



Instructions for Preparing and Submitting the Animal Use Protocol Form

PROCESS AND TIMELINES

Full Protocols

All protocols need to be reviewed by the full Animal Care Committee (ACC). Please see the links below for applicable protocol submission deadline dates and meeting schedule. **You should allow 6 – 8 weeks for the review process.**

Protocol Submission Deadlines and Meeting Dates

<https://umanitoba.ca/research/opportunities-support/ethics-compliance/animal-care-and-veterinary-services#animal-care-committees-acc-and-submission-deadlines>

NOTE: THE COMMITTEES DO NOT MEET IN THE MONTH OF JULY.

Pre-Review of Protocols

Any protocols involving anesthesia/sedation/chemical restraint (Schedule 2), surgery (Schedule 3) or humane endpoints (Schedule 4) require pre-review by the applicable veterinarian. The protocol submission deadlines (see links above) allow for sufficient time for the pre-review of the submitted protocol to take place.

All Protocols

Please provide an electronic copy of the entire protocol (including schedules etc.) to tracy.vanosch@umanitoba.ca. Your submission will be routed to the assigned veterinarian who will contact you upon receipt regarding any concerns or recommended changes.

Please note that for protocol submissions at the pre-review stage, only the signature of the PI is needed in Block 17. No other signatures are required at this stage.

Pre-Review of Schedule 10

Please ensure that an electronic copy of the protocol and the Schedule 10 is submitted to the Animal Care Occupational Health Specialist (OHS) for pre-review as per the Protocol Submission Deadlines (see links above). Fort Garry & Bannatyne OHS: Mr. Steven Cole (Steven.Cole@umanitoba.ca) / St. Boniface Research Centre OHS: Mr. Devon Liscum (dliscum@sbgh.mb.ca)

Please note that signatures on the Schedule 10 are not required at the pre-review stage.

Renewal-Short Form & Application for Amendment

Animal Protocol Renewal-Short Form

The short form for annual renewal of approved protocols can be used for 3 years (three renewals). In the fourth year, the full protocol application form must be used. Renewals should be submitted 5 weeks prior

to the protocol expiry date. For example, if the protocol expires June 15 2023, the renewal should be submitted no later than May 11 2023. **It normally takes 3-5 weeks to process a short form renewal.**

Application for Amendment to Animal Use Protocol

If you have a change in personnel associated with a protocol or require a change in numbers of animals (or species) used, anesthetics, analgesics or other drugs or agents administered to animals, or make minor changes in procedures from those given in the original protocol, you must complete an Application for Amendment for review and approval. Substantial changes or additions to procedures not reviewed in the existing protocol, or large changes in numbers or species of animals being used may require submission of a new protocol. You are free to consult the applicable ACC Chair and/or the clinical veterinarians if you have questions as to whether an amendment or new submission is necessary. **It normally takes 2 weeks to process an amendment. You may not implement the changes until approval of the amendment is obtained.**

For Fort Garry Renewals & Amendments: please submit one signed copy of the renewal/amendment to Charlene Hennessey (charlene.hennessey@umanitoba.ca).

For Bannatyne Campus Renewals & Amendments: please submit one signed copy of the renewal/amendment to Central Animal Care Services (cacs@umanitoba.ca).

For St. Boniface Research Centre Renewals & Amendments: please submit one signed copy of the renewal/amendment to the R.O. Burrell Lab (ROBurrell@sbr.ca).

Protocol Review Process (Following pre-review, if applicable. See above.)

For “B”, “C”, and “D” COI Protocols:

- a. Protocols are received and logged by the animal care coordinator and are distributed to the applicable ACC for review by the full committee at the monthly ACC meeting.
- b. Following review, a protocol will be assigned one of the following categories:
 - i. **Approved:** Full approval, no conditions, no requests from the committee/reviewers for clarification or additional information. The PI is allowed to begin the research.
 - ii. **Approved Subject to:** Minor clarifications and/or additional information is required. This category allows the PI to begin the project.
 - iii. **Provisional Approval:** When a protocol is received that is urgent and cannot wait until the next committee meeting for review, it is sent out to the chair, the applicable veterinarian and two primary reviewers which will consist of one scientific member and one community representative. Once the primary reviewers, the chair and the veterinarian are satisfied with the protocol and responses (if applicable) from the PI, it is provisionally approved which allows the PI to begin the research. Approval of the application remains provisional until the application is reviewed by the full committee at its next monthly meeting. If the committee is satisfied with the protocol, full approval is then granted. If the committee raises additional concerns or requires additional information, this request is forwarded to the PI who must comply by a specified date.
 - iv. **Conditional Approval:** Additional information/clarification is required; therefore, the PI cannot order the animals required for the research. A letter is sent to the PI indicating the concerns of the reviewers/committee. The PI's response to the concerns is forwarded to the primary reviewers, chair, and applicable veterinarian for consideration. When “conditional approval” is granted, the PI's comments do not need to go back to the full committee. Once all reviewers, the chair, and the veterinarian are satisfied with the PI's response(s), full approval is granted.
 - v. **Hold:** There are numerous and major concerns with the protocol. The PI does not get a protocol number and may not begin the research. A letter outlining the concerns is sent to the PI. The PI's response is reviewed by the full committee at the next monthly meeting. The protocol is not approved until the committee agrees that the PI has adequately addressed (in writing) all the concerns raised by the reviewers/committee. Once all concerns have been adequately addressed, full approval is granted.
 - vi. **Denied:** When the protocol is found to be ethically unacceptable or has failed to prove scientific merit. The PI does not get a protocol number and may not begin the research.

- c. Short Form Renewals will be reviewed by the chair, a veterinarian and one community representative.
- d. Minor amendments will be reviewed by the chair and a veterinarian. Major amendments will be reviewed by the ACC, and if deemed necessary, will require a full protocol submission. See Guideline 002 which describes what constitutes major and minor amendments.
- e. For projects involving collaboration, section 2.22 – 2.25 of the University of Manitoba Animal Care and Use Procedure document will apply.

For “E” COI Protocols:

Protocols containing E COI procedures are only approved by the ACC in exceptional cases. The onus is on the PI seeking approval to provide convincing evidence to the ACC that:

- i. the E COI procedures proposed are thoroughly justified;
 - ii. identified alternate models would be insufficient for the scientific work.
- a. Protocols are received and logged by the animal care coordinator and are distributed to the applicable ACC for review by the full committee at the monthly ACC meeting.
 - b. In most instances, the PI will be required to conduct a pilot study to determine, or confirm, endpoints and appropriate monitoring levels. In addition, the pilot study will serve as a training period to establish competency for all personnel involved with the model. A written report from the PI (in consultation with Veterinary Services) to the ACC must be provided at the end of the pilot study, prior to the start of the experimental phase of the project.
 - c. The minimal qualifications of personnel (research staff, facility animal care staff, Veterinary Services staff) responsible for assessing endpoints and caring for animals in E COI experiments (at the time of E-level effects) would normally be a diploma in Animal Health Technology and 1 year of experience with live animals in a research setting. An equivalent amount of experience as judged by the ACC, in consultation with the PI, may be considered. If research staff, animal care staff and/or Veterinary Services staff are not comfortable monitoring and/or caring for animals in E COI experiments, all reasonable efforts will be made to remove them from the project.
 - d. All palliative procedures will be performed unless the PI provides strong evidence that such procedures will be clearly detrimental to the acquisition of useful information. It will be considered ethically unacceptable to withhold any palliative care in an E COI experiment unless this directly prevents the acquisition of the knowledge sought.
 - e. At the time of E COI effects, rigorous levels of animal monitoring will be required by qualified (see 'e' above) research staff, facility animal care staff, and Veterinary Services personnel. This is to ensure compliance with approved humane endpoints. All monitoring and endpoint concerns must be reported in writing to the PI, facility director and a clinical veterinarian within 24 hours of detection of the occurrence. The facility director, in consultation with the clinical veterinarian, will provide a written report to the DACUP and the Chair of the ACC within 2 weeks of the occurrence. The DACUP and the Chair of the ACC will determine what further follow-up with the PI is required.
 - f. Protocol monitoring will consist of written reports from the PI (in consultation with the clinical veterinarian) to the ACC at predetermined intervals, but not less than every 6 months.
 - g. The PI will show due diligence in finding alternative experimental designs or methodologies and/or in developing alternatives that would allow earlier endpoints. Evidence of due diligence may include a summary and listing of published literature using alternative models; preliminary data or unpublished data addressing the possible appropriateness of an earlier endpoint, and confirmation that the model is currently being used elsewhere (including the name and contact information of a researcher or veterinarian from that institution involved with the model). Evidence of due diligence will be part of the required reporting and will be a requirement for protocol renewal.
 - h. During the review process, communication with the PI will be undertaken as necessary in order to

clarify and refine the experimental model. Following review, a protocol will be assigned one of the following categories:

- i. **Approved:** Full approval, no conditions, no requests from the committee for clarification or additional information.
 - ii. **Denied:** Denial is based on the judgement that the proposed work is ethically unacceptable or has failed to prove scientific merit.
- i. The decision of the ACC is final and non-appealable. However, refinements to the protocol resulting in a downgrade to a lower invasiveness level ("D" COI or lower) and then resubmission to the ACC for review is acceptable.
 - j. Multiyear studies must be submitted on the full protocol form every 12 months (a short form renewal will not be accepted).
 - k. For multiyear studies, a review of the scientific progress and design modifications will be undertaken as necessary.
 - l. Amendments will be considered for approval by the ACC.
 - m. For projects involving collaboration, section 2.22 – 2.25 of the University of Manitoba Animal Care and Use Procedure document will apply.

The Animal Use Protocol Form consists of:

- 1) The part of the protocol which must be completed by all applicants (Blocks 1-17, Schedule 1).
- 2) A set of 16 schedules (see list below).

Because this form is intended to serve all animal research at the University, there is much more in it than any one investigator will likely need to complete for his/her protocol submission.

Check List (Following pre-review, if applicable. See above.)

1. All necessary signatures have been obtained (Block 17, Schedules 3, 4, 10, 14).
2. All applicable Schedules are included.
3. You have forwarded the protocol to Tracy Van Osch (tracy.vanosch@umanitoba.ca).

List of Schedules

Each of the schedules is a form to be completed for a specific type of project. They are as follows:

Schedule 1, Personnel (Complete a Schedule 1 for all personnel as identified in Block 3 who are using live animals.)

Schedule 2, Anesthesia, Sedation, Chemical Restraint (When anesthesia, sedation, and/or chemical restraint agents are being used. If anesthesia immediately precedes euthanasia, a Schedule 2 is not required.)

Schedule 2B, Use of a Neuromuscular Blocking Agent (NMB)

Schedule 3, Surgery (When surgical procedures are being performed – both recovery and non-recovery).

Schedule 4, Humane Endpoints (Required for C, D or E category of invasiveness experiments. The schedule will ask you to provide a description of conditions that may cause distress/discomfort, how they will be identified and what will be done to alleviate them).

Schedule 5, Physical Restraint (For restricted housing, e.g. metabolism crates/cages, or any restraint not normally part of regular husbandry practices and longer or more severe than normally required for examination, injection or a single blood collection in conscious animals. Completion of this schedule is not required for cattle restrained in a head gate/squeeze chute for surgical procedure.)

Schedule 6, Nutrient and/or Diet Modifications (For any alteration to the diet in which (a) specific nutrients are added or removed from the diet; (b) feedstuffs not normally fed are being used; (c) physical

form of the diet is changed significantly from the usual form.)

Schedule 7, Behavioural Experiments (If the project involves behavioural manipulation, shock, negative reinforcement, punishment, removal of feed or water for behavioural reasons, predator/prey relationships, or sensory deprivation.)

Schedule 8, Environmental Manipulation (If the project involves environmental manipulation or imposes any potential adverse environmental effect. Examples: changes in atmospheric gases, temperature, exposure to noxious gases, etc.)

Schedule 9, Teaching (When the main purpose of animal use is education, including courses, workshops, demonstrations, etc.)

Schedule 10A & 10.2A, Risk Assessment (U of M) (To be completed if any of the administered agents in the protocol are: used to create a disease model, classified as risk group 1 or higher, radioactive, classified as hazardous under WHMIS, drugs used in a manner not recommended by the manufacturer (off label use).

Schedule 10F Safe Work Practice 001 Formaldehyde Perfusion of Animals (U of M) To be used when formaldehyde perfusion is the only hazardous agent used in the context of the research. If other hazardous agents are included include formaldehyde in the list of agents and reference Safe Work Practice 001.

Schedule 10, Risk Assessment (SBRC) (To be completed if any of the administered agents of the protocol meet the criteria described on the schedule instructions.)

Schedule 11, Field Study (Where animal use is in whole or in part conducted in the field and/or the project involves capture or release of animals in the wild.)

Schedule 12, Common Procedures (To provide more detail for common procedures including blood and/or tissue collection prior to euthanasia (including tail snips and ear punches), fecal and ingesta collections; individual marking; administration of compounds via injection, oral administration (gavage or via feed or water); catheter placement, physiological measurements such as blood pressure and ultrasound, etc., removal of all feed and/or water, indwelling osmotic pumps, etc. NOTE: Injectable anesthetic and euthanasia agents do not need to be listed here.)

Schedule 13, Genetically Engineered Laboratory Animals including establishment of a breeding colony (If using any genetically modified animal including transgenic, knockout, knock-in, knock-down, etc. A Schedule 13 must be submitted for each genetically modified animal model.)

Schedule 14, Offsite Housing (If the project involves the use of animals on non-university property, excluding SBRC and CancerCare Manitoba).

Schedule 15, Breeding Colonies for Non-Genetically Manipulated Animals (To provide details regarding the establishment and maintenance of an in-house breeding colony of laboratory animals which are neither "Livestock" nor genetically engineered. For example: rare species/strains which are not available commercially.)

Schedule 16, Imaging Procedures To be completed for all in vivo imaging procedures (ultrasound, CT, SPECT-CT, PET, PET-MRI, MRI, bioluminescence and fluorescence imaging) performed on live animals.

People to Contact for Assistance in Completing the Protocol Forms and Schedules

Clinical Veterinarians:	Dr. Richard Hodges, 474-6557 Dr. Leo Kenny, 474-6254 or 789-3806 Dr. Patricia Johnson, 474-8024 or 789-3806 Dr. Randy Aitken, 235-3630 (St. Boniface Research Centre)
Facility Managers:	Mr. Robert Madziak, 789-3861 (CACS Bannatyne Campus) Dr. Randy Aitken, 235-3630 (St. Boniface Research Centre)
Chairs of the ACCs:	Dr. Phil Gardiner, 977-5622 (Bannatyne Campus) Dr. Jason Treberg, 474-8122 (Fort Garry Campus)
Animal Care Occupational Health Specialist:	Mr. Steven Cole, 789-3675 (Fort Garry/Bannatyne Campuses)
Occupational Health Specialist:	Mr. Devon Liscum, 237-2184, (St. Boniface Research Centre)

Animal Care Coordinator: Mrs. Tracy Van Osch, 474-6182
Animal Care Office Assistant: Ms. Charlene Hennessey, 474-6402

Main Form Details

Block 1, Project

CCAC's Definition of Pilot Study (as per the CCAC Terms of Reference for ACCs):

Encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large-scale protocols. Ensure that animal users report on the results of any pilot studies, no matter whether they wish to pursue the study immediately or not, to preserve important data on various approaches to animal-based studies, whether they work well or not.

U of M's Definition of Pilot Study: normally a maximum of 10 animals are involved and valid for a maximum of 6 months; not renewable; may be exempt from scientific peer review. The ACC's encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large scale protocols. Ensure that animal users report on the results of any pilot studies, no matter whether they wish to pursue the study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not.

UM Project Number: Assigned by the Office of Research Services (ORS). If you submitted a sponsor-funded ethics application, then you should have a UM Project number. The UM Project # can be found using My Research Tools.

<https://research.ad.umanitoba.ca/>

Block 4, Canadian Council on Animal Care (CCAC) Report Data

CCAC Reporting Data requires that a protocol description and key words be provided. This information is used in the Animal Use Data Form Report which is required to be sent annually to the CCAC. This must be written in 40 words or less and in terms understandable to a non-scientist.

Definition of Acute and Chronic:

Acute: any study in which the animal is anesthetized and euthanized without recovering consciousness or humanely euthanized before any procedures are done on it. No manipulation may be performed on conscious animals.

Chronic: all other use.

Only one classification can be given. If a study has both acute and chronic components, then it must be classified as chronic.

Summary of CCAC Categories of Invasiveness (COI)

NOTE: FOR COI RELATED TO WILDLIFE STUDIES, PLEASE SEE THE CCAC GUIDELINES ON: THE CARE USE OF WILDLIFE, APPENDIX D.

<https://www.ccac.ca/Documents/Standards/Guidelines/Wildlife.pdf>

Category A: Experiments on Most Invertebrates or Not Involving Intact, Living Vertebrates. For example, *in vivo* experiments or invasive procedures on protists or most invertebrates. *In vitro* studies involving the use of living eggs or cells, tissues and/or organs, in culture or obtained by necropsy, from a slaughterhouse, etc. Purely observational studies of unrestrained vertebrates.

NOTE: It is not necessary to complete a protocol form for "A" COI projects.

Category B: Studies or Experiments Causing Little or No Discomfort or Distress. For example, short term skillful restraint of animals for observation, physical examination, blood sampling, or non-toxic injections (including injectable coded wire or transponder tags) by intravenous, subcutaneous, intramuscular, intra-peritoneal or oral routes (NOT intra-thoracic or intra-cardiac). Acute, non-survival experiments in which animals are anesthetized for entire procedure and do not regain consciousness. Standard methods of euthanasia that induce rapid unconsciousness, such as anesthetic overdose or decapitation preceded by sedation or light anesthesia.

Category C: Studies or Experiments Involving Minor Stress or Pain of Short Duration. For example, minor surgical procedures such as cannulation or catheterization of blood vessels or body openings, biopsy or laparoscopy done under anesthesia. Periods of food and/or water deprivation within established tolerances of the species. Behavioural experiments on conscious animals involving short term stressful restraint. Attachment of externally applied CCAC or professional society approved tags or radiotelemetry devices which require penetration of the skin for anchoring (e.g. Floy Tags, and jaw or opercular tags on fish, ear tags on small mammals. None of these may cause: significant, lasting changes in an animal's behaviour, appearance, respiratory or cardiac rate, food consumption or fecal or urinary output.

NOTE: fish handling (because of the stress involved in handling of fish) and capture techniques that involve no more than moderate stress (seine, fyke, trawl nets), is considered Category C.

Category D: Studies or Experiments Involving Moderate to Severe Distress or Discomfort. For example, major surgery under general anesthesia, with subsequent recovery of the animal, using approved surgical procedures, post-operative care, etc. Physical restraint for periods >2hrs. Behavioural stress such as maternal deprivation, aggression, predator-prey interactions, procedures which cause severe, persistent or irreversible disruption of sensorimotor organization or persistent anatomical and/or physiological abnormalities with pain or distress. Exposure to noxious stimuli while under restraint. Immunization using Freund's Complete Adjuvant by CCAC approved routes. (Consider using an alternate, less stressful adjuvant system.) Live capture and restraint of wild ungulates or other large, wild mammals using anesthetics or immobilizing agents administered by dart guns.

NOTE: All gill netting of fish (no matter what the duration) and all electrofishing because of the generally higher level of stress and potential for suffering involved, is considered Category D.

Category E: Procedures That Involve Severe Pain At or Above the Pain Tolerance Threshold of Unanesthetized, Conscious Animals. For example, not confined to surgical procedures. Inescapable noxious stimuli, agents with unknown but possibly severe effects, induction of burns, trauma, etc., highly invasive experiments, behavioural studies causing severe or unknown levels of stress and the use of paralytic agents or muscle relaxants without anesthesia all belong in this category.

Blocks 4, 6, and 8 and Renewal – Short Form: TERMS UNDERSTANDABLE TO A NON SCIENTIST

The protocol description (Block 4 – 40 words or less), the description of the project (Block 6) and the justification of animal usage (Block 8) must be provided in a language understandable to a layperson. This should include a lay description of the procedures and techniques being utilized to live animals from start to finish. The submission of sections of grant proposals containing excessive detail of procedures not related to the use of animals is inappropriate. All descriptions should be written with a minimum of technical jargon. It is important to remember that the ACC is primarily interested in the ethical, responsible, and humane use of animals.

If animal use protocols are not written in a language understandable to a layperson, animal users will be asked to rewrite accordingly. This may result in a delay to approval of your protocol.

This also applies to short form renewal submissions. Specifically, the protocol description (Block 3 – 40 words or less) and Block 5 (Animal Use Data) must be presented in language that all members of the ACC can understand. These sections also need to be presented in a concise and complete fashion. Again, if short form renewals are not written in a language understandable to a layperson, are not complete and concise when received for review, animal users will be asked to rewrite accordingly. This may result in a delay to approval of your short form renewal.

We appreciate that this is not always an easy task. However, as mandated by the CCAC, ACCs are charged with making informed, ethical decisions with regard to the appropriateness of including animals in research and teaching. This can only be done when ACC members clearly understand what is happening to live animals from the start of the project until the end.

Block 15, Funding/Merit Review

For projects that have not been peer reviewed, please follow the process for obtaining scientific or instructional merit of non-peer reviewed projects.

https://umanitoba.ca/research/sites/research/files/2022-01/scientific_merit_review.pdf

https://umanitoba.ca/research/sites/research/files/2022-01/teaching_merit_reviewteaching_merit_review.pdf