

**Appendix 2**

**Genetically Modified Animals**

Office of Research – Research Ethics Unit – GM 900 – 514-848-2424 ext. 7481 – oor.ethics@concordia.ca – www.concordia.ca/offices/oor.html

This form should be completed for the use of strains that have mutations generated for specific purposes whether induced by mutagenesis protocol, knock in/knock out technology, or by transgenesis methods, e.g. nuclear injection methods, or nuclear cloning but should NOT be completed for standard inbred strains that carry standard mutations, like agouti black or albino.

1. This study involves

1. the generation of new genetically modified animals.

[ ] YES [ ] NO

1. the use of existing genetically modified animals.

[ ] YES [ ] NO

2. Describe the species, strain, mutation(s) and/or genetic modification(s)

3. Do you and your assistant(s) have experience in the husbandry of the animals of the

 mutant strain you intend to use, or the generation of genetically modified animals by

 the methodology you intend to use

 [ ]  YES - State who and the person’s experience.

[ ]  NO - How will you acquire this skill?

4. Do you and your assistant(s) have experience in the detailed record-keeping

 necessary for breeding colony maintenance?

[ ]  YES - State who and the person's experience

[ ]  NO - How will you acquire this skill?

5. Are you familiar with the signs of distress in the species of study?

[ ]  YES

[ ]  NO - How will you acquire this information?

6. Describe your monitoring system for detecting anatomical, physiological and behavioural abnormalities indicative of animal distress

7. Provide information regarding

a) the known or expected phenotype

 b) the known or anticipated pain or distress levels in the genetically modified animals (include homozygotes and heterozygotes/hemizygotes)

c) measures which will be taken to identify or alleviate such distress

 d) for genetically modified animals that are clinically affected or distressed, what criteria will trigger the decision to terminate the animals?

8. For all genetically modified animals:

a) do the animals pose any potential health consequences to those working with the animals?

[ ] YES - Provide details

[ ]  NO

b) what special containment and security procedures are needed in the animal facility where these animals are held?

c) what special plans need to be in place for recapture should a breach of

 containment occur?

d) Should containment fail, what are the consequences to public health or wild animal populations?

In protocols using existing genetically modified animals:

9. Has the source (e.g. supplier) of the genetically modified animals discovered problems in the strains you will be receiving/using that may affect transport, fertility, resistance to infection, dietary requirements or other husbandry factors?

[ ] YES - Provide details

[ ]  NO

10. Does the phenotype include strain-specific age-related changes in health?

[ ]  YES - Provide details

[ ] NO

In protocols generating genetically modified animals:

11. Has the construct for genetic engineering been tested for expression in cultured cells.

[ ]  YES

[ ] NO - Why not?

12. What procedures are in place to detect the genetic modification?

a) molecular/biochemical

b) phenotypic

13. Provide estimates of numbers of animals to be used and/or generated in developing the genetically modified strain(s). Include oocyte donors, pseudopregnant females, male studs, successfully engineered offspring and non-modified or partially (incompletely) modified animals.

 (Please show the breakdown of numbers).

14. What will happen to the non-modified or inappropriately/unsuccessfully modified animals used in the creation of the desired genetically modified animals?

15. What criteria will be used to determine if the genetically modified animals meet the objectives of the project?

For the generation of genetically modified animals, other than rodents:

16. Have the containment requirements necessary for the generation of these genetically modified animals been ascertained, to ensure compliance with the Environmental Protection Act or related legislation?

[ ] YES - Please provide an explanation of the requirements to be met or a copy of the documentation from the appropriate governmental agency outlining this information.

[ ]  NO - When will this be done?