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Animal Research for the Industry: Scientific Merit by a Multilateral Review

Simon Authier, D.V.M., M.Sc., M.B.A.

Head of Veterinary Services LAB Research Inc.

Warning

- The views and opinions that are included in the following presentation represent a summary prepared by the speaker to initiate discussions and do not necessarily reflect the position of the institutions at which Simon Authier acts as a veterinarian.

Summary of Presentation

Should ACCs only look at protocols for humane animal care and use?

- Responsibilities for Scientific Merit Evaluation: Review of Key Players
  - External reviewers
  - Animal Care Committees
  - Principal Investigators
  - Canadian Council on Animal Care (CCAC)

- Regulated (GLP) Research compared with Non-Regulated Research
  - Is there a difference for requirements for scientific merit evaluation?
  - How to ensure that the research plan reflects regulator requirements?

- A Multilateral Approach
  - Parallel with research funded by granting agencies
  - Scientific Merit, an omnipresent requirement

Responsabilities: Scientific Merit Evaluation

- **External reviewers: *At arm's length***
  - **Minimum of 2 reviewers**
  - **Reviewer should not collaborate with the PI**
  - **At least one referee must be external to the (animal care) committee**
  - **Benefits of research committees: When it comes to practical considerations**
- **Animal Care Committees (ACCs)**
  - Recognized participation in scientific merit evaluation
    - CCAC: "ACC does need to be assured of the merit and to understand its value."
    - ex. Is justification of the number of animals in a protocol an evaluation of humane animal care and use or part of scientific merit review?

A judge relies on an independent expert to testify while the ACC relies on independent scientists to weigh the scientific merit.

Leveraging its composition, which includes scientists and veterinarians, the ACC has the resources to understand the scientific value of the protocol.

Responsabilities: Scientific Merit Evaluation

- **Principal Investigators**
  - **Is Scientific Merit a binary variable?**
  - **If not, what are the drivers to improvement the scientific merit in animal research**
    - **Collaborations between PIs or between organizations**
    - **New technologies (imaging, genomic and proteomic, etc.)**
    - **Changing paradigm: Abolish the myth that evolution of methods could alter research integrity or negatively impact research quality**
  - Encourage dialogues: ACC as a gate keeper (approval or refusal) but most importantly as a dynamic and interactive group.
  - Aim for continuous improvement once minimal requirements are met
- **Research Institutions**
  - **Support is a factor of success**
- **Canadian Council on Animal Care: A leadership role**
  - Guideline on protocol review
  - National forums
  - Site visits
  - Electronic and printed resources

Regulated and Non-Regulated Animal Research

- **Regulated research**
  - Normally conducted in accordance with Good Laboratory Practices (GLP)
  - Based on regulatory guidelines from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
  - Standard study design with relatively limited variations
- **Non-regulated research**
  - Efficacy models
  - Includes more invasive protocols
- **Scientific Merit**
  - Higher scrutiny for non-regulated research protocols
  - "The intensity of the review should vary directly with the level of invasiveness of the procedures" (CCAC, 1997)
  - Confidentiality concerns

Scientific Merit: A Multilateral Evaluation

- Scientific Merit -> Benefit -> Multilateral evaluation
  - Who is involved in scientific merit evaluation?
    - PI or organization (self evaluation)
    - External scientific merit review
    - ACCs: Risk-benefit analysis weighing the scientific merit (provided by external scientific) with potential harm for participants
- **Parallel with research funded by granting agencies**
  - From CCAC website: "Many researchers require the flexibility to adjust their research efforts in response to rapid changes in their fields, therefore the granting agency may not see the specifics of all associated animal use. Granting agencies do not have to worry about details of animal use as this is the role of the ACCs."

Scientific Merit: A Multilateral Approach

- **Difference between granting agencies and external scientific merit review at each institution**

  - Approval or refusal from granting agencies does not prevent experiments from being potentially conducted
  - In contrast, internal refusal prevents to project from any potential chance of conduct

- **Scientific Merit is an omnipresent consideration and a *sine qua non* condition to animal use in research**

Thank you!