

Code of Ethical Practice for the Provision of Genetic Services in Western Australia

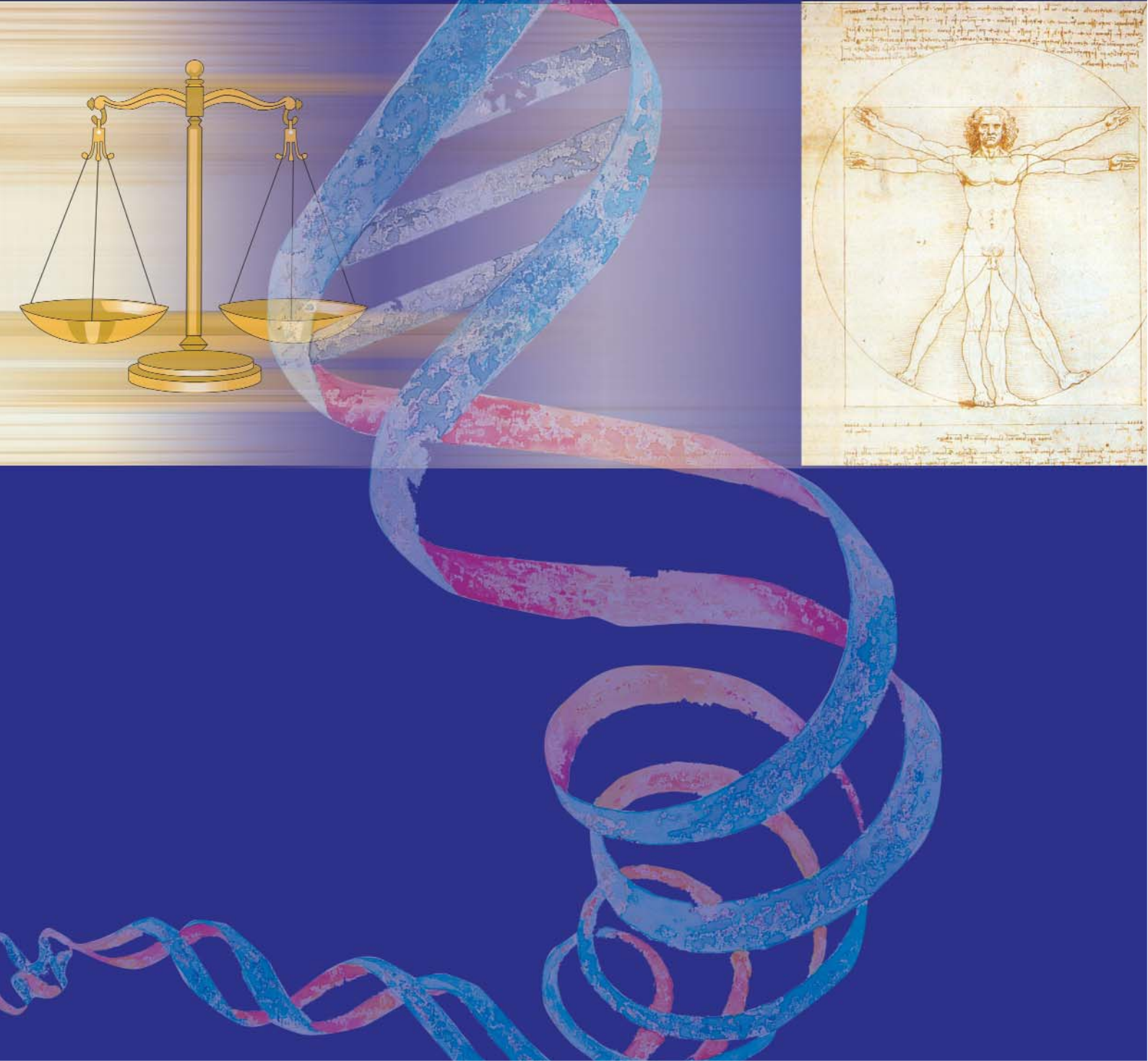




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Summary of Standards

Health professionals will:

1. Strive to provide the highest quality care based on current best practice guidelines at all times to individuals under their care.
2. Ensure that individuals in receipt of genetic services or participating in human genetic research are provided with comprehensive, accurate and objective information from which to make autonomous decisions.
3. Ensure that information provided to clients is delivered in a manner that is appropriate for the individual's level of comprehension.
4. Be aware of situations in which current action may compromise individual autonomy in the future, for example in the case of genetic testing in childhood.
5. Be respectful of cultural and religious beliefs and practices which may influence client decisions.
6. Take sufficient and reasonable care to avoid causing harm to clients, both physically and psychologically.
7. Ensure that human genetic research is ethically sound and will not result in risks of harm for the individuals involved.
8. Strongly encourage individuals to disclose genetic information of clinical relevance to their genetic relatives in circumstances in which this disclosure could prevent future harm.





Foreword

The Human Genome Project has greatly accelerated research in genetics, and as a result of these developments there have already been significant advances in what we know and understand about genetic information and its implications for health outcomes. The increased availability of human genetic information offers many health benefits, with the capacity to enhance diagnostics by identifying persons who are at risk, and to provide therapeutic or preventative intervention. Technological progress in this field has also facilitated the implementation of genetic advances on the health service level, enabling these services to be increasingly accessible to the public.

Genetic information may be considered to be different from other forms of health information as it has particular features that raise ethical dilemmas when applied to medicine. Some of these features include:

- that genetic information may affect an entire family, rather than only the individual;
- genetic discoveries may be predictive of future adverse events in an individual's or family member's health; and
- genetic information and present choices may affect future generations.

Therefore, medical genetics' main concerns extend beyond those of the traditional structure of medicine and require guidelines to assist health professionals in navigating new ground in health services.

There is a growing focus in the literature on codes of ethical practice to assist health professionals navigate the new ethical issues arising in genomics¹, and there exists a multitude of ethical policies and guidelines produced by many health care organisations both around Australia and internationally. This Code aims to articulate nationally established ethical guidelines, and provide health professionals with a clear ethical framework within which to apply genetic technology.

This code also provides a state government commitment to upholding and recommending ethically sound practice in the delivery of genetic services in human health. The term genetic services refers to the network of services which provide information and education, counselling, risk assessment, diagnosis, laboratory testing and clinical management for genetic disorders and birth defects.

As biotechnology is a rapidly developing area, it will be necessary for the code to be revised on a regular basis to take into account scientific developments, and changes in commonwealth and state policy. Therefore the code is an evolving articulation of ethically sound guidelines.

In preparing this document every effort was made to ensure that all information is accurate. Those who are in doubt of any information presented here are encouraged to seek their own advice. The Department of Health welcomes comment on this document.



Abbreviations

AHEC	Australian Health Ethics Committee
ALRC	Australian Law Reform Commission
ART	Assisted Reproductive Technology
DOH WA	Department of Health Western Australia
DNA	Deoxyribonucleic acid
GTRAP	Gene and Related Therapies Research Advisory Panel
HGSA	Human Genetics Society of Australasia
HREC	Human Research Ethics Committee
NHMRC	National Health and Medical Research Council
PGD	Pre-implantation genetic diagnosis
TGA	Therapeutic Goods Administration





PART 1: Guiding Principles

Ethical judgements are integrative judgements; they bring together relevant interests from the individual, familial, community and societal levels². Ethical judgements are not made in isolation from other factors, but rather reflect a considered appreciation of the issues that need to be taken into account when determining a course of action.

In a pluralist society, such as Australia, there is a range of ethical considerations and approaches that may be used to establish a framework for making and justifying ethical judgements. This may include utilisation of the four principles of biomedical ethics proposed by Beauchamp and Childress (1979). These are:

Promote justice - the requirement for treatment to be provided on a fair and equitable basis.

Respect autonomy - the principle of self determination, involving education, communication, consultation, respect and empowerment.

Beneficence - the obligation to ensure that policies and practices of health professionals are for the good of patients.

Non-maleficence - the requirement to do no harm.³

When applying these principles to genetics, the principles of justice and autonomy in particular may be problematic.⁴

Some question the suitability and adequacy of this approach and may use consequentialist ethics, professional codes of conduct or critical ethics to guide their decisions. Others may focus on the ethics of discussion, seeking to ensure that the processes of decision-making are effective.² Regardless of the approach taken, adequate consideration of the ethical issues involved will assist in guiding and promoting best practice in the delivery of genetic services.





PART 2: General Clinical Practice Guidelines


Informed and Voluntary Consent

1. As with most medical treatment, it is essential that informed consent is obtained before a person is provided with genetic services.
 - 1.1 Of critical importance for consent to be valid is that it is voluntary, meaning free of coercion, and the person giving it is judged to be capable of understanding what he/she is consenting to and informed as to the risks involved.
 - 1.2 Key components of 'informed' consent include:
 - The provision of appropriate information at the individual's level of comprehension;
 - Information regarding the potential benefits and risks of the service, as well as limitations and implications of the results; and
 - The ability to withdraw from the service at any stage without detriment or prejudice.⁵
 - 1.3 All testing should be offered under such circumstances that individuals are free to refuse or accept testing according to their wishes and moral beliefs, and these decisions must be respected.⁶

Counselling and Support

2. Appropriate counselling, that is genetic counselling which meets HGSA standards for this profession⁷ should be provided to individuals both prior to and after genetic testing.
 - 2.1 Genetic testing should only be offered to individuals after they have had the opportunity to consider the issues, be offered counselling on the risks, implications and benefits of testing, and be based on voluntary and informed consent.
 - 2.2 Professional counselling should aim to provide information that will enable individuals to decide whether they wish to undergo the testing and to help them manage the results of the tests, particularly when this information pertains to their future health or that of their children.⁸

Privacy and Confidentiality

3. The privacy and confidentiality of genetic information should be respected and disclosure of this information to third parties without the consent of the individuals concerned is not ethically or legally acceptable in most circumstances.
 - 3.1 Results of tests specific to an individual are confidential.⁹
 - 3.2 In some situations, the genetic information about an individual may be of clinical significance to their genetic relatives.
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PART 2: General Clinical Practice Guidelines

- 3.2.1 Those undergoing testing should be advised to carefully consider with whom the test result should be discussed before testing takes place.¹⁰ Health professionals should encourage, to the greatest extent possible, the sharing of this information. The person may wish to provide information directly to the relatives, or may provide consent for the health professional to provide the information.
- 3.2.2 It may be legal and ethical for health professionals to share genetic information with genetic relatives of an individual without that individual's consent in very limited circumstances if this is in the public interest. The circumstances in which the public interest exception to the requirements of confidentiality would apply are uncertain, but such disclosure may be permissible if it is necessary to prevent serious harm, and where treatment or prevention is available.^{11,12}
- 3.2.3 Health professionals need to work within the governing privacy and confidentiality of personal information set forth by appropriate State legislation. Health professionals must comply with provisions of the Commonwealth *Privacy Act (1988)* when dealing with personal identified information derived from, or held by Commonwealth agencies or private entities.
- 3.2.4 There is no formal duty for health professionals to warn the genetic relatives of their patients of any risks associated with the genetic status of the patient.¹³

Right to Respect and Dignity

4. The information that genetic tests yield have the potential to result in stigmatisation or discrimination for a group or an individual. In recognition of this, the principles 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" should be upheld.¹⁴





PART 3: Guidelines for Specific Clinical Situations

Testing of Children and Adolescents

5. The Human Genetics Society of Australasia (HGSA)¹³ has recommended that testing of children under 18 only be considered in circumstances where the result is likely to be of direct benefit to the child through medical surveillance or intervention.¹⁵
- 5.1 Health professionals need to take into consideration that testing in childhood or adolescence will eliminate the possibility for that individual to make an autonomous decision as an adult.¹⁵
- 5.2 A component of the health professional's role is to determine a child or adolescent's readiness, and competence to receive this information. Components of this process include:
 - Full discussion with the child about the testing, its risks and implications;
 - Discussion between parents and the child to be encouraged;
 - Ideally, the child should be capable of demonstrating an understanding of the nature of the tests, the risks and the implications. It is acknowledged that this is not always practical;
 - Psychological testing may be important to assess the psychological state of the child; and
 - In situations where there is significant difficulty, a second, professional opinion should be considered.¹⁵
- 5.3 A person under the age of 18 is considered to be a minor, and for many legal purposes does not have legal capacity to make decisions. In relation to health decisions a person under the age of 18 years may be considered competent to make decisions about his/her own genetic testing. This will depend on "when the child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed."¹⁶

Whilst it is preferable to only conduct genetic testing in children or adolescents under 18 years of age where there is a direct medical benefit to the child, there may be circumstances where this knowledge will benefit other family members. Some of these benefits include assisting parents to prepare children for the future and to enable the child and their parents¹⁵ to make informed life decisions. Benefits to other family members must never be to the detriment of the child's best interests.

- 5.5 The health professional should promote the child's best interests where possible.¹⁵

Adults with a Decision Making Disability

6. When seeking consent for either genetic intervention or research, consent must be obtained from:
 - The person with the intellectual or mental impairment if the person has sufficient capacity at that time to give informed consent; or
 - The person's legal guardian, or an authority or other organisation or person having the responsibility at law.³
- 6.1 No treatment or research may be undertaken which is contrary to the best interests of the person with the intellectual or mental impairment.⁵
- 6.2 Refusal by a person with an intellectual or mental impairment to participate in research must be respected.⁵



PART 3: Guidelines for Specific Clinical Situations

Pre-Implantation Genetic Diagnosis (PGD)

7. In Western Australia, the use of PGD of embryos is covered under the *Human Reproductive Technology Act 1991* (HRT Act).
- 7.1 At present genetic testing of embryos prior to implantation is not permitted. Amendments to the HRT Act that would permit PGD in cases where there is a significant risk of a serious genetic abnormality or disease being present in the embryo are currently before the Western Australian Parliament. If the amendments are passed, genetic testing of embryos will require the approval of the Reproductive Technology Council. A decision to request PGD should be a voluntary choice of the person for whom the embryo is developed.

Prenatal Diagnosis

8. The decision to undertake prenatal diagnosis procedures should be a voluntary choice made by the couple involved.
- 8.1 Prenatal diagnosis must present no pressure on couples to use the results of the test to compel either continuing or terminating a pregnancy when the fetus is affected with a genetic disorder.¹⁷

Bio-engineered Medicines and Procedures

9. All medicines and procedures developed for use in health care that have a biotechnological base should meet the highest standards of safety and comply with all requirements of the Commonwealth Therapeutic Goods Administration (TGA).¹⁸

Gene Therapy

10. Gene therapy is at an experimental stage and proposals to undertake this therapy must be reviewed and approved by the NHMRC's Gene and Related Therapies Research Advisory Panel (GTRAP), the Institutional Biosafety Committee for the institution where the research is occurring, and the relevant HREC.¹⁹





Part 4: Human Genetic Research Guidelines

Research Involving Humans

11. Research results, genetic material and information may be of significance to the health of blood relatives, including those who have not consented to participate in the research.¹⁹ Researchers should endeavor to weigh up the balance among these considerations when formulating, reviewing and conducting research studies involving human genetics.
 - 11.1 Research involving humans must comply with all relevant NHMRC guidelines, in particular the *National Statement on Ethical Conduct in Research Involving Humans* (1999).
 - 11.2 The *National Statement* requires that genetic research is required to be reviewed and approved by a multidisciplinary Human Research Ethics Committee (HREC) established by the institution for the purpose of providing ethical oversight of research proposals. This committee comprises:²⁰
 - A Chairperson;
 - Two lay people, one man and one woman who have no affiliation with the organisation;
 - A member with knowledge of and current experience in areas of research that are regularly considered by the HREC;
 - A member who has knowledge of and current experience in the professional care, counselling or treatment of people;
 - A member who is a minister of religion or a person who performs a similar role in a community; and
 - A member who is a lawyer.
 - 11.3 A fundamental aspect of research is the careful consideration of the importance of the ethical principles of respect for the persons, justice, beneficence, non-maleficence and co-dependency.⁵

Informed Consent for Research Studies

12. It is generally accepted that where researchers are attempting to use genetic information, be it stored or otherwise, for the purposes of research, informed consent must be sought from the person to whom the material relates.
 - 12.1 The NHMRC *National Statement* provides comprehensive guidance on what issues must be addressed in order to ensure consent is informed.
 - 12.2 There are circumstances where the requirements for consent may be waived by a HREC, and guidelines for this are documented in the NHMRC *National Statement*. Where the research involves the collection, use or release of personal information, involving a Commonwealth or private organisation, the requirements of Section 95 or 95 (a) of the *Privacy Act (1988)* must be observed before the need for consent can be waived.



Part 4: Human Genetic Research Guidelines

- 12.3 Researchers should ensure that consent procedures take into consideration the likelihood that the genetic information donated for research purposes may be used in future research for which the purpose is currently unknown. Further guidance may be found in the NHMRC *National Statement* and in the National Privacy Principles under the *Privacy Act (1988)*.
- 12.4 In cases where consent has only been given for the information to be used for specific research purposes, the researcher is obliged to obtain consent for using the information for purposes other than those specified. Again, further guidance may be found in the NHMRC *National Statement* and in the National Privacy Principles under the *Privacy Act (1988)*.
- 12.5 Researchers wishing to utilise genetic information collected for non-research purposes need to discuss the ethics of this with their HREC. It is appropriate that these individuals be given the opportunity to refuse consent for their material to be used. Furthermore, researchers should be considerate of the potential for genetic research results to be of clinical significance for family members other than the individual involved. In some cases, this information may create options that have the potential to improve current or future health. However, some family members may prefer not to be given information which may lead to knowledge of current or future health risk. This issue must be taken into consideration when determining consent procedures.¹⁹
- 12.6 Researchers must also be aware of the sensitivities to cultural and social beliefs and practices when obtaining consent.¹⁷ In circumstances where testing or research is performed on population groups, it is important to seek approval from the community involved, as well as from the individual if this is appropriate practice for the culture concerned.²¹
- 12.6.1 In relation to research involving Aboriginal and / or Torres Strait Islander people, researchers should consult the relevant NHMRC guidelines on this issue. At present the NHMRC are revising their document *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (1991)*.¹⁹ Health professionals should adhere to the replacement document once this becomes available.
- 12.7 NHMRC guidelines encourage the following issues to be satisfied before research with collectives is conducted:
- Whether, in addition to individual consent, collectivity leaders should be consulted for approval;
 - Issues of consent, privacy, confidentiality and harms within the collectivity, to either individuals or the collectivity;
 - The ownership of data and the manner of dissemination of research findings;
 - The manner in which disagreements between the researcher and the collectivity will be resolved; and
 - Whether arrangements to address the above issues have followed a process of negotiation.²¹



Part 4: Human Genetic Research Guidelines

- 12.7.1 Health professionals are encouraged to manage communication within specific cultural groups on a case by case basis.
- 12.8 It should also be noted that whilst researchers must endeavour to gain consent from participants for research purposes, there is likewise an obligation on behalf of individuals to notify organisations of changes in circumstances which would hinder the attainment of consent.

Cloning and Related Technologies

- 13. In Western Australia the therapeutic cloning of embryos is prohibited under the *Human Reproductive Technology Act (1991)*, and is also prohibited under The Commonwealth *Prohibition of Human Cloning Act (2002)*.





References

1. Limentani, A. (1999). The role of ethical principles in health care and the implications for ethical codes. *Journal of Medical Ethics*, 25, 394-398.
2. Australian Law Reform Commission. (2003). *Report 96: Essentially Yours: Protection of human genetic information in Australia*. Chapter 6, pp. 217-232.
3. Beauchampe, T., & Childress, J. (1979). *Principles of biomedical ethics*. New York: Oxford University Press.
4. Otlowski, M., & Williamson, R. (2003). Ethical and legal issues and the "new genetics". *Medical Journal of Australia*, 178, 582-585.
5. Department of Health, Education and Welfare. (1976). Belmont Report: *Ethical Principles and guidelines for the protection of human subjects of research*. Available at: <http://www.csu.edu.au/learning/ncgr/gpi/odyssey/privacy/Belmt.html>
6. World Health Organisation. (2002). *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services*. Available at: <http://www.who.int/ncd/hgn/hgnethic.htm>
7. Human Genetics Society of Australasia. (July 1998). *Policy Paper: DNA Predictive Testing for Genetic Disorders*. Available at: http://www.hgsa.com.au/policy/GPractGC_Sept99.htm
8. Human Genetics Society of Australasia. (July 1998). *Policy Paper: DNA Predictive Testing for Genetic Disorders*. Available at: <http://www.hgsa.com.au/policy/dnaptgd.html>
9. Human Genetics Society of Australasia. (March 1999). *Privacy Implications of Genetic Testing*. Available at: <http://www.hgsa.com.au/policy/pigt.html>
10. National Health and Medical Research Council. (2000). *Ethical Aspects of Human Genetic Testing: An Information Paper*.
11. Australian Medical Association. (1996). Code of Ethics. Available at <http://www.ama.com.au/webnsf/doc/SHED-5FK44X>
12. Knoppers, B.M., Strom, C., Wright Clayton, E., Murray, T., Fibison, W., & Luther, L. (1998). Professional disclosure of familial genetic information. *American Journal of Human Genetics*, 62, 474-483.
13. Australian Law Reform Commission and the Australian Health Ethics Committee. (October 2001). *Issues Paper 26: Protection of Human Genetic Information*.
14. UNESCO. (November 1997). *Universal Declaration on the Human Genome and Human Rights*. Available at: <http://www.unesco.org/ibc/en/genome/>
15. Human Genetics Society of Australasia. (March 1999). *Policy Paper: Predictive Testing in Children and Adolescents*. Available at: <http://www.hgsa.com.au/policy/ptca.html>
16. Department of Health Western Australia. (October 2000). Operational Circular: Guidelines for health practitioners: Patient consent to treatment and disclosure of material risks.
17. World Health Organisation. (2002). *Report of the Advisory Committee on Health Research: Genomics and World Health*.



References

18. Department of Innovation and Information Economy. (September 2001). *Code of Ethical Practice for Biotechnology in Queensland: Advancement through safe and ethical science*.
19. National Health and Medical Research Council. *Gene and Related Therapies Research Advisory Panel (GTRAP)*. Available at: <http://www.health.gov.au/nhmrc/research/gtrap/about.htm>
20. National Health and Medical Research Council. (1999). *National Statement on Ethical Conduct in Research Involving Humans*.
21. National Health and Medical Research Council. (2002). Draft Values and Ethics in Aboriginal and Torres Strait Islander Health Research. Consultation paper for the revision of the NHMRC *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research* (1991). Available at: <http://www.nhmrc.gov.au/issues/pdf/values.pdf>





Appendix: Legislation, Guidelines and Policies Relevant to this Code

AUSTRALIAN HEALTH ETHICS COMMITTEE (AHEC)

Scientific, ethical and regulatory considerations relevant to cloning of human beings (1998)

AHEC / AUSTRALIAN LAW REFORM COMMISSION

Website Link: <http://www.alrc.gov.au>

Protection of Human Genetic Information: Issues Paper 26. (October 2001)

Protection of Human Genetic Information: Discussion Paper 66 (August 2002)

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

Website Link: <http://www.nhmrc.gov.au>

National Health and Medical Research Council Act 1992 (Cth)

National Statement on Ethical Conduct in Research Involving Humans (1999)

Ethical Guidelines on Assisted Reproductive Technology (1996)

Guidelines for Ethical Review of Research Proposals for Human Somatic Gene Cell Therapy and Related Therapies (2000)

Guidelines for Genetic Registers and Associated Genetic Material (2000)

Ethical Aspects of Human Genetic Testing: An Information Paper (2000)

HUMAN GENETICS SOCIETY OF AUSTRALASIA

Website Link: <http://www.hgsa.com.au>

Australian Society of Genetic Counsellors Code of Ethics (2000)

DNA Presymptomatic and Predictive Testing for Genetic Disorders (2002)

Guidelines for Human DNA Banking (1990)

Guidelines for the Application of DNA Techniques for the Diagnosis of Human Genetic Disorders (1990)

Human Cloning (1999)

Newborn Screening (1999)

Prenatal Diagnosis Policy (2001)

Privacy Implications of Genetic Testing (1999)

Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs.

Predictive Testing in Children and Adolescents (2003)

THERAPEUTIC GOODS ADMINISTRATION

Website Link: <http://www.health.gov.au/tga/>

Therapeutic Goods Act 1989 (Cth)





Appendix: Legislation, Guidelines and Policies Relevant to this Code

OFFICE OF THE GENE TECHNOLOGY REGULATOR

Website Link: <http://www.health.gov.au/tga/genetech.htm>

Gene Technology Act 2000 (Cth)

Gene Technology Regulations 2001 (Cth)

WESTERN AUSTRALIAN REPRODUCTIVE TECHNOLOGY COUNCIL

Website Link: <http://numbat.murdoch.edu.au/RTC/rtchome.html>

COMMONWEALTH LEGISLATION

Prohibition of Human Cloning Act (2002)

Research Involving Human Embryos Act (2002)

Links for useful organisations:

Genetic Services of Western Australia

http://wchs.health.wa.gov.au/services/health_prof/csd/detail.php?deptid=96&clin_ord=Y&PHPSESSID=71895658ffed83ff36037500ae70d821

Genetic Support Council WA (Inc)

<http://www.geneticsupportcouncil.org.au/index.asp>

Genomics Directorate, Department of Health Western Australia

<http://www.population.health.wa.gov.au/Genomics/index.cfm>

The Nuffield Council on Bioethics

<http://www.nuffieldbioethics.org/home/>

The Royal Australasian College of Pathologists

<http://www.rcpa.edu.au>

The Wellcome Trust

www.wellcome.ac.uk/genome

World Health Organisation

<http://www.who.int/en/>



