



RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
Caritas Christi Hospice
St. George's Health Service
Prague House

BREEDING APPLICATIONS

Statement of Intent and Outcomes

The St Vincent's Hospital (Melbourne) Animal Ethics Committee (AEC) is committed to fulfilling the governing principles of the *Australian code for the care and use of animals for scientific purposes*, 8th Edition (2013) by ensuring competent, fair, consistent and timely review of breeding applications and reports related to the care and use of animals.

Definitions

Breeding Application: application for review by AEC for approval to breed established mouse lines (Specified Animal Breeding Colony)

GBNML: application to Generate and Breed a New Mouse Line

Investigator: any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys

SABC: Specified Animal Breeding Colony

Scientific purposes: all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

Wellbeing: an animal is in a positive mental state and is able to achieve successful biological function, to have positive experiences, to express innate behaviours, and to respond to and cope with potentially adverse conditions. Animal wellbeing may be assessed by physiological and behavioural measures of an animal's physical and psychological health and of the animal's capacity to cope with stressors, and species-specific behaviours in response to social and environmental conditions

Procedure

There are four types of breeding applications, which must be reviewed by the AEC at a quorate meeting:

- Breeding Application (SABCs)
- GBNML
- Transfer GBNML to SABC
- Transfer established strain from another institution (SABC)

All applications must be completed using plain English (lay language) throughout the entire application so that all AEC members are provided with sufficient information to participate effectively in the assessment of the application. Where the use of scientific language is deemed unavoidable, it must be supported by a suitable lay description, or a glossary of terms.

GBNML (Generate or Breed a New Mouse Line)

The creation and breeding of a new mouse line, including genetically modified and cloned animals, where the impact of the genotype on animal wellbeing is unknown or uncertain is regarded as a scientific purpose. Persons responsible for animals involved in such projects are regarded as investigators.

Investigators must not generate a new mouse line using genetic modification if a similar, suitable animal model is available to the investigator or a relevant in vitro method can be used to achieve the aims of the project.

Investigators must ensure that AEC approval is in place from the start of the process until the impact of the genotype on wellbeing is known, and data on mortality, morbidity and population health of the new line are available.

Investigators must use methods to support and safeguard the wellbeing of animals involved and advise the AEC when the clinical status of the animals changes to a kind of degree that was not predicted by submitting an Adverse Event Report.

GBNML applications should inform the AEC of the mouse line/s that will be generated and describe the anticipated phenotype including what organs or tissues will be affected as well as expected or anticipated abnormalities or effects on health, welfare, breeding or lifespan.

Breeding of new mouse lines must not be implemented until written AEC approval is obtained. GBNMLs approvals are valid for three years with 1000 animals approved, investigators can apply for GBNML renewals if the phenotype of the line is not established within the initial approval period.

Investigators must keep accurate records of animal numbers as these must be reported on the annual Animal Use Return Part A.

GBNML Renewals

If the phenotype of the line is not established within the initial approval period investigators can apply to renew GBNMLs for a further three year period. There are two types of GBNML renewals and review paths; applications that request additional animals are reviewed at a quorate AEC meeting and applications that do not require additional animals are reviewed by AEC Executive out of session.

Transfer GBNML to SABC

Once the phenotype of a mouse line is established or characterised, which is generally 5-6 generations of breeding, an application can be submitted to the AEC to transfer the GBNML to a Specified Animal Breeding Colony (SABC). This application should inform the AEC of the stability of the line and why it is now thought to be established, describe the distinguishing phenotype of the line and outline any special requirements for the ongoing care and management.

Investigators are responsible for reporting animal numbers for the annual Animal Use Return until the SABC approval date, after which the animal facility have responsibility for reporting animal numbers for all SABC's.

Transfer established strain from another Institution (SABC)

Investigators can apply to the AEC to transfer lines from another institution provided these lines are considered to be established and the phenotype is characterised. This application should inform the AEC of the stability of the line and why it is thought to be established, describe the distinguishing phenotype of the line and outline any special requirements for the ongoing care and management.

The animal facility has the responsibility for reporting animal numbers for all SABC's for the annual Animal Use Return Part A.

Breeding Application (SABCs)

The AEC must review applications for activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of animal lines. The AEC must consider breeding applications only at quorate meetings of the AEC and approve only applications that are ethically acceptable and conform to the requirements of the Code.

The purpose of a breeding application (SABC) is to enable the breeding and maintenance of established strains and to ensure there is AEC approval for all colonies being bred in the animal facilities; these colonies include mice, rats, guinea pigs and cats. Animals will be bred and maintained only under AEC approved breeding applications and once animals are requested for use within an AEC approved project the designated animals will be transferred to the appropriate AEC project ethics number.

Breeding applications must be completed using plain English (lay language) throughout the entire application so that all AEC members are provided with sufficient information to participate effectively in the assessment of the application. Where the use of scientific language is deemed unavoidable, it must be supported by a suitable lay description, or a glossary of terms.

Decisions by the AEC should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.

Standard Operating Procedures

Husbandry and Clinical Standard Operating Procedures (SOPs) which are current may be referenced by investigators within applications to reduce the repetitious explanation of procedural techniques.

Clinical SOPs can be written and revised by any research staff but must be submitted and approved by the AEC before implementation. If a variation to an SOP is proposed, the entire procedure must be comprehensively detailed in the application for review and approval.

Husbandry SOPs are written by animal facility staff with input from relevant research staff and must be submitted and approved by the AEC before implementation. If a variation to an SOP is proposed, the entire procedure must be comprehensively detailed in the application for review and approval.

Submission process

All breeding applications must be submitted using the appropriate St Vincent's Hospital (Melbourne) AEC form; no other formats will be accepted.

The original signed application plus 8 hard copies must be submitted to the Research Governance Unit by close of business on the closing date of each scheduled AEC meeting. Closing and meeting dates are available on the Research Governance Unit website. No exceptions will be made to this closing date, unless previously negotiated with the AEC Secretary. The only exemption is that GBNML Renewals not requiring additional animals can be submitted at any time and only the original signed application is required.

A word document (not pdf) of the breeding application must also be emailed to research.ethics@svhm.org.au. An AEC Fee form must be submitted with the Breeding Application (SABCs) to ensure fee payments are processed prior to project review at the scheduled AEC meeting. There are no fees associated with GBNMLs, GBNML Renewals, Transfer GBNML to SABC or Transfer established strain from another Institution (SABC).

Once the submission is received by the AEC Secretary an acknowledgement email will be sent to the Principal Investigator confirming the application has been received and the AEC Reference Number which has been assigned to the breeding application.

All documentation which is superfluous to record keeping requirements will be destroyed by the Research Governance Unit, via confidential shredding services used by the hospital.

Review outcomes

The AEC may decide that an application to commence a project or activity is approved with or without conditions, deferred subject to modification, or not approved. The AEC must advise investigators of their decisions in writing as promptly as possible. Breeding must not commence until written final approval has been received.

Conditional Approval:

If the AEC agrees that the breeding application requires clarification conditional approval is granted. A conditional approval letter is sent to the Principal Investigator stating each of the issues and requesting an appropriate response. Breeding must not commence until written final approval is obtained.

The Investigator must respond to the AEC by providing a cover letter of response, which addresses each of the issues identified, and a revised breeding application, with revisions highlighted in bold or strikethrough text. A signed hard copy must be submitted to the Research Governance Unit and a word document (not pdf) of the breeding application must also be emailed to research.ethics@svhm.org.au

Responses to conditional approval may be reviewed by Spokespersons, Executive, Chair or AEC Secretary which is delegated at the AEC meeting and recorded in the meeting minutes. If it is determined that all issues are resolved, delegated members may grant final approval. However, the delegates retain the right to request additional information, or defer

consideration to the full AEC as required. All out of session approvals must be ratified by the AEC at the next scheduled quorate meeting.

Final Approval:

Breeding applications that AEC deem acceptable and do not require any clarification may receive final approval at the AEC meeting. An approval letter is sent to the Principal Investigator and breeding may commence or continue.

Associated Procedures/Instructions

- 2.7 – Standard Operating Procedures (SOPs)
- 3.3 – Annual Animal Use Return
- 4.5 – Committee Executive
- 4.7 – Making and Communicating Decisions

Reference Documents

- Australian code for the care and use of animals for scientific purposes (2013)
- Australian Code for the Responsible Conduct of Research (2018)
- Prevention of Cruelty to Animals Act (1986)
- Prevention of Cruelty to Animals Regulations (2008)

Authorized by:



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