



New South Wales

Animal Research Amendment (Law Revision) Regulation 1999

under the

Animal Research Act 1985

His Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Animal Research Act 1985*.

RICHARD AMERY, M.P.,

Minister for Agriculture

Explanatory note

The objects of this Regulation are as follows:

- (a) to clarify the kinds of offences that ought to be disclosed by an applicant for accreditation as an animal research establishment or for an animal supplier's licence (Schedule 1 [1], [8] and [13]),
- (b) to alter certain requirements concerning the constitution, functions and procedure of ethics committees (Schedule 1 [2]–[6], [21], [22] and [23]),
- (c) to make amendments that are consequent on the abolition of animal research licences and other amendments made by the *Animal Research Amendment Act 1997* (Schedule 1 [7], [11], [16]–[19], [24] and [26]),
- (d) to alter the fee structure in relation to applications for accreditation as an animal research establishment or for an animal supplier's licence (Schedule 1 [9]),

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- (e) to provide for a 30-day time limit for the giving of certain notices concerning changes in the particulars of accredited establishments and holders of animal suppliers' licences (Schedule 1 [10] and [14]),
- (f) to require an applicant for an animal supplier's licence to provide particulars concerning the ethics committee for the applicant (Schedule 1 [12]),
- (g) to clarify when a school does not need to be accredited and provide for the conditions that need to be observed by schools in carrying out animal research (Schedule 1 [15] and [20]),
- (h) to make provision in relation to when certain animals are to be exempted from licensing requirements for animal suppliers (Schedule 1 [25] and [27]–[30]).

This Regulation is made under the *Animal Research Act 1985*, including the definition of ***exempt animal*** in section 3 (1), sections 25A (2) (b) and (f), 25B (2) (a), 25C (2) and (3) and 56A and section 62 (the general regulation-making power).

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1 Name of Regulation

This Regulation is the *Animal Research Amendment (Law Revision) Regulation 1999*.

2 Commencement

This Regulation commences on 12 July 1999.

3 Amendment of Animal Research Regulation 1995

The *Animal Research Regulation 1995* is amended as set out in Schedule 1.

4 Notes

The explanatory note does not form part of this Regulation.

Schedule 1 Amendments

(Clause 3)

[1] Clause 3 Definitions

Insert in clause 3 (1) in appropriate alphabetical order:

prescribed offence means:

- (a) an offence under the Act, the *Exhibited Animals Protection Act 1986*, the *Prevention of Cruelty to Animals Act 1979*, the *National Parks and Wildlife Act 1974* or the *Non-Indigenous Animals Act 1987* (or under the regulations in force under any of those Acts), or
- (b) an offence committed in New South Wales for which the penalty (or maximum penalty) is imprisonment for 2 years or more, or
- (c) an offence committed outside of New South Wales that, if committed in New South Wales, would have been an offence referred to in paragraph (a) of this definition, or
- (d) an offence committed outside of New South Wales that, if committed in New South Wales, would have been an offence for which the penalty (or maximum penalty) is imprisonment for 2 years or more.

[2] Clause 6 Constitution and procedure for ethics committees for research establishments (other than school-based establishments) and licensed animal suppliers

Insert “or licensed animal supplier” after “(other than a school-based establishment)” in clause 6 (1).

[3] Clause 6 (3)

Omit the subclause. Insert instead:

- (3) In addition to the requirements of subclauses (1) and (2):
 - (a) the membership of an ethics committee must comply with the requirements of Clauses 2.2.2–2.2.8 of the Australian Code, and

- (b) if an ethics committee has more than 4 members—at least one third of those members must fall within the membership Categories C and D specified in Clause 2.2.2 of the Australian Code.

[4] Clause 7 Constitution and procedure for ethics committees for school-based establishments

Omit “7” from clause 7 (4). Insert instead “6”.

[5] Clause 8 Constitution and procedure for ethics committees for holders of animal research authorities

Omit “animal research licences” from clause 8 (1).
Insert instead “animal research authorities”.

[6] Clause 10 Functions of ethics subcommittees

Omit the clause.

[7] Clause 11 Prescribed particulars

Omit “employed by the corporation or the holders of animal research licences” from clause 11 (2) (c).

[8] Clause 11 (4)

Omit the subclause.

[9] Clause 12 Prescribed fee

Omit clause 12 (1). Insert instead:

- (1) For the purposes of section 18 (2) (d) of the Act, the prescribed fee to accompany an application for accreditation as a research establishment is:
 - (a) if the holders or proposed holders of animal research authorities referred to in clause 11 (2) (c) are less than 10—\$250, or
 - (b) if the holders or proposed holders of animal research authorities referred to in clause 11 (2) (c) are 10 or more (but not more than 75)—\$500, or

- (c) if the holders or proposed holders of animal research authorities referred to in clause 11 (2) (c) are more than 75—\$1500.

[10] Clause 13

Omit the clause. Insert instead:

13 Changes in particulars to be notified

- (1) A corporation that is an accredited research establishment must give written notice to the Panel of a notifiable detail within 30 days of any of the following events:
 - (a) a change in the directors of the corporation,
 - (b) any prescribed offence of which the corporation or any director of the corporation is convicted.

Maximum penalty: 10 penalty units.

- (2) In this clause, a *notifiable detail* means:
 - (a) in the case of a change in directors—details of the change, or
 - (b) in the case of a prescribed offence of which the corporation or a director of the corporation is convicted—details of the offence and of any penalty imposed.

[11] Part 4, Division 2

Omit the Division. Insert instead:

Division 2 Applications to Director-General for animal research authorities: sec 25A

14 Prescribed particulars

For the purposes of section 25A (2) (b) of the Act, the particulars to be included in an application to the Director-General for an animal research authority are the matters listed in Clause 2.2.11 of the Australian Code.

15 Prescribed fee

For the purposes of section 25A (2) (f) of the Act, the prescribed fee to accompany an application to the Director-General for an animal research authority is:

- (a) if the application is the first, second or third application for an authority made by the applicant in the same calendar year—\$100, or
- (b) if the application is the fourth or more application for an authority made by the applicant in the same calendar year—nil.

16 Changes in particulars to be notified

The holder of an animal research authority issued by the Director-General must give written notice to the Director-General of details of any prescribed offence of which the holder is convicted, and any penalty imposed, within 30 days of the conviction or imposition of any such penalty (whichever is the later).

Maximum penalty: 10 penalty units.

Division 2A Applications to accredited animal research establishment for animal research authorities: secs 25B and 25C**16A Prescribed particulars**

For the purposes of section 25B (2) (a) of the Act, the particulars to be included in an application to an accredited research establishment for an animal research authority are the matters listed in Clause 2.2.11 of the Australian Code.

16B Prescribed maximum fee

For the purposes of section 25C (2) of the Act, the prescribed maximum fee is \$100.

16C Changes in particulars to be notified

The holder of an animal research authority issued by an accredited research establishment must give written notice to the establishment of details of any prescribed offence of

which the holder is convicted, and any penalty imposed, within 30 days of the conviction or imposition of any such penalty (whichever is the later).

Maximum penalty: 10 penalty units.

16D Prescribed period and particulars for keeping of records of research by independent researchers: sec 25C (3)

For the purposes of section 25C (3):

- (a) the prescribed period is 7 years after the application is made, and
- (b) the prescribed particulars are as follows:
 - (i) the applicant's name, postal address and contact telephone and facsimile numbers (if any),
 - (ii) the location of any premises used for the holding of animals for use in the research,
 - (iii) the types of animals held,
 - (iv) the name and identifying number of the research protocol concerned,
 - (v) the species of animals used by the applicant for research,
 - (vi) the type of research being conducted by the applicant,
 - (vii) whether the research was approved, approved subject to conditions or not approved by the ethics committee of the accredited research establishment.

[12] Clause 17 Prescribed particulars

Insert after clause 17 (2) (a):

- (a1) particulars (if any) of the ethics committee for the applicant, including the qualifications of its members and terms of reference, meetings, decisions and procedures of, and inspections made by, the committee,

[13] Clause 17 (3)

Omit the subclause.

[14] Clause 19 Changes in particulars to be notified

Omit clause 19. Insert instead:

19 Changes in particulars to be notified

- (1) The holder of an animal supplier's licence must give written notice to the Panel of a notifiable detail within 30 days of any of the following events:
 - (a) in the case of a corporation—a change in the directors of the corporation,
 - (b) any prescribed offence of which the holder (or, in the case of a corporation, any director of the corporation) is convicted.

Maximum penalty: 10 penalty units.

- (2) In this clause, a *notifiable detail* means:
 - (a) in the case of a change in directors—details of the change, or
 - (b) in the case of a prescribed offence of which the corporation or a director of the corporation is convicted—details of the offence and of any penalty imposed.

[15] Clause 20

Omit the clause. Insert instead:

20 Certain schools may carry on business of animal research without accreditation: sec 46

- (1) A non-government school is exempted from the operation of section 46 (1) of the Act with respect to the carrying on of the business of animal research:
 - (a) if the school belongs to, or is associated with, a relevant Association that is accredited under the Act, and
 - (b) so long as any animal research carried out at the school is carried out with the authority of an ethics committee for the relevant Association and in accordance with the Code of Practice.

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(2) In this clause, *relevant Association* means any of the following:

- (a) the Association of Independent Schools,
- (b) the Catholic Education Commission (New South Wales).

[16] Clause 21 School students may carry out animal research without authorities: sec 47

Omit “or animal research licence”.

[17] Clause 26 Records to be kept

Omit “and to the holder of an animal research licence” from clause 26 (1).

Insert instead “and to the holder of an animal research authority issued by an ethics committee appointed by the Director-General”.

[18] Clause 26 (2)

Omit “Maximum penalty: 5 penalty units”.

Insert instead “Maximum penalty: 10 penalty units”.

[19] Clause 26A

Insert after clause 26:

26A Prescribed period and particulars for keeping of records of approvals of lethality tests: sec 56A

For the purposes of section 56A:

- (a) the prescribed period is 7 years after the record is made, and
- (b) the prescribed particulars in relation to each lethality test that is approved are as follows:
 - (i) the species of animal concerned,
 - (ii) the number of animals concerned,
 - (iii) the type of procedure,
 - (iv) the justification for the approval,
 - (v) any alternatives or modifications being developed to replace the need to carry out the lethality test.

[20] Schedule 1 Supplementary provisions of the Code of Practice

Omit Parts 1 and 2. Insert instead:

Part 1 Additional conditions to be observed in relation to animal research conducted in schools**1 Functions of ethics committees**

- (1) An ethics committee for a school has the function of preparing, in consultation with the Panel, a list of approved procedures that links each procedure with an appropriate educational objective.
- (2) A proposal is not to be considered by the ethics committee unless it includes the following information:
 - (a) the matters listed in clause 2.2.11 of the Australian Code, and
 - (b) the name of the animal welfare liaison officer.
- (3) An ethics committee must ensure that a list of its approved procedures is sent to each school under its supervision.

2 Animal welfare liaison officer

- (1) For each school there is to be an animal welfare liaison officer.
- (2) The animal welfare liaison officer for a primary school is to be the Principal for the school.
- (3) The animal welfare liaison officer for a secondary school is to be such person as the Principal for the school may appoint.

3 Responsibilities of animal welfare liaison officers

The duties of the animal welfare liaison officer are as follows:

- (a) to submit proposals for teaching procedures that involve the use of animals for the approval of the ethics committee for the school,

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- (b) to liaise with the ethics committee for the school on all matters concerning teaching procedures that involve the use of animals,
- (c) to ensure that all teaching procedures at the school that involve the use of animals comply with the requirements of this Part,
- (d) to ensure that appropriate records are kept of all animal research carried out at the school,
- (e) to promote awareness of the requirements of this Part within the school.

4 Responsibilities of class teacher

A class teacher who uses animals in the course of teaching must ensure that any activity involving the animals that is included on the relevant list of approved procedures is to be entered in a school register, together with the teacher's name.

[21] Schedule 1

Insert after Part 4:

Part 5 Miscellaneous

31 Delegation of functions of ethics committees

An ethics committee may delegate any of its functions to its ethics subcommittees other than the following functions relating to research proposals:

- (a) considering the proposal,
- (b) approving, or refusing to approve the proposal,
- (c) revoking a previous approval of a proposal.

[22] Schedule 2 Constitution and procedure of ethics committees

Omit clause 6. Insert instead:

6 Quorum

- (1) The quorum for a meeting of the ethics committee (except the ethics committee for a school-based establishment) is one representative from each member category, subject to any additional requirements determined by the ethics committee under clause 5 of this Schedule.
- (2) The quorum for a meeting of the ethics committee for a school-based establishment is the lowest number of members who between them fulfil all the requirements listed in clause 7 (3) (a) to (e) (Constitution and procedure for ethics committees for school-based establishments), subject to any additional requirements determined by the ethics committee under clause 5 of this Schedule.
- (3) In this clause, *member category* means a category of member referred to in Clause 2.2.2 of the Australian Code.

[23] Schedule 2 Clause 8

Omit the clause. Insert instead:

8 Voting

A decision made in accordance with Clause 2.2.21 of the Australian Code at which a quorum is present is the decision of the ethics committee.

[24] Schedule 2 Clause 9 Minutes and other records

Insert at the end of clause 9:

- (2) The ethics committee must also record in its minutes the reasons for any decision it makes concerning a research proposal.
- (3) The ethics committee must keep each of its minutes and other records for a minimum of 7 years after the minute or record is made.

[25] Schedule 3, heading

Omit the heading. Insert instead:

Schedule 3 Animals exempted from licensing requirements for supply

(Cl. 24)

[26] Schedule 3, clause 1

Omit the definitions of *authorised researcher* and *relevant ethics committee*.

Insert instead:

authorised researcher means the holder of an animal research authority.

relevant ethics committee means:

- (a) in relation to an animal research authority that was issued by the Director-General—the ethics committee that supervises the animal research carried out by the authorised researcher, or
- (b) in relation to an animal research authority that was issued by an accredited research establishment—the ethics committee of the establishment.

[27] Schedule 3, clause 2

Omit clause 2 (a). Insert instead:

- (a) the procedure, test, experiment, inquiry, investigation or study:
 - (i) is innocuous and non-invasive, and
 - (ii) will not have foreseeable lasting adverse consequences to the animal, and

[28] Schedule 3, clause 3

Omit clause 3 (a). Insert instead:

- (a) the procedure, test, experiment, inquiry, investigation or study:
 - (i) is innocuous and non-invasive, and

-
- (ii) will not have foreseeable lasting adverse consequences to the animal, and

[29] Schedule 3, clause 5

Omit the clause. Insert instead:

5 Bred for the purpose animals

- (1) Animals that have been bred by an authorised researcher are exempt animals for the purposes of any procedure, test, experiment, inquiry, investigation or study to be carried out by an authorised researcher so long as:
 - (a) the use of the animals for those purposes is approved by the relevant ethics committee, and
 - (b) the animals are kept in a manner approved by the committee, and
 - (c) the ethics committee is satisfied that:
 - (i) the researcher intends to breed a strain or type of animal that is not otherwise available for a specific research project, and
 - (ii) if any of the animals are supplied direct to another authorised researcher—no person (including the authorised researcher who bred the animals) is to receive a financial benefit.
- (2) Animals that have been bred within an accredited research establishment or by an independent researcher (as defined in section 25C (5) of the Act) are exempt animals for the purposes of any procedure, test, experiment, inquiry, investigation or study to be carried out by an authorised researcher so long as:
 - (a) the use of the animals for that purpose is approved by the relevant ethics committee, and
 - (b) the animals are kept in a manner approved by the committee, and
 - (c) the committee is satisfied that the animals are being supplied for use in the establishment only, or by the researcher only, as the case may be, and the breeding and management of the animals is part of a protocol approved by the committee.

[30] Schedule 3, clause 9

Insert after clause 8:

9 Animals with certain medical or genetic conditions

- (1) An animal is an exempt animal for the purposes of any procedure, test, experiment, inquiry, investigation or study to be carried out by an authorised researcher so long as:
 - (a) the animal has a medical or genetic condition for which it has not specifically been bred, and
 - (b) the animal has been released by its owner for use in a procedure, test, experiment, inquiry, investigation or study related to its condition that has been approved by the relevant ethics committee by means of a declaration in a form approved by the Director-General, and
 - (c) the relevant ethics committee is satisfied that the animal would be detrimentally affected by spending a period of time in a supply unit.
- (2) In this clause:

supply unit means premises used by a licensed animal supplier for the receipt, holding and despatch of animals for use in animal research.

BY AUTHORITY