The Queensland Biotechnology Code of Ethics is currently being updated. This is an interim version.

If you have any queries, please use the contact details on the Queensland Biotechnology Code of Ethics page of the Queensland Science website.
General principles of the Code

As a biotechnology organisation, we will observe the following principles:

- **Integrity** – maintaining honesty and respect for the truth.
- **Beneficence and non-maleficence** – achieving the greatest possible good while doing the least possible harm.
- **Respect for persons** – treating patients, clients, research subjects and consumers as autonomous agents having freedom of choice, dignity and human rights.
- **Respect for the law and system of government** – complying with relevant laws and standards, fostering public participation and transparency in decision making, and demonstrating accountability for actions and use of resources.
- **Justice** – recognising wider community interests beyond the interests of the individual, organisation or corporation, providing redress for the vulnerable, and promoting equitable access to resources.
- **Care and protection of animals** – ensuring that the welfare of animals used for scientific purposes is respected.

Having regard to these fundamental principles, and the conduct outlined in this Code, we will pursue biotechnology activities with potential to improve human health, enhance quality of life, support the environment (by observing the precautionary principle, preserving ecosystem health and biodiversity), and promote sustainable agriculture and industry.
The Code

By subscribing to the Code, organisations agree to the following undertaking:

Integrity of research and product testing, risk assessment and risk management
1. We will ensure that staff are made aware of the Code and all other laws, standards and guidelines relevant to the safe and ethical conduct of biotechnology activities conducted by their organisations.

2. We will ensure that research and product testing are performed by qualified persons to optimal scientific standards and are conducted with integrity and with full regard to relevant facts and data.

3. We will maintain accurate and comprehensive records of research and product testing, (both positive and negative) and will report fully and accurately on the results of research, product trials and clinical trials as required by the appropriate regulatory authorities and professional standards.

4. In the conduct of research, product trialling, manufacturing or other biotechnology activities, potential conflicts of interest may arise. Whilst not necessarily unethical, conflicts of interest may result in poor decisions or, at worst, misleading or corrupt behaviour. We will manage and disclose such conflicts of interest to ensure that the integrity of research, product trials, manufacturing or other biotechnology activities, conducted by our organisation is maintained.

5. We will establish systems to ensure that conflicts or potential conflicts of interest are disclosed and that reasonable steps are taken to address and resolve any conflict. These steps are outlined in Appendix I of this Code.

6. We will work with relevant state and federal authorities (for example statutory regulators) and relevant advisory bodies (for example Human Research Ethics Committees and Institutional Biosafety Committees) to ensure that biotechnology products and other biotechnology activities are fully assessed for adverse impacts on human or animal safety or the environment. To the fullest extent possible, we will address long-term as well as short-term impacts, including consequences that may not be immediately apparent. Risk assessments will be conducted in accordance with accepted scientific principles. Where risks are identified, we will ensure that these risks are acknowledged through an open and accountable process and that they are managed in an appropriate manner to minimise the impacts of these risks.

7. We will not proceed with product development where assessed risks outweigh benefits, or where product development or commercial release is not approved by relevant regulatory authorities.

8. We will promptly report any risk or adverse consequence associated with research, or product development, to the relevant authority responsible for product oversight, regulation, risk assessment or risk management. If, following product approval, we become aware of risks or adverse consequences associated with the product that were not known or fully apparent at the time of approval, we will promptly inform the relevant authority.

Research into genetically modified organisms (GMOs)
The Queensland Government developed the Gene Technology Act 2001 (Qld) as part of the nationally consistent approach to regulating GMOs. The scheme was established by the Commonwealth and all state and territory Governments and is based on a science-based risk assessment process overseen by the independent Gene Technology Regulator. The purpose of this scheme is to ensure that gene technology research and its products are regulated and managed to minimise impacts on human safety and the environment.

9. We will ensure that research into GMOs meets all the requirements of the scheme, noting that failure to comply with the scheme may attract severe penalties. In particular:
   - We will not conduct research into GMOs unless our organisation is accredited by the Gene Technology Regulator. As part of the accreditation process, we will establish Institutional Biosafety Committees (IBCs) to oversee and monitor research within the organisation and to help ensure that the requirements of the national scheme are observed.

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1 The Australian New Zealand Standard on Risk Management AS/NZS 4360:2004 may provide a useful tool which includes sound risk management principles.

2 Smaller institutions may use another organisation’s Institutional Biosafety Committee if this is approved by the OGTR.
We will not conduct contained research on GMOs unless our laboratories are certified by the Gene Technology Regulator to the appropriate containment level.

We will not undertake contained research, field trials, or commercial releases of GMOs unless these activities have been reviewed and, where appropriate, licensed.

Where contained research, field trials or commercial releases are approved, we will comply with any conditions established by the Gene Technology Regulator, report any breaches of these conditions and will undertake any corrective action necessary or as directed.

We will cooperate with Commonwealth officers appointed by the Gene Technology Regulator to monitor compliance with the national scheme.

Biodiscovery

Article 15 of the United Nations Convention on Biological Diversity (1993) (the Convention) recognises the sovereign rights of states over their natural resources and their authority to determine access to genetic resources. The Commonwealth has ratified the Convention, the objects of which are the:

- conservation of biological diversity
- sustainable use of the components of biodiversity
- fair and equitable sharing of benefits arising from the use of genetic resources.

10. In this regard, the State Government developed the Biodiscovery Act 2004. The Biodiscovery Act 2004 (Qld) creates a streamlined, environmentally responsible access regime to permit collection of native biological material and requires sharing of benefits derived from the state’s biodiversity.

- We will comply with the Biodiscovery Act 2004 (Qld).
- We will collect native biological material from state land and Queensland waters only with the prior informed consent of the state.
- Before collecting samples from privately owned land, we will ensure that the prior informed consent of the landowner is obtained and we will negotiate reasonable benefit sharing arrangements with the landowner in return for access to the samples.
- We recognise that there may be culturally significant aspects of the knowledge of Aboriginal and Torres Strait Islander people, that we will treat in a sensitive and respectful manner if used in the course of biotechnology.
- Where in the course of biodiscovery we obtain and use traditional knowledge from indigenous persons, we will negotiate reasonable benefit sharing arrangements with these persons or communities.
- In the course of biodiscovery activities we will comply with the Native Title Act 1993 (Cth).
- We will not commit acts of biopiracy and will not assist a third party to commit such acts.7

Care and protection of staff and the public

11. We will comply with all relevant requirements of the Workplace Health and Safety Act 1995 (Qld) and will seek to comply with relevant Australian Standards governing laboratory safety.

12. We will institute adequate safety measures, and conduct our work in such a way as to ensure the health and safety of our staff and other persons, and we will ensure that our staff are properly trained in safety procedures.

Care and protection of animals

13. To ensure that the welfare of animals used for scientific purposes is respected, we will comply with the Animal Care and Protection Act 2001 (Qld) and the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.8

Transport of materials

14. When transporting biological materials or substances classified as dangerous, we will comply with all relevant international, Commonwealth and State guidelines governing safety in transport.9

Supporting discussion of ethical issues and resourcing ethics committees

15. We will encourage consideration and discussion of ethical issues.

16. We uphold the right of all persons to contribute to the debate and discussion about the ethical challenges created by biotechnology. We agree that many ethical issues cannot be resolved purely by the organisation or relevant profession engaged in the research, and that broader perspectives need to be engaged. We will seek to include these broader perspectives in our consideration of ethical challenges.

7 Biopiracy refers to the appropriation of developments or discoveries involving biological resources by another party without consent.
8 The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes has been endorsed by the NHMRC, CSIRO, Australian Research Council and the Australian Vice Chancellors’ Committee. The Code aims to ensure that the welfare of animals used in research is considered, the use of animals is justified, pain or distress to animals is avoided, and the number of animals used in projects is minimised.
9 For example, the Transport Operations (Road Use Management - Dangerous Goods) Regulation 1998 (Qld) and The Australian Dangerous Goods Code, 6th Edition.
17. We will ensure that all ethics and biosafety committees established within our organisation under relevant laws and guidelines, or under the Code, are given the support necessary to fulfil their responsibilities. This includes ensuring that they have adequate resources, have sufficient standing in the organisation, and have full and appropriate access to senior management. These committees include Human Research Ethics Committees, Animal Ethics Committees, Institutional Biosafety Committees and any committee or body established by the organisation for the purpose of promoting internal discussion of ethical issues or overseeing implementation of the Code.

Intellectual property and commercialisation

18. We will endeavour to ensure that new discoveries by Queensland researchers are developed in ways that provide appropriate returns to the state and, where appropriate, retain control of the intellectual property within Queensland. Where, despite best endeavours, it is not possible to develop our discoveries within Queensland, we will aim to license rather than sell the intellectual property.¹⁰

19. Recognising that many non-western and developing countries are also seeking to improve their biotechnology capacity, we will support exchange of technology between countries, including developing countries, for the broader benefit of the world economy and social development.

Consumer and patient information

20. We will provide clear, honest and verifiable information to consumers, patients and recipients about our products, the technologies employed, the materials used, and any risks or side effects.

Biological weapons

21. Noting that Australia is a signatory to the Geneva Protocol (1925) and the Biological Weapons Convention (1972), we will not use biotechnology to develop or produce biological weapons for use in warfare or terrorism, and will not assist any other organisation, person or country to develop, produce, duplicate, stockpile, acquire, retain or use such weapons in Australia or elsewhere.

22. We will aim to ensure that biological control agents directed at environmental protection and agriculture (for example in relation to the control of pests) are ecologically sustainable. We will ensure that such applications comply with relevant laws and biosafety requirements.

Import and quarantine controls

23. We will comply with all national standards administered by the Australian Quarantine and Inspection Service, Biosecurity Australia and the Australian Customs Service when importing or exporting biotechnology products or materials.

International obligations

24. We will observe all relevant laws and standards applicable to other countries in which we conduct biotechnology activities or to which we export biotechnology research or products.¹¹

Agriculture, food and the environment

25. Where we deal with agricultural, food and environmental biotechnology, we will aim to produce animal diagnostics and vaccines, crop varieties and biotechnology solutions that benefit consumers, improve agricultural productivity and sustain the environment.

Biodiversity and sustainable agriculture

26. Having regard to the uniqueness of the Australian environment, we will seek commercial release in Australia of genetically modified plants, animals or other organisms only where they have undergone adequate field trialling under Australian conditions in accordance with requirements set down by the Gene Technology Regulator.

27. We will seek to ensure that plants, animals and other organisms produced through gene technology do not interact with natural ecosystems in ways that may diminish Australia’s natural ecological capital.

¹⁰ For more information, refer to Chapter 3.3 Ownership of Intellectual Property, Queensland Public Sector Intellectual Property Guidelines.

28. A key community concern is the risk of unintended mixing on farms and along the supply chain of the harvested products from genetically modified (GM) crops and traditional crops. In addition to the quality assurance protocols, market pressures, and common law provisions that facilitate the adoption of coexistence measures, the Government has developed A framework to develop co-existence strategies for GM and non-GM crops in Queensland to ensure effective segregation along the supply-chain and to provide agricultural products that meet market requirements. We will work with the Queensland Government to support the Coexistence Framework.

29. If prescribed by the Gene Technology Regulator, we will establish and maintain adequate buffer zones around genetically modified crops to minimise unwanted transfer to conventional crop varieties, other organisms, or the environment, and will comply with all relevant conditions established by the Gene Technology Regulator.

30. Where we use gene technology applications in animals we will refer to the Gene Technology Regulator, the Animal Care and Protection Act 2001 (Qld), the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, and requirements of the local Animal Ethics Committee and Institutional Biosafety Committee.

31. Recognising that some traditional technologies have had significant environmental and ecological impacts that have only become apparent over time, we will cooperate with national and state authorities in monitoring the long term ecological impact of modern agricultural biotechnologies.

Consumers

32. Where we deal with food products developed using gene technology we will ensure that the food products meet the highest standards of safety, nutrition and benefit for consumers, and comply with relevant standards developed by Food Standards Australia New Zealand (FSANZ) and approved by the Australia New Zealand Food Regulation Ministerial Council.

33. To ensure consumers have freedom of choice, we will comply with the strict mandatory labelling requirements outlined in the Australia New Zealand Food Standards Code (FSANZ Standard 1.5.2) which requires genetically modified food and ingredients to be labelled as such.

Agricultural and veterinary chemicals

34. We will ensure that agricultural or veterinary chemicals produced through biotechnology are submitted to the Australian Pesticides and Veterinary Medicines Authority for pre-market safety assessment and registration.

Bioremediation and bioprocessing

35. We support the development of biotechnology solutions that deliver cleaner industrial and municipal processes to protect the environment and promote sustainable industries.

36. While acknowledging the potential for bioprocessing technologies to promote ecological and industrial sustainability (by eliminating harmful waste and generating alternative energy sources) we will seek to ensure that these technologies do not themselves threaten the environment or human health or safety. For example, we will ensure that fermentation, biogas production, and other biological processes employed do not pose unacceptable health risks to staff or other persons, and that development of new or enhanced bioprocessing industries utilising agricultural products are assessed for their impact on agricultural systems, ecosystems, land clearing, and water resources.

Medical research and health care

37. We will conduct any research involving humans with the highest standards of safety, integrity and respect for human dignity and will comply with all relevant National Health and Medical Research Council (NHMRC) guidelines as enforced from time to time, in particular the National Statement on Ethical Conduct in Research Involving Humans (1999).

38. To ensure biotechnology-based medicines and procedures meet the highest standards of safety and efficacy, we will comply with the Therapeutics Goods Act 1989 (Cth) and any requirements of the Therapeutics Goods Administration.

39. We will ensure that research involving humans is conducted only with the free, informed and voluntary consent of individuals participating in the research.

40. We will not allow unauthorised access, use, modification or disclosure of personal identifying information gained or used in the course of research without the consent of the individuals identified by that information.

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12 Effective segregation is defined in the Queensland Government publication Developing strategies for GM and non-GM crops in Queensland – A framework for co-existence as the “ability to grow and manage along the supply chain both GM and non GM crops in a way that avoids unwanted mixing and delivers products below predetermined market thresholds”.


14 In the event that consent is not readily obtainable, we will look to the Guardianship and Administration Act 2000 (Qld), the Powers of Attorney Act 1998 (Qld), the National Statement on Ethical Conduct in Research Involving Humans.

15 Disclosure of personal information is subject to guidelines outlined in the National Statement on Ethical Conduct in Research Involving Humans. Disclosure of patient data held by Queensland Government health authorities is governed by legal protections prescribed in the Health Services Act 1993 (Qld).
Genetic testing
We acknowledge the principle in the Universal Declaration on the Human Genome and Human Rights (1997) that “everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics and that dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity”.

41. We will not conduct tests for genetic conditions, or potential disease traits in individuals or their offspring, without the free, informed, and voluntary consent of the individuals to be tested.

42. We will not disclose personal, identifying data from genetic tests to third parties without consent of the individuals concerned – restrictions on disclosure are necessary to maintain patient confidentiality and ensure that the results of genetic testing are not used to stigmatise individuals or cause discrimination (for example, with respect to accessing life insurance or employment).

43. We will provide appropriate counselling and support to individuals prior to and after genetic testing to assist individuals to decide whether they wish to undergo genetic testing and to help them assess and manage the results of genetic tests.

44. We will respect the right of each individual to decide whether or not to be informed of the results of genetic testing, and the resulting consequences will be respected.

45. Counselling will address the limitations of genetic testing as well as the potential benefits – patients should be advised that genetic testing does not, in all circumstances, provide certainty that the person tested or their offspring will develop particular diseases (conditions may be linked to multiple rather than single genes; environmental factors may also play a significant or dominant role in whether particular people develop diseases for which they may have genetic susceptibility).

Gene therapy
46. We will not undertake somatic cell gene therapy unless the proposal has been reviewed and approved in accordance with NHMRC guidelines. This requires consideration by the relevant Human Research Ethics Committee, the NHMRC’s Gene and Related Therapies Research Advisory Panel, the Therapeutics Goods Administration and where relevant the Gene Technology Regulator.

Cloning and related technologies
47. We will comply with the Gene Technology Act 2000 (Cth), the Gene Technology Act 2001 (Qld) and the Gene Technology Regulation 2002 (Qld). We will also comply with the Research Involving Human Embryos and Prohibition of Human Cloning Act 2003 (Qld) which bans human cloning, germ line gene therapy and ensures that research involving human embryos is strictly regulated.

Xenotransplantation
48. We acknowledge that concerns exist about the safety and efficacy of xenotransplantation (for example, the risk of animal retroviruses being transmitted to humans through xenotransplants).

49. We will abide by the NHMRC’s decisions on issues surrounding xenotransplantation including the five year ban (until 2010) on conducting human clinical trials involving animal-to-human whole organ transplants.

50. We will only use animals in xenotransplantation research if suitable alternative therapies are not available. We will make every effort to keep the number of animals used in xenotransplantation research to a minimum and to ensure that these animals are provided with as high a quality of life as possible.

51. We note that research proposals involving xenotransplantation must be considered under arrangements administered by the NHMRC and that the NHMRC requires all research proposals involving xenotransplantation to be referred to the Gene and Related Therapies Research Advisory Panel (GTRAP) for scientific, medical and technical advice in the formulation and ethical review of the research. We also note that no Human Research Ethics Committee should approve any research proposal involving xenotransplantation without first seeking this advice.

16 Article 2, Universal Declaration on the Human Genome and Human Rights (1997).
Appendix One: Key steps in managing conflicts of interest

Point 5 under the Section Integrity of Research and Product Testing requires that biotechnology organisations establish systems to ensure that conflicts or potential conflicts of interest are disclosed and that reasonable steps are taken to address and resolve any conflict. These steps include:

- Requiring staff to disclose possible conflicts of interest.
- Requiring staff to disclose their pecuniary interests (including any business associations, shareholdings, sponsorships, donations, payments or fees).
- In particular cases:
  - determining whether a conflict or perceived conflict of interest exists that might call into question the integrity of the work; or
  - where appropriate, directing or advising a staff member to cease involvement in the work or to divest him or herself of external interests that are seen as incompatible with the integrity of the work; or
  - determining that a conflict (or perceived conflict) of interest is acceptable or unavoidable in the circumstances, is not detrimental to the integrity of the work, and is appropriately disclosed.

In cases where a conflict of interest exists or may exist, or where the circumstances could give rise to a reasonable perception of conflict, the biotechnology organisation should disclose the circumstances to relevant authorities having oversight of the activity concerned. The relevant authorities include:

- The ethics committee responsible for approval and/or monitoring of biotechnology activities within the organisation, where the circumstances relate to a matter or matters for which the committee has responsibility.
- An external research funding institution, where the circumstances relate to an activity funded, or proposed to be funded, by the institution.
- A regulatory authority where the circumstances relate to scientific advice or assessments that could be used by the authority to approve or monitor research or product release.
- An editor or producer of a professional journal, publication or media report, where the circumstances relate to scientific advice or assessments proposed for reporting in the journal, publication or media report.
- An advisory board or government authority where the circumstances relate to the provision of scientific advice provided to the board or authority (for example, where a member of our organisation is engaged or appointed to provide scientific advice on biotechnology matters in relation to which he or she may have, or may be seen to have, a beneficial interest).
- The organisation’s financial administrator, where biotechnology products or services are purchased, or are being considered for purchase, from an external source in relation to which the purchasing officer has, or may have, a beneficial interest.

As a general rule, biotechnology organisations should disclose to relevant authorities all funding sources associated with research activities (irrespective of whether a conflict of interest may exist or is perceived to exist).

19 “Staff” includes management.
20 Such committees include the relevant Institutional Biosafety Committee; the Animal Ethics Committee and the Human Research Ethics Committee.
See Part III, paragraphs 9, 13 and 50 for an outline of these committees.
Glossary and Abbreviations

Biodiscovery
Biodiscovery has the meaning given in the Biodiscovery Act 2004 (Qld) and includes the analysis of molecular, biochemical or genetic information about native biological resources for the purpose of commercialising the material.\(^{21}\)

Biotechnology
Biotechnology is formally defined as the science of using living things, and components of living things, to produce goods and services. It involves manipulating and modifying organisms, often at the molecular level.

Practically, modern biotechnology includes techniques ranging from chemistry through molecular and cellular biology, biochemistry and immunology to biological applications of information technology and the development of medical instrumentation. Its applications span health, agriculture, industry and the environment.\(^{22}\)

Cloning
The process of producing genetically identical organisms through various techniques, including culture of specific cells, artificial division of a single embryo, or cell nuclear transfer, that is, transferring the nucleus of a somatic cell into an oocyte (the mature female germ cell or egg) from which the nucleus has been removed.

Coexistence
Coexistence is defined as the ability to grow and manage along the supply chain both genetically modified and non-genetically modified or traditional crops in a way that avoids unwanted mixing and delivers products below predetermined market specification or thresholds.\(^{23}\)

Culture
The growing of micro-organisms, tissue cells, or other living matter in a specially prepared nutrient medium (an intervening substance through which something else is transmitted or carried on).

Gene
A sequence of DNA, located on a chromosome, which codes for the synthesis of a specific protein or has a specific regulatory function.\(^{24}\)

Gene technology research
Study involving the manipulation, modification and transfer of genes or segments of DNA or RNA.

Gene therapy
Treating or preventing genetic diseases by changing the expression of a patient’s genes through the introduction of DNA or RNA into the patient’s cells.

Genetic characteristic
A trait (distinguishing feature) of an organism determined by genetic inheritance.

Genetic inheritance
The acquiring of a set of physical or behavioural characteristics from a parent.

Genetic modification
Any process altering the genetic material of living organisms.\(^{25}\) This process allows genes to be isolated, amplified and transported into new locations, even between species, to effect desired characteristics in organisms. Examples include the duplication, insertion, or deletion of genes from another species, in situ in either microbes, plants or animals (humans included). Where this is done in humans, it is gene therapy, and only human genes are used.

Genetically modified food
A food produced using gene technology as ‘a food which has been derived or developed from an organism which has been modified by gene technology’. This definition does not include a food derived from an animal or other organism which has been fed GM feed, unless the animal or organism itself is a product of gene technology.\(^{26}\)

Genetically modified organism (GMO)
An organism (plant, animal, bacteria or virus) that has had its genetic material altered either by duplication, insertion or deletion of one or more new genes, or by changing the activities of an existing gene.\(^{27}\)

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\(^{21}\) Biodiscovery Act 2004 (Qld)


\(^{24}\) Biotechnology Australia - Glossary of Terms (www.biotechnology.gov.au)

\(^{25}\) Biotechnology Australia - Glossary of Terms (www.biotechnology.gov.au)

\(^{26}\) Australian Food Standards Code Standard 1.5.2

\(^{27}\) Ibid
Genetic testing
Genetic testing has considerable potential in health care as a means of identifying individuals' genetic make-up, and enabling early prevention strategies to be targeted at persons or offspring most at risk of genetically determined diseases.

Genetically modified crops
Modifying the genetic code of agricultural crops to produce improved characteristics such as pest and disease resistance, drought and salt tolerance, higher yields or greater nutritional value.

Somatic cell
Any cell in a multicellular organism except a sperm or egg cell.

Xenotransplantation
The term used to describe any procedure that involves the transplantation of live cells, tissues, or organs from one species to another, including animal to human transplantation (for example, from pigs to humans – animal-to-human transplantation). Xenotransplantation includes:
- animal to human whole organ transplants
- animal cellular therapies – are procedures in which animal cells are transplanted or implanted into a human patient to compensate for deficient functioning of the patient’s own cells (for example, pancreatic islet cells to treat people with diabetes, or brain cells to treat people with Parkinson’s Disease) and
- animal external therapies – are a range of procedures involving contact between human and animal cells or tissues outside the body of the patient (for example, cells or fluids from the patient are perfused through animal cells and returned to the patient).

Abbreviations

AEC Animal Ethics Committee
AHEC Australian Health Ethics Committee
ARC Australian Research Council
CRC Cooperative Research Centre
CSIRO Commonwealth Scientific and Industrial Research Organisation
DNA Deoxyribonucleic Acid
FSANZ Food Standards Australia New Zealand
GM Genetically Modified
GMO Genetically Modified Organism
GTRAP Gene and Related Therapies Research Advisory Panel
HREC Human Research Ethics Committee
IBC Institutional Biosafety Committee
NHMRC National Health and Medical Research Council
OGTR Office of the Gene Technology Regulator
RNA Ribonucleic Acid

Biotechnology Australia - Glossary of Terms (www.biotechnology.gov.au)