Research Office Use Only

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| **Phenotype Report ID** | PTR |
| **Approval Date** |  |
| **Expiry Date** |  |
| **Characterisation Status** | Choose an item. |
| **Version Approval Date** |  |

***Please read the instructions on the last page before completing this report.***

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| 1. **Animal Details** | | | |
| **Genetically modified animal species** |  | | |
| **Strain common name** |  | | |
| **Strain nickname** |  | | |
| **Strain/genetic description** |  | Background Strain |  |
| **Source** (in-house or specified external laboratory source) |  | | |
| **Genetic alteration** | Briefly describe which gene has been added/deleted/altered. | | |
| Affected organs/tissues (*e.g., gene expressed in liver only)* | | |

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| 1. **Phenotype characteristics** | | | |
| **Physical Characteristics** (coat colour, eye colour, other.) |  | | |
| **Breeding Characteristics** | What is the approximate litter size and any other identified breeding traits such as late onset breeding? | | |
| **Abnormalities** | What abnormalities are known (or do you expect) to exist in these animals? | | |
| **Effect on health** | How is animal health, welfare, breeding or lifespan affected by the abnormalities detailed above? | | |
| **How much is known about the biological characteristics of this strain?**  *NOTE: You must submit a revised version of this form via modification request to the AEC when there are any changes to the characterisation status of this strain.* | Well-characterised  (*i.e. rodents bred for at least six generations and monitored to at least 12 months of age*) | Partially-characterised/some information available  *(i.e., bred for less than six generations and/or monitored to less than 12 months of age*) | Unknown |
| **How has/will the phenotype be characterised?** | Established by another institution  List title here, and attach, published information or provide details of the basis on which the phenotype was established. | | |
| In-house observations  How many generations and up to what age? | | |
| Special monitoring based on predicted phenotype  Provide details. List title here and add an attachment, if necessary (not a URL). | | |
| Other  Please provide details. | | |
| **Characteristics – including phenotypes in the absence of agent/s used to induce/suppress phenotype where applicable** | Briefly detail the characteristics of the genetically modified animal strain (i.e., behavioural, physiological, reproductive and developmental characteristics and/or predisposition to disease).  *Details provided should inform the AEC about abnormalities or changes which may impact animal welfare.*  *Comparison of genetically modified animals with non-genetically modified litter mates is desirable.*  *If there is an age of onset of phenotype expression, please include this information.*  *If the strain is immune compromised, please described the immune system deficiency as mild, moderate or severe.* | | |
| **Breeding strategy and generation of intermediate strain/s** | If generating a new line in-house, outline the breeding strategy to obtain the strain and list intermediate strain/s if any that will be generated as part of the breeding strategy: | | |
| Inclusion of a flow diagram for breeding strategy: | | |
| Briefly detail the known or expected characteristics of the intermediate genetically modified animal strain (i.e., behavioural, physiological, reproductive and developmental characteristics and/or predisposition to disease) generated as part of the breeding strategy outlined above. If the phenotype of intermediate generations is expected to be different to either origin or destination phenotypes, then a full separate phenotype report is expected. | | |
| **Is the phenotype suppressible or inducible?** | YES Suppressible  Inducible  NO  If yes,  Briefly describe the chemical agent/s used to suppress or induce the phenotype (to be fully described in the related AEC- approved project under which the agent is used to induce/suppress phenotype.)    When (e.g. age of animal) is the chemical agent expected to be used? | | |
| **Characteristics after induction or suppression** | Briefly detail the characteristics of the genetically modified animal strain (i.e., behavioural, physiological, reproductive and developmental characteristics and/or predisposition to disease).  *Details provided should inform the AEC about abnormalities or changes which may impact animal welfare.*  *Comparison of genetically modified animals with non-genetically modified litter mates is desirable.*  *If there is an age of onset of phenotype expression, please include this information.*  *If the strain is immune compromised, please described the immune system deficiency as mild, moderate or severe.* | | |

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| 1. **Animal well-being** | |
| **Minimisation of pain and distress** | Describe any phenotypic characteristics that may cause pain or distress, and/or mortality (including euthanasia once reaching humane end-points). |
|  | State the cause(s), if known, and how these can be managed to minimise impact on animal welfare. Please provide details of any special husbandry or animal care requirements which will be used to safeguard animal wellbeing in light of the expected phenotype. |
| **Monitoring and care** | Where an adverse phenotype is expected please describe what monitoring will be undertaken to safeguard animal wellbeing.  *Include details of:*  *whether monitoring is needed prior to and/or after phenotype induction/suppression (where applicable).*  *age at which monitoring will begin*  *monitoring frequency*  *age at which monitoring will be discontinued (if applicable)*  *parameters being monitored*  *objective criteria that will be used to clearly define intervention points and the humane endpoint (where applicable)*    Please reference or attach a copy of the AEC approved monitoring sheet(s) which detail monitored parameters, intervention points and humane endpoint where applicable. |

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| 1. **Declaration** | |
| **Name of investigator submitting this report** |  |
| **AEC approval number(s) of expected project(s) using these animals** |  |
| **By submitting this request, I, the Investigator named above, declare that:**  Due care has been taken to ensure that the information I have provided is true and correct.  I understand my obligations under the [*Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013)*](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes)and the [*Prevention of Cruelty to Animals Act (1986)*](https://www.legislation.vic.gov.au/in-force/acts/prevention-cruelty-animals-act-1986/096) and [*Prevention of Cruelty to Animals Regulations (2019)*](https://www.legislation.vic.gov.au/as-made/statutory-rules/prevention-cruelty-animals-regulations-2019)*.*  The information contained in this report is given on the basis that it remains confidential in accordance with relevant University and statutory requirements. | |

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| **5. How to submit this application** |
| Log in to  [PRIME Researcher portal](https://prime.latrobe.edu.au/portal/) to submit a new phenotype report application:   1. Select +New Animal Ethics Application 2. Enter the Phenotype Name under “Ethics Application Title” 3. A grey symbol with arrows     Description automatically generatedChange the “Record Type” to SOP/Phenotype Report by selecting 4. Upload a completed Phenotype Report and any supporting documents in the “Documents” tab 5. Select “Review by Research Office” and “Mark as Current Status” in the progress bar at the top of the screen to submit |

**Instructions for completing a Phenotype Report and Post Approval Reporting of GM animal use**

* The information provided is designed to assist with monitoring and assessment of the impact of the genetic modification upon the health and welfare of the affected animal(s). A detailed description of *in vitro* methodology is not required.
* **Please use lay language where possible and define terms where necessary.**
* It is a requirement under [*s2.4.27 of the Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition, 2013 (the Code)*](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes), that regular reports are provided to the AEC for all genetically modified animals.
* Reporting on the use of genetically modified animals is required:
  + As a part of an application for approval to use animals for scientific purposes
  + As soon as an adverse phenotype is identified
  + As soon as the characterisation status of the animal changes
  + When an annual report or the final report is submitted for any linked project
* The purpose of this reporting is to provide information about animals which are genetically modified (GM) or which may have an adverse phenotype. (For convenience, all animals are referred to as “genetically modified” in the form.)
* The AEC will approve phenotype reports independently of project applications or amendments (i.e. you must submit new phenotype reports as a separate applications in PRIME).
* The phenotype report will be considered final with ongoing approval once the AEC has received notice of and approved a phenotype report for a well characterised line.
* Once a new line has been well characterised and the AEC has approved the updated phenotype report, the new line can be treated as breeding stock ([*s 2.4.26 of the Code*](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes#toc__753)).