# CCAC guidelines: Categories of welfare impact

**Draft for Public Review**

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## 1. Introduction

The *Canadian Council on Animal Care (CCAC) policy statement on: categories of invasiveness* (CCAC, 1991) 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 this document: the *CCAC guidelines: categories of welfare impact*. Thus, this guidelines document aims to:

1. improve understanding of the welfare impacts on the animals involved in the proposed scientific activity;
2. encourage consideration of how those impacts might be minimized; and
3. assist in accurate reporting of the experiences of the animals used in science across Canada.

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 also acknowledges that the welfare of animals is also affected by elements other than the experimental procedures (for example their living conditions or phenotype). Because this document focusses 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 this document.

According to the CCAC 1991 policy, Category of Invasiveness ‘A’ encompassed an assortment of animal-based work involving, for example: invertebrates; dead animals (e.g. obtained from slaughter houses or commercial suppliers of specimens for dissection); wildlife under observation; and cell cultures. 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. This is no longer necessarily the case. Instead, any scientific activity that meets the [CCAC requirements for submitting an animal protocol](https://www.ccac.ca/Documents/Standards/Policies/Requirement-for-Including-Animals-and-Animal-Based-Activities-in-a-Protocol-%28ADDENDUM%29.pdf) will need to be described in an approved protocol and assigned a Category of Welfare Impact (even if the welfare impact is positive or negligible). This document will also supersede other former practices related to assignment of Categories of Invasiveness. Most notably, this means the removal of the different scoring metrics used for wildlife and the *de facto* assignment of novel transgenics to a category ‘D’.

Finally, this document outlines the expectation that Categories of Welfare Impact will be assigned to protocols both prospectively, before undertaking any animal-based scientific activity, as well as retrospectively, after the scientific activity is complete. Thus, the prospective assignment of Categories of Welfare Impact should become part of a continuous learning and review process rather than a final conclusion, as it is important to verify predictions rather than simply assume them to be true. The retrospective Categories of Welfare Impact can ultimately be used to improve the prospective process and must be reported to the CCAC as part of the annual animal data collection process, contributing to the improvement of transparency and accuracy in annual animal data reporting.

## 2. The Five Categories of Welfare Impact

There are five Categories of Welfare Impact. Each category is assigned an alphabetical label[[1]](#footnote-1) with categories B-E reflecting different gradations of negative impact. The Categories of Welfare Impact are (in order from least to most impact on the animals in question):

A – Negligible or positive welfare impact

B – Mild negative welfare impact

C – Moderate negative welfare impact

D – High negative welfare impact

E – Severe negative welfare impact

If different subgroups of animals within a single protocol experience different levels of welfare impact, each subgroup should be assigned to the appropriate category, resulting in as many categories as required to describe the experiences of the animals within the protocol.

## 3. Prospective Assignment

This section describes how and why, prior to any scientific activity, protocols should be assigned a Category of Welfare Impact (i.e. prospectively).

### 3.1 Purpose

Prospective Categories of Welfare Impact assignment is used primarily to assist animal care committees in the oversight of animals within their ethics and care 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;
* 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; and
* identify instances where personnel may require enhanced training or supervision.

### 3.2 Process for Prospectively Determining the Category of Welfare Impact

The Category of Welfare Impact for each subgroup of animals should be determined during the comprehensive evaluation of each protocol. The steps outlined below are a formalization of the thought processes that are often used when preparing and reviewing protocols. This systematic process aims to facilitate a more comprehensive account of the welfare impacts on animals used in Canadian science.

Animal care committees and protocol authors are expected to work harmoniously in assigning Categories of Welfare Impact. Together, they should incorporate available scientific evidence in combination with their collective professional judgement to determine expected impacts of the scientific activity on animal welfare. Note that the relative impact of each factor can vary between protocols (see Section 3.3). Therefore, each protocol should be evaluated based on its unique variations in environmental, animal, and procedural factors that collectively will create a distinctive impact on the animals involved. Finally, a goal for every protocol should be to implement potential refinements for each factor.

The following three broad categories should be considered when assessing the welfare impact of a scientific activity:

1. Attributes of the environment;
2. Attributes of the animals themselves;
3. Attributes of the scientific procedure(s).

Step 1 assesses the probable welfare impacts of the animals’ environment, including transportation and standard husbandry procedures. It is understood that the welfare impact of these factors can vary greatly depending on the protocol. Based on this expected impact, a Step 1 Category of Welfare Impact is assigned. Depending on the situation, this value can be anywhere from A-E (see Section 3.3.1 and Appendix A).

Step 2 evaluates the attributes of the animals themselves. This second evaluation involves determining the overall impact of eight factors (see Section 3.3.2 and Appendix A). Evaluation of these eight factors will likely involve a value judgement regarding the relative importance of each factor in contributing to the final Step 2 Category of Welfare Impact, and this weighting may differ between protocols.

Step 3 focuses on the impact of the scientific procedure(s). There are six factors to be considered within this step (see Section 3.3.3 and Appendix A). Similar to Step 2, a value judgement will likely be required to weigh the relative importance of each factor, which can differ between protocols. A Step 3 Category of Welfare Impact should be assigned following evaluation of these factors.

Note that some factors may not be applicable, and some factors may be unknown, within the context of a specific scientific activity. In such cases, they should be acknowledged as N/A, and can subsequently be ignored.

Once these three broad aspects of welfare impact have been considered, an overall Category of Welfare Impact must be assigned that reflects the impacts noted within each of the previous steps. This will likely include a value judgement, and the relative importance of each step will vary between protocols. Section 3.4 provides some additional considerations for this process.

### 3.3 Factors that Influence the Prospective Category of Welfare Impact

#### 3.3.1 Step 1 – Attributes of the Environment

##### 3.3.1.1 Housing and Husbandry

Holding animals in a scientific setting has an impact on their welfare. There is an impact even if the animals are healthy, phenotypically normal, and not subject to scientific procedures (e.g. Balcombe et al., 2004; Castelhano-Carlos and Baumans, 2009; Hannibal et al., 2016). Thus, animals maintained in accordance with all relevant CCAC standards should have a Category of Welfare Impact B for this factor. Institutions are encouraged to create standard operating procedures (SOPs) for consistency. These should incorporate relevant CCAC standards and describe the expectations for compliant animal housing (i.e. what would be a B-level welfare impact). SOPs should also include the minimally-expected enrichment provision. Finally, SOPs should account for any difficulties imposed by the infrastructure in conducting health and welfare assessments (e.g. stocking densities, visual obstructions).

Animals held in significantly enriched conditions (e.g. semi-naturalistic cages for rats [Makowska & Weary, 2016]) and that have been desensitized to benign husbandry procedures through positive reinforcement, or those being observed in the wild, should have a preliminary Category of Welfare Impact A assigned for this factor. Conversely, animals held in conditions that adversely affect their welfare to a greater extent, and those that experience aversive husbandry (e.g. solitary caging of a social species) or industry (e.g. castration or dehorning without adequate pain control) procedures, should have a higher category assigned as appropriate. The magnitude of the deviations from CCAC standards, and thus the increase from a B-level impact, should be judged based on the impact of husbandry procedures and the environment’s ability (or lack thereof) to meet the animals’ behavioural needs.

##### 3.3.1.2 Transportation

Transportation is widely regarded as a likely source of negative animal welfare impact, especially for larger species (e.g. Broom, 2005; Gregory 2008). The extent of the welfare impact will vary depending on a myriad of factors such as stocking density, microclimate, duration of travel, animal condition, and various management factors (Schwartzkopf-Genswein et al., 2012). Increases in welfare impact should be judged based on any increases in the duration or severity of these factors. Transportation may even cause motion sickness (e.g. Santurtun and Phillips, 2015). Thus, even very brief transport warrants a B-level impact for this factor. Note that this factor includes animals that are ordered and shipped from commercial suppliers.

#### 3.3.2 Step 2 – Attributes of the Animals

##### 3.3.2.1 Species, Strain, and Sex of the Animals

The species, strain, and sex of an animal will partially determine the welfare impact of a given procedure. As examples, handling fish out of water (e.g. Brydges et al., 2009) or performing a procedure on nocturnal animals during the light-phase (e.g. Abou-Ismail et al., 2008) can increase the negative welfare impact. Similarly, strain- and sex-based criteria should also be considered, as phenotypes can vary widely within species and even between sexes. Anxiety levels are known to differ between mouse strains (e.g. Griebel et al., 2000), and sex differences in pain sensitivity/reactivity are common across many strains of rats and mice (e.g. Mogil et al., 2000). Many other examples exist where the expected impact of a procedure is influenced by the species, strain, and sex of the animals. Thus, these three attributes should be incorporated in protocol assessments as appropriate.

##### 3.3.2.2 Age/Developmental Stage of the Animal

The baseline assumption is that adult animals, uniform in age, are used. In that case, this category would be neutral in terms of affecting the overall Category of Welfare Impact. However, if juvenile or elderly animals are used, consideration may need to be given to increasing the Category of Welfare Impact. Generally, juvenile and elderly animals are more vulnerable than healthy adults and thus the potential welfare impact to these age groups is greater, even though the risk to both groups is qualitatively different. In some cases, juvenile animals are more sensitive to stressors than adults (Romeo, 2010), but they are also at risk of having their development compromised, potentially in a way that affects their long-term welfare (e.g. Isgor et al. 2004; Chaby et al. 2013). Meanwhile, the relative physiological cost for elderly animals to respond to stressors is increased (e.g. Hughes, 2008), and their ability to recover from stressors decreases with age (e.g. McEwen and Morrison, 2013; Lupien et al., 2009). Additionally, there may be sensitive periods (e.g. pregnancy [Christian, 2012]) when animals are vulnerable to increased negative welfare impacts. These age-related concerns may vary between species and experimental contexts, so prudent judgment is required in analysing this factor (e.g. potential developmental compromises may not matter if the animals won’t live long enough for them to become apparent). If animals of varying ages are used simultaneously, additional consideration should be given to increasing the Category of Welfare Impact for this factor due to the potentially increased difficulty in monitoring all the animals.

##### 3.3.2.3 Whether the Animal is Wild-Caught or Domestic/Captive Born

Wild-caught animals are thought to be more affected by scientific activities than similar captive-born animals (all else being equal). There are three main reasons for this: first, many wild adaptations (e.g. flightiness, increased vigilance) have been eliminated or reduced through domestication over time (Price, 1999). Reduced welfare impacts on domesticated animals are the result of decreased reactivity to humans and handling (e.g. Hughes et al., 1976; Ericsson et al., 2014) and less aggression towards conspecifics (e.g. Künzl et al., 2003). It is important to note that this is a gradual process that has taken place over a number of generations (Price, 1999), so animals only a few generations removed from the wild might be considered tame, but not domesticated.

Second, captive-born animals typically experience early exposure to humans, thus reducing fear and stress responses throughout their life (e.g. Pedersen and Jeppesen, 1990; Feenders and Bateson, 2011); something that wild animals do not experience. Third, the act of catching wild animals (including confining them and separating them from social partners) has a large welfare impact in and of itself (e.g. Dickens et al., 2009) that is not typically experienced by captive-born animals. Thus, a B-level welfare impact for this factor assumes that the animals are domestic and captive-born.

##### 3.3.2.4 Inherent Welfare Status of the Animal

In some cases, animals may have compromised welfare before the commencement of the scientific activity. For example, this may be due to a deleterious genetic mutation (e.g. Buehr et al., 2014), an induced disease state (e.g. cachexia [DeBoer, 2009]), or a neuropathic pain model (e.g. Jaggi et al., 2011) that generates a harmful phenotype. Healthy, phenotypically normal animals should be assigned an A-level welfare impact for this factor, and the welfare impact of any pre-existing compromises should be reflected in the assignment of a higher category.

##### 3.3.2.5 Energy Status/Body Condition

Body condition scoring is a common method used to quantify the nutritional state and general health status of an animal by noting the amount of flesh covering bony protuberances. This is typically done by scoring animals on a 1 – 5 scale, where 1 is emaciated, 3 is well-conditioned, and 5 is obese. Body condition scoring is a valuable tool for welfare assessment and has been implemented for many different species (e.g. mammals from mice [Ullman-Culleré and Foltz, 1999] to cattle [Roche et al., 2009], birds [Gregory and Robins, 1998], reptiles [Rawski and Józefiak, 2014], and fish [Nash et al., 2006]). Animals at either end of the scale may face additional health and welfare impacts, and thus an A-level welfare impact should be assigned to animals who are in ideal body condition for their breed/strain, sex, and stage of life (typically a 3).

For wildlife, potential metabolic demands should be considered in addition to body condition (which indicates energy reserves). To provide a few examples, wild animals may face increased metabolic demands from climate conditions, seasonal processes (e.g. migration), specific life-stage events (e.g. smoltification in anadromous fish) or if they are pregnant, lactating, or otherwise caring for offspring. These may compound the welfare impact that a scientific activity has on the animals and should be captured in the welfare impact assigned to this factor.

##### 3.3.2.6 Social Disruption

Generally it is acknowledged that keeping social animals in social groups benefits their welfare. However, animals’ social groups can also be a source of negative welfare impact, particularly when these groups are unstable or are otherwise disrupted. Social introductions can lead to increased aggression, anxious behaviour, and biomarkers of stress that can last for several days while a dominance hierarchy is established (Hannibal et al., 2016). In fact, one paradigm for studying chronic stress is to constantly change animals’ social partners, thus continually repeating the period of social upheaval and hierarchy establishment (e.g. Sterlemann et al., 2008). For wild animals, even temporary removal of territorial individuals may lead to increased aggression when that animal is returned. Thus, if the scientific activity requires mixing social groups or may result in a stable social network being disrupted (e.g. through removal of the dominant animal) the welfare impact of this factor should be elevated. A stable social group with no aggression should be scored as an A-level impact.

##### 3.3.2.7 The Previous Experiences of the Animal (Cumulative Effects)

Consideration of an animal’s cumulative lifetime experiences is important when determining welfare impact. It is important to note that even mild or moderate procedures can have a cumulative impact on the welfare of an animal (Wolfensohn et al., 2015). Note that consideration of cumulative effects also applies to animals who are held long-term but used infrequently (e.g. reptiles held for annual teaching exercises). Furthermore, animals may find a single procedure increasingly aversive as it is repeated multiple times (e.g. Rushen, 1986; Boulanger Bertolus et al., 2015). Thus, all available information about the prior experiences of an animal should inform the current risk to its welfare. This information may come from welfare assessments (see *CCAC guidelines: animal welfare assessment* [in preparation]), health records (see *CCAC guidelines: husbandry of animals in science* [2017]), previous protocols, or personal knowledge of individual animals’ histories. The *CCAC guidelines: identification of scientific endpoints, humane intervention points, and cumulative endpoints* (in preparation) provides more information and a framework for helping to assess cumulative welfare impacts. It is important to note that an A-level impact should be assigned only if the animals have no previous scientific activity experiences to take into consideration.

##### 3.3.2.8 Known Aspects of Individual Animals

Temperament can have a large influence on the amount of welfare impact each animal is likely to experience (e.g. Coleman, 2012). Generally, there will be a distribution of temperaments within a population, even within the same species or strain, where some animals will be more calm/bold (conversely, anxious/fearful) than others (e.g. Walker and Mason, 2011). While it can be hard to predict the temperaments of newly acquired animals, scientific team members or animal care staff may come to recognize the temperaments of certain individual animals, particularly those that they have worked with on prior protocols. In such cases, this information should be taken into consideration by assigning a higher level of welfare impact to animals known to be more timid, anxious, or fearful.

#### 3.3.3 Step 3 – Attributes of the Scientific Procedures

##### 3.3.3.1 The Scientific Procedure(s)

The expected level of pain and/or distress associated with a procedure is generally known or can reasonably be predicted in advance. Note that all animals included in the CCAC’s mandate are assumed to have the capacity to feel pain and to experience distress. The anticipated level of pain and/or distress should also take into account any potential long-term consequences of the procedure (e.g. Cattet et al, 2008), not just acute impacts to welfare. Potential indirect effects of the procedure should also be considered. For example, this includes any negative outcomes that result from interacting with a cagemate that has undergone the procedure, even if the animal in question did not experience the procedure itself (e.g. rats exposed to acoustic trauma become more aggressive to cage mates [Zheng et al., 2011]; stressed fish are more susceptible to disease, thus increasing background levels of virulence for pathogens within the entire tank [Conte, 2004]).

Another consideration for wildlife work, or work on domestic animals held in proximity to wild animals (e.g. on pasture), is that the effects of a procedure may have additional effects beyond the specific animals under study (e.g. trapping non-target species, Sikes et al., 2011). Welfare impacts on potential bycatch should be accounted for as much as possible at this stage, and then confirmed retrospectively.

The welfare impact that a procedure has on the animals is determined by the severity of the procedure (i.e. the magnitude of pain or distress it causes), the frequency with which it is carried out, and its duration (including time to make a full recovery). Even similar procedures may have markedly different impacts on animal welfare depending on the quality of refinements made by the protocol author. These refinements can take many forms, but the quality of each should be judged based on the likelihood of it reducing or removing any potential pain and/or distress. For example, providing post-surgical analgesia should reduce the impact of a surgery, but the magnitude of this benefit depends on the drug and dose provided (e.g. Roughan and Flecknell, 2003). Similarly, keeping animals in their social groups is not only beneficial for their welfare generally (e.g. Rault 2012; Patterson-Kane et al., 2002; Novak and Suomi, 1991), but keeping them with their social partners improves outcomes following a procedure (e.g. Johansson and Ohlsson, 1996; Detillion et al., 2004).

In order to assess this factor, both the severity and frequency/duration of all procedures might reasonably be considered as follows:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Welfare Impact | Procedure(s) Severity | Procedure(s) Frequency and/or Duration | Example Procedure | Additional Examples?(To be filled in by reviewers) |
| A – Negligible/ positive | None/positive | - | Observation of animals with no intervention |  |
| Categories of negative impact | B – Mild | Low | Low | Brief restraint for physical examination  |  |
| C – Moderate | Low | Medium | Monthly ultrasound (incl. restraint)  |  |
| Low | High | Weekly blood sampling  |  |
| Medium | Low | Assessing cutaneous reactions to a new vaccine (where preliminary safety has previously been tested) |  |
| Medium | Medium | Short periods of food deprivation for longer than would occur in nature |  |
| D – High | Medium | High | Repeated social hierarchy disruptions (incl. potentially aggressive interactions) |  |
| High | Low | Surgical procedure and recovery from anaesthesia |  |
| E – Severe | High | Medium | Intermittent sleep deprivation |  |
| High | High | Model of neuropathic pain with no analgesia provided |  |

##### 3.3.3.2 Monitoring

Peri- and post-procedural monitoring is an essential activity to ensure animal welfare (e.g. Weary et al., 2006); animals that are not monitored sufficiently are at greater risk of having unnecessarily long durations of compromised welfare. The frequency and intensity of monitoring should be commensurate with the expected impact of the procedure, and should be determined as part of the process to establish humane intervention points (*CCAC guidelines: identification of scientific endpoints, humane intervention points, and cumulative endpoints* [in prep.]). Similarly, the quality of the monitoring should be taken into account. For example, a surgical procedure conducted using advanced monitoring technologies (*CCAC guidelines: experimental procedures B – analgesia, anaesthesia, and surgery* [in prep.]), should be given a better score than one done without the use of these additional resources. A sufficiently rigorous monitoring regime should be assigned a B-level impact for this factor.

##### 3.3.3.3 Euthanasia Method

The method of euthanasia can have a profound impact on an animal’s welfare. The [*CCAC guidelines on: euthanasia of animals used in science*](https://www.ccac.ca/Documents/Standards/Guidelines/Euthanasia.pdf) (2010), along with the [*Addendum to the CCAC guidelines on: euthanasia of animal used in science*](https://www.ccac.ca/Documents/Standards/Guidelines/Additional-Information-on-Effects-of-Euthanasia-Methods-on-Research-Results.pdf) (in prep.) set the standards for acceptable euthanasia methods in Canada and provide guidance as to when each method is permissible. In terms of evaluating the welfare impact of this factor, an A-level impact would only be appropriate if the animals are not going to be euthanized. If they are going to be euthanized, the impact should be scored in-line with the ‘acceptability’ of the method as noted in the documents above (i.e. acceptable, conditionally acceptable, not acceptable), relating to the risk that animals may experience pain and distress prior to loss of conscious awareness.

##### 3.3.3.4 The Setting in Which the Scientific Activity is Being Conducted

Scientific activities taking place within a clean, controlled setting should be scored with a B-level impact. However, the potential impact of some procedures may vary based on the physical location of the activity, particularly due to the technology available, the capacity to intervene in the case of adverse events, and the ability to separate animals. For example, performing surgery in the wild or on a farm, as opposed to a laboratory, means that there are additional challenges in terms of maintaining asepsis, providing adequate pain relief, monitoring medium-to-long-term recovery, maintaining body temperature, etc. (Hawkins, 2004), that increase the potential for greater impacts on welfare. Similarly, if aversive procedures are performed on animals in the presence of other animals, for example when performing a procedure on multiple animals sequentially, the animals who experience the procedure later in the process may be impacted to a greater extent as a result of the distress cues given off by animals who experience the procedure first (e.g. Boissy et al., 1998; Inagaki et al., 2014).

##### 3.3.3.5 Skill/Experience of the Person Performing the Procedure

If the person performing the procedure is a highly skilled, experienced person, this factor should be scored with a B-level impact. While all personnel involved are expected to be competent at handling animals and performing the stated procedures, those with more experience are more likely to perform the procedure faster with fewer complications, and be better at dealing with problems that may arise. Note that the level of experience refers to the individual’s experience with the specific procedure and/or animal-model, not just general experience working with the animals in question. If the procedure is novel (i.e. the lab/protocol author has not performed it before), the animal care committee should recommend that a pilot study be conducted to inform: 1) the expected level of welfare impact; 2) the skill of the person performing the procedure; and 3) to suggest refinements. When procedures are being done as part of a training exercise or otherwise by an early-learner, a collaborative team approach should be used involving the scientist/teacher, the veterinarian, and the technical staff (as appropriate) to ensure that relevant expertise is present (Brown et al., 1993).

##### 3.3.3.6 Whether or Not the Animal Has Been Trained to Participate in the Procedure

In some cases, animals may be trained through positive reinforcement to actively participate in a procedure (e.g. Bassett et al., 2003; Coleman et al., 2008). If implemented appropriately, this type of training reduces: the fear, anxiety, and distress associated with procedures; the need to separate animals from their social group to perform a procedure; the need for anesthesia or physical restraint; and aggression towards human handlers (e.g. Laule et al., 2003; Prescott et al., 2004; Laule, 2010). Therefore, if trained animals are participating in a procedure for a positive reward, this factor should be considered a B-level impact which may serve to reduce the impact of the procedure itself. If animals are untrained, this factor should not be considered when determining the Step 3 Category of Welfare Impact.

### 3.4 Process for Evaluating Overall Prospective Category of Welfare Impact

Once a preliminary Category of Welfare Impact has been assigned to each step, they are then summarized into an overall score for each protocol (or each distinct group of animals within a protocol). For the purposes of this summary, each of the three steps (animals, environment, and procedure) should be considered similarly in that they are all important areas of potential welfare impact. However, depending on the nature of the scientific activity, any of three different areas of welfare impact could factor most prominently. Therefore, if any one of these areas of welfare impact is considered to have overwhelming importance (i.e. because the welfare impact is much larger than the other areas), that area should be given disproportionately more weight in determining the overall prospective Category of Welfare Impact. Thus, this summary must be evaluated through a lens of professional judgement (by both the protocol author and the animal care committee), adjusted as necessary, and accompanied by a transparent rationale as required. There are no hard-and-fast rules for this process, and it is expected that the accuracy and consistency with which Categories of Welfare Impact are assigned will improve with experience. In particular, comparison of the prospective and the retrospective Categories of Welfare Impact should be a constructive learning exercise which will help inform future prospective Categories of Welfare Impact.

### 3.5 Summary of General Principles for Prospectively Assigning Categories of Welfare Impact

1. There are many potential avenues for animal welfare to be affected when the animals are involved in a scientific activity, broadly captured by looking at attributes of the environment, the animals, and the scientific procedures. These avenues have been further identified as the above mentioned 16 different factors for consideration when determining the Category of Welfare Impact.
2. The assigned Category of Welfare Impact must reflect the cumulative lifetime experience of the animals. This is especially important for animals who are used repeatedly on different protocols or are held long-term.
3. Each protocol should be divided into groups of animals who experience approximately equal welfare impacts. As many categories as are appropriate should be assigned to any given protocol. Thus, protocols should not be assigned a single Category of Welfare Impact based on the highest impact that any one animal may experience. For example, if the experience of control animals differs from animals in the treatment groups, this should be indicated by assigning two (or more) different Categories of Welfare Impact to the protocol. If there are multiple different scientific treatments being tested, they only need to be assigned different Categories of Welfare Impact if the animals’ experiences quantitatively differ (i.e. each treatment group doesn’t need to be assigned separately if the impacts are equal in magnitude).
4. The animal care committee is ultimately responsible for assigning the appropriate Categories of Welfare Impact.

**Appendix A provides an example framework that may be helpful for prospectively assigning Categories of Welfare Impact. It is not mandatory to use.**

## 4. Retrospective Assignment

This section describes how and why the Category of Welfare Impact must be reassessed after the scientific activity has taken place, most often at the time of protocol renewal or completion.

### 4.1 Purpose

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 (e.g. wildlife). Thus, the primary purpose of retrospectively assigning a Category of Welfare Impact is to describe 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; and
* 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 3Rs initiatives. Finally, starting in 202X (date TBD) the CCAC will be expecting institutions to report retrospective Categories of Welfare Impact annually[[2]](#footnote-2) in an effort to provide the public with more transparent information on the welfare impacts of Canadian animal-based science and the steps that institutions are making to minimize these impacts.

### 4.2 Process for Retrospectively Determining the Category of Welfare Impact

A suggested framework for this process is to consider each factor described in Section 3 (and Appendix A), and evaluate whether or not the predicted welfare impact of that factor was accurate. Normally, it is likely that most of the factors will have been assessed accurately, and thus the protocol author and animal care committee should focus the retrospective assessment of factors where the welfare impact was different than expected. Ideally, review of this information will coincide with the protocol renewal process. The animal care committee, including the veterinarian, is ultimately responsible for confirming the retrospective Category of Welfare Impact.

The purpose of the retrospective process is to answer the question “did what was predicted to happen, actually happen?” Thus, the retrospective Category of Welfare Impact should be based on the prospective Category of Welfare Impact, and modified (either up or down) as necessary based on information from the following sources:

* Husbandry and health records, including mortality records and animal incident reports (see *CCAC guidelines: husbandry of animals in science* [2017])
* Environmental monitoring records (*CCAC guidelines: husbandry of animals in science* [2017])
* Welfare assessment records (see *CCAC guidelines: animal welfare assessment* [in prep.])
* Post-approval monitoring reports (see *CCAC policy statement for: senior administrators responsible for animal care and use programs* [2008])
* Protocol author self-reports (see *CCAC policy statement: terms of reference for animal care committees* [2006])

The goal of this step is for the protocol author to reflect on this information and determine whether the welfare impact to the animals was greater than, equal to, or lesser than expected, and modify the category as appropriate. If the welfare impacts are greater than were expected, this should be reported to the ACC, and additional follow-up may be warranted (see *CCAC guidelines: animal welfare assessment* [in prep.]). In the event that the welfare impact of the protocol was higher than expected, yet not so large as to warrant a shift in the Category of Welfare Impact, the areas of unanticipated welfare impact should still be noted and corrected or accounted for in the future. If everything went according to plan and the welfare impact was as expected, deferring to predicted outcomes is acceptable. Finally, instances where the impact was less than expected should be highlighted for the ACC as a way to promote the 3Rs.

**Appendix B provides an example worksheet that institutions may find helpful when implementing this process. It is not mandatory to use.**

### 4.3 Reporting to the CCAC

*Note that the annual animal data collection and reporting process is under revision* *by the CCAC at this time. This section is currently included as a place to cross-reference to the noted future instructions document. Thus, any new requirements to this process will be enacted at a later date.*

For the purposes of publishing annual animal data, only the retrospective Categories of Welfare Impact are required to be reported to the CCAC. If a protocol included more than one Category of Welfare Impact, the number of animals in each group should be reported. More specific instructions for reporting annual animal data can be found in the CCAC Instructions for Submitting Annual Animal Data (in preparation).

## Glossary

**Protocol Author** – the person who is ultimately responsible for the work performed under the protocol. Frequently, this person is the primary investigator, but may also be the course instructor or testing lead.

**Scientific Activity** – includes all aspects of any research, teaching/training, or testing activities.

**Procedure** – the part of the scientific activity specifically related to data collection (research and testing), or hands-on demonstration/interaction with animals (teaching and training). For example, this would not include routine husbandry activities such as cage cleaning.

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## Appendix AProspective Animal Welfare Impact Assessment Worksheet

The purpose of this appendix is to supply the protocol author with a structured framework to identify anticipated and/or potential critical welfare impacts (based on the experience of the animal), and may be used by protocol authors and animal care committees to facilitate communication. The form can be modified to suit each institution’s needs as necessary. **However, the use of this form is not mandatory.** The prompts included within each factor are example questions and are meant to provide a starting point. They do not represent all of the considerations that should be made. This worksheet is intended to be used in conjunction with the rest of the document.

The factors listed in the worksheet are relevant aspects of an animal’s life that can reasonably be expected to impact its welfare, either positively or negatively, when involved in scientific activities. For most factors, justification for inclusion is provided in the main text of this document, along with what an A- or B-level impact might be for that factor. Deviations from this A- or B-level impact should be recognized with an increased score for that factor. For each of the three over-arching areas of welfare impact (environment, animals, and procedures), some examples of varying welfare impacts have been provided following each table to help facilitate identifying an accurate welfare impact. **Protocol authors and ACCs are strongly encouraged to prepare their own examples of welfare impacts (A through E) for each factor that are most relevant to their own work.** While potentially time-consuming up-front, this may help expedite the process over time.

Note that some factors may not be applicable, and some factors may be unknown, within the context of a specific scientific activity. In such cases, they should be acknowledged as N/A, and can subsequently be ignored. Finally, as noted in Sections 2 and 3.5, as many Categories of Welfare Impact as are applicable should be assigned; for example, if different experimental groups will have different experiences.

### PROSPECTIVE ANIMAL WELFARE IMPACT ASSESSMENT WORKSHEET

**Protocol Title**:

**Protocol Number (if available**:

**Name of Person Filling Out Form**:

**Role of Person Filling Out Form:**
(e.g., protocol author, ACC member)

The levels of welfare impact are: A – Negligible/Positive; B – Mild; C – Moderate; D – High; and E – severe, with levels B-E pertaining to gradation of negative impact.

#### Step 1 – Attributes of the Environment

*If a factor is not applicable, write N/A in the explanation box.*

|  |  |  |  |
| --- | --- | --- | --- |
| Factor | Explanation | Welfare Impact For Each Group | Potential Refinements |
| [**1.1**](#Housing) **Housing/environment**Infrastructure suitability to support behavioural needs |  |  |  |
| [**1.2**](#Transportation) **Transportation** duration and conditions of any travel |  |  |  |

**Step 1 (Environment) Category of Welfare Impact: \_\_\_\_\_\_\_\_\_\_\_**

##### Step 1 Examples – Attributes of the Environment Criteria for Each Category of Welfare Impact

The following examples provide a guide as to the level and type of welfare impact that warrant each respective Category of Welfare Impact in Step 1 (considerations related to attributes of the environment). However, they are not exhaustive or definitive and professional judgement is required.

###### A – Negligible welfare impact or positive welfare impact

Animals live in the wild or in captive conditions well above the CCAC-standard in terms of complexity and supporting behavioural needs

Benign husbandry procedures are employed, and animals are rewarded through positive reinforcement training

Animals have access to appropriate amounts of food and water; animals are supplemented with highly palatable treats

Animals are not transported

###### B – Mild negative welfare impact

Animals are held in accordance with all relevant CCAC standards for the duration of the protocol

Benign husbandry procedures are employed; animals are habituated

Animals have access to appropriate amounts of food and water

Animals are transported within a facility

###### C – Moderate negative welfare impact

Animals are held in accordance with all relevant CCAC standards for most of the protocol, but may spend short periods of time held in moderately substandard conditions (relative to CCAC guidelines); OR animals are kept in slightly substandard conditions (relative to CCAC guidelines) for the duration of the protocol

Additional husbandry procedures are employed (e.g. genotyping via removal of tissue)

Animals have access to appropriate amounts of food and water

Animals are transported short distances (e.g. across campus or within the local area) in conditions that meet CCAC or industry standards

###### D – High negative welfare impact

Animals are kept in substantially substandard conditions for the duration of the protocol; OR animals are kept in barren conditions for portions of the protocol

Deviations from routine husbandry procedures (animals are not habituated)

Animals show increased aversion to humans

Animals are food or water restricted

Animals are transported long distances; OR are transported in conditions that are below CCAC or industry standards

###### E – Severe negative welfare impact

Animals are kept in barren or highly restrictive conditions

Husbandry is greatly substandard (e.g. cages are not cleaned at appropriate intervals)

Animals have learned to be fearful of humans (lack of positive reinforcement)

Animals are severely food or water restricted

Animals are transported very long distances; OR are transported in conditions way below CCAC or industry standards that result in deprivation (e.g. without sufficient food or water)

#### Step 2 – Attributes of the Animal

*If a factor is not applicable, write N/A in the explanation box.*

| Factor | Explanation | Welfare Impact For Each Group | Potential Refinements |
| --- | --- | --- | --- |
| [**2.1**](#Species) **Species/strain characteristics**considerations specific to species/ strain choice |  |  |  |
| [**2.2**](#Age) **Age/developmental stage**specific considerations, re: how that stage will react to procedure |  |  |  |
| [**2.3**](#CaptiveBorn) **Wild-caught or domestic/captive born**wild-caught vulnerable#generations removed from wild |  |  |  |
| [**2.4**](#WelfareStatus) **Preceding welfare status of the animal**genetic mutation? |  |  |  |
| [**2.5**](#BodyCondition) **Energy status/Body condition**low energy reserve?high metabolic demands? |  |  |  |
| [**2.6**](#Social) **Social disruption**Is the social dynamic disrupted? |  |  |  |
| [**2.7**](#Cumulative) **Previous experience of the animal (cumulative effects)**animal previously used in another procedure or protocol? |  |  |  |
| [**2.8**](#Individuals) **Known aspects of individual animals**individual temperament known? |  |  |  |

**Step 2 (Animal Attributes) Category of Welfare Impact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

##### Step 2 Examples – Attributes of the Animal Criteria for Each Category of Welfare Impact

The following examples provide a guide as to the level and type of welfare impact that warrant each respective Category of Welfare Impact for Step 2 (considerations related to the attributes of the animals). However, they are not exhaustive or definitive and professional judgement is required.

###### A – Negligible welfare impact or positive welfare impact

No special concerns about the species or strain chosen

Animals are domestic and captive born, healthy, and phenotypically normal

Animals are uniform in age

Animals have not been re-used from another protocol

Animals are in good body condition for their breed/strain, sex, and stage of life (typically a 3 on the standard 1-5 scale)

Animals are in a stable social group

###### B – Mild negative welfare impact

No special concerns about the species or strain chosen

Animals are domestic and captive born, mostly healthy, and phenotypically normal

Animals may vary in age, but there are no specific concerns about their developmental stage

Animals have not been re-used from another protocol

Animals are in good body condition (3/5) for the majority of the protocol with only slight deviations (±0.5).

Social hierarchy disruptions are possible, but won’t lead to aggression

###### C – Moderate negative welfare impact

Species- or strain-specific considerations are mostly able to be accommodated

Animals are captive born, but parents were wild-caught

Animals have slightly compromised welfare prior to the scientific activity (e.g. animals have a genetic mutation that has a noticeable, but small, impact on welfare)

Animals have been involved in other protocols or procedures and show signs of increased aversion from previous exposure to procedures

Animals are in acceptable body condition (2-4/5).

Social hierarchy disruptions lead to short term aggression

###### D – High negative welfare impact

Species- or strain-specific considerations are mostly unable to be accounted for

Animals are wild-caught

Animals are in obese body condition (>4/5)

Animals are not naïve and show strong avoidance behaviour when presented with procedural stimuli

Animals have compromised welfare prior to the scientific activity (e.g. genetic mutations that inhibit, but do not prevent normal functions like eating, drinking, or grooming)

Animals have a novel genetic mutation and the phenotype is unknown (NB. This should be changed retrospectively to reflect the actual impact of the phenotype).

Social hierarchy disruptions lead to long-term or severe aggression.

###### E – Severe negative welfare impact

Species- and strain-specific accommodations cannot be made (e.g. not providing nesting material to nude mice). Species- or strain-specific traits leave animals especially vulnerable.

Animals are wild-caught

Animals are in poor body condition (<2/5)

Animals are not naïve and show very strong avoidance behaviour when presented with procedural stimuli.

Animals have severely compromised welfare prior to the scientific activity (e.g. genetic mutations that prevent normal functions like eating, drinking, or grooming)

Social groups are completely unstable with high levels of aggression and wounding

#### Step 3 – Attributes of the Procedure(s)

*If a factor is not applicable, write N/A in the explanation box.*

|  |  |  |  |
| --- | --- | --- | --- |
| Factor | Explanation | Welfare Impact For Each Group | Potential Refinements |
| [**3.1**](#Procedures) **Scientific Procedure\***expected pain/distresslong term effects?indirect procedure effects on others?refer to table below to assist with assigning welfare impact based on procedure severity and frequency/duration |  |  |  |

*\*Complete a separate table for each procedure. Consider evaluating complex procedures in multiple steps or components. For example, step 1 could be the surgical preparation and step 2 the treatment regime (exercise, diet, disease, etc.).*

*Reference table informing the welfare impact of the procedures:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Welfare Impact | Procedure(s) Severity | Procedure(s) Frequency and/or Duration |
| A – negligible/ positive | None/positive | - |
| Categories of negative impact | B – mild | Low | Low |
| C – moderate | Low | Medium |
| Low | High |
| Medium | Low |
| Medium | Medium |
| D – high | Medium | High |
| High | Low |
| E – Severe | High | Medium |
| High | High |

| Factor | Explanation | Welfare Impact For Each Group | Potential Refinements |
| --- | --- | --- | --- |
| [**3.2**](#Monitoring) **Monitoring**what is the quality and frequency of monitoring? |  |  |  |
| [**3.3**](#Euthanasia) **Euthanasia**what level of ‘acceptability’ is the chosen method?See [*CCAC guidelines on: euthanasia of animals used in science*](https://www.ccac.ca/Documents/Standards/Guidelines/Euthanasia.pdf) |  |  |  |
| [**3.4**](#Setting) **Physical setting**surgery suite vs. in wildtechnology availablesupport availability |  |  |  |
| [**3.5**](#Skill) **Personnel skill/experience with procedure**have people done the procedure(s) before? |  |  |  |
| [**3.6**](#Trained) **Procedure training for the animal**positive reinforcement training? |  |  |  |

**Step 3 (procedure) Category of Welfare Impact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

##### Step 3 Examples – Aspects of the Procedures Criteria for Each Category of Welfare Impact

The following examples provide a guide as to the level and type of welfare impact that warrant each respective Category of Welfare Impact for Step 3 (considerations relating to the aspects of the scientific procedures). However, they are not exhaustive or definitive and professional judgement is required. Note that ‘severity’ refers to the magnitude of any pain or distress experienced by the animals.

###### A – Negligible welfare impact or positive welfare impact

The procedures have negligible negative effects on the animal; OR the procedures have immediate beneficial effects on the animals’ welfare

Personnel are highly trained and have lots of experience with the procedure(s)

Animals are not euthanized

###### B – Mild negative welfare impact

The severity of the procedure is low and the frequency/duration is also low

The procedure takes place in controlled conditions with ample support available

Personnel are highly trained and have lots of experience with the procedure(s)

Animals are trained to participate in the procedure through positive reinforcement training

Animals are euthanized with an acceptable method according to CCAC guidelines

###### C – Moderate negative welfare impact

The severity of the procedure is low-medium and the frequency/duration is medium-high; OR the severity of the procedure is medium and the frequency/duration is low-medium

Procedure takes place in a controlled setting

Personnel are trained and have some experience performing the procedure or similar procedures

Animals are untrained

Animals are euthanized with a conditionally-acceptable method according to CCAC guidelines

###### D – High negative welfare impact

The severity of the procedure is medium and the frequency/duration is high; OR the severity of the procedure is high and the frequency/duration is low

Procedure takes place in an uncontrolled setting with minimal support available

Personnel are experienced working with the animals, but the procedure is novel

Animals are euthanized with a non-approved method according to CCAC guidelines

###### E – Severe negative welfare impact

The severity of the procedure is high and the frequency/duration is medium-high.

Procedure takes place in a remote location with no support in case of adverse events

Personnel are untested or new in working with the animals and performing the procedure (particularly a procedure with high severity or complexity)

Animals are expected to be found dead as part of the procedure

#### Final Categories of Welfare Impact

For each distinct group of animals within a protocol (i.e. they are expected to experience varying levels of welfare impact), an overall prospective Category of Welfare Impact should be assigned. This assessment should take into consideration the relative impact that each of the three areas (environment, animal, procedure) is likely to have, and weight the overall prospective Category of Welfare Impact accordingly.

**Input Welfare Impacts Determined Above:**

Step 1 (environment) impacts: \_\_\_\_\_\_\_\_\_\_\_\_\_

Step 2 (animal) impacts: \_\_\_\_\_\_\_\_\_\_\_\_\_

Step 3 (procedure) impacts: \_\_\_\_\_\_\_\_\_\_\_\_\_

**= Overall Prospective Protocol Category\*:** \_\_\_\_\_\_\_\_\_\_\_\_\_

\*repeat this process as many times as is applicable; for example, if different experimental groups will have different experiences.

*Excerpt from Section 3.4: Once a preliminary Category of Welfare Impact has been assigned to each step, they are then summarized into an overall score for each protocol (or each distinct group of animals within a protocol). For the purposes of this summary, each of the three steps should be considered similarly in that they are all important areas of potential welfare impact. However, depending on the nature of the scientific activity, any of three different areas of welfare impact (animals, environment, and procedure) could factor most prominently. Therefore, if any one of these areas of welfare impact is considered to have overwhelming importance (i.e. because the welfare impact is much larger than the other areas), that area should be given disproportionately more weight in determining the overall prospective Category of Welfare Impact. Thus, this summary must be evaluated through a lens of professional judgement (by both the protocol author and the animal care committee), adjusted as necessary, and accompanied by a transparent rationale as required. There are no hard-and-fast rules for this process, and it is expected that the accuracy and consistency with which Categories of Welfare Impact are assigned will improve with experience. In particular, comparison of the prospective and the retrospective Categories of Welfare Impact should be a constructive learning exercise which will help inform future prospective Categories of Welfare Impact.*

Explanation for Overall Prospective Category of Welfare Impact:

|  |
| --- |
|  |

## Appendix BRetrospective Animal Welfare Impact Assessment Worksheet

The purpose of this appendix is to supply the protocol author with a structured framework to review their work in terms of identifying outcomes that were not as predicted, how those may have impacted animal welfare differently than predicted, and how their work can be refined in the future. The relevant factors (see Section 3 or Appendix A) should be filled in as appropriate. This form may also help facilitate communication between protocol authors and animal care committees. **It is not mandatory, and may be modified to suit each institution’s needs as necessary.** This worksheet is intended to be used in conjunction with the rest of the document.

| Factor | Deviations from Expected Outcomes | Actual Welfare Impact | Potential Refinements in the Future |
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**Overall Retrospective Protocol Categories\*:** \_\_\_\_\_\_\_\_\_\_\_\_\_

\*assign as many as are applicable; for example, if different experimental groups had different experiences.

1. While there are five letters describing the categories of welfare impact, as in the previous policy describing the categories of invasiveness (CCAC, 1991), these should not be considered as necessarily equivalent with the old system, due to the shift to an animal-centric focus. [↑](#footnote-ref-1)
2. In place of categories of invasiveness [↑](#footnote-ref-2)