The Animal Use Protocol Form – Tips

The following is a breakdown of the research animal use protocol form and what information each section should include. Note that in RISe, each section of the protocol has detailed guidance notes.

Section 1 - Study Team Information

- All personnel involved in the animal project must be listed in this section, whether or not they will work directly with the animals. These individuals will automatically populate section 4.8.B of the animal care application, where their animal user training certificates will be displayed along with the procedures they will perform.

Section 2 - Funding Information

- **2.2:** Select the FAS number/grant title associated with the project (e.g. F22-XXXX).

- **2.3:** Include funding which does not have a FAS number.

- **2.4:** If the researcher indicates that funding is from industry or internal UBC funds, the protocol will be sent for peer review through the UBC peer review process. Section 7 will ask you to provide a summary of the proposed research for the peer reviewers. There will be a fee-for-service for applications funded by for-profit agencies.

Section 3 - Animal Information & Type of Animal Review

- **3.1:** Emergency Personnel: There must be at least two people who can be contacted in case of animal emergency must be named with 24-hour contact numbers listed so they can be contacted in case of an animal emergency. Every effort will be made to reach designated personnel; however, if the contacts cannot be reached in the case of a pressing health and welfare problem, a UBC clinical veterinarian has the authority to take appropriate action as deemed necessary to protect the health and welfare of the animals (up to and including humanely euthanizing the animal(s)).

- **3.2/3.3:** Keywords and Purpose of Animal Use (PAU) are information required by CCAC. Keywords can be selected from drop-down list. PAU can be completed by selecting the appropriate category for your study. The guidance notes explain the PAU from 0-5.

- **3.4:** Select the type of application required – research, pilot project, teaching or breeding. Please note that this tips sheet focuses on the research application.

- **3.5:** If this project is a renewal of a previous project, a progress report must be submitted. The progress report must describe the following:
    - any complications encountered relative to animal use (unpredicted outcomes, and any animal pain, distress or mortality);
    - a brief report on the adequacy of the endpoints for the protocol;
    - any complications encountered or refinements made relative to protecting animals from pain, distress or mortality;
    - any progress made with respect to the Three Rs of replacement, reduction and refinement of animal use; and,
    - the number of animals used in the preceding year.

Section 4 - Animal Information – Procedures, Justification, and Objectives

- **4.1 a and b:** The objectives of the studies, the potential value of the results and the methods (i.e., what happens to the animals) must be clearly described. These summaries are required by CCAC and must be written in language that the non-scientific person can understand. Avoid scientific and technical jargon and spell out any acronyms at first use. If the lay summaries are not clear to all Committee members, they will be sent back to be rewritten.

- **4.2:** Explain why animals must be used and indicate if there are suitable alternatives available. If you have used alternatives (e.g., in vitro) as part of this research, mention that here. If alternatives to animals are available, indicate why they cannot be used in this study. Any alternatives as well as the 3Rs must be addressed. The use of animals for research purposes is subject to implementation of the three Rs, first introduced by Russell and Burch in 1959. The three Rs are defined as the Replacement of animals by other methodologies not requiring animals (such as the use of computer programs); Reduction in the number of animals used; and Refinement of the techniques so that the animals are subjected to the least possible distress. A detailed analysis of the 3 Rs is available on the CCAC website. The ACC requires that applications to use animals must satisfy the Committee that animal use is essential and that no suitable alternatives exist. If there is an alternative justification as to why it is not being used is required.

- **4.3:** List each species and strains and numbers used per year. If wild or endangered species are used then list all license and permit numbers required for the capture, transportation, housing, and disposal of the species.

- **4.4** Justify why certain species and/or strains must be used in relation to the goals of the studies as outlined in section 4.1.A. If genetically modified animals are used, then include whether strain exhibits a specific phenotype that affects the animal's welfare. Note multiples species cannot be combined on a protocol unless they are rodents.

  4.5 Describe the animal numbers used over 4 years. You must provide scientific justification for numbers. Stating that "the number requested is necessary for statistical analysis" is not sufficient. This section should provide a summary of the experimental design and different experiments so that reviewers can follow what happens to animal groups in section 4.8.A (procedures). Ensure the numbers for 4 years reflect the numbers represented per year in section 4.3.

- **4.8.A:** Procedures - Describe in detail all procedures animals will undergo. Details should be sufficient to ensure that the reviewer understands what will happen to each animal or group of animals from the start to finish of the experiments. Reviewers need sufficient detail to be evaluate monitoring and humane endpoints in later sections. The use of flow charts, summary statements or tables and headings are helpful. There may be some uncertainties, but try to outline the various things that will happen to all animals, in what sequence, at what frequency, over what time frame, etc. For established or common procedures where there is an approved UBC ACC SOP, refer to those.

- **4.8.B:** Team members listed in section 1 will automatically populate here. For each team member, fill in the field: “Procedures Performed by Individual”. Make sure procedures listed here match what was described in section 4.8.A. For procedures for which there is no official UBC ACC training program, fill in the field: "Qualifications/Training for Procedures Performed by Individual". If a team member will have no contact with animals, please indicate that. If a study team member has not completed all the

necessary practical training, please note what procedures they are able to perform and explicit state which they will not perform certain procedures until they are fully trained. If the CCAC/NIAUT Training certificate number is not appearing, the study team member needs to update their RISe profile. Any practical training courses that are successfully completed will be updated approximately two weeks upon successful completion. For practical training that is not appearing in section 4.8.B, please contact train.acs@ubc.ca

- **4.8.C:** Morbidity & Mortality - Many experimental procedures or models produce effects on the health and welfare of animals. In this section, any possible complications or adverse events should be detailed so that reviewers can evaluate the monitoring plan, attempts can be made to refine the protocol and determine whether study team members are prepared for these potential complications. This information is important for assessing the degree of risk to animals of a deterioration of health and welfare. If a lab has experience, provide estimates of morbidity and mortality. A higher than expected incidence of complications may indicate a basic problem existing with the animals or with the procedures being employed.
    - The CCAC has a requirement for reporting morbidity and mortality (including euthanized at humane endpoint) that goes above a certain percent of what is reported in the protocol. Researchers must include a percentage estimate of morbidity and mortality from various experiments/procedures.

- **4.9.C:** If a lab has their own ACC-approved Standard Operating Procedures, they can be attached to this section. Contact the ACC for further information.

Section 5 - Animal Monitoring

- **5.1 - Monitoring:** This section should outline details of how animals will be monitored. What clinical signs, the frequency and duration of monitoring must be determined for each study and clearly stated in this section. Monitoring frequency and duration will depend on a variety of factors such as severity of clinical signs, potential for deterioration, the expected time course of the experiment, and unexpected complications. For standard models, e.g. diabetes, surgery, infection models etc. the appendices associated with the UBC ACC Monitoring Policy 17 identify monitoring criteria: what clinical signs one has to monitor (e.g., appearance, activity, respiration), for how long after a procedure and how often. It is helpful to divide this section by procedures. Appropriate monitoring records should also be attached to this section. Name the attached sheets within the text.

- **5.2: Experimental Endpoint** - Experimental endpoints should always precede humane endpoint. If experimental and humane endpoints are the same or have the potential for occurring at the same time, please provide justification.

- **5.3: Humane Endpoints** - Provide the specific humane endpoints which will be used to determine when animal suffering or distress will result in euthanasia. (e.g. if weight loss is listed, specify how much weight loss will result in euthanasia). For more information on humane endpoints select here. As per CCAC: In experiments involving animals, any actual or potential pain, distress, or discomfort should be minimized or alleviated by choosing the earliest endpoint that is compatible with the scientific objectives of the research.

Humane endpoints may differ for different types of procedures or studies (e.g., humane endpoints for infection models will be different than humane endpoints for post-surgical animals). For protocols

including multiple procedures or studies, the humane endpoints for each should be described. The clinical signs and humane endpoints listed in this section should be included on the attached monitoring sheets in Section 5.1.

- **5.4:** There are a number of procedures which by their nature are considered contentious. The UBC ACC takes particular care when reviewing proposals involving these procedures. For that reason, the justification for carrying out the procedure must be carefully detailed in section 5.5. In addition, the exact procedure must be described together with any factors which may influence the outcome of the procedure at any stage (e.g., the frequency, intensity and duration of electric shocks and the interval between testing of the equipment providing the shocks).

Section 6 - Drugs & Chemicals/Fate of the Animal/Hazardous Materials

- **6.1-6.4:** List all experimental drugs or chemicals that will be used. Include dosages, routes of administration, and an estimate of volumes. Most drugs are available for selection from the drop-down list. Use generic drug names, not the brand names). Drugs are organized according to their use (Anesthetics/Sedatives, Analgesics, Antibiotics, Other). Dosages are important since there is considerable variability between species and there may be contraindications for the use of certain drugs in some species. Note that all drugs also should have been identified in section 4.8.A. Include all anticipated drugs because ordering from ACS requires that drugs are listed on protocols.

- **6.6:** Several techniques of euthanasia are available, some involving the use of chemicals (refer to UBC-ACC Standard Operating Procedures https://animalcare.ubc.ca/planning-your-research/sops-guidelines). The technique chosen should render the animal irreversibly unconsciousness rapidly with death following soon after. Secondary methods must be applied and death must be confirmed. If a physical method of euthanasia is required on conscious animals (e.g., because the use of drugs is impacts the results of the study), the technique will have to be demonstrated satisfactorily to a UBC veterinarian, and after which, will be added to "ACS Certified for Physical Euthanasia" in section 4.8.b.

- **6.7:** If biohazardous / radioactive materials are to be used, the Biosafety / Radiation Committees must approve applicable permit(s) and the facilities for handling the materials. This section is to alert people who may be working with the animals of potential dangers and to ensure that appropriate precautions are being taken to protect both people and animals.

Section 7 - Peer Review

- The peer review summary, should it be required, will be reviewed by a separate committee independent of the ACC. This page will only populate if the answer to section 2.4 is “yes”.

Section 8 - Declaration

- This section confirms that the Principal Investigator will follow the guidelines established by the CCAC. This section also confirms that all personnel listed on the protocol have read the application and are aware of its contents. Once submitted, the UBC department head's approval confirms that the facilities are available and that the standards are met in those facilities.