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| Project Number |  |
| Project Title |  |
| Last updated | DD MM YEAR |

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1.1- Investigators

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| Name | Institution | Role e.g. Co-Investigator | Contact Details (Mobile Number and Email) |
|  |  | Principal Investigator |  |
|  |  | Second in Charge |  |
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1.2 - Funding and Licence

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| Funding Source |  |
| Commercial in Confidence | Yes  No |
| Scientific Procedures Premises Licence (SPPL) | Austin Health SPPL20286  Austin Health BRF SABL20363  University of Melbourne at Austin Health SPPL20190  Olivia Newton-John Cancer Research Institute SPPL20261 |

1.3 - Conflicts of Interest

Is there any affiliation or financial interest for any researcher in this project which might represent a perceived, potential or actual conflict of interest?

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| Yes  No | If yes, please explain. |

1.4 - **Additional Ethics Approval**

Do you require any of the following approvals?

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| Human Ethics Approval | Yes, HREC approval number  No |
| IBC (GMO) Approval | Yes, IBC approval number  No |
| Other Approvals (Please see appendix for more details) | Death as an endpoint  Immunomodulation and production of antibodies  Reuse and Repeated Use of Animals  Prolonged restraint or confinement  Cosmetic testing (prohibited in Australia) |

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2.1 - Glossary

Please list the terms alphabetically and only include terms that aren’t already outlined in the general glossary.

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| Scientific Term | Lay Description |
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2.2- Lay Summary

In 200 words or less describe in lay terms what will happen in this project. This should not be written above a Year 8 reading level.

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* 1. – Significance

Please clarify why the work is significant, the benefits of the outcomes and how the impact on wellbeing of the animals is justified by the potential benefits. This is in regard to clause 2.7.4 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes).

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2.4 - Protocol

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| **Aims**  The aims of this project are to determine/study/investigate:   * INSERT   **Hypothesis**  The research hypotheses/questions that this study seeks to address are: INSERT  **Pilot Study**  Please explain whether there will/will not be a pilot study. If so, please clearly outline what the study will include.  **Maximum Tolerated Dose (MTD) Study**  Please provide details of the MTD study if applicable. Please be aware that these studies require additional monitoring and a report back to the AEC upon their completion. Delete if not applicable.  **Aim No.**  Experiment No.  Please provide the below details:   * Cohort size and strains to be used. * Procedures to be performed including how many times and how frequently they will occur. * Potential hazards to humans. * Monitoring required for each procedure/therapy/technique and surgery (ensure monitoring sheet/s are attached to this application). Please note this should be the standard monitoring. * Euthanasia method and disposal of mice. Please include both the experimental and ethical endpoints. * Anaesthesia to be used. * Analgesics to be used. * For compounds include the dose rate of the compound (e.g. mg/kg), concentration, volume, route of administration and site. Please include all cell lines to be used and their site of inoculation if applicable. * Flowcharts   **Which compounds are to be used?**  Please use the below table to define any compounds that will be used within this project. Copy the table as many times as necessary. You are not required to list saline, PBS, Matrigel, analgesia, anaesthesia, polyvisc or nutritional supplements.   |  |  | | --- | --- | | Compound/agent: |  | | Vehicle: |  | | Route of administration: |  | | Dose/dose rate (per gram): |  | | Volume (maximum) in µl/gram: |  | | Concentration (mg/mL): |  | | Frequency of administration:  *e.g. Twice daily for 3 weeks* |  | | Purpose: |  | | Has this substance been used previously in this laboratory? |  | | Are there any adverse effects of administration or withdrawal of drugs expected? |  |   **Training**   |  |  |  | | --- | --- | --- | | **Person(s) to be trained** | **Procedure** | **Trainer(s)** | |  |  |  |   **Reduction**  Please outline the number and the strains of animals requested for both experimental and training purposes.  **Experimental Animals**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Species** | **Strain Name** | **Sex** | **Age** | **Total Number** | |  |  |  |  |  | | **Subtotal:** | | | |  |   **Training Animals**  Mice will be used under ethics INSERT  If training animals are requested, please provide the below details:   * Purpose of training animals * Procedures to be performed including how many times and how frequently they will occur. * Monitoring required for each procedure/therapy/technique and surgery (ensure monitoring sheet/s are attached to this application). Please note this should be the standard monitoring. * Euthanasia method and disposal of mice. Please include both the experimental and ethical endpoints.  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Species** | **Strain Name** | **Sex** | **Age** | **Total Number** | |  |  |  |  |  | | **Subtotal:** | | | |  |   **Justification of Animal Numbers**  Please clarify how the numbers stated above were calculated.  INSERT |

2.5 - Standard Operating Procedures

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| SOP Number | SOP Title | Approved | Need Approval |
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3.1 - **Replacement**

Please describe the alternatives which were investigated prior on deciding on the use of animals as per clause 1.1 and 1.18-1.20 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes).

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3.2- Refinement

Please clarify which techniques could have a negative impact on animal welfare and how this will be minimised as per clause 1.1 and 1.28-1.30 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes). In this section, please mention any expected adverse events and the mortality rate if applicable. Please also add information regarding any abnormal phenotypes and if they require additional care.

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| **Minor** Insert the procedure/treatment/model/phenotype  Consider providing the below relevant details:   * The negative impact on the animal * What interventions will be put in place to make sure the animal doesn’t experience distress e.g. analgesia, heat mat, nutritional supplements, additional monitoring.   **Moderate**  Fill in as above  **Substantial**  Fill in as above |

3.3- Repetition

Please clarify whether any animals used in this project will be subject to previous research or teaching activity. Also comment on whether this duplicates work done currently or previously either at this or another institution.

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* 1. – Phenotype Reports

Please clarify if any new genetically modified strains that have not been used in the BRF before will be used in this project.

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| Yes  No | If yes, please submit the phenotype reports alongside this application. These can either be in the Austin Health form or an approved format from another institution. |

* 1. - Source, Transport, Acclimatisation and Housing of Animals

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| **Source**  Animals will be obtained from INSERT.  **Transport**  Animals will be transported as per SOP-232. Include any transport of animals including between BRF and other premises. Specify period without food or water, the duration and mode of transport, environmental conditions (particularly extremes of temperature); and monitoring during transport.  **Acclimatisation**  Upon entering the BRF animals will be given a minimum of INSERT days to acclimatise. If any other special conditions, please list them here.  **Housing**  BRF housing conditions will be followed as per SOP-251. However, there may be instances when a mouse needs to be housed individually. For example, if co-housed males exhibit aggressive behaviour, or survival of (male) mice to endpoint is at different lengths resulting in singly housed animals that cannot be pooled with other animals in the experiments. Appropriate enrichment will be provided to any singly housed animal until endpoint. Mice will be housed for a maximum of INSERT. |

* 1. – Declaration

By submitting this application **all** investigators declare that they have:

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| (Please tick this box to confirm your declaration) | * Read the application and certify the information written to be correct. * Agree to act in accordance with what has been approved by the AEC and accept responsibility for the conduct of the experimental procedures as detailed in this application. If changes need to be made to the application, then an amendment will be submitted for review by the AEC. * Have read Part III of the *Prevention of Cruelty to Animals Act 1986* (the *Act*), the *Prevention of Cruelty to Animals Regulations 2019* (*Principal Regulations*) and the current version of the *Australian code for the care and use of animals for scientific purposes (8th Edition 2013)* (the *Code*) and accept the responsibilities detailed therein. |

# **Appendix**

**Death as an endpoint**

When the death of an animal is the deliberate measure used for evaluating biological or chemical processes, responses or effects—that is, the investigator will not intervene to kill the animal humanely before death occurs in the course of a scientific activity. 'Death as an endpoint' does not include the death of an animal by natural causes or accidents, or the humane killing of an animal as planned in a project or because of the condition of the animal. Death as an endpoint needs approval by the Minister for Agriculture. Please refer to sections 1.13 and 3.3.23 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes) and Part 5 section 115.4 of the Prevention of Cruelty to Animals Regulations 2019 for more information.

**Immunomodulation and production of antibodies**

Please refer to section 3.3.431 and 3.3.32 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes) for more information.

**Prolonged restraint or confinement**

Please refer to section 3.3.4 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes) for more information.

**Reuse and Repeated Use of Animals**

Please refer to sections 1.22-1.24 and 2.3.15 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes) for more information.

**Cosmetic testing**

The use of animals for cosmetic testing is banned in Australia. Investigators must only consider using animals for testing of a chemical ingredient if such use is justified by a purpose other than use in a cosmetic (Clause 2.4.6). Please refer to section 7 of [the Code](https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes) for more information.