RESEARCHERS' GUIDE TO REGULATIONS: Animals in scientific research

The rules and regulations governing animal research are numerous, complex, and can sometimes be difficult to navigate. While these regulations intend to be supportive of the research community and protective of the animal subjects, they sometimes may feel like a hindrance to your research efforts.

Both the researcher and the institution, however, have a legal responsibility to federal, provincial, and funding agencies to remain fully compliant with all rules and regulations. Non-compliance can damage the reputation of both researchers and the institution at large, and can have a negative impact on the ability of the institution or researcher to obtain or continue to receive funding.

To help you in maintaining compliance in your research, here are some key points to remember:

Regulations, policies, and/or laws for animal research and use are established by:

- **The Canadian Council on Animal Care (CCAC):** The CCAC sets national standards for the ethical use and care of animals in science. The CCAC formally assesses and certifies U of T every three years with a Certificate of Good Animal Practice (GAP). This certification is based on compliance with CCAC guidelines and policies. CCAC accreditation is required for the U of T to receive Tri-Agency (e.g. NSERC, CIHR) and many other research funds.
- **The Ontario Ministry of Agriculture and Food (OMAF):** OMAF established the provincial Animals for Research Act, which requires U of T to register annually as an operator of research facilities that are legally permitted to conduct animal research. The Act is enforced through unannounced inspections by the provincial veterinary inspector.
- **Granting and funding agencies:** Granting agencies, before releasing funds, generally require proof of institutional approval and assurance that research is carried out in accordance with all relevant guidelines, laws, and regulations (e.g. CIHR and NSERC require CCAC accreditation).
- **Section 446 of the Criminal Code of Canada:** Under the Code, it is illegal to willfully cause or allow unnecessary pain, suffering, or injury to an animal.

THE ESSENTIALS OF REGULATORY COMPLIANCE

Education and training: U of T researchers and lab staff working with live animals must complete mandatory training through U of T before commencing animal-based work. Each person must be competent in the procedures they are required to perform.

Authorization or approval: Before a project begins, approval is needed from the Local Animal Care Committee and any other relevant committees or offices (i.e. Biosafety, Radiation Protection Authority, Health Canada). Grant funds cannot be released until approval is granted.

Expiration dates and resubmissions: Local Animal Care Committee approvals are valid for one year. Protocols must be resubmitted for review on an annual basis.

Approvals for modifications: Any changes to an approved protocol must be reviewed and approved by the Local Animal Care Committee before being implemented.

Post-Approval Review: Ongoing compliance support for active protocols is provided by scheduled Quality Assurance visits and active collaboration with veterinary, animal care, and administrative staff.

COMPLIANCE ESSENTIALS:

- **Treat animals with respect.** Working with live animals is a privilege, not a right. Laboratory animals are living creatures that deserve to be treated with care and compassion.

- **Perform only those procedures approved in your protocol.** Ensure that everyone on the protocol is familiar with all its procedures and that they understand that protocols must be followed to the letter.

- **Submit amendments for any changes to your protocol.** If you need to make a change or addition to your protocol, submit an amendment for approval to the Local Animal Care Committee.

- **Follow institutional Standard Operating Procedures (SOPs).** SOPs incorporate current best practices for animal welfare and institutional and facility specifics.

- **Wear Personal Protective Equipment (PPE).** Know what protective equipment is required for your procedure and workspace. Items such as gloves, masks, gowns, and lab coats protect both you and the animal from hazards.

- **Develop and follow a reliable system for endpoint monitoring**. Ensure that everyone on the protocol can recognize signs of animal distress and/or compromised health that would necessitate intervention or euthanasia.

- **Document any observations or procedures.** All procedures performed on an animal should be recorded on a document (e.g. cage card) that is accessible by the veterinary staff.

- **Monitor post-procedure animals according to the schedule outlined in the approved protocol.** Follow the protocol exactly as written, even if it means checking on an animal on the weekend or in the middle of the night. If the monitoring frequency seems too stringent, check with the veterinary staff to see if it can be modified by submitting an amendment.

- **Communicate with veterinary staff regarding the health status of post-procedural animals.** If an animal develops any complications following a procedure, you must promptly communicate those complications with the veterinary staff.

- **Allow only lab staff listed on the approved protocol to perform procedures on animals.** Ensure that all staff are added to the protocol and have been satisfactorily trained to perform all procedures assigned to them.

- **Store controlled substances in secured locations.** Always keep controlled substances double-locked. Keep accurate and current records of use.

- **Maintain a valid exemption for controlled substances.** The use or possession of controlled substances, including many anaesthetics and analgesics, requires an annual exemption from Health Canada.

- **Know your protocol's annual expiry date.** Protocol approvals are valid for one year. For a study to continue, a protocol renewal should be resubmitted prior to the expiry of the current protocol.