FREQUENTLY ASKED QUESTIONS

CATEGORIES OF WELFARE IMPACT

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These frequently asked questions (FAQs) are intended to assist investigators, instructors, and members of animal care committees in the implementation of the <u>CCAC guidelines: Categories of welfare impact</u>. FAQs provide general responses to comments and questions received by the Canadian Council on Animal Care (CCAC) during the external reviews of this guidelines document.

If you do not find the answer to your question here, do not hesitate to contact the CCAC and we will be pleased to provide assistance.

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1. What is the purpose of assigning a category of welfare impact?

The <u>CCAC policy statement on: categories of invasiveness in animal experiments</u> was originally designed as a tool for protocol authors to use as a method of judging the potential impact of their proposed scientific activity (i.e. research, teaching/training, or testing) on the animals involved. Since 1995, categories of invasiveness have also been included in all animal data submitted to the CCAC in an effort to describe the experiences of animals used in science. These two purposes remain the focus of the <u>CCAC guidelines:</u> <u>Categories of welfare impact</u>. Therefore, this guidelines document aims to:

- 1) provide a framework to describe the experiences of animals used for scientific activities
- 2) improve understanding of the various welfare impacts on the animals involved in scientific activities
- 3) encourage consideration of how those impacts might be minimized
- 4) assist in accurate reporting of the experiences of the animals used in science across Canada

Thus, the primary purpose of this document is not to provide guidance on how to work with or keep animals; that information is covered in other CCAC guidelines. The guidance provided in this document is focused on how to accurately reflect the experiences of animals used in scientific activities.

2. Why did CCAC shift from categories of invasiveness to categories of welfare impact?

The change from categories of invasiveness to categories of welfare impact signifies a shift from focusing on the procedures carried out on the animals, to a focus on the animals' experiences. This perspective takes into consideration that not all animals experience similar procedures in the same way, and acknowledges that the welfare of animals is affected by elements other than the experimental procedures (e.g., living conditions, phenotype, researcher experience, transportation conditions, the animal's cumulative lifetime experience).

3. How do categories of welfare impact relate to categories of invasiveness?

The category of invasiveness was informed only by the procedures performed on animals, whereas the category of welfare impact should reflect the experiences of the animals and is informed by much more than just the scientific procedures they undergo. This means that there is not necessarily a correlation between the two systems: e.g., a Category of Invasiveness C will not always translate to a Category of Welfare Impact C. Thus, protocols that may have previously been classified at a certain category of invasiveness may now be categorized as more or less severe, depending on the impact of factors other than the procedures performed. Importantly, the category of welfare impact must be confirmed retrospectively, and thus should more accurately represent the actual experience of the animals.

4. How will the shift to categories of welfare impact affect protocol authors and animal care committees when writing and reviewing protocols?

The process of assigning categories of welfare impact is more complex than assigning categories of invasiveness. It is expected that it may take more time, especially at the beginning when the process is new. However, many of these factors are already a consideration for protocol authors. Thus, the learning curve should be front-end loaded and the process will get easier over time, especially for those who are doing similar scientific activities with animals year after year. As tools, examples, and best practices are developed and shared, the work of determining categories of welfare impact will be lessened as well.



5. Where did the 16 factors that influence animal welfare come from?

The 16 factors stem from current understanding of the scientific literature on animal welfare, and are also pulled from other CCAC guidelines. The following table outlines the factors listed for consideration when determining the category of welfare impact alongside each one's associated CCAC guidelines requirements. The factors listed in the *CCAC guidelines: Categories of welfare impact* are already considerations required by other documents throughout the course of a scientific activity. What is new, however, is that these 16 factors are now brought together in one guideline in order to be systematically considered in terms of how they impact the welfare of the animals.

Table 1 Factors to Consider When Determining Categories of Welfare Impact and Associated CCAC Guidelines Requirements

NUMBER	CATEGORY OF WELFARE IMPACT FACTOR	STEMMING FROM CCAC GUIDELINES ON:
1	Housing and husbandry	Husbandry; various animal-types ¹
2	Relocation and transportation	Procurement; various animal-types
3	Species, strain, and sex of the animals	Various animal-types
4	Age/developmental stage of the animals	Various animal-types
5	Domesticated or non-domesticated	Wildlife
6	Inherent welfare status	Endpoints
7	Energy status/body condition	Welfare assessment; various-animal types
8	Social disruption	Welfare assessment; various animal-types
9	Previous experience (cumulative lifetime experiences)	Endpoints; welfare assessment; various animal-types
10	Known aspects of individual animals	Non-human primates; dogs (in prep.); rats
11	Scientific procedures	Experimental procedures (Part A – Administration of substances and biological sampling; in prep.); Experimental procedures (Part B – analgesia, anaesthesia, and surgery; in prep); various animal-types
12	Monitoring	Husbandry; welfare assessment; Experimental procedures (Part B – analgesia, anaesthesia, and surgery; in prep); various animal-types
13	Humane killing method	Euthanasia; various animal-types
14	Setting in which the scientific activity is being conducted	Facilities; various animal-types
15	Skill/experience of the personnel performing the procedure	Training of personnel
16	Whether or not the animal has been trained to participate in the procedure	Non-human primates; dogs (in prep.); rats

¹ "Various animal-types" refers to the different animal-type guidelines published by CCAC (e.g., mice, rats, zebrafish). Each of these documents has specific content on the noted category of welfare impact factor related directly to the titular animal-type.

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6. Why do so many factors need to be assessed?

As a scientific subject, there are many possible ways that an animal's welfare can be impacted throughout its lifetime. The 16 factors described in the <u>CCAC guidelines: Categories of welfare impact</u> were chosen as the most important ways an animal's welfare could be affected. Importantly, examination of these factors provides protocol authors and animal care committees many opportunities for refinements that can lead to substantially better animal welfare.

Bringing these 16 factors together in this guideline will foster a more consistent process of welfare assessment within and between institutions. This approach establishes an organized framework to help direct discussion amongst all stakeholders (protocol authors, technical staff, veterinarians, animal care committees, administrators, CCAC) involved in assessments of welfare impact.

However, the CCAC recognizes that not all of the factors are relevant to all scientific activities. It is expected that protocol authors and animal care committees will use prudent judgment to determine when certain factors are 'not applicable'. For example, assessing 'known aspects of individual animals' may not be possible for large groups of densely-housed animals (e.g., zebrafish), but including this information is much more practical for larger animals that have been in institutions for long periods of time (e.g., non-human primates or dogs).

7. Why can more than one category of welfare impact be assigned to a single animal use protocol?

It is not uncommon for different animals to undergo different procedures or be in different treatment groups within a single protocol. This in turn can mean that animals have differing experiences and thus different welfare impacts. It is, therefore, important to capture these impacts. From an institutional perspective, this will help to focus oversight on higher levels of welfare impact while more efficiently directing monitoring resources. It also promotes transparency and accurate portrayal of animal-based science when presenting this information to the Canadian public (the previous method of assigning the highest category that any one individual animal may experience on a protocol led to overestimating the invasiveness of Canadian science).

8. Within a scientific activity, which animals, or groups of animals, need to be assigned a category of welfare impact?

Within a protocol, only the animals that are the subjects of the scientific activity (including control animals) should be considered when determining the category of welfare impact. Animals that may be indirectly affected by the scientific activity do not need to be assigned a category of welfare impact (though they should factor into the protocol review at large). For example, scientific activities involving livestock on pasture need only assign categories to the livestock, not to any wildlife that may potentially be impacted by the work.

Additionally, because this document focuses on the experiences of individual animals within the context of scientific activities, considerations of higher levels of organization (e.g., populations, ecosystems) are beyond the scope of these guidelines.

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9. We are already considering all these factors during protocol review, why are they repeated here?

Most of the factors included in the <u>CCAC guidelines: Categories of welfare impact</u> are already part of animal use protocol review. This means that protocol authors are already providing this information to animal care committees on a regular basis. Thus, the document <u>CCAC guidelines: Categories of welfare impact</u> formalizes how all this information should be synthesized into assigning categories of welfare impact. A future revision to the <u>CCAC policy statement: terms of reference for animal care committees</u> will ensure that the requirements for animal use protocols harmonize with the <u>CCAC guidelines: Categories of welfare impact</u>.

In terms of assigning a category of invasiveness, the <u>CCAC policy statement on: categories of invasiveness in animal experiments</u> indicates that a letter (B-E) should be assigned based on the experimental procedure performed; there is no other CCAC documentation that indicates other factors should be considered. However, some institutions currently consider more than just the procedure when they assign a category of invasiveness. Thus, the <u>CCAC guidelines: Categories of welfare impact</u> plays an important role in updating best practices and harmonizing categorization between institutions.

10. Why does the category of welfare impact need to be assigned prospectively?

Prospective categories of welfare impact assignment is used primarily to assist animal care committees in the oversight of animals within their ethical care and use program. Specifically, this process helps to:

- focus on the animals' experiences, and identify the potential welfare impacts of the scientific activity
- provide an impetus for minimizing any potential animal pain and distress
- inform animal care committees about the expected harms to animals and help identify protocols that may require more scrutiny prior to approval and more oversight once approved
- identify animals who may require more monitoring or additional resources to ensure adequate care, especially in cases where the animals are more vulnerable than normal (e.g., because they are compromised prior to the scientific activity or because the procedures are new to the individuals performing them)
- initiate discussions with protocol authors regarding the potential animal welfare impacts of their work
- identify instances where personnel may require enhanced training or supervision

Many of these outcomes are also seen with the use of categories of invasiveness, and are intended to continue in the assignment of categories of welfare impact.

11. Why does the category of welfare impact need to be reviewed retrospectively?

Prospective assignment of categories of welfare impact is inherently a prediction based on a risk assessment, and it is important that these predictions be verified rather than simply assumed to be true. This is especially important for scientific activities that have greater amounts of uncertainty. Thus, the primary purpose of

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retrospectively assigning a category of welfare impact is to assess more accurately the experiences of the animals. Retrospective assignment of categories of welfare impact accomplishes the following:

- helps identify where refinements are needed
- allows for tracking national/institutional/personal trends in welfare impact
- provides a feedback mechanism that facilitates improved prediction of the welfare impacts of a protocol for both parties
- creates an opportunity to reflect on how to potentially reduce the welfare impact of the scientific activity in the future

Retrospective assignment of categories of welfare impact also helps the CCAC prioritize guidelines development and identify opportunities for broad Three Rs initiatives.

12. How will scientific activities that were formerly Category of Invasiveness A be affected?

Animal-based scientific activities that require a protocol are detailed in the <u>Requirement for submitting an animal protocol: Addendum to the CCAC policy statement on terms of reference for animal care committees.</u>

According to the <u>CCAC policy statement on: categories of invasiveness in animal experiments</u>, Category of Invasiveness A encompassed an assortment of animal-based work involving, for example: invertebrates (excluding cephalopods); dead animals (e.g., obtained from slaughter houses or commercial suppliers of specimens for dissection); wildlife under observation; and cell cultures. Historically, these scientific activities did not require animal care committee approval (although many animal care committees chose to require protocols for these activities), and were not included in the CCAC annual animal data report. Any scientific activity that meets the CCAC requirements for submitting an animal protocol will need to be described in an approved protocol and assigned a category of welfare impact.

13. Do scientific activities involving wildlife still have their own categorization scheme?

No. The <u>CCAC guidelines: Categories of welfare impact</u> apply to all animal-based scientific activities that fall within the CCAC's mandate.

14. How should the impact of monitoring wild animals be determined?

Monitoring wild animals, both in captivity and in the wild, can have a large impact on their welfare due to the presence of humans or technological devices (e.g., drones). Generally, the impact of monitoring wild animals will be larger than on domesticated animals, though the actual welfare impact will vary substantially based on the type of monitoring performed. Animal care committees and protocol authors should use their expertise to predict this impact prospectively and then confirm it retrospectively.

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15. Should novel transgenics still be prospectively assigned to Category of Welfare Impact D by default, as was previously required?

No. Due to technological advancements and ever-increasing scientific knowledge, transgenic research is no longer a 'D' by default. Instead, protocol authors are expected to be able to predict the resulting phenotype of any genetic manipulations with reasonable accuracy, along with the expected welfare impacts due to those phenotypes. If there is some uncertainty, erring on the side of prospectively assigning a higher category is recommended. These predictions should then be confirmed retrospectively.