



REQUIREMENT FOR SUBMITTING AN ANIMAL PROTOCOL

Addendum to the CCAC policy statement on: terms of reference for animal care committees

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INTRODUCTION

The goal of this addendum is to describe:

- which animal-based activities require an animal protocol be submitted to, and approved by, an animal care committee; and
- which animal-based activities are excluded from the requirement.

For the purpose of the Canadian Council on Animal Care (CCAC)'s mandate, an animal* is used in science if it is an essential component of a research*, teaching*, or testing* project or program. This applies whether the animal is the subject of science (e.g., wildlife or farm animal studies), or is supporting science either directly (e.g., animal model of disease or of a biological process, animals used in clinical trials) or indirectly (e.g., breeding colonies, sentinel animals, animals used for training*, animals used as food for other animals).

ANIMAL-BASED ACTIVITIES THAT FALL WITHIN CCAC'S MANDATE AND REQUIRE ANIMALS BE INCLUDED IN A PROTOCOL

All proposed animal-based research, teaching, and testing activities must be clearly described in an animal protocol, which must be approved by an institutional animal care committee before any animal-based work begins. This includes herd and colony animals, animals used outside of Canada by Canadian researchers, as well as animals in courses not associated with a degree, diploma, or certificate (e.g., professional development/continuing education workshops) provided by faculty or other institutional personnel under the aegis of a certified institution.

* The terms marked with an asterisk (*) in this document are defined in the Terminology section.

EXCEPTIONS TO THIS REQUIREMENT

Animal-based activities that fall outside of CCAC's mandate and do not require animals be included in a protocol

- Animal work for and/or by regulatory agencies for regulated monitoring* of contaminants or disease, or to obtain abundance estimates or other population variables required for assessing and managing animal populations. Monitoring involves the routine (i.e., actions repeated in the same way on an ongoing basis) collection of information obtained in a prescribed manner using standardized methods. This includes:
 - fish being counted at installations such as counting fences and traps, and fish being lethally sampled for regulatory purposes;
 - bird banding overseen by the Canadian Bird Banding Council;
 - population/abundance estimates; and
 - animal work for environmental effects monitoring strategies or other environmental assessments, for example, to assess the health of fish at contaminated sites (this does not involve placing fish in potentially contaminated water to detect contaminants).
- Animals held separately and exclusively for commercial purposes unrelated to science (the CCAC encourages institutions to house these animals in conditions that meet CCAC or industry standards);
- Service animals (e.g., animals that support people with disabilities, therapy dogs for stress relief, drug detection dogs, etc.), unless the subject of research or involved in teaching;
- Pets or display animals* (often fish) kept in offices or public areas, unrelated to teaching or research;
- Third-party, animal-based activities conducted on campus (e.g., dog or horse clubs using college facilities); and
- Community outreach*
 - if research or teaching animals are involved in these activities, an *Oversight of Animal-Based Community Outreach Activities Form* must be completed and forwarded to the animal care committee.

Certified institutions must ensure that research, teaching and testing animals (within the CCAC mandate) are not adversely affected (e.g., cross-contamination) by animals outside the mandate (above).

To avoid any animal welfare issues, institutions are encouraged to have a policy, understanding, or agreement in place that sets conditions and expectations for keeping animals in an institution for purposes other than research, teaching, or testing.

Animal-based activities that fall within CCAC's mandate but do not require animals be included in a protocol

It is the responsibility of individuals wishing to undertake the following activities to inform the animal care committee of such, and for the animal care committee or delegate to confirm that these animal-based activities do not require an animal protocol.

- Clients' animals treated routinely in veterinary teaching hospitals (and not used in any research projects including clinical trials, etc.) of a certified university;
- Practicums*;
- Any work that is currently categorized in CCAC category of invasiveness A (see the [CCAC policy statement on: categories of invasiveness in animal experiments](#) (CCAC, 1991) and Appendix D, "CCAC Categories of Invasiveness for Wildlife Studies", in the [CCAC guidelines on: the care and use of wildlife](#) (CCAC, 2003)). This includes:
 - the use of eggs, embryos, fetuses, and larvae in research, teaching, or testing (except fish and amphibian larvae that have reached a stage where survival can reasonably be expected);
 - cadavers of animals not killed specifically for the research or teaching in question, including use of animals killed in the course of established industry or commercial practices and animal tissues shared from other approved protocols; and
 - animals that will only be observed* in formal teaching and in research, that are not being held captive for these purposes, and where there is no expected impact on these animals or those around them.

TERMINOLOGY

The terms marked with an asterisk (*) in this document are defined below; and, CCAC recognizes these definitions for the purpose of its mandate.

Animal – a nonhuman vertebrate or a cephalopod.

Community outreach (animal-based) – non-invasive activities involving animals meant to informally educate the public and for which there is no formal assessment of understanding or retention of knowledge obtained from the involvement of animals.

Competency – an observable ability related to a specific activity that integrates knowledge, skills, values, and attitudes.¹

Display animal – keeping animals for personal or public display with no specific educational or research goal.

Monitoring – monitoring is mostly for regulatory purposes and refers to the measurement of changes in a system over time, for example to detect the spread of disease agents in the wild or assessing parameters at the animal population level. It involves the routine collection of information obtained in a prescribed manner using standardized methods.

Observed animals (no expected impact) – Given current knowledge of the behaviour of a particular species, the proposed study design is unlikely to alter normal behaviour, including the timing and duration of specific behaviours (e.g., feeding, grooming) and interactions between conspecifics.

¹ Definition adapted from Englander R., Frank J.R., Carracio C., Sherbino J., Ross S. and Snell L. (2017) Toward a shared language for competency-based education. *Medical Teacher* 39(6):582-587.

Practicum – activities related to the supervised practical application of previously or concurrently studied theory, in which students often participate in performing tasks. These activities (e.g., time spent handling animals in an animal shelter, veterinary clinic, or farm beyond formal teaching or training) unlike structured laboratories are not undertaken in direct support of formal learning objectives described in a course outline as part of a formal curriculum. There is generally no formal process to assess the acquisition of skills obtained from animal involvement.

Research (animal-based) – any study aimed at the generation of new knowledge² where animals are involved.

Teaching (animal-based) – activities involving animals that formally educate participants enrolled in a course within a recognized academic curriculum, and for which there is a formal process to assess understanding and retention of knowledge obtained from animal involvement.

Testing (animal-based) – experimental manipulation of animals with the measurement of defined experimental endpoints, generally for regulatory purposes. Safety testing involves procedures to determine, for example, whether, in what ways, and to what extent a compound is toxic. Efficacy testing involves procedures to determine whether a compound or device will be effective for a given condition. Environmental testing involves actively placing animals under environmental conditions that may impact them.

Training (animal-based) – activities involving animals that formally (e.g., directed studies) and informally (e.g., workshops) assist learners in acquiring competency*, and for which there is a process to assess competency derived from animal involvement.

² While research studies may include the examination of already existing data under a new hypothesis, the CCAC does not require the submission of protocols for the secondary use of data.