Canadian Council on Animal Care
Conseil canadien de protection des animaux

INSTRUCTIONS FOR COMPLETION OF THE CCAC ANIMAL USE DATA FORM

TABLE OF CONTENTS

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1. PREAMBLE

Publication of animal use data is important to provide accountability for the use of animals to the Canadian public, and to contribute to a better understanding of scientific animal use in Canada. The CCAC has been publishing national animal data reports since 1975. The complete results and analysis from these reports are available for the previous five years on the CCAC website.

The CCAC *Animal Use Data Form* (AUDF) allows the CCAC to collect information on animal use in science. The CCAC uses the information from the AUDF to prepare the animal data reports. The reports present aggregate information (individual institutions are not identified) on the numbers of animals used per genus and species, the purpose of animal use (PAU) and the degree of invasiveness of the procedures used on the animals.

Analysis of the AUDF data provides valuable information for assessment visits, guideline and policy development, and education and Three Rs activities. The *Instructions for Completion of the CCAC Animal Use Data Form* aims to provide information and assistance to CCAC constituents in filling out the AUDF. As the CCAC works to improve the collating and reporting of animal use in science, this document will be revised. The most current version will be available on the CCAC website and will accompany the annual request for submission of data sent to CCAC program participants.

2. INTRODUCTION

Participants in the CCAC program are required to submit to audf@ccac.ca, all of their animal use data for a calendar year by **March 31st** of the following year as stated in Section 5c of the *CCAC policy statement on: terms of reference for animal care committees*.

Institutions are required to submit their animal use information using the AUDF template provided on the CCAC website. This instructions document describes and explains each element to be completed on the AUDF. It provides answers to some frequently asked questions and examples on how to submit animal use data. In cases where two or more institutions are involved in an animal-based project, in general, it is the responsibility of the host institution only (i.e. the institution where the animals are located) to report the number of animals used. This responsibility should be clarified with all of the partners prior to the start of the project.

The CCAC staff reviews and validates all institutional AUDF submissions to ensure that the composite data is as accurate as possible. If there are any questions concerning missing data or inconsistencies, the institution will be contacted to request additional information. A prompt response is

appreciated as it assists the CCAC to publish the animal data in a timely manner. If any of the data is re-classified by the CCAC, the amendments will be communicated to the institution to ensure that institutional records are consistent with the CCAC dataset.

3. ANIMALS TO BE INCLUDED ON THE AUDF

All animals that are used on a protocol that is active at any point during the calendar year must be included on the AUDF. For more information on 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, refer to the *Requirement for submitting an animal protocol: Addendum to the CCAC policy statement on terms of reference for animal care committees*.

4. REQUIRED ELEMENTS

The following **eight (8)** fields **must** be completed on the AUDF, while the ninth field is optional:

1) unique protocol number
2) category of invasiveness (CI)
3) protocol description and/or keywords
4) purpose of animal use (PAU)
5) animal genus and species
6) number of animals used in the calendar year of submission
7) number of animals reused from protocols within the calendar year of submission
8) for reused animals, protocol number of first use
9) number of animals carried over from protocols from a previous calendar year (optional information)

1. Unique Protocol Number

Institutions attribute a unique number to each protocol for ease of reference and follow-up of activities. Identification of the protocol is particularly important for pre-assessment purposes since panel members visiting the institution may wish to review a particular protocol or it may be necessary to identify a protocol for comments in the assessment report. It also assists the CCAC to follow up with an institution where any errors or omissions are noted in the submission. This information is not published in CCAC annual animal data reports.

2. Category of Invasiveness

CIs are categorized differently for laboratory animals compared to those involved in wildlife and field studies. CIs are to be assigned according to the Categories of Invasiveness in Animal Experiments. For descriptions of the CI categories and examples, refer to Appendix A.

In Table 1, a protocol with more than one CI is shown. Details should be given using separate rows starting with the same protocol number. The form has been devised to collect information protocol by protocol, so that a specific number of animals used can be linked to a CI; in this way, it will be possible to determine exactly how many animals are used within each CI.

Table 1 Examples of an AUDF Reporting a Protocol with More Than One CI

UNIQUE PROTOCOL NUMBER	CI	PROTOCOL DESCRIPTION	KEYWORDS	PAU	ANIMAL GENUS AND SPECIES	NUMBER OF ANIMALS USED	NUMBER OF ANIMALS REUSED	PROTOCOL NUMBER OF FIRST USE	OPTIONAL ANIMALS CARRIED OVER FROM PREVIOUS YEAR
2018-001	B	Rodent models of cardiac disease used to identify or validate common mediators of hypertensive cardiac growth	Non-survival surgery; tissue/organ collection	1	House mouse	20	0	n/a	n/a
2018-001	D	Rodent models of cardiac disease used to identify or validate common mediators of hypertensive cardiac growth	Major survival surgery; chemical exposure	1	House mouse	10	0	n/a	n/a

Answers to Frequently Asked Questions in Relation to CIs

1) Procedures that involve removing an appropriate amount of tissue from the tip of the tail of an animal to identify its genotype should be assigned a CI B.
2) Protocols involving oral gavage (tube feeding) should be assigned a CI C.

3) Protocols involving electrofishing should be assigned a level D of invasiveness. CCAC encourages institutions to use alternatives to electroshocking.

4) Protocols where generation of genetically-engineered animals involves creation of a novel genotype should be assigned a CI D. Once the genetically-engineered animal is created, the CI assigned depends on the resulting phenotype and on the nature of procedures to be conducted on the animal, and should be reclassified if necessary with an amendment or upon animal use protocol renewal.

3. Protocol Description and/or Keywords

The protocol description and keywords help to validate the animal use data. The protocol description should be brief and must convey, in simple terms, the PAU. For protocol descriptions for PAU 3 (regulatory testing) it is useful to include the name and/or number of the specific regulatory test that is being conducted. This assists the CCAC to identify any potential alternative methods that have been validated and accepted for regulatory use. In addition, field studies must be identified as such to ensure that these protocols have been assigned the correct CI for wildlife studies. The keywords should describe the procedures used, indicative of the assigned CI. This information is not published in CCAC annual animal data reports.

4. Purpose of Animal Use

PAU should be assigned according to the primary purpose of the study. Currently, it is not mandatory to include protocols assigned to PAU 0 (Breeding colonies, herd, and holding protocols), although submission is encouraged. For descriptions of the PAU categories and example assignments of them to types of animal studies commonly conducted, refer to Appendix B.

In Table 2, a protocol with more than one PAU is shown. Details should be given using separate rows starting with the same protocol number. The form has been devised to collect information protocol by protocol, so that a specific number of animals used can be linked to a PAU; in this way, it will be possible to determine exactly how many animals are used within each PAU.

Table 2 Example of an AUDF Reporting a Protocol With More Than One PAU

UNIQUE PROTOCOL NUMBER	CI	PROTOCOL DESCRIPTION	KEYWORDS	PAU	ANIMAL GENUS AND SPECIES	NUMBER OF ANIMALS USED	NUMBER OF ANIMALS REUSED	PROTOCOL NUMBER OF FIRST USE	OPTIONAL ANIMALS CARRIED OVER FROM PREVIOUS YEAR
2018-002	C	Anti-diabetic effect of novel chemical will be studied in rats. Fasting blood glucose and oral glucose tolerance will be tested and some animals will be used to train graduate students.	Blood sampling; biopsy; oral gavage	1	Rat	20	0	n/a	n/a
2018-002	C	Anti-diabetic effect of novel chemical will be studied in rats. Fasting blood glucose and oral glucose tolerance will be tested and some animals will be used to train graduate students.	Blood sampling; biopsy; oral gavage	5	Rat	2	0	n/a	n/a

Answers to Frequently Asked Questions in Relation to PAU

1) Usually, protocols are assigned one PAU, which reflects the primary objective of the study. A protocol can have more than one PAU but the number of animals used for each purpose within the protocol must be reported on separate rows in the AUDF submission. Please refer to Table 2 for an example of a submission with a protocol with more than one PAU.

2) It is sometimes the case in an academic institution that professors conduct research studies and then invite their students to witness or conduct some procedures on the animals as part of their

academic training. However, the primary objective of the study remains research. Accordingly, this should be the only PAU indicated on the AUDF.

3) Non-regulatory testing projects should not be categorized as regulatory testing (PAU 3), but should be categorized according to the nature of the studies conducted on the animals. For example, if the purpose of a project is to test a new technology (e.g., dispenser of pills for cows) or to test a new anti-inflammatory candidate at an early stage, then the protocols should be categorized as a PAU 4 (development of products) and PAU 2 (medical studies), respectively. Protocols assigned to PAU 3 should include the name of the test method in the protocol description.

5. Animal Genus and Species

All animals must be clearly identified by genus and species. Common names that distinguish species may be used, but general categories, such as "fish", "avian", "small mammals", "various amphibians", "wild rodents", "poultry", or "farm animals", **must not** be used to identify animals.

When multiple species are used within a single protocol (e.g., small mammals in field studies) each species must be reported on a separate row of the AUDF template (see Table 3).

Having institutions identify animal species:

- enables the CCAC to search its database to identify trends in animal use in science;
- helps the CCAC Standards Committee identify species on which to focus for the development of new guidelines; and
- contributes to public accountability for animals used in science.

Cats and Dogs

For protocols involving cats and/or dogs, it must be specified on the AUDF whether the animals were acquired from a random source (i.e. were not bred specifically for research, teaching or testing, either by a commercial supplier or within your own or another institution; these animals are generally obtained from humane societies, or are the animals of students or clients) or whether they were purpose-bred (i.e. were bred specifically for research, teaching, testing, either by a commercial supplier or within your own or another institution).

Table 3 Example of an AUDF Reporting the Use of Multiple Species Within a Single Protocol

UNIQUE PROTOCOL NUMBER	CI	PROTOCOL DESCRIPTION	KEYWORDS	PAU	ANIMAL GENUS AND SPECIES	NUMBER OF ANIMALS USED	NUMBER OF ANIMALS REUSED	PROTOCOL NUMBER OF FIRST USE	OPTIONAL ANIMALS CARRIED OVER FROM PREVIOUS YEAR
2018-003	C	Field study: trapping small mammals for population estimates and health status	Behavioural observation; trapping; blood sampling	1	House mouse	47	0	n/a	n/a
2018-003	C	Field study: trapping small mammals for population estimates and health status	Behavioural observation; trapping; blood sampling	1	Common vole	51	0	n/a	n/a

6. Number of Animals Used in the Calendar Year of Submission

This field must contain the number of animals used for each protocol active at any point between **January 1st and December 31st of the reporting year**.

In cases where the same animals are used in a protocol that spans over two or more calendar years their numbers should be reported on the AUDF **each** year.

In some cases, the number of animals used for the submission year is missing but the protocol is still reported to CCAC. In these cases where no animals are used, a zero should be entered instead of leaving a blank space, or the protocol line could be deleted. Otherwise, it is unclear if no animals were used for this protocol or if they were omitted in error and you will be contacted for clarification.

7. Number of Animals Reused

The CCAC defines reuse as any time an animal is transferred from one protocol to another **within the same calendar year.**

Indicating the number of animals that are reused within the calendar year allows the CCAC to calculate the absolute number of animals used (i.e. number of uses minus reuse).

Animals reused from a previous year should **not** be marked as reuse (see point 9 below). These animals are considered a new use for each current calendar year.

8. For Reused Animals, Protocol Number of First Use

If animals are reused within the same calendar year, the original protocol number must be entered into the column next to the number of animals that were reused. This information enables the CCAC to ensure that these reused animals are not double counted when reporting the annual number of animals used in science at CCAC-certified institutions by animal type.

In Table 4, animals are used in one protocol and then transferred to and reused in a separate protocol within the same calendar submission year as the original use. The protocol number of the original protocol is reported next to the number of reused animals.

Reuse only refers to animals that have been included in protocols with PAUs 1-5; therefore, reuse should never refer back to a breeding, herd, or holding protocol (PAU 0).

Table 4 Example of an AUDF Reporting Animals Reused from a Protocol Within the Current Submission Year

UNIQUE PROTOCOL NUMBER	CI	PROTOCOL DESCRIPTION	KEYWORDS	PAU	ANIMAL GENUS AND SPECIES	NUMBER OF ANIMALS USED	NUMBER OF ANIMALS REUSED	PROTOCOL NUMBER OF FIRST USE	OPTIONAL ANIMALS CARRIED OVER FROM PREVIOUS YEAR
2018-004	B	Teaching animal handling skills to student veterinary technicians	Behavioural observation; physical restraint	5	Dog – random	5	0	n/a	n/a
2018-005	D	Teaching surgical skills to student veterinarians	Major surgery; anesthesia	5	Dog – random	2	2	2018-004	n/a

9. Animals Carried Over from a Previous Year (Optional)

In some situations, particularly with larger mammals, individual animals are used a number of times over a period of several years in either single or multiple protocols. If applicable, institutions may choose to indicate on the AUDF when animals have been carried over from previous years.

They may do this by adding a short descriptive comment (stating the number of years the animal has been used and the type of research) in the appropriate column in the AUDF template (see Table 5).

Table 5 Example of an AUDF Reporting Animals Carried Over from a Previous Year

UNIQUE PROTOCOL NUMBER	CI	PROTOCOL DESCRIPTION	KEYWORDS	PAU	ANIMAL GENUS AND SPECIES	NUMBER OF ANIMALS USED	NUMBER OF ANIMALS REUSED	PROTOCOL NUMBER OF FIRST USE	OPTIONAL ANIMALS CARRIED OVER FROM PREVIOUS YEAR
2018-006	B	Teaching animal handling skills to student veterinary technicians	Behavioural observation; physical restraint	5	Dog – purpose-bred	5	0	n/a	Same 5 dogs used for teaching in past 2 years

APPENDIX A
CATEGORIES OF INVASIVENESS IN ANIMAL EXPERIMENTS

Investigators and teachers who consider it essential to use vertebrates or invertebrates in their research, teaching or testing in the laboratory or in the field, must adhere to humane principles, and take cognizance of the *CCAC policy statement on: ethics of animal investigation* and other CCAC documentation in assigning a category. Protocols must be submitted to an appropriate review committee for all studies and courses which involve the use of vertebrates and some invertebrates in Categories B through E. Cephalopods and some other higher invertebrates have systems as well developed as in some vertebrates, and may therefore warrant inclusion in Category B, C, D, or E. The following list of categories provides possible examples of experimental procedures which are considered to be representative of each category:

A. Experiments on most invertebrates or on live isolates

Possible examples: the use of tissue culture and tissues obtained at necropsy or from the slaughterhouse; the use of eggs, protozoa or other single-celled organisms; experiments involving containment, incision or other invasive procedures on non-cephalopod invertebrates.

B. Experiments which cause little or no discomfort or stress

Possible examples: domestic flocks or herds being maintained in simulated or actual commercial production management systems; the short-term and skillful restraint of animals for purposes of observation or physical examination; blood sampling; injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral, but not intrathoracic or intracardiac (Category C); acute non-survival studies in which the animals are completely anesthetized and do not regain consciousness; approved methods of euthanasia following rapid unconsciousness, such as anesthetic overdose, or decapitation preceded by sedation or light anesthesia; short periods of food and/or water deprivation equivalent to periods of abstinence in nature.

C. Experiments which cause minor stress or pain of short duration

Possible examples: cannulation or catheterization of blood vessels or body cavities under anesthesia; minor surgical procedures under anesthesia, such as biopsies, laparoscopy; short periods of restraint beyond that for simple observation or examination, but consistent with minimal distress; short periods of food and/or water deprivation which exceed periods of abstinence in nature; behavioral experiments on conscious animals that involve shortterm, stressful restraint; exposure to nonlethal levels of drugs or chemicals. Such procedures should not cause significant changes in the animal's appearance, in physiological parameters such as respiratory or cardiac rate, or fecal or urinary output, or in social responses.

During or after Category C studies, animals must not show self-mutilation, anorexia, dehydration, hyperactivity, increased recumbency or dormancy, increased vocalization, aggressive defensive behavior or demonstrate social withdrawal and self-isolation.

D. Experiments which cause moderate to severe distress or discomfort

Possible examples: major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioral stresses such as maternal deprivation, aggression, predator-prey interactions; procedures which cause severe, persistent or irreversible disruption of sensorimotor organization; the use of Freund's Complete Adjuvant (see *CCAC policy statement on: acceptable immunological procedures*). Other examples include induction of anatomical and physiological abnormalities that will result in pain or distress; the exposure of an animal to noxious stimuli from which escape is impossible; the production of radiation sickness; exposure to drugs or chemicals at levels that impair physiological systems.

Procedures used in Category D studies should not cause prolonged or severe clinical distress as may be exhibited by a wide range of clinical signs, such as marked abnormalities in behavioral patterns or attitudes, the absence of grooming, dehydration, abnormal vocalization, prolonged anorexia, circulatory collapse, extreme lethargy or disinclination to move, and clinical signs of severe or advanced local or systemic infection, etc.

E. Procedures which cause severe pain near, at, or above the pain tolerance threshold of unanesthetized conscious animals

This Category of Invasiveness is not necessarily confined to surgical procedures, but may include exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs or chemicals at levels that (may) markedly impair physiological systems and which cause death, severe pain, or extreme distress; completely new biomedical experiments which have a high degree of invasiveness, behavioral studies about which the effects of the degree of distress are not known; use of muscle relaxants or paralytic drugs without anesthetics; burn or trauma infliction on unanesthetized animals; a euthanasia method not approved by the CCAC; any procedures (e.g., the injection of noxious agents or the induction of severe stress or shock) that will result in pain which approaches the pain tolerance threshold and cannot be relieved by analgesia (e.g., when toxicity testing and experimentally-induced infectious disease studies have death as the endpoint).

CCAC CATEGORIES OF INVASIVENESS FOR WILDLIFE STUDIES

The unedited information below was previously published in the 2003 *CCAC guidelines on: the care and use of wildlife*, a document which has been replaced by the *CCAC guidelines: Wildlife*.

Category of Invasiveness A

Methods used on most invertebrates or on live isolates

Possible Examples: The use of tissue culture and tissues obtained at necropsy; the use of eggs, protozoa or other single-celled organisms; experiments involving containment, incision or other invasive procedures on metazoa; and studies in which the animals are observed without any disturbance to them.

Category of Invasiveness B

Methods used which cause little or no discomfort or stress

Possible Examples: Observational studies in which there is some disturbance to the animals, but not to the point that the same individuals are repeatedly observed so as to habituate or otherwise modify their behaviour; census or other surveys which disturb animals but which do not involve capture or marking individuals; noninvasive studies on animals that have been habituated to captivity; and short periods of food and/or water deprivation equivalent to periods of abstinence in nature.

Category of Invasiveness C

Methods which cause minor stress or pain of short duration

Possible Examples: Capture, using methods with little or no potential to cause injury and marking of animals for immediate release; long-term observational studies on free ranging animals where the behavior of individuals may be altered by repeated contact; brief restraint for blood or tissue sampling; short periods of restraint beyond that for simple observation or examination, but consistent with minimal distress; short periods of food and/or water deprivation which exceed periods of abstinence in nature; exposure to non-lethal levels of drugs or chemicals; low velocity darting and slow-injection darts with immobilization chemicals. Such procedures should not cause significant changes in the animal's appearance, in physiological parameters (such as respiratory or cardiac rate, or fecal or urinary output), in social responses or inability to survive.

Note: During or after Category C studies, animals must not show self-mutilation, anorexia, dehydration, hyperactivity, increased recumbency or dormancy, increased vocalization, aggressive-defensive behavior, or demonstrate social withdrawal and self-isolation.

Category of Invasiveness D

Methods which cause moderate to severe distress or discomfort

Possible Examples: Capture, using methods that have the potential to cause injury (e.g., high velocity darting and rapid-injection darts with immobilization chemicals, net gunning, etc.); maintenance of wild caught animals in captivity; translocation of wildlife to new habitats; major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioral stresses such as maternal deprivation, aggression, predator-prey interactions; procedures which cause severe, persistent or irreversible disruption of sensorimotor organization.

Other Examples in Captive Animals Include: induction of anatomical and physiological abnormalities that will result in pain or distress; the exposure of an animal to noxious stimuli from which escape is impossible; the production of radiation sickness; exposure to drugs or chemicals at levels that impair physiological systems **(N.B. Experiments described in this paragraph would be Category E if performed on wildlife immediately prior to release)**.

Note: Procedures used in Category D studies should not cause prolonged or severe clinical distress as may be exhibited by a wide range of clinical signs, such as marked abnormalities in behavioral patterns or attitudes, the absence of grooming, dehydration, abnormal vocalization, prolonged anorexia, circulatory collapse, extreme lethargy or disinclination to move, and clinical signs of severe or advanced local or systemic infection, etc.

Category of Invasiveness E

Procedures which cause severe pain near, at, or above the pain tolerance threshold of unanesthetized, conscious animals

Possible Examples: This Category of Invasiveness is not necessarily confined to surgical procedures, but may include exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs or chemicals at levels that (may) markedly impair physiological systems and which cause death, severe pain, or extreme distress; behavioral studies about which the effects of the degree of distress are not known; environmental deprivation that has the potential to seriously jeopardize an animal's well-being; use of muscle relaxants or paralytic drugs without anesthetics; bum or trauma infliction on unanesthetized animals; a euthanasia method not approved by the CCAC; any procedures (e.g., the injection of noxious agents or the induction of severe stress or shock) that will result in pain which approaches the pain tolerance threshold and cannot be relieved by analgesia (e.g., removal of teeth without analgesia, or when toxicity testing and experimentally-induced infectious disease studies have death as the endpoint); capture methods with a high potential of causing severe injury that could result in severe chronic pain and/or death (e.g., leghold traps).

APPENDIX B
PURPOSE OF ANIMAL USE

PURPOSE OF ANIMAL USE	DESCRIPTION	EXAMPLES
PAU 0	Breeding Colony/Stock	Animals held in breeding colonies (e.g. fish, rodents, farm animals) that have not been assigned to a particular research, teaching or testing protocol.
PAU 1	Studies of a fundamental nature in sciences relating to essential structure or function	Basic science studies, including biology, psychology, biochemistry, pharmacology, physiology). **Examples**: studies designed to understand the cellular and/or mo-lecular basis of inflammatory reactions or other basic physiologi-cal or biochemical reactions; studies designed to understand one or some of the various facets of the role played by a hormone or other compound produced by mammals; studies designed to bet-ter understand the behavior of various species; studies designed to better understand the population dynamics of various species
PAU 2	Studies for medical purposes, including veterinary medicine, that relate to human or animal diseases or disorders	Studies carried out to better understand a specific disease or disorder and to help find therapies for it. **Examples:** development of a mouse model for a specific type of cancer or other disease; studies to determine which antibodies are the most likely to contribute positively to the therapy of a specif-ic type of cancer; studies to determine which molecule within a particular class of compounds is the most likely to contribute to maintaining stable blood glucose levels in an animal model of diabetes

PURPOSE OF ANIMAL USE	DESCRIPTION	EXAMPLES
PAU 3	Studies for regulatory testing of products for the protection of humans, animals, or the envi-ronment	Studies required by government authorities. **Examples:** safety testing, regulatory toxicology, vaccine efficacy trials, and testing of new therapeutic compounds (if it is to generate data that is going to be used in a submission for an investigational new drug application (IND) or for a new drug application (NDA)); shellfish toxin testing
PAU 4	Studies for the development of products or appliances for hu-man or veterinary medicine	Studies carried out to investigate potential therapies (as determined following studies of PAU 2) for humans or animals, before regulatory testing (PAU 3) is carried out on the most promising therapies. **Examples:** studies undertaken in animals to investigate the role and effects of a specific drug or immunotherapy candidate for cancer; studies undertaken to develop physical devices to assist heart function; studies undertaken to develop artificial organs
PAU 5	Education and training of individuals in post-secondary institutions or facilities	Teaching or training programs where animals are used to intro-duce students to scientific work and teach manual skills and techniques.

HOW TO REACH US

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