Australian Government
National Health and Medical Research Council

Mapping: GM Guidelines and the Code

The *Australian code for the care and use of animals for scientific purposes 8th edition (2013)* (the Code) is published by the National Health and Medical Research Council (NHMRC) and is adopted in all state and territory legislation. The Code provides the governing principles and ethical framework to guide the decisions and actions of all those involved with the care and use of animals for scientific purposes. Each person involved in the care and use of animals for scientific purposes must consider the governing principles when applying the Code to their specific circumstance. This includes circumstances involving the generation, breeding, care and use of genetically modified and cloned animals.

The *Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes* (GM Guidelines) were published by NHMRC in 2007. The GM Guidelines were developed in consultation with the Office of the Gene Technology Regulator. While the content of this publication was current at the time of its publication, the document is more than five years of age and may no longer reflect current best practice. Following consideration of advice from NHMRC's Animal Welfare Committee, Research Committee and Council, the GM Guidelines have been rescinded. These guidelines continue to be available on NHMRC's website for information purposes only.

The 8th edition of the Code provides improved guidance for the creation and breeding of a new animal line, including genetically modified and cloned animals, where the impact on animal wellbeing is unknown or uncertain. The guidance in the Code incorporates many of the recommendations in the GM Guidelines.

The following table provides information on how the recommendations in the GM Guidelines have been encompassed in the Code.

Table: Mapping of recommendations in the GM Guidelines and the Code

Users should refer to relevant international literature and information resources for technical and scientific information on specific topics, and current best practice[1] for specific methods and techniques. Information is also available from the Office of the Gene Technology Regulator (http://www.ogtr.gov.au).

GM Guidelines (Chapter/Section)	The Code
Introduction	Not applicable.
Definitions of terms used in the context of the guidelines	Definitions include clone; cloning to generate embryonic stem cells; genetic modification (of animals); replacement, reduction and refinement (3Rs); scientific purposes; somatic cell nuclear transfer; standard operating procedures; wildlife; xenotransplantation.
Scope	Not applicable.
Aims	Not applicable.
Background A) Genetic modification B) Cloning C) Random mutagenesis	Not applicable. Users should refer to international literature for technical and scientific information about these topics.
Regulation of the use of genetically modified and cloned animals	General references; for example: • *Introduction* refers to relevant Commonwealth, state and territory legislation. • Responsibilities of investigators (Clause 2.4.8 [xxi]) require appropriate permits and licences to be in place. • Responsibilities of facility managers (Clause 2.5.15 [ix]) require appropriate permits and licences to be in place, including those required by the OGTR.
Ethical and welfare issues	
A) Ethical issues	Governing principles (Section 1).
B) Welfare Issues	• Governing principles (Section 1). • Strategies to support and safeguard animal wellbeing (Chapter 3.1). • Clause 3.3.24.

[1] *Current best practice* is defined in the Code as a practice, procedure, method or process that has proven to be most effective in supporting and safeguarding animal wellbeing, and that:
- takes into consideration the relevant aspects of species-specific biology, physiology and behaviour
- is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals
- includes strategies to minimise adverse impacts.

GM Guidelines (Chapter/Section)	The Code
Guidelines	
1. The role of animal ethics committees in assessing proposals to generate, maintain and use strains of genetically modified and cloned animals	Specific information for animal ethics committees (AECs) on this topic is not included in the Code. The following sections apply: • Governing principles (Section 1). • Responsibilities of AECs (Chapter 2.3).
1.1 Generation of genetically modified animals	Technical and scientific information about this topic is not included in the Code. Users should refer to international literature for relevant information.
1.2 Generation of cloned animals	Technical and scientific information about this topic is not included in the Code. Users should refer to international literature for relevant information.
1.3 Scope of impact on the animals	General information is covered by: • Governing principles (Section 1). • Responsibilities of investigators (Clauses 2.4.6–2.4.7). • Responsibilities of facility manager (Clause 2.5.15 [i]). • Responsibilities of AECs (Chapter 2.3).
1.3.1 Monitoring of animals	General information is covered by: • Responsibilities of AECs (Clauses 2.3.17–2.3.23). • Responsibilities of investigators (Clause 2.4.18). • Responsibilities of animal carers (Clauses 2.5.5, 2.5.6). • Animal Wellbeing (Clause 3.1.20–3.1.25). Specific information regarding genetically modified and cloned animals is provided in Clause 3.3.24.
1.3.2 Collection of relevant data on the outcome of the genetic modification and cloning	• Responsibilities of investigators (Clauses 2.4.26, 2.4.27). • Responsibilities of facility manager (Clauses 2.5.15 [i] and [x]).
1.3.3 Provision of full phenotype description to the AEC regarding welfare issues at designated stages	Report or evidence of welfare issues at designed stages: • Responsibilities of investigators (Clauses 2.4.26 and 2.4.27). • Responsibilities of facility manager (Clause 2.5.15 [i]).
1.3.4 Subsequent breeding for scientific procedures	• Responsibilities of investigators (Clauses 2.4.26, 2.4.27). • Responsibilities of facility manager (Clauses 2.5.15 [i] and [x]).
2. Reporting requirements of investigators	
2.1 Phenotype report and assessment of welfare	Encompassed in general terms under responsibilities of investigators (Clauses 2.4.26, 2.4.27 and 2.4.34).

GM Guidelines (Chapter/Section)	The Code
2.2 Final report on the generation of new genetically modified and cloned animals	Encompassed in general terms under responsibilities of investigators (Clauses 2.4.26, 2.4.27 and 2.4.34).
3. Reduction, Refinement and Replacement	The principles of replacement reduction and refinement underpin the requirements in the entire Code.
4. Animal husbandry	Sections relevant to all information in Part 4 of the GM Guidelines: • Clause 1.16 (Governing Principles) requires all methods used to accord with current best practice, which is defined in the Code. • Clause 1.29 (Governing principles) outlines the necessity for competence, which is defined in the Code. • Standard Operating Procedures are covered under Clauses 2.2.33–2.2.36. • Clause 3.3.1 outlines general requirements that apply to all procedures.
4.1 Determination of genotype of genetically modified and cloned animals	In addition to the information above related to Part 4 of the GM Guidelines, encompassed under Clause 3.3.24 (least invasive method must be used for genotyping).
4.2 Tail biopsy of mice	In addition to the information above related to Part 4 of the GM Guidelines, encompassed under Clause 3.3.24 (least invasive method must be used).
4.3 Blood collection 4.3.1 Retro-orbital bleeding 4.3.2 Other blood collection methods	In addition to information above related to Part 4 of the GM Guidelines, encompassed under Clause 3.3.7 which applies to any situation involving blood collection.
4.4 Identification of individuals 4.4.1 Identification of neonatal mice 4.4.2 Toe clipping of mice	In addition to information above related to Part 4 of the GM Guidelines, encompassed under: • Clause 3.3.24 (least invasive method must be used for identification). • Clause 3.3.6 which applies to any situation involving identification of animals.
5. Determination of the phenotype of genetically modified and cloned animals	• Clause 3.3.24. • Requirements for current best practice (Clause 1.16).
5.1 Genetic basis for adverse phenotypes 5.1.1 Genetically modified animals 5.1.2 Cloned animals	Technical and scientific information about this topic is not included in the Code. Users should refer to international literature for relevant information.

GM Guidelines (Chapter/Section)	The Code
5.2 Monitoring genetically modified animals	General information and principles for monitoring apply: • Responsibilities of institutions (Clauses 2.1.5 [v] and 2.1.7). • Responsibilities of AECs (Clauses 2.3.17–2.3.23). • Responsibilities of investigators (Clause 2.4.18). • Responsibilities of animal carers (Clauses 2.5.5 and 2.5.6). • Animal Wellbeing (Clause 3.1.20–3.1.25). Specific information regarding genetically modified and cloned animals is provided in Clause 3.3.24.
Appendix 1: Checklist to assist AECS	Specific information such as a checklist for AECs in addressing applications for genetically modified and cloned animals is not included in the Code. Appendix 1 is available on NHMRC's website for information purposes.
Appendix 2: Model record sheets for the monitoring of mice during the establishment of a new genetically modified strain	Information on records of monitoring: • Responsibilities of investigators (Clause 2.4.30–2.4.33). • Responsibilities of animal carers (Clauses 2.5.11 and 2.5.12) • Animal Wellbeing (Clause 3.1.20–3.1.25). Specific information such as model record sheets is not included in the Code. Appendix 2 is available on NHMRC's website for information purposes.
Appendix 3: Example phenotype report for genetically modified animals	Specific information such as an example of a phenotype report is not included in the Code. Appendix 3 is available on NHMRC's website for information purposes.
Additional Reading	
• General Background • Welfare of genetically modified animals • Physiology of genetically modified animals • Phenotype characterisation of genetically modified animals • Transgenic animals in research on pain • Random (chemical) mutagenesis	Not relevant for inclusion in the Code. Users should refer to current international literature and information resources for relevant information.