicant, within the last five years.
* Reviewers should not have been a supervisor or student of the lead investigator or any of the co-applicants, within the past ten years.
* Reviewers must not have any personal, professional, or financial interests that would be directly or indirectly impacted by the outcome of the application or funding opportunity under review
* Reviewers should be able to conduct an impartial evaluation of the application.
* Recommendations for appropriate reviewers (who meet the conditions above) will be submitted by the applicant in the AUP. A minimum of two potential reviewers must be provided.

**Managing the Review Process and Scientific Merit Approval Process:**

Reviewers suggested by the PI and/or from the list maintained by the Research Ethics Office will be approached by the Research Ethics Office administrator to provide a written assessment of the proposed research subject to absence of conflicts of interest. An email is sent asking the reviewers to provide a scientific merit review of the protocol, along with the PI’s name and the title of the research protocol. The reviewer is asked to confirm that no conflict exists based on the criteria above. Once this is received, a scientific summary, developed by the PI, is sent for review along with a REO reviewer’s comment form which includes a statement requesting formal declaration of the relationship between the reviewer and the Principal Investigator to ensure an arm’s-length review. In addition, the reviewer must declare that they are scientifically qualified to review the proposal.

The reviewers’ comments and recommendations are reviewed and maintained on file by the REO administrator. Comments from the reviewers will recommend that the proposal is either accepted, or that it is rejected for lack of scientific merit. If two reviews are received, and these are in agreement on acceptance, then the recommendation will stand and the AUP is sent for ethics review by the ACUC. A third review may be requested where two reviews offer differing recommendations. If the merit reviewers recommend that changes are needed before it is accepted, or if reviewers have differing opinions, the reviews will be sent to the Department Chair (or delegate such as Associate Chair or Division Director), or to the Associate Dean (Research) of the PI’s faculty, who will communicate with the PI to ensure that the study is changed to satisfy the recommendations of the reviewers. When this is complete, the Chair or Associate Dean will communicate the decision to the REO administrator. Whether or not the proposal is found to be meritorious, the PI is given the feedback of the reviewers, except comments that are noted as confidential, to allow them to consider the questions and recommendations and make changes to the study if desired. Rejected proposals may be resubmitted for additional merit review after changes are made.

University Animal Policy and Welfare Committee

Approved: February 13, 2017

**Research Study Summary for Scientific Merit Review**

*To be completed by the Principal Investigator.*

Research studies that involve the use of animals require Scientific Merit approval prior to being considered for Animal Care and Use Committee (ACUC) approval. When the funding/sponsor agency does not provide such merit reviews, a Scientific Merit review will be solicited by the Research Ethics Office. Principal Investigators are asked to provide this information supplemental to the Animal Use Protocol to facilitate the Scientific Merit review of the project.

***Please note: there are no specific page length requirements for this document, but past experience has shown that 3-5 pages will usually provide sufficient information for the reviewers.***

***An extensive literature review is not required; but please cite important background and methodological references to put the proposal into context.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator:** | | Click or tap here to enter text. | |
| **Title:** | Click or tap here to enter text. | | |
| **Protocol number (if one was assigned):** | | | Click or tap here to enter text. |

*Sections will expand to allow text entry*

|  |
| --- |
| 1) State the research hypothesis/hypotheses of the proposed study. A good hypothesis must be based on a good research question at the start of a study and, indeed, drive data collection for the study. |
| Click or tap here to enter text. |
| 2) Outline the current scientific literature and background information related to the development of this study. |
| Click or tap here to enter text. |
| 3) Describe the scientific objectives of the current study. |
| Click or tap here to enter text. |
| 4) Describe the experimental design and methods (including details related to the choice of animal model) employed to collect the data to support the proposed study. |
| Click or tap here to enter text. |
| 5) Describe how the methodology will contribute to successful reproducibility. |
| Click or tap here to enter text. |
| 6) Describe the expected contributions the study will make to knowledge in the research area (i.e. scientific importance of the research. |
| Click or tap here to enter text. |
| 7) Describe the statistical methods that will be used to analyze data. |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| ***Signature of the Principal Investigator\**** | |
|  | **Date:** Click or tap to enter a date. |

*\* Sending this document from your UAlberta CCID counts as an electronic signature*