

RESEARCH GOVERNANCE UNIT

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

SCIENTIFIC PROCEDURES PREMISES LICENCE (SPPLs)

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* (2013), *Prevention of Cruelty to Animals Act 1986* and the Department of Economic Development, Jobs, Transport and Resources (DEDJTR) guidelines, by ensuring that all scientific procedures involving animals are performed in licensed premises.

Definitions

Animal: any live non-human vertebrate (that is fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods.

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.

Procedure

Organisations or individuals wishing to conduct scientific procedures with animals in Victoria must hold a licence issued by the Manager DEDJTR that authorises the work. Scientific Procedures may be authorised by a Scientific Procedures Premises Licence (SPPL) or a Scientific Procedures Fieldwork Licence (SPFL) depending on the type of use of the location where the work will be conducted.

The Prevention of Cruelty to Animals Act 1986 also requires that the breeding of Specified Animals in Victoria for use in Scientific Procedures be authorised by a licence issued by the Manager DEDJTR.

A Scientific Procedures Premises Licence (SPPL) may be used to authorise the breeding of specified animals. This breeding, however, is restricted to providing animals for the use of the licence holder only. The SPPL does not authorise breeding of Specified Animals for supply to other institutions. If breeding for supply is undertaken, a Specified Animals Breeding Licence (SABL) is required. In line with the principle of Reduction however, if the numbers of Specified Animals approved for use in a project under a SPPL are subsequently found to be in excess of project requirements, these animals may be passed on to other licence holders without the need for a Specified Animals Breeding Licence.

There is no requirement that the breeding of non-specified animals in Victoria for use in Scientific Procedures be licensed.

Licences will only be issued to legal entities; that is, entities able to be prosecuted in Victoria. Legal entities include natural persons and bodies corporate.

A person must be nominated to be responsible to the licence holder for procedures under a Scientific Procedure Premises Licence or a Scientific Procedures Fieldwork Licence - the "Licence Nominee". The Licence Nominee is the first point of contact for the DEDJTR as the licensing authority, and will be corresponded with on all matters relating to the licence, such as breaches of licence conditions, licence audits, reporting of animal use, and Animal Ethics Committee composition and conduct. This person must hold a position in the licensed institution such that they are familiar with the work being conducted, yet senior enough to be able to effect change where necessary.

All practices carried-out under a licence must be in compliance with the Australian code for the care and use of animals for scientific purposes (2013), the Victorian code of practice for the housing and care of laboratory mice, rats, guinea pigs and rabbits, and the Code of practice for the use of animals from municipal pounds in scientific procedures.

Where practical, copies of the licence must be placed outside premises listed on the licence.

Investigators working under a licence and wishing to conduct Scientific Procedures must apply for approval for the project to the nominated AEC listed on the licence.

Scientific Procedures Premises Licence (SPPL)

A Scientific Procedures Premises Licence authorises the use of facilities for Scientific Procedures. Scientific Premises are listed on the licence and are regularly inspected by the DEDJTR as the licensing authority, as well as by the Animal Ethics Committee. All Scientific Premises must be inspected at least annually by the AEC listed on the Licence to ensure that the facility is compliant with the relevant guidelines.

Any facility being used to hold or conduct research must have a Scientific Procedures Premises Licence. There must be a clear line of management of all persons conducting Scientific Procedures at that premises linking their activities to a SPPL.

If a laboratory/room is to be added to a SPPL, the AEC must inspect the room and provide guidance on necessary changes required to ensure the room is compliant with the relevant guidelines. Once the room is considered to be compliant a variation to the licence should be submitted to the DEDJTR by the AEC Secretary on behalf of the Licence Nominee. Scientific Procedures involving animals can only begin once an updated licence is issued.

Scientific Procedures Fieldwork Licence (SPFL)

A Scientific Procedures Fieldwork Licence authorises the use of premises or locations that are not to be ordinarily used by the licence holder for Scientific Procedures (i.e. that are not to be used as Scientific Premises). Examples might include the use of animals on farms, the use of technology at another site (imaging etc), the intermittent use of Scientific Premises licensed under a Scientific Procedures Premises Licence held by another institution, or the use of non-captive animals in the wild.

Variation to Licences

SPPLs must be updated during the period of approval to reflect changes to Licence Nominee, AEC Membership and listed facilities. All variations must be submitted to the DEDJTR via the "Licence Variation" form and all variations must be approved prior to implementation.

Submission Process

Investigators must specify which licence they will work under on their project application to the AEC. The researchers must ensure all work involving animals is performed in rooms specified on the SPPL or SPFL. Fieldwork Notifications can be used if premises are required for procedures but listed on a different SPPL. The AEC must be notified if Fieldwork Notification is required.

Any Scientific Procedures conducted in rooms not listed on the licence or without Fieldwork Notification will be reported to the AEC and the DEDJTR as a breach of the Code and may result in withdrawal of ethical approval by the AEC. The required course of action will be determined on a case by case basis.

The SPPLs on St Vincent's (Melbourne) Campus are held by:

- St Vincent's Hospital (Melbourne)
- St Vincent's Institute
- Bionics Institute
- Centre for Eye Research Australia
- University of Melbourne at St Vincent's Health

Associated Procedures/Instructions

- 2.1 New Project Applications
- 2.2 Project Amendments
- 2.6 Fieldwork Notification

Reference Documents

- Australian code for the care and use of animals for scientific purposes (2013)
- Australian Code for the Responsible Conduct of Research (2018)
- Victorian code of practice for the housing and care of laboratory mice, rats, guinea pigs and rabbits (2004)
- Prevention of Cruelty to Animals Act 1986
- Prevention of Cruelty to Animals Regulations 2008

Authorized by:

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