



**Guide to the
Preparation of
Codes of
Ethical Conduct**

The purpose of this document is to give guidance to applicants on the preparation of a code of ethical conduct when making their applications. Applicants are requested to consider carefully the relevant provisions under Part 6 of the Animal Welfare Act 1999 and seek independent advice or legal assistance if necessary.

September 2006

Disclaimer

While every effort has been made to ensure the information in this guide is accurate, MAF and NAEAC, their employees and consultants expressly disclaim all and any liability to any person in respect of anything, and the consequences of anything, done or omitted to be done in reliance, whether wholly or partly, upon the whole or any part of the contents of this publication.

Contents	Page
A. Introduction.....	4
B. Format of application for a CEC	6
C. The application: documentation checklist.....	6
Appendix 1: Application form.....	11
Appendix 2: Sample codes	12
Appendix 3: Signature page.....	18
Appendix 4: Animal Welfare Act 1999 sections 87 to 104	19

A. Introduction

1. The Guide

- 1.1 This guide is designed to assist persons wishing to apply for, or renew, a code of ethical conduct under section 87 of the Act and gives additional information on what should be contained in such codes. Any person who engages in research, testing, or teaching and wishes to use animals for such purposes must have an approved code of ethical conduct, unless that person is working for a person who holds such a code. It must be approved by the Director-General of MAF prior to commencing such activities.
- 1.2 The requirement to have a code of ethical conduct is set out in Part 6 of the Animal Welfare Act 1999 (“the Act”). Part 6 is that part which deals with the use of animals in research, testing and teaching. This guide is a companion to the general Users Guide to Part 6 of the Animal Welfare Act 1999 (“the Guide to Part 6”). The Guide to Part 6 is available to you on request from MAF. It can also be accessed from the Biosecurity New Zealand website <http://www.biosecurity.govt.nz/legislation/animal-welfare-act/part6/index.htm>
- 1.3 The relevant sections of the Animal Welfare Act 1999 are set out in full in Appendix 4 to this document and should be consulted when preparing an application for a code of ethical conduct. These sections cover codes of ethical conduct and animal ethics committees.
- 1.4 The term “organisation” refers to any individual, company, institution or organisation that might apply for approval of a code. It should be noted that in the case of an organisation, the code holder is the organisation, not a person such as a chief executive. The code is not transferable to another organisation if companies are sold or merge, unless the Director-General of MAF gives specific approval to the transfer prior to the sale or merger.

2. What is a code of ethical conduct?

- 2.1 A code of ethical conduct (“CEC”) is a document that contains the protocols, that is, the details of the policies to be adopted and procedures to be undertaken by the code holder and the animal ethics committee (AEC) appointed by the code holder to ensure that the use of animals in research, testing and teaching is regulated according to the requirements of the Animal Welfare Act 1999 (“the Act”). The person making the application on behalf of the organisation would normally be the chief executive as a representative of the organisation that is covered by the code. The CEC lists the responsibilities of the code holder, the steps to be undertaken in setting up an animal ethics committee, and the policies and procedures to be adopted and followed by the code holder and the AEC. The Director-General of MAF may approve a CEC for a maximum of five years.
- 2.2 The details of what is required in a code of ethical conduct are set out in the Act. Additional information is provided in the Guide to Part 6. It is not possible to provide applicants with a specific or rigidly designed draft code as there are wide differences between organisations. A one-size-fits-all template would not be appropriate. Instead, in

Section B, this document suggests a format within which the particular needs and circumstances of each applicant can be accommodated.

3. Role of the Director-General of MAF

- 3.1 The Director-General is required to consult with, and invite comments from, the National Animal Ethics Advisory Committee (“NAEAC”) on each application. The Director-General will be guided by the comments received from NAEAC. The Director-General is required to notify the applicant of the decision within 40 working days of the application being lodged. This can be extended to 80 working days if the Director-General requires more information or needs to consult with the applicant. If the Director-General does not notify the applicant of the decision within the time period, the Director-General is deemed to have refused to approve the proposed code.

4. What does a code of ethical conduct look like?

- 4.1 All CECs will not be identical but the format suggested in section B of this guide may be helpful. The contents that should be inserted into each section are presented as a check list in section C. The style should be such that it can be approved by the Director-General as a statement of how the organisation in general, and the AEC in particular, will meet the requirements of the Act when animals are used in research, testing or teaching.

5. Proposed code of ethical conduct

- 5.1 The details of the CEC are described in a suggested format on the following pages. It is emphasised that, in following this format and checklist, the application should describe the in-house rules that will ensure that all manipulations, as defined in section 3 of the Act, are in accordance with the purpose of Part 6 of the Act (under section 80), and carried out by appropriately trained personnel.
- 5.2 It is important that any proposed code must incorporate, as a minimum, the requirements specified in section 88 of the Act. A system of keeping records and monitoring all activities involving animal use and husbandry is essential. This must be to a standard that is acceptable to the reviewer at the time of the mandatory five-yearly audit of the ethical system set up under each CEC. There may be conditions or extra instructions that apply to an individual code holder that are not in the Act but are specific to the organisation. In such cases these should be clearly stated and separated from those sections that reflect the mandatory requirements of the Act.

6. Public access to AEC meetings

- 6.1 Some public organisations undertaking research, testing and teaching may be subject to the Local Government Official Information and Meetings Act 1987. Where this is the case, committee deliberations must take place in meetings that are open to the public unless there is good reason for excluding the public. The committee must apply section 48(1)(a)(ii) of the Local Government Official Information and Meetings Act. This means sections 6, 7 and 9 of the Official Information Act 1982 apply including commercial sensitivity and legal professional privilege. However, section 9(2)(g)(i) of the Official Information Act (which relates to free and frank expression of opinion between members of an organisation) is not available.

B. Format of applications for a CEC

1. Part 6 of the Act contains information relevant to the use of animals in research, testing, and teaching. New applicants and those renewing their CECs must submit applications to the Director-General that are consistent with the Act.
2. The form of the application will comprise a number of documents. The detailed contents of each section are summarised in the check list in section C of this guide. The check list can be used by both the applicant and the Director-General (with the advice of MAF and NAEAC) to assist in ensuring that the CEC contains the appropriate policies and procedures. This approach can then accommodate the diversity of code holders. Applicants can vary the content of their CECs to suit their organisation and at the same time maintain a format that is consistent to all applications, without diverging from the requirements of the Animal Welfare Act 1999. Such consistency will assist the Director-General and NAEAC when processing applications.
3. The mandatory review of code holders and AECs, in sections 105 - 107 of the Act, makes it highly desirable for the code holder and the AEC to document their policies and procedures. This will also help new AEC members to understand their roles. Any review audit would require the AEC to account for its procedures and verify that these have been followed carefully and minuted appropriately. Similarly, the allocation of responsibilities regarding the distribution of information on the regulation of animal use in the organisation would also be set out clearly.
4. Every application to the Director-General should be accompanied by
 - the draft CEC itself
 - an application form incorporating the information required by section 89(1) of the Act
 - independent references as specified in section 89(2)(b) of the Act.
 - where the application is for a renewal of the CEC, a satisfactory report from an accredited reviewer. (Both MAF and NAEAC will have been supplied with a copy of the accredited reviewer's report as required by section 115 of the Act.)

C. The application: documentation checklist

1 Application form

The application form must include:

- the full legal name of the organisation or individual applying for approval of a code
- if an organisation, the name, contact details and role within the organisation of the person completing the application form
- if an individual, the person's contact details
- A description of the type and range of work that is covered by the proposed AEC - see section 89(1)(a)
- The period for which the approval is sought - see section 89(1)(b)
- Particulars of any convictions against certain Acts - see section 89(1)(c).

See Appendix 1 for a sample form.

2 Qualifications and references

The purpose of this legal requirement is to ensure that the applicant or the applicant's staff have the appropriate qualifications and expertise to carry out the type of research, testing or teaching intended to be undertaken. In the case of organisations, qualifications and references relating to the senior member of staff undertaking or overseeing animal research, testing and teaching will suffice, although a brief description of the types of staff employed by the organisation is useful.

3 Draft code of ethical conduct

The guide below contains items for possible inclusion in a code of ethical conduct. Detailed information should be provided under each part of the CEC. The Guide to Part 6 contains a considerable amount of helpful information on each part and should also be consulted when drafting a code.

The code holder must be satisfied that procedures are in place to enable the AEC to exercise its powers and functions. Once it has been established, an AEC is required to set in place its own procedures. The code should differentiate clearly between those procedures that are to be established by the code holder and those to be set in place by the AEC once it has been established.

3.1 Animal Ethics Committee – see section 101

In establishing an AEC the code holder must appoint members to the AEC in accordance with section 101 of the Act. This part should contain a description of the number and categories of persons constituting the members of the AEC. This should specify:

- the number and classification of persons on AEC
- appointment, reappointment and replacement details
- training of new members and expectations of AEC members
- remuneration (if any) of external members, that is, those not employed by the code holder,
- procedures as to how such external members will have effective input into the work of the AEC.

3.2 Policies and procedures to ensure effective functioning of the AEC – see section 88(2)(b)

The Act requires that the AEC be able to function effectively. The following items, although not statutorily required, will enable effective functioning and can be separated into those to be established by the code holder and those to be set up by the AEC once it has been appointed. This includes any criteria that will be used by the AEC to approve the protocols that are not in the Act, that is, additional to powers, functions, and criteria under sections 99, 100 of the Act:

- appointment of the chairperson and deputy chairperson

- frequency of meetings
- policy on the use of teleconferences
- what constitutes a quorum
- dealing with protracted absences by AEC members
- method of decision making e.g. consensus, majority
- whether separate procedures in terms of type of application and duration are required for research and teaching protocols
- the criteria used in accepting protocols for approval
- the use of standard operating procedures for the organisation in applications
- timing for processing and considering protocols
- changes to protocols after approval
- methods for approving any variations to the contents of an approved project
- possible fast track provisions
- use of subcommittees including terms of reference and mechanisms for set up
- treatment of commercially sensitive information
- management of possible conflict of interest by AEC members
- complaints procedures on the part of applicants, work associates, or the public
- public attendance at AEC meetings and possible application of Local Government Official Information and Meetings Act 1987 (see section A6 of this Guide)
- secretarial support
- preparation and distribution of agenda including timing
- minute taking
- information storage
- provision of guidance for applicants on the application process
- educational role of AEC.

3.3 Project approvals – see section 99

There must be policies and procedures in place to:

- set, vary and revoke conditions of approval (s99(1)(c))
- renew project approvals (s99(1)(f))
- suspend or revoke, where necessary, project approvals (s99(1)(g)).

Most codes also specify a maximum approval period.

3.4 Input by external members – see section 88(2)(b)

There must be a policy in place to ensure that persons who are members of the animal ethics committee but who are not employed by the code holder have an effective input into the working of the committee.

3.5 Monitoring and compliance - see section 88(2)(c)

This will include policies and procedures for:

- monitoring approved protocols
- requiring animal users to report back to the AEC
- monitoring of adherence to specific operating procedures
- monitoring of animal facilities, routine animal husbandry and animal welfare.

These policies should also cover external organisations using the AEC, where relevant.

3.6 Information management - see section 88(2)(d)

The code holder is required to make provision for collecting information and maintaining records relevant to its decisions, operations and functions under the above section and the Animal Welfare (Records and Statistics) Regulations 1999. Policies and procedures relating to the storage and collection of information and records should be clearly set out.

These should include policies and procedures for grading the impact of animal manipulations including the possible regrading of estimated grades following the actual manipulations.

3.7 Animal facilities and practices - see section 88(2)(e)

The code holder must specify policies and procedures relating to the animal management practices and facilities to be undertaken to ensure that owners or persons in charge of animals used in research, testing and teaching attend properly to the welfare of those animals. These should be in accordance with the NAEAC publication *Good Practice Guide for the Use of Animals in Research, Testing and Teaching* which can be found on the Biosecurity New Zealand website at www.biosecurity.govt.nz/animal-welfare

3.8 Complaints procedures - see section 88(2)(f)

The Act requires the code holder to ensure that any complaints from members of AECs are dealt with promptly and fairly either by the AEC or by the code holder. The CEC should identify policies and procedures for dealing with such complaints. NAEAC recommends that the complaints procedure should also cover complaints from staff members or members of the public, as well as AEC members.

3.9 Arrangements with external parties - see section 88(2)(f)/84(1)(b)

Organisations or individuals without their own code of ethical conduct may make arrangements to use the code and AEC of an organisation which does have them. It is the code holder's decision as to whether external parties will be allowed to do this. If the code holder intends to allow use by external parties, the CEC must stipulate policies and procedures in respect of such arrangements should this occur.

Policies should include the process and information required and differentiate between "local" and "distant" supervision.

NB It is the code holder's legal responsibility to notify MAF in writing of the arrangement before the external party begins any research, testing and teaching using animals.

3.10 Amendments to the CEC - see section 99(1)(h)

There must be a procedure in place to enable the AEC to recommend to the code holder that the CEC be amended.

NB Minor amendments must be notified to MAF. Any amendments to the code which are not minor must be approved by MAF.

3.11 Additional information

Any additional information that is relevant but it not a statutory requirement under the Act.

Appendix 1: Application form

Application for a Code of Ethical Conduct

- (1) Full legal name of code holder (organisation or individual):

- (2) Name of person completing form on behalf of organisation:

- (3) Designation: -----
- (4) Site/location of company/institution where activity is to take place:

- (5) Postal address: -----

email: -----
telephone: ----- fax: -----
- (6) Does the applicant or senior staff of the organisation have any convictions against the Acts specified in section 89(1)(c) of the Act? Yes / No
If yes, please give particulars:

- (7) A brief summary of the general nature and extent of the research, testing, or teaching in which the applicant will be engaged:

- (8) Statement of the period in respect of which the approval is sought (maximum 5 years):

[Note: Independent references and appropriate academic qualifications should be attached to this form – section 89(2)(b) In the case of organisations, a description of the types and qualifications of staff employed is helpful.]

Appendix 2: Sample codes

Examples - the following are hypothetical examples only. They indicate how persons from two different types of organisations might have used the information in this guide to apply for a code of ethical conduct. The examples are suggested as a framework only for the purposes of assistance. Given that they are brief, many code holders will wish/need to expand on the content.

The Biosecurity New Zealand website contains links to some approved codes of ethical conduct.

Example 1:

A code of ethical conduct that might be submitted by the chief executive of a fictitious research institute.

Introduction

This code of ethical conduct is designed to comply with all the requirements of the Animal Welfare Act 1999 (“the Act”) so that the specified animals can be used in research and teaching in this institution.

1 Animal Ethics Committee

In accordance with the Act, an animal ethics committee (“AEC”) will be set up to approve projects (which may include protocols) to regulate the use of animals.

The AEC will consist of nine members as follows:

- (a) Appointed by the chief executive (5 members):
 - the chair and two members with experience in pharmacology, physiology and genetics,
 - one person with experience in animal husbandry and animal experimentation,
 - the animal laboratory manager.
- (b) External members (3 members):
 - a veterinarian nominated by the New Zealand Veterinary Association
 - a person to represent animal welfare and nominated by an approved animal welfare organisation,
 - a lay person nominated by a local territorial or regional council.
- (c) A person co-opted from time to time for their particular expertise.

The chairperson will be instructed to ensure that all members are fully prepared for their role on the AEC. Members will be appointed for a period of three years with the possibility of renewal, and replaced at intervals that ensure the continuity of experience. The institute has a consultant veterinary officer who will not be a member of the AEC but is responsible to the AEC for ensuring that appropriate welfare standards are maintained. The AEC has

the power to co-opt experts where necessary.

2 AEC procedures

- (a) The AEC will meet at monthly intervals, at a time and place to be confirmed by the chairperson at the previous meeting.
- (b) A quorum will be five members and must include at least two external members. All decisions will be by consensus.
- (c) The institute will provide secretarial assistance to the AEC and a budget to cover administrative and related expenses as well as any expenses related to the monitoring regime.
- (d) The chairperson will establish written rules for AEC meeting and operating procedures that will be approved by the AEC. These will include: terms of reference, notice of meetings, distribution of agendas and documents, minute taking and circulation, procedures for the appointment of subcommittees, policies for fast tracking applications, and the treatment of commercially sensitive information. Such procedural rules will be updated from time to time and will be kept under observation by the Research Committee of the Council of the Institute.
- (e) Generally AEC meetings will not be open to the public and the Human Resources Department of the Institute will advise on any possible requirements of the Local Government Official Information and Meetings Act 1987. Any requests received under the Official Information Act 1982 will also be dealt with by the same department in consultation with the chairperson and any persons who may be involved.
- (f) The AEC will provide the chief executive with an annual report that summarises the AEC's activities for that calendar year outlining approved protocols, difficulties encountered, complaints received, and a copy of the statistical returns on animal use and severity required by the Animal Welfare (Records and Statistics) Regulations 1999.
- (g) All information will be stored securely by the secretary for a period of not less than seven years, access to which will be only with the approval of the AEC chairperson or chief executive.
- (h) Complaint procedures to deal fairly and promptly with complaints by applicants, AEC members, staff and the public will be established by the chairperson.
- (i) All these procedures will be included in the written rules of the AEC.
- (j) A copy of the AEC procedures will be prepared before any protocols applications are accepted.

3 Additional protocols

An AEC application form and instructions for applicants will be prepared, together with a check list of items that are required for the approval process. This will include all items mentioned in sections 99 and 100 of the Act. In addition, the AEC will insist on a firmly-based endpoint for the research and a short report will be required at the end of the experiments to confirm that the conditions of the approval have been met and verify or otherwise that any unexpected side effects have not been encountered and, where relevant, how they were dealt with.

4 Monitoring and compliance

Adequate processes will be set up to monitor the activities of research personnel, particularly in relation to their adherence to the conditions of project approvals. These policies will be applicable to all applicants. The consultant veterinary officer will be asked to visit the animal accommodation at random intervals and confirm that all animal husbandry conforms to recognised animal welfare standards. The results of such visits will be reported at the following AEC meeting.

5 Arrangements for external parties to use the code and AEC

In the event of persons or outside organisations requesting permission to operate under the CEC of this institute, this will be acceptable only if the expertise of the AEC is appropriate for the supervision of such persons. Similarly, if arrangements cannot be made to monitor the activities of the applicants, they will not be accepted. A standard letter of request for information will be prepared to cover these situations.

6 Information management

A person with the appropriate skills will be employed to act as AEC secretary to ensure that all minutes of AEC proceedings, its decisions, operations and records are stored and maintained in a satisfactory manner.

7 Animal facilities and practices

Procedures and policies will be put in place to ensure that animal facilities and practices are in accordance with good practice and scientific knowledge.

A veterinarian will be engaged on a consultancy basis to oversee all animal practices and facilities and required to report to each meeting of the AEC in respect of the practices and facilities relating to the colonies of laboratory mice and rats, rabbits and pigeons.

8 Complaints procedures

Procedures and policies to ensure that any complaints from members of the AEC are dealt with promptly and fairly will be put in place when the AEC is in place. This will be undertaken by the code holder in consultation with AEC members. Similarly, policies relating to complaints from other staff members and members of the public will be developed and implemented.

A final page with signatures and other details is not included with this example. A blank form for this will be available on request from the Secretary of NAEAC (see Appendix 3).

Example 2:

A code of ethical conduct that might be submitted by the manager of a fictitious small agricultural research company

Introduction

This CEC is to cover the activities of the Agriscan Company Limited of Taihape. The main business of this company is to run clinical trials on various animal remedies and dietary supplements. These are mostly newly developed drugs and anthelmintics that have yet to be trialed in New Zealand. The animals used will be sheep, cattle, and horses.

1 Animal Ethics Committee:

As managing director of this company, I shall take full responsibility for setting up an animal ethics committee (“AEC”) so that any activities that are classified as a “manipulation” under the Animal Welfare Act 1999 (“the Act”) can be assessed according to the requirements of the Act.

The AEC will consist of five members as follows:

- (a) a senior veterinary officer of this company,
- (b) a graduate in agricultural science, with experience in animal husbandry,
- (c) a person to represent animal welfare and nominated by an approved animal welfare organisation, such as the RNZSPCA,
- (d) a lay person having no connections with this company, nominated by the district council,
- (e) a veterinarian nominated by the New Zealand Veterinary Association.

2 AEC procedures

- (a) The senior veterinary officer will take the chair of the AEC and will be responsible for holding and conducting meetings, ensuring that records are kept, minutes taken by the secretary, and appropriate information is distributed to all persons concerned.
- (b) Written operating procedures for the AEC will be available to all AEC members and to the company directors.
- (c) The AEC has the power to co-opt one outside expert to the AEC, that person being chosen by the AEC members. A quorum is four members of whom two must be from outside the company. All decisions will be by consensus.
- (d) Meetings will be held at two monthly intervals unless notice is given in writing to members that a meeting is to be cancelled for lack of

business or other specified reason.

- (e) Agenda and accompanying material will be circulated to AEC members at least five working days before each meeting.
- (f) The senior veterinary officer will be responsible for ensuring that animal husbandry meets the required animal welfare standards. At each AEC meeting the officer will certify that the health and condition of the relevant animals have been monitored regularly. The AEC will have access to the animal health register that is kept as part of company policy.
- (g) Provided that all members are in agreement, a policy will be set up covering the holding of teleconferences from time to time instead of meetings. Consecutive meetings held in this way will not be permitted.
- (h) The code holder will set down rules to cover how matters of commercial sensitivity will be handled and how to avoid conflicts of interest in decision making.
- (i) Any changes to protocols may be approved by the chairperson and one external member if they are considered to be of a minor nature provided they are confirmed by the whole committee at the next meeting.

Note: At this time it is not considered that mechanisms for fast tracking decisions will be required.

3 Approval of protocols by the AEC

Instructions for applicants will be according to a standard format and will cover all items mentioned in the Act (section 100). Special emphasis must be given to keeping specific operating procedures and ensuring that all personnel are properly trained. Protocols will be approved for a fixed period and a maximum of three years. A well-defined endpoint to experiments will be expected. A copy of the final report on each investigation will be submitted to the AEC.

4 Monitoring processes

Adequate processes will be set up to monitor the activities of research personnel, particularly in relation to their adherence to the conditions of project approvals. At the final meeting of each year an assessment exercise will be held to determine whether the AEC is functioning with optimum effectiveness to the satisfaction of the whole committee. It will be determined whether there has been sufficient monitoring of animals throughout the year and whether these activities have been recorded in an appropriate way. All conclusions of this exercise will be included in the minutes of that meeting and made available in a form that is adequate for the independent audit review required by the Act. Statistics on animal use and severity of use will be forwarded to MAF each year as required.

5 Arrangements for external parties to use the code and AEC

It is not anticipated that this AEC will act for any other companies or groups. If this is a possibility in the future, the Director-General of MAF will be informed with a request for a change in the company's CEC.

6 Information management

A person with the appropriate skills will be employed to act as AEC secretary to ensure that all minutes of AEC proceedings, its decisions, operations and records are stored and maintained in a satisfactory manner.

7 Animal facilities and practices

Procedures and policies will be put in place to ensure that animal facilities and practices are in accordance with good practice and scientific knowledge.

A veterinarian will be engaged on a consultancy basis to oversee all animal practices and facilities and required to report to each meeting of the AEC in respect of the practices and facilities relating to the sheep, cattle, and horses.

8 Complaints procedures

Procedures and policies to ensure that any complaints from members of the AEC, staff members and members of the public are dealt with promptly and fairly will be put in place when the AEC is in place. This will be undertaken by the code holder in consultation with AEC members.

A final page with signatures and other details is not included with this example. A blank form for this will be available on request from the Secretary of NAEAC (see Appendix 3).

Appendix 3: Signature page

An example of final page with signatures and other details to be included with CEC application. A blank form for this will be available on request from the Secretary of NAEAC.

This is to certify that the code holder undertakes to conform to all the requirements of the Animal Welfare Act 1999 and will ensure that all persons involved in the animal manipulations and carrying out of these activities are appropriate persons according to that Act. It is accepted that the code holder is also responsible for distributing information on the requirements of the Act to the animal ethics committee to help ensure that the animal ethics committee follows the requirements of the law.

Signature of applicant: _____

Date: _____

Application to be sent to:

The Secretary
National Animal Ethics Advisory Committee
Biosecurity New Zealand
P O Box 2526
WELLINGTON

Appendix 4: Animal Welfare Act 1999 sections 87 to 104

Codes of Ethical Conduct

87 Codes of ethical conduct

Any person who—

- (a) Is engaged in, or wishes to be engaged in, research, testing, or teaching; and
- (b) Wishes to use animals in that research, testing, or teaching,—
may apply to the Director-General for approval of a code of ethical conduct in relation to the use of animals.

88 Contents of code of ethical conduct

- (1) Each code of ethical conduct must contain provisions that set out, in relation to the carrying out of the research, testing, or teaching to which the code relates, the policies to be adopted and the procedures to be followed,—
 - (a) By the code holder; and
 - (b) By an Animal Ethics Committee appointed by the code holder.
- (2) The policies and procedures must—
 - (a) Enable the Animal Ethics Committee to carry out its functions effectively; and
 - (b) Enable persons who are members of the Animal Ethics Committee but who are not employed by the code holder to have an effective input into the working of the committee; and
 - (c) Make provision for adequate monitoring of compliance with the conditions of project approvals to be carried out; and
 - (d) Make provision for the code holder to collect the information and to maintain the records required by regulations made under this Act; and
 - (e) Specify animal management practices and facilities that are such as to enable the purposes of this Part to be met adequately; and
 - (f) Be such as to ensure that where any member of the Animal Ethics Committee makes a complaint, that complaint may be dealt with fairly and promptly by the Animal Ethics Committee or the code holder; and
 - (g) Include, if necessary, the policies and procedures referred to in section 84(1)(b).
- (3) The provisions of each code of ethical conduct must—
 - (a) Be consistent with this Act and with any standards or policies prescribed by regulations made under this Act; and
 - (b) Be such as to enable any requirements specified in regulations made under this Act to be met.

89 Application for approval

- (1) Every application under section 87 must be in writing and must contain—
 - (a) Information on the general nature and extent of the research, testing, or teaching in which the applicant is engaged or proposes to be engaged; and
 - (b) A statement of the period in respect of which the approval is sought; and

- (c) Particulars of any convictions against—
 - (i) This Act; or
 - (ii) The Animals Protection Act 1960; or
 - (iii) The Agricultural Compounds and Veterinary Medicines Act 1997; or
 - (iv) The Biosecurity Act 1993; or
 - (v) The Companies Act 1993; or
 - (vi) The Crimes Act 1961; or
 - (vii) The Dog Control Act 1996; or
 - (viii) The Serious Fraud Office Act 1990; or
 - (ix) The Trade in Endangered Species Act 1989; or
 - (x) The Veterinarians Act 1994; or
 - (xi) Any Act that was replaced by any of the Acts specified in subparagraphs (ii) to (x); or
 - (xii) Any Act passed in substitution for any of the Acts specified in subparagraphs (iii) to (x).
- (2) Every application under section 87 must be accompanied by—
 - (a) The proposed code of ethical conduct to which the application relates; and
 - (b) Evidence, in the form of independent references and appropriate academic qualifications, that the applicant, or the persons employed or engaged to do the work, have the capability, skills, and experience to carry out the type of research, testing, or teaching to which the application relates; and
 - (c) Where the application relates to a second or subsequent period of research, testing, or teaching, a report—
 - (i) Made by an accredited reviewer; and
 - (ii) Showing that the work carried out during the previous period of research, testing, or teaching was satisfactory in terms of section 106(1).
- (3) The Director-General must refer to the National Animal Ethics Advisory Committee for its comments every application made under section 87 and must consult with that Committee with regard to every such application.
- (4) Where a person, who is deemed, by section 192(b)(ii), to be a code holder for the purposes of section 105(3), makes an application under section 87, that application is deemed for the purposes of this section to be an application relating to a second or subsequent period of research, testing, or teaching.

90 Changes to proposed code

The Director-General may, before deciding whether to approve, or to refuse to approve, a proposed code of ethical conduct, change the contents of the code if the National Animal Ethics Advisory Committee so recommends after consultation with the applicant.

91 Approval of code of ethical conduct

- (1) The Director-General must, in considering any application under section 87, have regard to the following matters:
 - (a) The contents of the proposed code of ethical conduct; and
 - (b) The evidence and other information and particulars supplied to the Director-General in accordance with section 89(1) and paragraphs (b) and (c) of section 89(2); and

- (c) The consultation conducted under section 89(3).
- (2) On approving the proposed code of ethical conduct, the Director-General may impose such conditions as he or she considers appropriate.
- (3) Where the Director-General approves a proposed code of ethical conduct, the Director-General must publish a notice of the approval in the Gazette.
- (4) Where the Director-General refuses to approve a proposed code of ethical conduct, the Director-General must give the applicant written notice of—
 - (a) The refusal; and
 - (b) The reasons for the refusal.

92 Time limits

- (1) Subject to subsection (3), the Director-General must, within 40 working days after receiving an application under section 87—
 - (a) Decide whether to approve the proposed code of ethical conduct, with or without changes, and, if it is to be approved, any conditions to be imposed; and
 - (b) Give or post to the applicant written notice of the decision on the application.
- (2) If the period specified in subsection (1) expires without the Director-General having approved the proposed code of ethical conduct and without having given a notice under subsection (1)(b), the Director-General is deemed to have refused to approve the proposed code of ethical conduct.
- (3) If, within the period specified in subsection (1), the Director-General notifies the applicant in accordance with subsection (1)(b) that either the Director-General or the National Animal Ethics Advisory Committee either—
 - (a) Requires more information from the applicant; or
 - (b) Needs to consult the applicant,—
 - the period specified in subsection (1) is deemed to be extended by a further 40 working days.

93 Approval to be personal to code holder

- (1) An approval of a code of ethical conduct is personal to the code holder and, except with the consent of the Director-General, is not transferable.
- (2) An approval of a code of ethical conduct does not vest by operation of law in any person other than the code holder.
- (3) For the purposes of subsection (1), where—
 - (a) A code holder assigns the assets and goodwill of the code holder's business to another person; or
 - (b) A transfer of all or some of the share capital of the code holder has the effect of transferring control of the code holder's business to another person,—
 - every such assignment or transfer has the effect of revoking the approval of the code of ethical conduct held by the code holder unless that assignment or transfer is effected with the consent of the Director-General.

94 Duration of approval

- (1) Every approval under section 91 of a code of ethical conduct has effect for such period, not exceeding the period of 5 years beginning with the date of the publication in the Gazette of notice of the approval of that

- code, as the Director-General specifies in that notice.
- (2) Subsection (1) is subject to sections 95 and 96.

95 Application for amendment, suspension, or revocation of code of ethical conduct

- (1) Every code holder may apply to the Director-General for his or her approval to the amendment, suspension, or revocation of the approval of the code of ethical conduct in respect of which the code holder holds the Director-General's approval.
- (2) Every such application must be in writing and must state the reason why the code of ethical conduct should be amended, suspended, or revoked.
- (3) The Director-General must refer to the National Animal Ethics Advisory Committee for its comments every application made under subsection (1) for his or her approval to the amendment of a code of ethical conduct and must consult with that committee with regard to every such application.
- (4) Despite subsections (1) to (3), nothing in this section prevents a code holder from making minor amendments to a code of ethical conduct (being minor amendments that would not materially affect the purposes of the code) without the approval of the Director-General.
- (5) Where, in any year ending with 31 December, a code holder makes minor amendments to a code of ethical conduct, that code holder must, as soon as practicable after the end of that year but not later than 31 March in the succeeding year, give to the Director-General in writing particulars of those minor amendments.

96 Amendment, suspension, or revocation

- (1) The Director-General must, in considering any application under section 95 for approval to the amendment to a code of ethical conduct, consider—
- (a) Whether the current provisions of the code of ethical conduct are appropriate to the activities of the code holder; and
- (b) Whether scientific developments make it appropriate for the code of ethical conduct to be amended; and
- (c) The consultation conducted under section 95(3).
- (2) The Director-General may, whether or not an application is made under section 95, suspend or revoke the approval of a code of ethical conduct if the Director-General believes, on reasonable grounds, that the code holder—
- (a) Is no longer carrying out research, testing, or teaching; or
- (b) Has been convicted of an offence against—
- (i) This Act; or
- (ii) The Animals Protection Act 1960; or
- (iii) The Agricultural Compounds and Veterinary Medicines Act 1997; or
- (iv) The Biosecurity Act 1993; or
- (v) The Companies Act 1993; or
- (vi) The Crimes Act 1961; or
- (vii) The Dog Control Act 1996; or
- (viii) The Serious Fraud Office Act 1990; or
- (ix) The Trade in Endangered Species Act 1989; or
- (x) The Veterinarians Act 1994; or

- (xi) Any Act that was replaced by any of the Acts specified in subparagraphs (ii) to (x); or
 - (xii) Any Act passed in substitution for any of the Acts specified in subparagraphs (iii) to (x); or
 - (c) No longer has the capability and skills necessary to carry out research, testing, or teaching; or
 - (d) Has failed to comply in a material respect with this Act or any regulations made under this Act or the code of ethical conduct; or
 - (e) Has provided in or with the code holder's application under section 87 information that was false in a material respect.
- (3) Except where a code holder applies under section 95(1) for the suspension or revocation of the approval of a code of ethical conduct, the Director-General must, before revoking or suspending the approval of a code of ethical conduct, give the code holder an opportunity to be heard and must consult with the National Animal Ethics Advisory Committee with regard to the proposed revocation or suspension of the code of ethical conduct.
- (4) Where the Director-General decides to approve the suspension or revocation of the approval of a code of ethical conduct, the Director-General must publish a notice of the decision in the Gazette.
- (5) Where the Director-General refuses to approve an amendment to a code of ethical conduct, the Director-General must give the applicant written notice of—
- (a) The refusal; and
 - (b) The reasons for the refusal.

97 Review of decisions

- (1) Where a decision under section 85 or section 86 or section 91 or section 96 is made by a person acting under the delegated authority of the Director-General, the person seeking an approval or holding an approval under section 85 or the applicant or the code holder, as the case may be, are each entitled to have the decision reviewed by the Director-General.
- (2) Where a decision under section 85 or section 86 or section 91 or section 96 is made by the Director-General, the person seeking an approval or holding an approval under section 85 or the applicant or the code holder, as the case may be, are each entitled to have the decision reviewed by the Minister.

Animal Ethics Committees

98 Establishment of Animal Ethics Committees

Every code holder must establish and maintain an Animal Ethics Committee.

99 Functions and powers

- (1) The functions of an Animal Ethics Committee are—
- (a) To consider and determine on behalf of the code holder applications for the approval of projects:
 - (b) To consider and determine, under section 84(1)(a), applications for the approval of projects:
 - (c) To set, vary, and revoke conditions of project approvals:
 - (d) To monitor compliance with conditions of project approvals:
 - (e) To monitor animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct:

- (f) To consider and determine applications for the renewal of project approvals:
 - (g) To suspend or revoke, where necessary, project approvals:
 - (h) To recommend to the code holder amendments to the code of ethical conduct.
- (2) Each Animal Ethics Committee has such powers as are reasonably necessary to enable it to carry out its functions.

100 Criteria

- (1) In considering any application for the approval of a project and in setting, varying, or revoking conditions of the approval of a project, every Animal Ethics Committee must have regard to such of the following matters as are relevant:
- (a) The purposes of this Part; and
 - (b) Any matters that the Committee is required to consider by regulations made under this Act; and
 - (c) The scientific or educational objectives of the project; and
 - (d) The harm to, or the distress felt by, the animals as a result of the manipulation, and the extent to which that harm or distress can be alleviated by any means (including, where the pain or distress cannot be held within reasonable levels, the abandonment of the manipulation or the humane destruction of animals); and
 - (e) Whether the design of the experiment or demonstration is such that it is reasonable to expect that the objectives of the experiment or demonstration will be met; and
 - (f) The factors that have been taken into account in the choice of animal species; and
 - (g) Whether the number of animals to be used is the minimum necessary to ensure a meaningful interpretation of the findings and the statistical validity of the findings; and
 - (h) Whether adequate measures will be taken to ensure the general health and welfare of animals before, during, and after manipulation; and
 - (i) Whether suitably qualified persons will be engaged in supervising and undertaking the research, testing, or teaching; and
 - (j) Whether any duplication of an experiment is proposed and, if so, whether any such duplication will be undertaken only if the original experiment—
 - (i) Is flawed in a way that was not able to be predicted; or
 - (ii) Needs to be duplicated for the purpose of confirming a result that was unexpected or has far-reaching implications; and
 - (k) Whether the same animals are to be used repeatedly in successive projects, and, if so, the cumulative effect of the successive projects on the welfare of the animals; and
 - (l) Whether there is a commitment to ensuring that findings of any experiment will be adequately used, promoted, or published; and
 - (m) Any other matters that the Committee considers relevant.

101 Membership

- (1) Each Animal Ethics Committee is to consist of at least 4 members.

- (2) If the code holder is an organisation, the members of the Animal Ethics Committee must be appointed by the chief executive of the organisation or his or her nominee.
- (3) One member must be—
 - (a) The code holder; or
 - (b) If the code holder is an organisation, a senior member of the organisation appointed by the chief executive to be a member of the committee.
- (4) Any senior member of an organisation who is appointed under subsection (3)(b) must be a person who is capable of evaluating—
 - (a) Each proposal for a project; and
 - (b) The qualifications and skills of the proposer of a project; and
 - (c) The scientific value or the teaching value, as the case may require, of a project.
- (5) One member must be a veterinarian (not being a veterinarian who is an employee of, or is otherwise associated with, the code holder) appointed by the code holder on the nomination of the New Zealand Veterinary Association or a similar national body of veterinarians.
- (6) One member must be a person appointed by the code holder on the nomination of an approved organisation.
- (7) The person appointed under subsection (6) must not be—
 - (a) A person who is in the employ of, or is otherwise associated with, the code holder; or
 - (b) A person who is involved in the use of animals for research, testing, or teaching.
- (8) One member must be a person appointed by the code holder on the nomination of a territorial authority or regional council.
- (9) The person appointed under subsection (8) must not be—
 - (a) A person who is in the employ of, or is otherwise associated with, the code holder; or
 - (b) A person who is associated with the scientific community or an animal welfare agency.
- (10) The appointed members of each Animal Ethics Committee hold office for such terms and on such conditions as are specified in the code of ethical conduct.

102 Procedure

The procedure of an Animal Ethics Committee must, except as provided in this Act or in regulations made under this Act or in the code of ethical conduct, be determined by the committee.

103 Report of non-compliance

- (1) Any member of an Animal Ethics Committee who believes that the Committee or the code holder is failing to comply in a material respect with this Act or with any regulations made under this Act or with the code of ethical conduct, may report the non-compliance to the Director-General.
- (2) A member of an Animal Ethics Committee who makes a report under subsection (1) in good faith is not to be liable to any civil or criminal proceedings or to any disciplinary proceedings by reason of having made that report.
- (3) The Director-General must use his or her best endeavours not to disclose any information that might identify the person who made the report unless—

- (a) The person consents to the disclosure of that information; or
- (b) The Director-General reasonably believes that disclosure of the identifying information—
 - (i) Is essential to the investigation of the allegations made in the report; or
 - (ii) Is essential having regard to the principles of natural justice.
- (4) Nothing in the Official Information Act 1982 or the Privacy Act 1993 requires the Director-General to disclose information that might identify the person who made the report.

104 Protection of members of Animal Ethics Committees

No member of an Animal Ethics Committee is personally liable for any act done or omitted by the member or the committee in good faith in the course of the operations of the committee.