Australian Law Reform Commission and Australian Health Ethics Committee Report
Essentially Yours: The Protection of Human Genetic Information in Australia

Government Response to Recommendations

INTRODUCTION

The inquiry into the legal and ethical issues surrounding the protection of human genetic information was conducted pursuant to a joint reference to the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee of the National Health and Medical Research Council (AHEC) by the former Attorney-General and the former Minister for Health and Aged Care.

The focus of the ALRC/AHEC inquiry was the rapid advances in human genetic technology. The inquiry was prompted by concerns about privacy and discrimination, especially in the contexts of insurance and employment, and about ethical and other oversight of medical and scientific research, clinical practice, and the use and collection of genetic databases.

The use of gene technology poses sensitive legal and ethical dilemmas. It also provides an exciting opportunity to use technology wisely to improve the human condition. The challenge is to obtain benefits from genetic information without compromising the personal privacy we value and expect our society to protect.

The ALRC/AHEC inquiry sought expert advice on the diverse areas of law and medicine dealt with in the report, ***Essentially Yours: The Protection of Human Genetic Information in Australia.*** It established an advisory committee, working group and panel of consultants.

The report has also been informed by an extensive consultation process, with the ALRC and AHEC holding open forums and meetings with interested parties in Australia and overseas. The report followed publication of an issues paper and a discussion paper. Over 300 written submissions were received from the general community as well as experts and interest groups.

The Report

The ARLC/AHEC report contains 144 wide ranging recommendations covering information privacy, protection against unfair discrimination in employment and insurance, the use of genetic information in forensic investigations and parentage testing and ensuring the highest ethical standards in medical research and practice. The recommendations in the report are directed at Commonwealth, State and Territory governments as well as statutory authorities.

In preparing its response, the Government has considered carefully the recommendations that are directed to it. The recommendations affect many Australian Government agencies. It has also written to State and Territory governments, drawing their attention to relevant recommendations.

The Government has already taken action on some recommendations. Other issues are also being considered, in collaboration with State and Territory Governments, through the Standing Committee of Attorneys-General and the Australian Health Ministers' Conference. Key themes of the report and the Government's response are addressed below.

A Human Genetics Advisory Committee

One of the key recommendations in the report is that a statutory body be established to provide advice to Australian governments about current and emerging issues in human genetics. The Government has agreed to establish an independent expert advisory body on human genetics. The Government will provide new funding of $7.6 million over four years from 2005-6 to establish the body as a principal committee of the National Health and Medical Research Council. The Committee will provide on-going advice to government on high-level technical and strategic issues in human genetics.

Regulatory Framework

Genetic information is a type of information, but it is not a totally new type of information. It is a more sophisticated form of information that we have been dealing with for a long time, such as in blood tests, fingerprinting and physical observation of familial characteristics. Some genetic information is shared with our family members, referred to in the report as genetic relatives.

The Government agrees with the report that a separate regulatory regime for genetic information is unnecessary (see report pp140-1). Instead, it considers that genetic information should remain within the protective framework that the *Privacy Act 1988* (Cth) provides. It agrees that genetic information should be characterised as 'sensitive information' under the Act. This means that the uses, manner of collection and storage of such information will be given additional protection under the Act.

However, the Government acknowledges that additional legislative protection may be required to ensure appropriate safeguards in the uses that may be made of genetic information. For example, the Government has accepted recommendations 7-4 and 7-5 to fine tune the definitions of 'health' and 'sensitive information' in the Privacy Act.

The fundamental concept that the Privacy Act does not prevent a person consenting to disclosures or uses of their personal information remains. This means that an individual may consent to his or her own genetic information being used for valuable research.

The Government also agrees that in the area of discrimination, any potential misuses of genetic information should be dealt with within the existing context

of the *Disability Discrimination Act 1992* (Cth) (see report page 301). This approach is consistent with the general approach that a separate regulatory regime for genetic information is unnecessary.

Ethical Guidelines for Genetic Testing and Human Genetic Research

The Report proposes improving and strengthening ethical guidelines, including those made by the National Health and Medical Research Council (NHMRC). Ethical guidelines are instruments which do not have the force of legislation and are traditionally used by professional associations to govern the behaviour of their members. The NHMRC has indicated to the Government that it is already addressing the report's recommendations in its review of the *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement).

Parentage Testing

The report makes a number of recommendations dealing with genetic testing for parentage. The report's main concern is that testing is regulated to ensure the highest quality technical and ethical standards. The Government response notes that recommendations dealing with consent, counselling and single parent testing will be considered by the National Association of Testing Authorities, Australia (NATA) in its review of accreditation requirements. The Government does not consider that additional legislation is needed to regulate testing as there is already a strong accreditation system in place where test results are used in family law or immigration proceedings. As noted in the response, the Government is currently reviewing the relevant family law regulations in conjunction with the NATA review of accreditation requirements.

Criminal Law and the use of DNA

The report makes recommendations about the forensic uses of genetic information. It discusses the use of DNA material in criminal investigations and proceedings. It recommends the creation of a new criminal offence for testing a person's genetic material without consent. The report also discusses how DNA material can assist in the identification of deceased persons. DNA identification played an important role in the identification of victims of the Bali nightclub bombings on 12 October 2002. The report discusses the Australian Government's 'rapid and effective' establishment of a new DNA database for disaster victim identification in the aftermath of the bombings. It also discusses how the national DNA databases are operating.

The report highlights the importance of national co-operation and harmonisation of criminal laws relating to the storage and forensic uses of genetic information. The Government has already implemented some recommendations. It agrees that harmonisation of the laws is vital. It has been working with State and Territory Governments on the recommendations and has referred matters raised by the report to the Standing Committee of Attorneys-General and Australasian Police Ministers Council Joint Working Group.

The Government has already implemented some recommendations. It will be continuing this task through collaboration with other organisations such as the National Association of Testing Authorities, Australia. It will urge State and Territory Governments to implement the recommendations directed at them through the Standing Committee of Attorneys-General, and Australasian Police Ministers Council Joint Working Group. The Government will also encourage other organisations that are the subject of recommendations to give them serious consideration.

The Government's full response to the recommendations of the Australian Law Reform Commission, Australian Health Ethics Committee report, *Essentially Yours: The Protection of Human Genetic Information in Australia* is set out below.

CHAPTER 5 A HUMAN GENETICS COMMISSION OF AUSTRALIA

Recommendation 5–1
The Commonwealth should establish a Human Genetics Commission of Australia (HGCA) under federal legislation as an independent statutory authority with sufficient resources to fulfil its mission.

Recommendation 5–2
As a general matter, the role of the HGCA should be to provide:

- on-going, high-level, technical and strategic advice to Australian governments about current and emerging issues in human genetics;
- similar high-level advice on the ethical, legal and social implications arising from these developments, including consideration of any impact on human rights, and analysis of cost-benefit issues;
- national leadership in managing the process of change in relation to human genetics, including engagement of the public on these issues;
- relevant expertise and a consultative mechanism for the development of policy statements and national guidelines in this area, where appropriate in association with other government agencies or the relevant industries and organisations;
- assistance with the development and coordination of community, school, university and professional education about human genetics;
- advice and a consultative mechanism to assist relevant bodies in identifying strategic priorities for research in human genetics; and
- a focus for the coordination and integration of various national—and perhaps regional and international—programs and initiatives.

Recommendation 5–3
The HGCA also should have specific role in:

- identifying genetic tests that have particular concerns or sensitivities attached to them, and thus may require special treatment;

- making recommendations about the suitability of specific genetic tests (and the appropriate analysis and treatment of results) for use by the insurance industry (for example for risk-rating purposes), and by employers (for example for occupational health and safety reasons);
- performing any similar function or providing expert advice on any other matters relating to human genetics, whether on its own motion or in response to a formal reference from the responsible minister or ministers; and
- monitoring the implementation of the broad strategies and specific recommendations identified in this Report.

Recommendation 5–4
The HGCA structure should involve at least two principal committees: (a) a Technical Committee, and (b) an Ethical, Legal and Social Implications Committee. However, this should not preclude the HGCA from establishing other committees or working groups (for example, on education, or community consultation) from time to time, as it sees fit.

Recommendation 5–5
Appointments to the HGCA should ensure a balanced and broad-based range of expertise, experience and perspectives relevant to the evaluation and delivery of genetic health services, and the use and protection of human genetic information and genetic samples. The appointments process should involve consultation with state and territory governments, relevant communities and other stakeholders.

Recommendation 5–6
The HGCA should operate in an open and transparent manner, to the greatest extent practicable, in order to promote public confidence and engage the wider community in uses of human genetic information.

Recommendation 5–7
The HGCA should be required to present an annual report to Parliament and also should be empowered to make such other reports to Parliament from time to time as it sees fit.

Recommendation 5–8
The HGCA should liaise closely with relevant government departments and authorities, as well as other key stakeholders, in order to promote a national approach to the protection of human genetic information.

Recommendation 5–9
The HGCA should be subject to a basic review two years after establishment, and then a more thorough, independent review after five years of operation.

Response[1]
The Government has agreed to the establishment of an independent advisory body for the provision of high-level advice to Australian governments on human genetic issues and the complex issues raised by the rapid developments in human genetic and related technologies. The Government will provide new funding of $7.6 million over four years from 2005-6 to establish the body as a principal committee of the National Health and Medical Research Council.

The Committee will provide on-going advice to government on high-level technical and strategic issues in human genetics, and on the social, ethical and legal implications of these technologies. It will provide national leadership in responding to new developments in human genetic and related technologies, including engagement of the public on these issues. It will also monitor the emergence of new technologies and give early advice on their potential, including cost and other impacts.

The Government notes that existing advisory bodies, such as the National Health and Medical Research Council, through its Research Committee, Health Advisory Committee and the Australian Health Ethics Committee (AHEC), play an important role in advising government in relation to medical research and ethics. Establishing a specific genetics advisory body within the NHMRC will be an effective mechanism to provide advice to Australian governments on the complex issues raised by the rapid developments in human genetic and related technologies.

The Government agrees that the provision of a balanced and broad-based range of expertise, experience and perspectives in the membership of the proposed body is essential and will assist in fostering community confidence in it.

REGULATORY FRAMEWORK

CHAPTER 7 INFORMATION AND HEALTH PRIVACY LAW

Recommendation 7–1
As a matter of high priority, the Commonwealth, States and Territories should pursue the harmonisation of information and health privacy legislation as it relates to human genetic information. This would be achieved most effectively by developing nationally consistent rules for handling all health information. (See also Recommendation 8–1 in relation to genetic samples.)

Recommendation 7–2
States and Territories and privacy regulators should consider harmonising their privacy regimes, as applicable, in a manner consistent with the

[1] The Government's responses appear immediately below each of the report's recommendations. Where appropriate, the Government has provided a single response to a number of recommendations.

Recommendations in this Report. (See also Recommendations 7–4 to 7–7, 8–1 to 8–4, 21–1 to 21–3, and 22–1.)

Recommendation 7–3
The Commonwealth, States and Territories should take into account the Recommendations in this Report in developing the proposed National Health Privacy Code. (See also Recommendations 7–4 to 7–7, 8–1 to 8–4, 21–1 to 21–3, and 22–1.)

Response
The Government supports these recommendations.

As noted in the report, Commonwealth, State and Territory Health Ministers established a National Health Privacy Working Group in July 2000 to develop a national health policy framework to achieve national consistency for privacy arrangements across both the public and private sectors throughout Australia. The proposed National Health Privacy Code is the key element of that framework.

The draft Code was finalised in late 2003 following consideration of submissions received as part of an extensive consultation process in 2002 and 2003. The Code contains national health privacy principles based on privacy principles in Commonwealth, State and Territory legislation.

In developing and revising the draft Code, the Privacy Working Group considered the recommendations in this report. The Code is currently under consideration by Health Ministers.

Recommendation 7–4
The Commonwealth should amend s 6 of the *Privacy Act 1988* (Cth) (*Privacy Act*) to define 'health information' to include genetic information about an individual in a form which is or could be predictive of the health of the individual or any of his or her genetic relatives. (See also Recommendation 8–2 in relation to genetic samples.)

Response
The Government supports this recommendation in principle. The Government notes that this recommendation has been considered in the context of the proposed National Health Privacy Code. The definition of health information in the Code expressly includes genetic information.

Recommendation 7–5
The Commonwealth should amend s 6 of the *Privacy Act* to define 'sensitive information' to include human genetic test information.

Response
The Government supports this recommendation in principle.

The Privacy Act provides additional protection for sensitive personal information when the information is handled by a private sector organisation. Sensitive information is defined in subsection 6(1) of the Act to include health

information. As noted above, it is proposed that the definition of health information be amended to expressly refer to genetic information. However, there may be other genetic information, such as the result of a parentage or kinship test, that is not health information. Amending section 6 of the Privacy Act as suggested will ensure that such information is also treated as sensitive information and will attract the additional protection provided by the Act.

Recommendation 7–6
The Commonwealth should amend the *Privacy Act* to provide that 'health information' includes information about an individual who has been dead for 30 years or less. These amendments should include provision for decision making by next-of-kin or an authorised person in relation to the handling of a deceased individual's health information. (See also Recommendation 8–2 in relation to genetic samples.)

Response
This Government notes that this recommendation is being considered in the context of the development of the National Health Privacy Code.

Recommendation 7–7
The Commonwealth should amend the *Privacy Act* to ensure that all small business operators that hold genetic information are subject to the provisions of the Act. (See also Recommendation 8–2 in relation to genetic samples.)

Response
The Government does not support this recommendation.

The Government recognises that many small businesses are a low privacy risk and has provided that they are exempt from coverage under the Privacy Act. However, where a small business provides a health service, trades in personal information, provides services under a contract with the Australian Government, or is part of a larger business covered by the Privacy Act, it is required to comply with the Act.

The Government considers that this coverage is sufficient to protect the privacy of genetic information that may be held by small businesses while at the same time ensuring that small businesses are not unfairly burdened by the costs and processes of complying with the privacy legislation.

CHAPTER 8 PRIVACY OF GENETIC SAMPLES

Recommendation 8–1
The Commonwealth, States and Territories should enact legislation to provide legally enforceable privacy standards for handling genetic samples, including in relation to the collection, storage, use and transfer of samples. The standards should be consistent with those that apply to the handling of genetic information derived from the analysis of genetic samples under existing information and health privacy legislation such as the *Privacy Act 1988* (Cth) (*Privacy Act*).

Recommendation 8–2
The Commonwealth should amend the *Privacy Act* to extend the coverage of the Information Privacy Principles and National Privacy Principles (or similar privacy principles) to identifiable genetic samples. This may be done by:

(a) defining 'personal information' and 'health information' to include bodily samples from an individual whose identity is apparent or can reasonably be ascertained from the sample; and

(b) defining a 'record' to include a bodily sample.

Response
The Government does not accept these recommendations.

The Privacy Act is the appropriate vehicle for ensuring the privacy protection of personal information derived from genetic samples but the Act should not cover the handling of genetic samples. The privacy principles are designed to regulate the collection, use and disclosure of personal information, not the source of that information.

Accordingly, the Government does not consider that privacy legislation is the appropriate place for regulating genetic samples.

The concerns raised about the use and handling of genetic samples could be addressed in the Human Tissues Acts. In addition, issues raised about samples used in research could also be dealt with by revision of relevant ethical research guidelines.

Recommendation 8–3
The Commonwealth should amend the *Privacy Act* to provide that an individual has a right to access his or her own bodily samples, through a nominated medical practitioner, for the purpose of medical testing, diagnosis or treatment. The right of access should be limited to a right to obtain access to part of the sample. Access may be refused where:

(a) it is not physically possible to provide part of a sample;

(b) providing part of a sample means that the remaining portion is insufficient for the purposes of the organisation retaining it; or

(c) releasing a sample to an individual raises public health concerns.

Response
The Government does not support this recommendation.

As noted above, the Government does not consider that the Privacy Act is the appropriate vehicle for regulating genetic samples. Information derived from a genetic sample is accessible to that individual through existing rights under the Privacy Act.

As most genetic information needed for the purposes of medical testing, diagnosis and treatment could be readily obtained through a new genetic

sample, there is no apparent need served by the creation of a right of access to previously donated bodily samples.

Recommendation 8–4
The Commonwealth should amend the *Privacy Act* to provide that an individual has a right to access bodily samples of his or her first-degree genetic relatives, through a nominated medical practitioner, where access is necessary to lessen or prevent a serious threat to his or her life, health, or safety, even where the threat is not imminent. The right of access should be limited to a right to obtain access to part of the sample. Where an organisation subject to the *Privacy Act* receives a request for access, the organisation should be obliged to seek consent from the genetic relative, where practicable, before determining whether to provide access. Access may be refused where:

(a) it is not physically possible to provide part of a sample;

(b) providing part of a sample means hat the remaining portion is insufficient for the purposes of the organisation retaining it;

(c) releasing a sample to an individual raises public health concerns; or

(d) providing access would have an unreasonable impact upon the privacy of the individual from whom the sample comes.

Response
The Government does not accept that an individual should have a right to access bodily samples of his or her first-degree genetic relatives.

First-degree genetic relatives, who suspect that a relative's genetic sample contains important genetic information that could lessen or prevent a serious threat to his or her life, health, or safety**,** could easily access that genetic information by undertaking a genetic test themselves. This assumes that the person understands the basic nature of the genetic risk that they face. In the absence of such knowledge, access to their relative's sample, as distinct from the relevant genetic information contained in that sample, would provide little advantage.

CHAPTER 9 ANTI-DISCRIMINATION LAW

Recommendation 9–1
Discrimination on the ground of genetic status should continue to be dealt with under the framework of existing federal, state and territory anti-discrimination laws, subject to the legislative amendments and other safeguards recommended in this Report.

Response
The Government accepts this recommendation in principle**.** It agrees that discrimination based on genetic status should not be the subject of 'stand alone' legislation. However, the Government acknowledges that additional legislative protection may be required to ensure appropriate safeguards in the uses that may be made of genetic information. Consistent with this approach, the Government has accepted

recommendations 7-4 and 7-5 to fine tune the definitions of 'health' and 'sensitive information' in the Privacy Act.

Recommendation 9–2
The Commonwealth should amend the objects clause of the *Disability Discrimination Act 1992* (Cth) (DDA) to clarify that the Act applies to discrimination in relation to past, present, possible future or imputed disability, including discrimination on the ground of genetic status.

Response
The Government does not accept this recommendation. The Productivity Commission has recently reviewed the *Disability Discrimination Act 1992* (DDA). The Government's response to that report was tabled on 27 January 2005. The Government agrees with the Productivity Commission's Finding 7.4 that the objects of the DDA are appropriate and do not require amendment.

Recommendation 9–3
In order to provide a consistent approach to addressing discrimination on the basis of genetic status, the Commonwealth, in consultation with the Human Genetics Commission of Australia and other stakeholders, should:

- amend the definitions of 'disability' in the DDA and 'impairment' in the regulations made under the Human Rights and Equal Opportunity Commission Act 1986 (Cth) (HREOC Act) to clarify that the legislation applies to discrimination based on genetic status;
- amend the definition of 'impairment' in the regulations made under the HREOC Act to clarify the application of the legislation to a disability that may exist in the future; and
- define 'disability' in the *Workplace Relations Act 1996* (Cth) by reference to the definition of 'disability' in the DDA.

Recommendation 9–4
The Commonwealth should amend the definition of 'impairment' in the regulations made under the HREOC Act to include discrimination on the basis of association with a person who has an impairment or disability.

Response
These recommendations are consistent with the Government's policy to eliminate discrimination, as far as possible, in all areas of community life. The Government aims to ensure that people with disabilities have the same rights to equality before the law as the rest of the community by promoting recognition and acceptance of the principle that persons with disabilities have the same fundamental rights as the rest of the community.

The Productivity Commission's recommendations in its *Review of the Disability Discrimination Act* partly overlap with the ALRC's recommendations, with respect to the definition of disability. Recommendation 11.1 of the Productivity Commission review is:

Recommendation 11.1
The definition of disability in the Disability Discrimination Act 1992 (s.4) should be amended to ensure that it is clear that it includes:

- *medically recognised symptoms where the underlying cause is unknown*
- *genetic predisposition to a disability that is otherwise covered by the Act.*

A note should be added to the Act to explain that behaviour that is a symptom or manifestation of a disability is part of the disability for the purposes of the Act.

In its response to that recommendation, the Government supported the Productivity Commission's underlying objective of clarifying the scope of the definition of disability to make it clear that it includes genetic predisposition to a disability and accepted the recommendation in part.

In that context, the Government agreed that an advisory note will be inserted into the DDA to clarify that the definition of disability for the purposes of the DDA includes a genetic predisposition to a disability. The Government agrees with the view that, for the purposes of the DDA, the relevant genetic condition, predisposition or status should be clearly linked to a disability as defined in the DDA. It is desirable that proposals for legislative amendment are carefully considered to overcome any implication that genetic variation automatically equates to a disability.

The Government also agrees that the definition of 'impairment' in the HREOC regulations should be clarified to ensure that impairment includes a disability that may exist in the future. The Government will amend the regulations to insert an advisory note that 'impairment' includes a genetic predisposition to impairment. The Government accepts recommendation 9-4 that the definition of 'impairment' in the HREOC regulations should also be clarified to ensure that impairment includes discrimination on the basis of association with a person who has an impairment or disability.

The Government does not accept the recommendation to define disability in the *Workplace Relations Act 1996* by reference to the DDA. This would be inconsistent with the structure of that Act which does not define any of the relevant grounds of discrimination but requires the Australian Industrial Relations Commission to have regard to the anti-discrimination legislation including the DDA in performing its functions.

Recommendation 9–5
The States and Territories should consider harmonising their anti-discrimination legislation, and other relevant laws, in a manner consistent with the recommendations in this Report.

Response
This recommendation is a matter for the States and Territories. The Government has written to the States and Territories drawing this recommendation, and other relevant recommendations, to their attention.

GENETIC TESTING

CHAPTER 11 REGULATING ACCESS TO GENETIC TESTING

Recommendation 11–1
In order to complement existing pathology laboratory accreditation arrangements, the Commonwealth, States and Territories should enact legislation to require laboratories to: (a) be accredited for any genetic test that they conduct for medical, diagnostic or treatment purposes; and (b) comply with the relevant accreditation standards. The legislation should make provision for exemptions in appropriate circumstances, such as for genetic tests performed by research laboratories.

Response
The Government supports this recommendation but notes that it is primarily a matter for State and Territory governments. In the federal sphere, the Therapeutic Goods Administration (TGA), following endorsement by the Australian Health Ministers' Conference (AHMC) and the Australian Health Ministers' Advisory Council (AHMAC), is finalising legislation for the regulation of in-vitro diagnostic devices (IVDs) for therapeutic use, both those supplied commercially and manufactured in house. The regulatory model includes four risk classes of IVDs, Class 1 being the lowest risk and Class 4 being the highest risk. Genetic tests will fall under either Class 2 or 3. The majority, being for predictive screening, are expected to be Class 3, when the outcome of the test would ordinarily result in a substantial impact on the life of the individual. Genetic tests used for research purposes will be exempt from regulation.

Recommendation 11–2
While the primary focus of laboratory accreditation should remain on matters of technical proficiency and scientific reliability, the National Pathology Accreditation Advisory Council (NPAAC) should continue to develop ethical standards for medical genetic testing, in consultation with the Human Genetics Commission of Australia and the National Health and Medical Research Council.

Response
The Government supports, in principle, the development of ethical standards for medical genetic testing but notes that this recommendation is a matter for NPAAC.

The National Health and Medical Research Council (NHMRC) has developed many clinical and ethical guidelines. NPAAC requires laboratories to conduct tests in accordance with these guidelines.

NPAAC has advised that it will address ethical issues when updating relevant guidelines. These issues will be considered in its current review and update of the Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection Techniques. The review of the NPAAC Guidelines for Cytogenic Laboratories will also give consideration to ethical issues.

Recommendation 11–3
NPAAC, in consultation with the National Association of Testing Authorities, Australia (NATA) and the Royal College of Pathologists of Australasia (RCPA), should examine how compliance with its accreditation standards in relation to consent, counselling and other ethical considerations in medical genetic testing should be assessed as part of the NATA/RCPA accreditation process.

Response
The Government supports this recommendation and notes that implementation is a matter for NPAAC. NPAAC has advised that it is currently reviewing its accreditation standards in relation to consent, counselling and other ethical considerations. It anticipates that the proposed new standards will be released for public comment.

Recommendation 11–4
NATA, in consultation with the RCPA, should develop training programs to equip its officers and peer assessors to verify compliance with NPAAC accreditation standards relating to consent, counselling and other ethical considerations.

Response
The Government supports this recommendation and notes that implementation is a matter for NATA. NATA has advised that it will continue to provide training sessions for its assessors on relevant topics and can expand its training program to cover these issues as required.

Recommendation 11–5
The Commonwealth should amend the *Therapeutic Goods Act 1989* (Cth) (*Therapeutic Goods Act*) and regulations made under that Act to enable the Therapeutic Goods Administration (TGA) to regulate more effectively in vitro diagnostic devices used in genetic testing provided directly to the public.

Response
A working group, the National Coordinating Committee on Therapeutic Goods In Vitro Diagnostic Devices Working Group, established under the Australian Health Ministers' Advisory Council (AHMAC) has examined these issues. The working group has recommended that all health related in vitro diagnostic devices intended for home use (that is, tests not carried out under the supervision of a health care provider) should be regulated in accordance with the risk class of the test, taking into account particularly the aspects relating to the use of the test by the lay person. In October 2003, the matter was referred to AHMAC for consideration and AHMAC endorsed the banning of all health related home use genetic tests.

Recommendation 11–6
The Commonwealth should amend the *Therapeutic Goods Act* and regulations made under that Act to enable the TGA to regulate DNA identification test kits used in genetic testing provided directly to the public, including for parentage and other kinship testing.

Response
The Government does not accept this recommendation.

DNA identification tests, including parentage testing, are not covered by the Therapeutic Goods Act as they are not for therapeutic use. The Government does not propose, at this stage, to include such tests within the scope of the Therapeutic Goods Act (see also recommendation 35-1).

Recommendation 11–7
The HGCA should develop codes of practice and advice relating to technical and ethical standards for genetic testing services provided directly to the public, including advice to the TGA or its statutory advisory committees.

Response
The Government agrees in principle with this recommendation but notes that it is a matter for the proposed genetics advisory body.

It should be noted that, in their response to the TGA's consultation on home use IVD tests, the Human Genetics Society of Australasia did not support the use of health related genetic tests in the home setting. AHMAC endorsed this approach. Therefore any Code of Practice should exclude health related genetic tests for home use as the decision of AHMAC is that such tests not be permitted.

CHAPTER 12 A NEW CRIMINAL OFFENCE

Recommendation 12–1
The Standing Committee of Attorneys-General should develop a model criminal offence relating to non-consensual genetic testing, for enactment into Commonwealth, state and territory law. Criminal liability should attach to any individual or corporation that, without lawful authority, submits a sample for genetic testing, or conducts genetic testing on a sample, knowing (or recklessly indifferent to the fact) that the individual from whom the sample has been taken did not consent to such testing.

Response
The Government supports this recommendation. It has referred the proposal for a model criminal offence relating to non-consensual genetic testing to the Standing Committee of Attorneys-General (SCAG) for consideration after advice from the Model Criminal Code Officers Committee. The Commonwealth Attorney-General will recommend that SCAG consult with relevant government bodies, including the Australian Health Ministers' Advisory Council, when considering this proposal.

HUMAN GENETIC RESEARCH

CHAPTER 14 ENFORCING COMPLIANCE WITH THE NATIONAL STATEMENT

Recommendation 14–1
The National Health and Medical Research Council, as part of its review of the *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement) in the 2003–2005 triennium, should review the mechanisms for achieving compliance with the National Statement, with particular regard to human research conducted wholly within the private sector.

Response
This recommendation is a matter for the National Health and Medical Research Council (NHMRC).

The *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement) is a statement of ethical principles and guidelines for conducting research involving humans. The National Statement is available on the NHMRC website at <www.nhmrc.gov.au>.

The guidelines only apply to researchers who are funded by the NHMRC. However, many State and private organisations voluntarily comply with the guidelines. This level of voluntary compliance demonstrates that the guidelines have been effective in promoting ethical research in Australia.

The NHMRC will consult with stakeholders to consider possible mechanisms for ensuring compliance with the National Statement as part of its current review of the National Statement. Information about the review of the National Statement is available on the NHMRC website at <www.nhmrc.gov.au/issues/natstrev.htm>.

CHAPTER 15 HUMAN GENETIC RESEARCH AND CONSENT

Recommendation 15–1
The National Health and Medical Research Council (NHMRC), as part of its review of the *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement) in the 2003–2005 triennium, should amend the National Statement to provide that Human Research Ethics Committees (HRECs) must report annually to the Australian Health Ethics Committee (AHEC) with respect to human genetic research proposals for which waiver of consent has been granted under the National Statement. Until such time as the National Statement has been so amended, the NHMRC should exercise its existing authority to request information from HRECs to require them to report annually to AHEC with respect to such human genetic research proposals.

Recommendation 15–2
The NHMRC, as part of its review of the National Statement in the 2003–2005 triennium, should ensure that the provisions of the National

Statement relating to waiver of consent and reporting of decisions are consistent with privacy laws and, in particular, with guidelines issued under s 95 and s 95A of the *Privacy Act 1988* (Cth).

Recommendation 15–3
The NHMRC, in strengthening the level of training and other support provided to HRECs in accordance with Chapter 17 of this Report, should ensure that adequate attention is given to: (a) the interpretation of the waiver of consent provisions of the National Statement; and (b) HREC decision making in relation to such waiver.

Recommendation 15–4
The NHMRC, as part of its review of the National Statement in the 2003–2005 triennium, should amend the National Statement to provide clear guidance to researchers about obtaining consent to unspecified future human genetic research.

Response
These recommendations are a matter for the NHMRC.

The NHMRC has advised that it is considering these recommendations in the context of the review of the *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement).

The NHMRC has issued guidelines under sections 95 and 95A of the Privacy Act. These guidelines provide a framework for the conduct of medical research where identified information needs to be used and it is not feasible to obtain consent to use the information. In such cases an Australian Government agency or a private organisation may collect, use or disclose information for medical research purposes where the medical research has been approved in accordance with the guidelines.

The guidelines are available on the NHMRC's website at <www.nhmrc.gov.au>. It is important that any proposed amendments to the National Statement are consistent with these guidelines. The NHMRC has advised that it will consult with the Federal Privacy Commissioner on this matter.

CHAPTER 16 ENCOURAGING BEST PRACTICE IN HUMAN GENETIC RESEARCH

Recommendation 16–1
The National Health and Medical Research Council (NHMRC) should develop information and advice for the preparation of human genetic research protocols, including examples and practical guidance on:

(a) the mechanisms for coding or de-identifying genetic samples and information used in research, and the relative advantages and disadvantages of each approach in different research contexts;

(b) the use of independent intermediaries, in appropriate cases, to hold codes linking genetic samples or information with the identifiers;

(c) the discharge of legal and ethical obligations to inform research participants about the health implications of testing of genetic samples; and

(d) disclosure by researchers to research participants of information about actual or anticipated commercial arrangements connected with human genetic research proposals.

Response
This recommendation is a matter for the NHMRC.

The NHMRC has indicated that the issue of informed consent, especially regarding de-identification of information, is of particular importance for genetic research as samples can reveal information about other relatives, in addition to the research participant.

Practical guidance to researchers for coding or de-identifying genetic information would help to ensure appropriate protection of personal information. The development of model research protocols for human genetic research to provide guidance to Human Research Ethics Committees **(**HRECs), researchers and research participants about best practice in the conduct of human genetic research is a significant issue. Patients may be deterred from providing samples if they believe that their privacy may be compromised, or that the researcher has not been completely honest in disclosing financial interests regarding the research.

Commercial arrangements relating to human genetic research proposals could have an effect upon the purpose for which research is undertaken and the further use of information. Therefore it may be appropriate for HRECs to report to the Australian Health Ethics Committee on these arrangements.

The NHMRC has indicated that these issues are being considered during the review of the National Statement. It will also take into account the work being managed by the Australian Institute of Health and Welfare, which has expertise in data management and coding.

Recommendation 16–2
The NHMRC should develop information and advice for preparing consent forms for human genetic research, including examples and practical guidance on such matters as:

(a) graduated consent options;

(b) disclosure by researchers about actual or anticipated commercial arrangements;

(c) ownership or property interests in genetic samples or information;

(d) methods or protecting the privacy interests or participants; and

(e) withdrawal of consent by participants.

Response
The NHMRC has advised that these issues are being considered as part of its current review of the National Statement and provision of associated practical guidance for researchers.

The NHMRC has also advised that in line with its policy to review guidelines at least five years from their date of issue, the *Guidelines for Genetic Registers and Associated Use of Genetic Material* (2000) will be reviewed as part of the work program for the 2003-2005 triennium. The review will include consultation with stakeholders.

CHAPTER 17 STRENGTHENING REVIEW BY HRECS

Recommendation 17–1
The National Health and Medical Research Council (NHMRC) should develop and implement procedures to promote consistency, efficiency, transparency and accountability in the review of human genetic research by Human Research Ethics Committees (HRECs). In developing such procedures, the NHMRC should initiate a systematic quality improvement program that addresses:

(a) consolidation of ethical review by region or subject-matter;

(b) the membership of HRECs and, in particular, the balance between institutional and non-institutional members;

(c) the need for expertise of HRECs in considering proposals for human genetic research;

(d) on-going monitoring of approved human genetic research projects;

(e) the education and training of HREC members;

(f) payment of HREC members for their work in reviewing research proposals;

(g) independent audit of HREC processes; and

(h) standardised record keeping and reporting to the NHMRC, including in relation to commercial arrangements.

Response
The NHMRC has advised the Government that the NHMRC, through its principal committee, the Australian Health Ethics Committee (AHEC), has already initiated several actions to address this recommendation. For example, the review of the National Statement on Ethical Conduct in Research Involving Humans will review membership and expertise requirements of Human Research Ethics Committees (HRECs), and other issues identified under this recommendation. AHEC also continues to provide advice and training for members of HRECs.

The NHMRC has also advised the Government that it is currently developing a national application form to be used by all researchers when submitting research proposals to Human Research Ethics Committees (HRECs). This

initiative will facilitate standardised record keeping and reporting to the NHMRC.

NHMRC, through AHEC, is currently reviewing its role regarding developing quality improvement measures aimed at strengthening review of research proposals by HRECs. The system of ethical review draws in many stakeholders in addition to AHEC, who exercise responsibility and authority at different levels and at different stages of the research endeavour. The NHMRC is considering issues of research governance as part of its current review of the National Statement. The NHMRC is also currently revising the complementary document, the Joint NHMRC/AVCC Statement, and guidelines on Research Practice.

Recommendation 17–2
In the course of developing a quality improvement program for HRECs in accordance with Recommendation 17–1, the NHMRC should review the need for an accreditation system for HRECs in their ethical review of human genetic research.

Response
NHMRC, through its principal committee, the Australian Health Ethics Committee (AHEC), has established a Working Party to consider the issue. While a system of accreditation could be a mechanism by which institutions could demonstrate the quality of their ethical review processes, AHEC considers that such a move, and whether it should be voluntary or mandatory, is a decision for institutions and their funding bodies. AHEC readily accepts that it should take a policy leadership and advisory role in setting the standards for, and advising on, the framework for ethical review, but it does not have the statutory mandate to assume responsibility for the operational aspects of the system of ethical review.

Recommendation 17–3
As part of the process of strengthening HREC review of human genetic research, each relevant institution and organisation should provide adequate resources to enable its HREC to fulfil its institutional responsibilities and achieve the standards set in accordance with Recommendations 17–1 and 17–2.

Response
As noted under recommendation 17-1 above, issues of research governance, including the adequate resourcing of HRECs, are being considered through the current reviews of the National Statement and the Joint NHMRC/ AVCC Statement and Guidelines on Research Practice.

HUMAN GENETIC DATABASES

CHAPTER 18 HUMAN GENETIC RESEARCH DATABASES

Recommendation 18–1
The National Health and Medical Research Council (NHMRC), as part of its review of the *National Statement on Ethical Conduct in Research*

Involving Humans (the National Statement) in the 2003–2005 triennium, should amend the National Statement to provide ethical guidance on the establishment, governance and operation of human genetic research databases. The amendments (whether by means of a new chapter or otherwise) should include specific guidance on obtaining consent to unspecified future research. (See also Recommendation 15–4.)

Response
The Government supports the strengthening of the existing regulatory framework for the overall management of human genetic research databases.

The NHMRC has advised that these issues are being considered as part of the review of the National Statement. The NHMRC has noted that very detailed specifications regulating genetic research databases may be too explicit for inclusion in the National Statement. However, AHEC has published specific guidelines relevant to genetic registers. The NHMRC has also advised that in line with its policy to review guidelines at least five years from their date of issue, the *Guidelines for Genetic Registers and Associated Use of Genetic Material* (2000) will be reviewed as part of the work program for the 2003-2005 triennium. The review will include consultation with stakeholders.

Recommendation 18–2
The NHMRC should establish and administer a public register of human genetic research databases. The National Statement, as revised in accordance with Recommendation 18–1, should establish conditions of registration and provide that no genetic research under the National Statement can be conducted using information from a database unless it is duly registered.

Response
The NHMRC has advised the Government that it accepts this recommendation in principle.

Recommendation 18–3
The NHMRC, in revising the National Statement in accordance with Recommendation 18–1, should provide guidance on the circumstances in which the use of an independent intermediary is to be a condition of: (a) registration of a human genetic research database; or (b) approval by a Human Research Ethics Committee of research involving a human genetic research database.

Response
The NHMRC has advised the Government that it accepts this recommendation. It notes the risk of misuse or abuse of genetic information supports the need for guidance in this area.

Recommendation 18–4

The Australian Health Ministers' Advisory Council, in consultation with state and territory Attorney-General's Departments and police services, the Human Genetics Commission of Australia and the NHMRC, should develop nationally consistent rules governing the disclosure, for law enforcement purposes, of genetic samples and information held in human genetic research databases. These rules should provide for disclosure only: (a) with the consent of the sampled person or a person authorised to consent on his or her behalf; or (b) pursuant to a court order.

Response
The Government supports the development of nationally consistent rules governing disclosure of genetic information for law enforcement purposes. AHMAC, in advising on this issue, would consult broadly with relevant government bodies, including the Standing Committee of Attorneys-General and police services.

CHAPTER 19 HUMAN TISSUE COLLECTIONS

Recommendation 19–1
The Australian Health Ministers' Advisory Council (AHMAC), in consultation with the Human Genetics Commission of Australia (HGCA), the National Health and Medical Research Council (NHMRC) and key professional bodies, should develop nationally consistent rules in relation to the collection, storage, use and disclosure of, and access to, newborn screening cards. In particular, and in consultation with State and Territory Attorney-General's Departments and police services, AHMAC should develop nationally consistent rules governing disclosure of newborn screening cards for law enforcement purposes. These rules should provide for disclosure only: (a) with the consent of the person sampled or a person authorised to consent on his or her behalf; or (b) pursuant to a court order.

Recommendation 19–2
AHMAC, in consultation with the HGCA, the NHMRC and key professional bodies, should review the need for nationally consistent rules in relation to the collection, storage, use and disclosure of, and access to, other human tissue collections—including collections of pathology samples and banked tissue.

Response
The Government supports the development of nationally consistent legislation and/or policies and practices governing the collection, storage, use and disclosure of, and access to, genetic information and samples on Guthrie cards.

The proposed National Health Privacy Code provides for the disclosure of personal health information to law enforcement bodies only under certain conditions, for example, in order to avoid an immediate threat to a person's safety or under order such as a warrant. The proposed regulatory regime needs to be sufficiently rigorous in order to encourage compliance.

The AHMAC Advisory Group on Human Gene Patents and Genetic Testing is investigating these issues with a view to developing a nationally consistent

approach. Where these rules relate to disclosure of newborn screening cards for law enforcement purposes, the advisory group will consult with Commonwealth, State and Territory Attorneys-General and police services.

CHAPTER 20 OWNERSHIP OF SAMPLES AND THE HUMAN TISSUE ACTS

Recommendation 20–1
The proprietary rights in preserved samples, which are currently enjoyed by hospitals and others under the common law, should continue to be upheld on a case-by-case basis. Legislation should not be enacted to confer full proprietary rights in human genetic samples.

Response
The Government accepts this recommendation.

Recommendation 20–2
Pending any comprehensive review of relevant laws, the regulation of the collection, storage, access to, or use of genetic samples (whether for the purposes of human genetic research or otherwise) should rely primarily on the *Privacy Act 1988* (Cth) as amended in accordance with the Recommendations in Chapter 8, rather than on amendment of the Human Tissue Acts.

Response
The Government does not accept this recommendation for the reasons set out in the response to Chapter 8.

HEALTH SERVICES

CHAPTER 21 HEALTH PROFESSIONALS AND FAMILY GENETIC INFORMATION

Recommendation 21–1
The Commonwealth should amend the *Privacy Act 1988* (Cth) (*Privacy Act*) to permit a health professional to disclose genetic information about his or her patient to a genetic relative of that patient where the disclosure is necessary to lessen or prevent a serious threat to an individual's life, health or safety, even where the threat is not imminent.

Response
The Government supports this recommendation in principle. It notes that this recommendation has been considered in the context of the proposed National Health Privacy Code. The Code contains a provision which allows a health professional to disclose predictive genetic information about his or her patient to a genetic relative of that patient where the disclosure is necessary to lessen or prevent a serious threat to an individual's life, health or safety, even where the threat is not imminent.

The Privacy Act already allows an organisation to disclose personal information if it believes that the disclosure is necessary to lessen or prevent a serious and imminent threat to an individual's life, health or

safety. The recommendation, if implemented, would extend the right of disclosure of predictive genetic information where the threat is serious. It recognises that a genetic condition may be serious but not necessarily imminent.

Recommendation 21–2
The National Health and Medical Research Council (NHMRC), in consultation with the Office of the Federal Privacy Commissioner, should develop guidelines for health professionals dealing with disclosure of genetic information to the genetic relatives of their patients. The guidelines should address the circumstances in which disclosure to genetic relatives is ethically justified or required, and the need for patients to be counselled about the disclosure of information in these circumstances. The guidelines should be made pursuant to either new provisions of the *Privacy Act* (amended consistently with Recommendation 21–1) or s 7 of the *National Health and Medical Research Council Act 1992* (Cth).

Response
The Government supports the development of guidelines for health professionals addressing the circumstances in which disclosure to genetic relatives is permissible.

The AHMAC National Health Privacy Working Group has developed draft guidelines as part of the proposed National Health Privacy Code.

Recommendation 21–3
The Commonwealth should amend the *Privacy Act* to provide that an individual has a right to access genetic information about first-degree genetic relatives where such access is necessary to lessen or prevent a serious threat to the individual's life, health, or safety, even where the threat is not imminent. Where an organisation subject to the *Privacy Act* receives a request for access, the organisation should be obliged to seek consent, where practicable, before determining whether to provide access. The right of access should be exercisable only through a nominated medical practitioner or genetic counsellor and may be refused where providing access would have an unreasonable impact upon the privacy of the individual whose information is sought or other individuals. (See also Recommendation 8–4.)

Recommendation 21–4
In developing the guidelines referred to in Recommendation 21–2, the NHMRC should include advice to health professionals in dealing with requests for access to genetic information by the genetic relatives of their patients.

Response
The Government does not accept these recommendations.

It is noted that implementation of recommendation 21-1 would extend the circumstances in which a health professional may disclose important information to a genetic relative.

CHAPTER 22 GENETIC REGISTERS AND FAMILY GENETIC INFORMATION

Recommendation 22–1
Organisations operating genetic registers should seek a Public Interest Determination (PID) under the *Privacy Act 1988* (Cth), where applicable, to ensure that they can continue to collect family medical history information from registrants without breaching the National Privacy Principles. The PID process should review whether any other acts or practices of genetic registers, including those involving the use or disclosure of personal information, may justify exemption under the PID.

Response
This recommendation is a matter for organisations operating genetic registers.

As noted in the report, the Privacy Act has limited coverage of genetic registers as these are generally based in public hospitals. Genetic registers that operate in the private sector may come within the terms of PIDs 9 and 9A which allow a health service provider to collect and record medical history of family members without obtaining the consent of family members.

The Government agrees that the collection of family information from registrants is essential to the operation of genetic registers. If an organisation considers that a PID is necessary to ensure that it can continue to collect family medical history the organisation should raise this directly with the Office of the Federal Privacy Commissioner.

Recommendation 22–2
The National Health and Medical Research Council (NHMRC) should review the *Guidelines for Genetic Registers and Associated Use of Genetic Material* with particular regard to the de-identification of information. In conducting its review, the NHMRC should ensure that the Guidelines are consistent with privacy laws.

Response
The NHMRC has advised that, in line with its policy to review guidelines at least five years from their date of issue, the *Guidelines for Genetic Registers and Associated Use of Genetic Material* (2000) will be reviewed as part of the work program for the 2003-2005 triennium. The review will include consultation with stakeholders.

CHAPTER 23 GENETIC COUNSELLING AND MEDICAL EDUCATION

Recommendation 23–1
As a matter of priority, the Commonwealth, States and Territories should develop strategies to assess and respond to the need for increased and adequately resourced genetic counselling services.

Response

The Australian Health Ministers' Advisory Council (AHMAC) Advisory Group on Human Gene Patents and Genetic Testing is considering this recommendation.

Recommendation 23–2
The Commonwealth, States and Territories should examine options for the further development of genetic counselling as a recognised health profession, including the use of certification, accreditation or registration systems for genetic counsellors.

Response
While the Government recognises the risks relating to the provision of incorrect information by unqualified counsellors, it is important that primary health care and other medical professionals are able to provide basic level counselling without being required to be registered as genetic counsellors. The Australian Health Ministers' Advisory Council (AHMAC) Advisory Group on Human Gene Patents and Genetic Testing is monitoring the issues surrounding the appropriate qualifications of genetic counsellors and will consult with relevant stakeholders as necessary.

Recommendation 23–3
The Human Genetics Commission of Australia (HGCA) should develop genetic testing and counselling practice guidelines, in consultation with the Human Genetics Society of Australasia, state clinical genetics services, and other interested organisations. These guidelines should identify genetic tests, or categories of genetic tests, that require special treatment in relation to procedures for ordering testing and ensuring access to genetic counselling. (See also Recommendation 5–3.)

Response
The Government notes that this is a matter for the proposed genetics advisory body.

As noted above the Australian Health Ministers' Advisory Council (AHMAC) Advisory Group on Human Gene Patents and Genetic Testing is considering the issues surrounding the development of guidelines for the appropriate delivery of genetic tests and genetic counselling services. It would be desirable for the proposed genetics advisory body to build on the work done by this group and other relevant stakeholders. The National Pathology Accreditation Advisory Committee (NPAAC) is developing guidelines for quality assurance and accreditation of genetic testing which will address some of these issues.

Recommendation 23–4
The HGCA should work with the Australian Medical Council, the Committee of Deans of Australian Medical Schools, and the Committee of Presidents of Medical Colleges to develop an integrated approach to medical education and training in human genetics. This approach should ensure that present and future medical practitioners are appropriately trained and equipped in clinical genetics and in the use of relevant genetic counselling and genetic services.

Recommendation 23–5
The HGCA should work collaboratively with key professional and educational bodies to design and enhance education and training programs aimed at improving genetic health services provided by medical practitioners and other health professionals.

Response
The Government notes that these recommendations are a matter for the proposed genetics advisory body.

In general, the Government supports proposals to enhance medical education and training in human genetics. The Government also supports the strengthening of training and continuing professional development programs for medical professionals. The development of integrated approaches to human genetics in undergraduate, postgraduate and continuing education programs will require consultation with the relevant bodies.

CHAPTER 24 POPULATION GENETIC SCREENING

Recommendation 24–1
The Australian Health Ministers' Advisory Council, in cooperation with the National Health and Medical Research Council, the Human Genetics Commission of Australia and key professional bodies, should develop national standards in relation to the development and implementation of:

(a) population genetic screening programs—covering such matters as informed consent, counselling, testing standards, quality assurance, cost-benefit considerations, and reporting and data collection; and

(b) newborn screening programs—promoting both universal participation and informed decision making by parents.

Response
The Government supports this recommendation.

As noted above the AHMAC Advisory Group on Human Gene Patents and Genetic Testing is currently considering issues related to genetic testing. It is currently considering the development of a national strategy governing newborn screening programs. The Australian Screening Advisory Committee (ASAC) has been established to provide high level policy advice on population screening programs. The ASAC should be involved in any discussions on population genetic screening programs as the Committee may wish to delineate between population genetic screening and large scale targeted genetic testing.

INSURANCE

CHAPTER 26 GENETIC DISCRIMINATION IN INSURANCE

Recommendation 26–1
As a general matter, there should be no departure from the fundamental principle underlying the market in voluntary, mutually rated insurance,

namely, equality of information between the applicant and the insurer. However, where the underwriting of insurance involves the use of human genetic information, the insurance process should be subject to the Recommendations in this Report (see Chapters 27 and 28).

Response
The Government notes that most of the recommendations in Chapters 26-28 are directed at the insurance industry.

The Government agrees that current principles of equality of information between the applicant and insurer have provided a sound basis for equality in the underwriting of insurance.

The Government also believes that it is important that genetic information be used appropriately and that the use of genetic information in underwriting for insurance should not discourage people from undergoing genetic testing for health reasons.

Recommendation 26–2
The Human Genetics Commission of Australia, in consultation with peak industry bodies and regulators, should keep a watching brief on developments in the insurance industry in relation to the use of human genetic information, both in Australia and overseas, with a view to reviewing Australian insurance practices as the need arises.

Response
This recommendation is directed at the proposed genetics advisory body.

The Government agrees that the proposed genetics advisory body would be an appropriate body to monitor developments in the use of human genetic information in the insurance industry.

CHAPTER 27 IMPROVING THE UNDERWRITING PROCESS

Recommendation 27–1
The Human Genetics Commission of Australia (HGCA) should, as a matter of priority, establish procedures to assess and make recommendations on whether particular genetic tests should be used in underwriting mutually rated insurance, having regard to their scientific reliability, actuarial relevance and reasonableness.

Recommendation 27–2
The Investment and Financial Services Association (IFSA) and the Insurance Council of Australia (ICA) should develop mandatory policies for their members to ensure that, once the HGCA has made a recommendation in relation to the use of a particular genetic test in underwriting, that test is used only in conformity with the recommendation. As a transitional arrangement, insurers should be permitted to continue using genetic tests in underwriting in accordance with industry policies, until such time as the HGCA makes a recommendation in relation to those tests.

Recommendation 27–3
IFSA and the ICA should require their members to state, on relevant insurance application forms, that not all genetic test results have to be disclosed and that applicants may obtain further information about this from the insurer. In addition, IFSA and the ICA should require their members to provide, upon request, accurate information to applicants in relation to those genetic tests that the HGCA has recommended not be used in underwriting in accordance with Recommendation 27–1.

Recommendation 27–4
IFSA and the ICA, in consultation with the HGCA and the Institute of Actuaries of Australia, should develop and publish policies for their members on the use of family medical history for underwriting mutually rated insurance.

Response
These recommendations are directed at IFSA and ICA.

In general, the Government supports proposals that encourage the insurance industry to implement the recommended reforms on the use of genetic tests and on the provision of information on how personal information is used in the underwriting process.

Recommendation 27–5
The Commonwealth should amend the *Insurance Contracts Act 1984* (Cth) to clarify the nature of the obligation of an insurer to provide written reasons for an unfavourable underwriting decision upon the request of an applicant. Where such a decision is based on genetic information, including family medical history, the insurer should be required to give reasons that are clear and meaningful and that explain the actuarial, statistical or other basis for the decision.

Recommendation 27–6
IFSA and the ICA should require their members to inform applicants of their statutory entitlement to reasons for an adverse underwriting decision based on genetic information, including family medical history. IFSA and the ICA should also develop mandatory policies for their members about appropriate mechanisms for providing sensitive information to applicants in response to a request for reasons.

Recommendation 27–7
IFSA and the ICA should develop mandatory policies for their members regarding the provision of reasons by an insurer to an applicant following an unfavourable underwriting decision based on family medical history. These policies should ensure that the reasons given are clear and meaningful and that they explain the actuarial, statistical or other basis for the decision.

Response
The Government agrees that persons denied insurance should, on request, be provided with clear and meaningful reasons. However, it believes the

best way to achieve this result is through appropriate IFSA and ICA policies rather than an amendment to section 75 of the Insurance Contracts Act. The Government notes that the report considers that IFSA's genetic testing policy is a sound model in relation to the giving of reasons.

Recommendation 27–8
The Commonwealth should amend the *Disability Discrimination Act 1992* (Cth) and related legislation to clarify the nature of the information required to be disclosed by an insurer to the Human Rights and Equal Opportunity Commission in the course of resolving a complaint. The legislation should ensure that the complainant is entitled to access to the information so disclosed.

Response
The Government does not accept this recommendation. The Government notes its response to a similar recommendation in the Productivity Commission's *Review of the Disability Discrimination Act*. Recommendation 12.2 of that review states:

The Disability Discrimination Act 1992 should be amended to limit the application of the insurance and superannuation exemption (s.46). It should only apply if, when requested, insurance and superannuation providers give clear and meaningful reasons for unfavourable underwriting decisions (including an explanation of the information on which they have relied). Applicants should be advised of their entitlement to request these reasons.

The Government's response to that recommendation states:

The Government does not believe that it is desirable or appropriate to regulate directly in this area. The Government believes it would be more appropriate to use industry codes and agreements to provide adequate reasons to consumers.

The Government agrees that it is appropriate for industry to disclose reasons to persons subject to unfavourable underwriting decisions. The Government will encourage the industry to implement this recommendation. Industry policies should ensure that the reasons given are clear and meaningful and they explain the actuarial, statistical or other basis for the decision, where relevant data is available.

The Government will raise this issue with the Insurance Council of Australia (ICA) so that it is included in its Draft Code of Practice. Section 3.3 of the ICA Draft Code of Practice relates to reasons for decisions. The Draft Code outlines that if an insurer declines cover, refuses to issue a contract of insurance, or cancels the contract of insurance, they will provide reasons.

If it were demonstrated that an ICA Draft Code of Practice including reasons for unfavourable underwriting decisions (including an explanation of information on which they have relied) was not being adequately implemented

by insurers, the Government will give further consideration to whether legislative amendment is appropriate.

Recommendation 27–9
IFSA and the ICA should expand the jurisdiction of the Financial Industry Complaints Service Ltd (FICS) and Insurance Enquiries and Complaints Ltd (IEC) to allow those organisations to review underwriting decisions involving the use of genetic information, including family medical history. The amended rules should ensure that the complaint handling processes are:

- timely and efficient;
- carried out by suitably qualified individuals with a demonstrated understanding of insurance law and anti-discrimination law, underwriting practice, and clinical genetics;
- binding on the insurer but not on the complainant; and
- available in respect of a substantial majority of complaints, having regard to the monetary sum in question.

Response
The Government supports the proposal for the insurance industry to provide independent review mechanisms for decisions involving genetic information. However, it notes that implementation of this recommendation is a matter for IFSA and the ICA.

Recommendation 27–10
IFSA, the ICA and other relevant bodies should review their policies and practices in relation to training and education of members regarding the collection and use of genetic information in insurance.

Recommendation 27–11
The National Finance Industry Training Advisory Body, in consultation with IFSA, the ICA and the HGCA, should review relevant competency standards and the Financial Services Training Package to incorporate an appropriate level of competence regarding the collection and use of genetic information in insurance.

Response
The Government agrees that education and training about the use of genetic information in insurance is important. It agrees with the observation in the report that responsibility for education and training in this area falls primarily on the insurance industry itself**.**

CHAPTER 28 INSURANCE AND GENETIC PRIVACY

Recommendation 28–1
Insurers should review their consent forms, including medical authority forms, to ensure that they contain sufficient information about the collection, use and disclosure of genetic information to allow applicants to make an informed decision about whether to proceed with their

application and consent to the collection of the information. In undertaking this review, insurers should consult with the Human Genetics Commission of Australia and the Office of the Federal Privacy Commissioner.

Response
The Government notes that IFSA believes that its existing forms contain sufficient information to allow applicants to make an informed decision. However, it also notes that IFSA would support a review of these forms.

Recommendation 28–2
In reviewing consent and medical authority forms in accordance with Recommendation 28–1, insurers should ensure that consent to collect genetic information for the purpose of assessing an application for insurance is not bundled together with consent for other purposes. The provision of insurance should not be made conditional on the giving of consent to other, unrelated or secondary uses of the genetic information.

Response
The Government notes the report's view that the bundling of consent is not good privacy practice. It agrees that it would be appropriate for any review of the relevant forms to also examine consent issues.

Recommendation 28–3
Insurers should seek a Public Interest Determination under the *Privacy Act 1988* (Cth) in relation to the practice of collecting genetic information from applicants about their genetic relatives for use in underwriting insurance policies in relation to those applicants.

Response
This recommendation is a matter for the insurance industry.

If an insurer considers that a Public Interest Determination is necessary to ensure that it can continue to collect family medical history the insurer should raise this directly with the Office of the Federal Privacy Commissioner.

EMPLOYMENT

CHAPTER 30 GENETIC DISCRIMINATION IN EMPLOYMENT

Recommendation 30–1
Employers should not collect or use genetic information in relation to job applicants or employees, except in the limited circumstances where this is consistent with privacy, anti-discrimination, and occupational health and safety legislation, as amended in accordance with the Recommendations in this Report. (See Chapters 31 to 34.)

Response

The Government agrees in principle that collection or use of genetic information should be consistent with privacy, anti-discrimination and occupational health and safety legislation. The issue of discrimination in employment on the ground of genetic status is likely to increase in prominence as the variety and availability of genetic tests increase.

CHAPTER 31 INHERENT REQUIREMENTS OF THE JOB

Recommendation 31–1
The Commonwealth should amend the *Disability Discrimination Act 1992* (Cth) (DDA), the *Human Rights and Equal Opportunities Commission Act 1984* (Cth) and the *Workplace Relations Act 1996* (Cth) to provide that, except where it is reasonable to do so, the assessment of an applicant or employee's ability to perform the inherent requirements of a job should not include an assessment of whether he or she will be unable to perform the inherent requirements in the future on the basis of his or her genetic status.

Response
The Government sees merit in preventing discrimination on the basis of a person's potential future inability to perform the inherent requirements of the position, noting that genetic results are not capable of predicting this accurately and that future events are uncertain. This recommendation is consistent with the definition of disability in the *Disability Discrimination Act 1992* (DDA) and its current provisions.

The Government has accepted, in its response to the Productivity Commission's *Review of the Disability Discrimination Act*, that an advisory note will be inserted into the DDA to clarify that the definition of 'disability' for the purposes of the DDA includes a genetic predisposition to a disability. The Government considers that, with this clarification, the current provisions of the DDA adequately protect people with disability from discrimination on the grounds that they will be unable to perform the inherent requirements of a job in the future.

The inherent requirements defence in section 15 of the DDA allows consideration of 'relevant factors that it is reasonable to take into account' in assessing whether a person because of his or her disability would be unable to carry out the inherent requirements of the particular employment. The scheme of the Act prevents discrimination on the basis of a disability that may exist in the future or be imputed to a person. Therefore, assumptions about a person's ability to perform the inherent requirements of the job into the future would probably be irrelevant and unreasonable in most cases.

The inherent requirements defence will also be extended through the Government's response to the Productivity Commission's *Review of the Disability Discrimination Act* to include all stages of employment, including the stages in between hiring and dismissal where it is not currently provided for. This will allow employers more flexibility to make alternative working arrangements if they employ a person who later becomes unable to perform

the inherent requirements of the job, thus minimising employers' concerns about employing a person who may in the future become unable to perform the inherent requirements.

Recommendation 31–2
Where genetic information is used to assess an applicant or employee's ability to perform the inherent requirements of a job, employers should develop clearly defined job descriptions that identify these inherent requirements. Employers should also develop policies to ensure that genetic information is used for these purposes only in relevant and reasonable circumstances.

Response
The Government agrees in principle that, if genetic information is used to assess the ability of an applicant or an employee to perform the inherent requirements of a job, the employer should clearly set out these requirements. The Government notes that it is reasonable for employers to take account of the costs of developing new policies as well as benefits.

Recommendation 31–3
The Commonwealth should amend the DDA to prohibit an employer from requesting or requiring genetic information from a job applicant or employee except where the information is reasonably required for a purpose that does not involve unlawful discrimination, such as ensuring that a person is able to perform the inherent requirements of the job.

Response
The Government accepts in principle that employers should be prohibited from requesting genetic test results for use in a discriminatory way. As pointed out in the report, section 30 of the DDA is not clear. The provision will be redrafted to clarify that it prohibits an employer from requesting or requiring information relating to a person's disability (including genetic information) except where the information is reasonably required for a purpose that does not involve unlawful discrimination. The Government agrees that employers should be required to produce evidence that a question was asked for a reason that did not involve discrimination but should not bear the onus of proving, on the balance of probabilities, that this was the case.

Exceptions that allow employers to request information for the purposes of compliance with occupational health and safety legislation or other laws will be considered when redrafting the provision.

Recommendation 31–4
The Human Rights and Equal Opportunity Commission, in consultation with the Human Genetics Commission of Australia and other stakeholders, should develop guidelines dealing with the collection and use of genetic information in employment. The Attorney-General should consider the development of Disability Standards in this area pursuant to the DDA.

Response

The Government will ask the Attorney-General's Department to consult with other relevant agencies in regard to this recommendation.

In relation to the development of disability standards in this area, the Government agreed in its response to the Productivity Commission's review that the DDA be amended to allow disability standards to be formulated in all areas of the DDA. However, this response notes that any formulation of new disability standards involves a rigorous cost-benefit analysis and thorough consultation process. Therefore, in this context, developing guidelines as suggested here, rather than standards, would be more appropriate at this time.

CHAPTER 32 OCCUPATIONAL HEALTH AND SAFETY

Recommendation 32–1
The Human Genetics Commission of Australia (HGCA) should establish procedures to assess and make recommendations on whether particular genetic tests should be used in employment for screening for susceptibility to work-related conditions. In assessing particular genetic tests, the HGCA should consider whether:

- there is strong evidence of a clear connection between the working environment and the development of the condition;
- the condition may seriously endanger the health or safety of employees; and
- the test is a scientifically reliable method of screening for the condition.

Recommendation 32–2
The HGCA and the National Occupational Health and Safety Commission (NOHSC) should collaborate with other stakeholders to develop national guidelines for the conduct of genetic screening for susceptibility to work-related conditions. The guidelines should indicate:

- that genetic screening of job applicants and employees for susceptibility to work-related conditions should not be conducted if the danger can be eliminated or significantly reduced by reasonable measures taken by the employer to reduce the environmental risk;
- that employers should use genetic tests only where they have been recommended for that purpose by the HGCA;
- how genetic test results are to be interpreted;
- that screening should not be conducted on a job applicant until the applicant has been made an offer of employment;
- that screening should be conducted on a voluntary basis except in those rare circumstances in which the HGCA has recommended that screening be mandatory;
- the circumstances in which family medical history may be collected and used;

- what provision should be made for genetic counselling of those undergoing testing;
- appropriate responses by employers where genetic screening reveals relevant susceptibilities; and
- what measures should be taken to ensure the confidentiality of screening results.

Response
The Government is aware of the potential for employers to use genetic screening to exclude susceptible employees from the workplace, rather than eliminate exposure to workplace hazards. However, the conduct of genetic screening currently has limited application to Australian workplaces. Accordingly the Government considers that the development of national guidelines or regulatory material is unnecessary at this stage. Any work in this area should be limited to the development of broad principles for the conduct of genetic screening.

Recommendation 32–3
NOHSC should consider adopting the national guidelines on the conduct of genetic screening for susceptibility to work-related conditions as a national code of practice. NOHSC should ensure that the National Priority Action Plans developed under the *National OHS Strategy 2002–2012* reflect these developments.

Response
The Government does not support the recommendation that the National Occupational Health and Safety Commission (NOHSC) adopt national guidelines (or principles) on the conduct of genetic screening, as a national code of practice. The development of a NOHSC national code of practice would normally lead to its incorporation into the Occupational Health and Safety regulatory frameworks of the States and Territories.

The Government considers that incorporating guidelines and principles in the OHS regulatory frameworks is premature at this time. However, it would be appropriate for NOHSC to include in its database of practical guidance material, any principles or other material developed by the genetics advisory body to facilitate their dissemination to employers and other relevant stakeholders.

Recommendation 32–4
Within the framework of the National Hazardous Substances Regulatory Package, NOHSC, in consultation with the HGCA and other stakeholders, should develop a national code of practice for the conduct of genetic monitoring of employees exposed to hazardous substances in the workplace. Under this code of practice, genetic monitoring of employees should be conducted only where:

- there is strong evidence of a connection between the working environment and the development of the condition;

- the condition may seriously endanger the health or safety of employees; and
- there is a scientifically reliable method of screening for the condition.

Response
The NOHSC Hazardous Substances package includes national model regulations for the control of workplace hazardous substances and associated codes of practice. These instruments include provisions for the health surveillance of employees, including biological monitoring. Additional regulatory material is considered unnecessary at this stage.

Recommendation 32–5
The HGCA and NOHSC should collaborate with other stakeholders to develop national guidelines for the collection and use of genetic information from applicants and employees for the protection of third party safety. The guidelines should indicate that genetic information from an applicant or employee should not be collected or used for the protection of third party safety if the danger can be eliminated or significantly reduced by other reasonable measures taken by the employer. Where this is not possible, genetic information should be collected or used only where:

- the applicant or employee's condition poses a real risk of serious danger to the health or safety of third parties; and
- there is a scientifically reliable method of screening for the condition.

Recommendation 32–6
NOHSC should consider adopting the national guidelines on the collection and use of genetic information for the protection of third party safety as a national code of practice. NOHSC should ensure that the National Priority Action Plans developed under the *National OHS Strategy 2002–2012* reflect these developments.

Response
See response to recommendations 32-1 and 32-2.

CHAPTER 33 WORKERS' COMPENSATION

Recommendation 33–1
The Human Genetics Commission of Australia, in consultation with the Heads of Workplace Safety and Compensation Authorities, should develop a policy regarding the appropriate use of genetic information in the assessment of workers' compensation claims.

Response
The Government considers that it would be premature at this stage to develop such a policy given the absence of any evidence of the use of such information in assessing workers' compensation claims in Australian jurisdictions. It also notes that the role of the Heads of Workplace Safety and Compensation

Authorities is principally information collection and would not be the appropriate body to undertake policy development.

CHAPTER 34 EMPLOYMENT AND GENETIC PRIVACY

Recommendation 34–1
The Commonwealth should amend the *Privacy Act 1988* (Cth) (*Privacy Act*) to ensure that employee records are subject to the protections of the Act, to the extent that they contain genetic information.

Recommendation 34–2
The Commonwealth Attorney-General's Department and the Department of Employment and Workplace Relations, in their pending inter-departmental review of the employee records exemption, should consider whether the *Privacy Act* should be amended to ensure that employee records are subject to the protections of the Act, to the extent that they contain health information other than genetic information.

Response
These recommendations will be considered as part of the employee records review. The Government, as part of that review, has published a discussion paper, *Employee Records Privacy*, which is available on the internet at <www.ag.gov.au>. Following consideration of submissions on the discussion paper a report will be made to the Government.

OTHER CONTEXTS

CHAPTER 35 PARENTAGE TESTING

Recommendation 35–1
The Commonwealth should enact legislation to provide that DNA parentage testing in Australia is conducted only by laboratories accredited by the National Association of Testing Authorities, Australia (NATA), and only in accordance with NATA accreditation requirements.

Response
NATA currently runs a forensic science laboratory accreditation program for laboratories providing parentage and kinship testing.

In family law proceedings parenting testing procedures must be carried out at a laboratory that is accredited by NATA. Where DNA testing is done for immigration purposes, the Government uses, wherever possible, NATA accredited laboratories to ensure the highest possible testing standards.

The Government considers that there is no need for additional legislation to regulate parentage testing at this time, as there is already a strong accreditation system in place where test results are to be used in family law or immigration proceedings. The Government will, however, continue to monitor the use of non-accredited laboratories that are offering parentage testing.

Recommendation 35–2

NATA should review its accreditation requirements for DNA parentage testing to ensure that they meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing information about counselling.

Response
The Government notes that NATA is currently reviewing its accreditation requirements for DNA testing. NATA has advised that this review will include issues such as consent, availability of counselling, single parent parentage testing and kinship testing. The Government is participating in this review.

The National Pathology Accreditation Advisory Council (NPAAC) review of *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection Techniques* may also have implications for the NATA review.

Recommendation 35–3
The Commonwealth should review Part IIA of the *Family Law Regulations 1984* (Cth) (FL Regulations) to ensure that the requirements for parentage testing meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing information as to counselling. In so doing, the Commonwealth should have regard to the accreditation requirements for parentage testing developed by NATA in accordance with Recommendation 35–2.

Response
This recommendation is currently being implemented. The Government is reviewing the Family Law Regulations in conjunction with the NATA review of accreditation requirements.

The Regulations were amended on 23 December 2004. The amendment added a requirement that, in addition to providing an affidavit, the donor of a bodily sample which is provided for the purposes of a parentage testing procedure, must attach to the affidavit a signed and witnessed photograph.

Recommendation 35–4
The Commonwealth should enact legislation to provide that parentage testing reports are not admissible in proceedings under the *Family Law Act 1975* (Cth) (FLA) unless the testing complies with the relevant provisions of the FL Regulations. The States and Territories should consider enacting parallel legislation to ensure that parentage testing reports are not admissible in state or territory proceedings unless the testing complies with NATA accreditation requirements.

Response
The Government does not consider that there is any need for further legislation at the federal level as the existing legislative requirements require parentage testing procedures to be done at a laboratory that is accredited by NATA. The combined effect of section 69ZB of the Family Law Act, the regulation making power for parentage testing, and Regulation 21D of the *Family Law*

Regulations 1984, is that parenting testing procedures under family law must be carried out at a laboratory that is accredited by NATA.

Recommendation 35–5
NATA should develop accreditation requirements that require laboratories to be satisfied that the sample of each adult donor has been supplied for parentage testing with his or her consent. Provision should also be made for obtaining consent from the deceased's next-of-kin or other authorised person in relation to a sample from a deceased person.

Response
The Government notes that NATA is currently reviewing accreditation requirements. NATA has advised that the issue of consent is being considered in this review.

Recommendation 35–6
The Commonwealth should amend the Family Law Regulations to insert a prescribed consent form in relation to parentage testing for each adult donor indicating that the sample has been supplied with his or her consent. Provision should also be made for obtaining consent from the deceased's next-of-kin or other authorised person in relation to a sample from a deceased person.

Response
This recommendation has been partly implemented. Form 2 in Schedule 1 of the Family Law Regulations was amended on 23 December 2004 to add a requirement that the donor of a bodily sample which is provided for the purposes of a parentage testing procedure, must attach to the affidavit a signed and witnessed photograph.

Provision for obtaining consent in relation to a sample from a deceased person is being considered as part of the Government's review of the Family Law Regulations in conjunction with the NATA review of accreditation requirements.

Recommendation 35–7
The Commonwealth should enact legislation to provide that where a child: (a) has attained 12 years of age; and (b) has sufficient maturity to make a free and informed decision, testing of the child's genetic sample can be performed only with the written consent of the child or pursuant to a court order. The child's maturity, and the voluntariness of the child's consent, should be assessed by an independent professional, being a family and child counsellor as defined under the FLA, a social worker or a psychologist.

Response
The Government does not accept this recommendation. It would be inconsistent with the Family Law Act to make a distinction between children under the age of 12 and those over the age of 12.

Under section 69W of the Act, the court may make a parentage testing order. If this order is directed at children under the age of 18, consent to the testing must be given by the child's parent or guardian, or the person responsible for the child's long-term or day-to-day care, welfare and development. The recent amendment to Form 2 (see response to recommendation 35-6) requires written consent.

The Government considers that rather than making a distinction between children under the age of 12 and those over the age of 12, it would be more appropriate if the court made an assessment based on the existing approach to children's participation in family law—that is, by determining what is in the best interests of the child.

Recommendation 35–8
NATA should develop accreditation requirements to ensure that laboratories conducting DNA parentage tests obtain the written consent of each mature child in accordance with Recommendation 35–7.

Response
As noted in the responses to recommendations 35-2 and 35-5, NATA is currently reviewing accreditation requirements. This review will consider consent requirements.

Recommendation 35–9
The Commonwealth should enact legislation to provide that where a child is:

(a) under 12 years of age; or

(b) 12 years of age or over but less than 18 years of age and does not have sufficient maturity to make a free and informed decision whether to submit a genetic sample for parentage testing;

such testing can be performed only with the written consent of all persons with parental responsibility for the child, or pursuant to a court order. Where one person with parental responsibility withholds consent or cannot reasonably be contacted, a court should be authorised to make a decision on behalf of the child.

Response
As noted in the response to recommendation 35-7, it would be inconsistent with the Family Law Act to prescribe a specific age for certain things to occur, within the context of the Act. However, the Government is consulting with NATA about the appropriate form of a possible legislative amendment in relation to written consent from persons with parental responsibility.

Recommendation 35–10
NATA should develop accreditation requirements to ensure that laboratories conducting DNA parentage tests obtain, in relation to each child's sample, the written consent of all persons with parental responsibility for the child, in accordance with Recommendation 35–9.

Recommendation 35–11

NATA should develop accreditation requirements that require laboratories performing DNA parentage tests to inform all persons who provide genetic samples of the availability of counselling, both at the time the samples are submitted for testing and at the time the results are available.

Recommendation 35–12
NATA should extend its accreditation program to cover DNA kinship testing other than parentage testing (for example, sibling testing). NATA should apply the requirements for parentage testing, as amended by the Recommendations in this Report, to other kinship testing, in so far as they are applicable.

Response
As noted above, the Government is currently participating, through the Attorney-General's Department, with NATA in a review of its accreditation requirements for DNA parentage testing. This review will include issues such as consent, availability of counselling, single parent parentage testing and kinship testing.

CHAPTER 37 IMMIGRATION

Recommendation 37–1
The Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) should review its policies and procedures on kinship testing. In particular, the revised policies should ensure that:

(a) visa applicants are advised at an early stage in the application process that they may be asked to undergo genetic testing to prove an asserted kinship relationship;

(b) where DIMIA doubts the veracity of documentary evidence submitted to establish the existence of a kinship relationship, visa applicants should be provided with adequate reasons and given an opportunity to address the doubts by undergoing genetic testing or providing other evidence;

(c) information in community languages is disseminated to visa applicants about the potential implications of the test and the desirability of seeking counselling;

(d) in relation to offshore testing, the panel doctor who takes a sample for kinship testing offers the applicant counselling, or information about the availability of counselling;

(e) DIMIA has adequate procedures for preventing identity fraud; and

(f) consent is obtained for the disclosure of genetic test results to third parties, including sponsors.

Response
(a) The Government will consider amending information in booklets, forms and the DIMIA website to include advice to applicants that DNA testing is one means of providing evidence of a relationship and may be an option in cases where documentary evidence is considered unreliable or is unavailable.

To ensure the integrity of the procedure (including verification of donor identity, secure despatch of samples, laboratory accreditation), it is strongly preferred that genetic testing for migration purposes be carried out according to the Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) guidelines and using a DIMIA preferred laboratory. Any information included in booklets, forms and the internet will advise that a genetic test result obtained outside DIMIA's guidelines may not be accepted.

(b) Under principles of procedural fairness, immigration decision-makers are required to provide applicants with reasons for considering that criteria for the grant of a visa are not satisfied, and to provide applicants with an opportunity to comment and/or provide additional evidence.

In cases where genetic testing may provide a resolution, DIMIA makes the applicant a formal written offer of testing, setting out comprehensive reasons (other than non-disclosable information concerning, for example, DIMIA investigations into suspected organised migration fraud) for considering the existing evidence insufficient to establish a genetic relationship.

(c) In general, communication with applicants through official forms and notifications is undertaken in English. Whilst some migration information is translated into other languages the Government is of the view that providing all of its immigration material in all community languages would unduly increase the cost burden this would ultimately place on applicants.

However, given the small percentage of migration applicants who actually undergo genetic testing, and the fact that some posts use this tool more than others, the Government will examine the feasibility of translating genetic testing information into key community languages.

(d) The Government is investigating a number of avenues, including through our existing panel doctors, for the provision of counselling to applicants who have been offered genetic testing. Applicants will be alerted to the advisability of obtaining counselling in the letter of offer of genetic testing (see comments at (b)). Counselling will be at the applicant's own expense.

(e) The Government considers existing policy and procedures adequately safeguard the integrity of the genetic testing process. For overseas sample donors, guidelines stipulate the attendance of an Australian officer at the relevant clinic to witness sampling, as far as possible, verify the identity of sample donor/s and securely despatch sample/s.

The identity of sample donors in Australia is verified by the clinic according to procedures stipulated for family law purposes. Under Government policy, it is open to the case officer in a high risk case to provide an additional briefing to the clinic on the question of identity and/or request the presence of a Department of Immigration and Multicultural and Indigenous Affairs (DIMIA) officer to witness sampling and verify identity. There have been no known cases of identity substitution among sample donors and the risk of such is considered low.

(f) The Government will develop procedures to ensure that clear and informed consent is obtained from donors for the disclosure of genetic results to third parties, including sponsors. This will most likely be addressed in DIMIA's planned review of forms completed by donors at the time of sampling.

Recommendation 37–2
In implementing Recommendation 37–1, policies and procedures for conducting genetic kinship testing for the purpose of migration decision making should be formalised through a Minister's direction made under s 499 of the Migration Act 1958 (Cth), amendments to the Procedures Advice Manual, or both, as appropriate.

Response
The Government notes that although DIMIA offers testing for a variety of genetic relationships, only a very small number of applicants undergo genetic testing. The results of many of these tests are open to interpretation. For example the relationship of uncle and niece cannot be proven conclusively through genetic testing.

DIMIA's Procedures Advice Manual contains detailed policy and procedural advice on genetic testing. In accordance with the Government's view that genetic testing evidence be treated consistently with other evidence submitted in support of an application, the Government believes that the Procedures Advice Manual is the best place for this material rather than formalising the procedures for genetic kinship testing in legislation.

The Government has initiated a general review of these guidelines that will focus on concerns raised in this report.

The Government is working to increase the number of laboratories that are accredited by NATA that can accommodate additional DIMIA specific standards (including privacy matters, international transportation, sample destruction, etc) when undertaking genetic testing for migration purposes. The Government is also concerned that the testing should remain practical and cost effective for visa applicants.

Recommendation 37–3
The Department of Health and Ageing, in consultation with DIMIA and the Human Genetics Commission of Australia, should develop policies on genetic tests and the use of genetic information (including family medical history) for the purpose of assessing the health requirement under migration legislation. These policies should include detailed guidelines for Medical Officers of the Commonwealth on the use of genetic information.

Response
The Government does not use genetic tests or genetic information for assessing the health status of prospective migrants. There are already a number of other tests used for this purpose. The Government has no plans to use genetic tests in this context.

CHAPTER 38 SPORT

Recommendation 38–1
The Australian Sports Commission (ASC) should monitor the use of genetic testing and genetic information for identifying or selecting athletes with a view to developing policies and guidelines for sports organisations and athletes. The policies and guidelines should be developed in consultation with the Human Genetics Commission of Australia (HGCA), the Human Rights and Equal Opportunity Commission (HREOC), the Office of the Federal Privacy Commissioner (OFPC), and other stakeholders.

Recommendation 38–2
The ASC should develop policies and guidelines for sports organisations and athletes on the use of genetic information in relation to predisposition to sports-related illness or injury. The policies and guidelines should be developed in consultation with the HGCA, HREOC, OFPC and other stakeholders.

Response
The Australian Sports Commission (ASC) has advised that it is developing a policy in relation to its involvement in the use, or the application of, genetic testing in its research program. This policy is being developed in consultation with relevant stakeholders, including the ALRC, AHRC, genetics researchers, the Australian College of Sports Physicians, Sports Medicine Australia, the Australian Sports Drug Agency and the Privacy Commissioner. The ASC has also advised that it has established a reference group to guide this process. The Board of the ASC has placed a moratorium on the use or application of genetics research until policy and guidelines are in place.

The Government also notes the recommendations that the ASC develop policies and guidelines for sports organisations and athletes on the use of genetic information for identifying or selecting athletes and in relation to predisposition to sports related illness or injury.

The Government notes that there is an ongoing requirement for the Australian Sports Drug Agency (ASDA) and the Australian Sports Drug Medical Advisory Committee (ASDMAC) to contribute to, and monitor developments and research into, the detection of genetic manipulation through the use of gene technology to ensure that Australia's anti-doping response remains effective.

LAW ENFORCEMENT AND EVIDENCE

CHAPTER 40 HARMONISATION OF FORENSIC PROCEDURES LEGISLATION

Recommendation 40–1
In order to facilitate an effective national approach to sharing genetic information for law enforcement purposes, the Commonwealth, States and Territories should collaborate to develop adequate national minimum

standards in Australian forensic procedures legislation with respect to the collection, use, storage, destruction and index matching of forensic material, and the DNA profiles created from such material.

Recommendation 40–2
The Commonwealth, States and Territories should not engage in inter-jurisdictional sharing of genetic information—whether on a bilateral basis or through a national DNA database system—unless there is legislation requiring that any information transferred to that jurisdiction will be treated in accordance with the national minimum standards developed under Recommendation 40–1.

Recommendation 40–3
In order to facilitate an effective national approach to sharing genetic information the States and Territories should amend their forensic procedures legislation in a manner consistent with the recommendations made in this Report in relation to the *Crimes Act 1914* (Cth).

Recommendation 40–4
For the purpose of achieving greater transparency, the Commonwealth, States and Territories should publish all ministerial agreements for sharing genetic information, as well as protocols for inter-jurisdictional matching.

Response
The recommendations in the law enforcement and evidence part of the report directly impact on the Commonwealth's forensic procedures laws.

A number of the issues considered in this report were also examined by the Independent Review of Part 1D of the *Crimes Act 1914*, which was undertaken by a review committee chaired by Mr Tom Sherman AO. The review committee included the Federal Privacy Commissioner and representatives of the Commonwealth Ombudsman, Australian Federal Police and the Commonwealth Director of Public Prosecutions. The *Report of the Independent Review of Part 1D of the Crimes Act 1914 - Forensic Procedures* (the Part 1D Report) was tabled in Parliament on 14 May 2003. The Government is of the view that the procedures in place for the consideration and implementation of the Part 1D Report recommendations are also the appropriate context to deal with the recommendations in this report.

The Government has referred the recommendations raised by both reports to SCAG, which has referred the recommendations to the SCAG and Australasian Police Ministers Council Joint Working Group. The Joint Working Group includes State and Territory police and justice officers and is also tasked with examining issues raised in other Commonwealth and State reviews.

CHAPTER 41 CRIMINAL INVESTIGATIONS

Recommendation 41–1
The Commonwealth should consider amending the *Crimes Act 1914* (Cth) (*Crimes Act*) to:

(a) remove the consent provisions in relation to suspects and serious offenders so that a forensic procedure only can be conducted on these persons pursuant to an order made by a judicial officer or an authorised police officer in accordance with the *Crimes Act*; and

(b) provide that, once the appropriate authority has made an order for a compulsory forensic procedure, the person who is the subject of the order should be able to choose the method by which the sample is taken.

Recommendation 41–2
The Commonwealth should amend the *Crimes Act* to provide that:

(a) the prescribed information about the nature, purpose and consequences of a forensic procedure should be given to a suspect, serious offender or volunteer in a form that is capable of being easily understood by the person receiving the information;

(b) a child or incapable person who is a volunteer, suspect or serious offender should be given the prescribed information in a form that is capable of being easily understood by that child or incapable person, as far as circumstances permit; and

(c) in addition to information provided to a parent or guardian, the prescribed information also should be given to a child or incapable person who is a volunteer.

Recommendation 41–3
The Commonwealth should amend the *Crimes Act* to provide that a forensic procedure may be carried out on a child volunteer of 12 years or more only: (a) with the consent of the child and his or her parent or guardian; or (b) pursuant to a magistrate's order under s 23XWU of the *Crimes Act*.

Recommendation 41–4
The Commonwealth should make separate provision for the collection, use, storage, index matching and destruction of forensic material, and profiles obtained from that material, for each main category of volunteer, whether by amending Part 1D of the *Crimes Act* or through regulations.

Recommendation 41–5
The Commonwealth should amend the *Crimes Act* to specify that a known victim of crime must be treated as a volunteer, and to require that all reasonable measures be taken to:

(a) separate the DNA belonging to a victim of crime from a crime scene sample where the latter contains mixed samples;

(b) ensure that a victim's DNA profile is not stored in the crime scene index of a DNA database system; and

(c) ensure that a victim's DNA profile is not matched against the crime scene index of a DNA database system.

Recommendation 41–6

The Commonwealth should develop and publish guidelines for the conduct of mass screening programs in relation to both the process for approving the initiation of programs and the manner in which they are conducted.

Recommendation 41–7
The Commonwealth should amend the *Crimes Act*, or regulations made thereunder, to provide that forensic analysis of genetic samples for use by law enforcement authorities should be conducted only by laboratories accredited by National Association of Testing Authorities, Australia (NATA) in the field of forensic science.

Recommendation 41–8
The Commonwealth should amend the *Crimes Act* to provide that forensic material obtained pursuant to Part 1D must be destroyed as soon as practicable after a DNA profile has been obtained from the material.

Recommendation 41–9
The Commonwealth should amend the *Crimes Act* so that the provisions limiting use and disclosure of information held on a DNA database system also apply to forensic material.

Recommendation 41–10
The Commonwealth should amend the *Crimes Act* to define the destruction of forensic material and information obtained from it in terms of physical destruction of samples and permanent and irreversible de-identification of profiles.

Recommendation 41–11
The Commonwealth should amend the *Crimes Act* to assign ultimate responsibility for managing the destruction of forensic material and any information obtained from it.

Recommendation 41–12
The Commonwealth should develop formal policies and procedures to:

(a) enable a volunteer (or parent or guardian) to specify, from a range of options, the retention period for his or her forensic material and any information obtained from it; and

(b) establish a process for persons to obtain confirmation that their forensic material, and any information obtained from it, has been destroyed.

Recommendation 41–13
The Commonwealth should amend the *Crimes Act* to provide that, with the exception of crime scene samples, law enforcement officers may collect genetic samples only from: (a) the individual concerned, pursuant to Part 1D; or (b) a stored sample, with the consent of the individual concerned (or someone authorised to consent on his or her behalf), or pursuant to a court order.

Response
As noted in the response to the recommendations in Chapter 40, many of the recommendations in this report overlap with the report of the review of Part 1D of the Crimes Act. The recommendations of both reports have been referred to the SCAG and Australasian Police Ministers Council Joint Working Group. The Government considers this body is best placed to consider the matters raised in this report as it is important to achieve a harmonised approach to the recommendations in each jurisdiction.

CHAPTER 42 IDENTIFICATION OF DECEASED PERSONS

Recommendation 42–1
The Commonwealth should amend the *Crimes Act 1914* (Cth) (*Crimes Act*) to delete reference to the DNA profiles of genetic relatives of missing persons from the definition of the 'missing persons index'.

Recommendation 42–2
The Commonwealth, States and Territories should clarify the arrangements under which police officers of one jurisdiction are authorised to act on behalf of another jurisdiction in collecting, using, storing or destroying forensic material from a missing or deceased person (or from a genetic relative of a missing or deceased person).

Recommendation 42–3
The Commonwealth should amend Division 11A of Part 1D of the *Crimes Act* to provide that where information stored on a DNA database system is accessed by, or disclosed to, a person for a 'permitted purpose', the information may be used only for that purpose.

Response
As noted in the response to recommendations in Chapters 40 and 41, many of the recommendations in this report overlap with the recommendations in the report of the review of Part ID of the Crimes Act. In accordance with the approach outlined above, recommendations 42-1, 42-2, 42-3 and 42-5 dealing with the identification of deceased persons have been referred to the SCAG and Australasian Police Ministers Council Joint Working Group.

Recommendation 42–4
The Commonwealth should amend s 23YUD of the *Crimes Act*, which regulates inter-jurisdictional sharing, to extend its coverage beyond criminal investigations to include the identification of missing or deceased persons.

Response
The Government agrees with this recommendation. Section 23YUD was amended by the *Crimes Legislation Enhancement Act 2003* to give effect to the recommendation. The amendment enables the Minister to enter into arrangements with a responsible Minister of a participating jurisdiction to allow sharing of information on the national DNA database system.

Information may be shared for the purposes of an investigation of a missing person or an investigation for the purpose of identifying a deceased person.

Recommendation 42–5
Where information stored on a DNA database system is disclosed to Interpol or any foreign agency, the Commonwealth must take reasonable steps to ensure that the information transferred will not be held, used or disclosed by the recipient inconsistently with the national minimum standards established in accordance with Recommendation 40–1.

Response
This recommendation has been referred to the SCAG and Australasian Police Ministers Council Joint Working Group together with recommendations 42-1, 42-2 and 42-3.

CHAPTER 43 DNA DATABASE SYSTEMS

Recommendation 43–1
The Commonwealth should amend the *Crimes Act 1914* (Cth) (*Crimes Act*) to provide that forensic material taken from a suspect, and any information obtained from its analysis, must be destroyed as soon as practicable after the person has been eliminated from suspicion, or police investigators have decided not to proceed with a prosecution against that person in relation to that investigation. However, in any event, the forensic material and information must be destroyed no later than: (a) 12 months after the material was taken or the information obtained; or (b) the period stipulated in an order made under s 23YD of the *Crimes Act*.

Recommendation 43–2
The Commonwealth should amend the definition of a 'DNA database system' in the *Crimes Act* to mean a database (whether in computerised or other form and however described) containing identifiable DNA profiles maintained for law enforcement purposes.

Recommendation 43–3
The Commonwealth should expand CrimTrac's board of management to include independent members, such as nominees of the Office of the Federal Privacy Commissioner and the Commonwealth Ombudsman, legal academics and ethicists.

Response
In accordance with the approach outlined in the responses to Chapters 40, 41 and 42, recommendations 43-1, 43-2, 43-3 and 43-5 dealing with the DNA database systems have been referred to the SCAG and Australasian Police Ministers Council Joint Working Group.

Recommendation 43–4
The Commonwealth should amend the *Crimes Act* to provide for a periodic audit, by an independent body, of the operation of all DNA database systems operating pursuant to the Act. The audit should include

the forensic laboratories participating in the DNA database system and the audit report should be made publicly available.

Response
The Government has referred the issue of accountability raised by this recommendation and the Part 1D Report to SCAG. State and Territory Privacy Commissioners and Ombudsmen have reported to SCAG on this issue and, in consultation with SCAG officers, are working on proposals for consideration by SCAG for improving the current legislative and administrative arrangements for cross-border law enforcement authorities, including forensic procedures.

Recommendation 43–5
In its annual report to Parliament, the Australian Federal Police should provide information on the number and category of samples obtained pursuant to Part 1D of the *Crimes Act* in that year; the authority under which these samples were obtained; and compliance with the required destruction dates for those samples and profiles.

Response
This recommendation has been referred to the SCAG and Australasian Police Ministers Council Joint Working Group together with recommendations 43-1, 43-2 and 43-3.

CHAPTER 44 CRIMINAL PROCEEDINGS

Recommendation 44–1
The National Judicial College of Australia and the Law Council of Australia (through its constituent professional associations) should develop and promote continuing legal education programs for judges and legal practitioners, respectively, in relation to the use of genetic information in criminal proceedings.

Recommendation 44–2
In order to provide better guidance for judges and juries, the judiciary should develop a model jury direction for use where DNA evidence has been admitted in criminal proceedings.

Response
The Government has drawn recommendations 44-1 and 2 to the attention of the Judicial College of Australia and recommendation 44-1 to the notice of the Law Council of Australia.

Recommendation 44–3
The National Institute of Forensic Science, in consultation with members of the criminal justice and science communities, should provide ongoing guidance to forensic scientists and legal practitioners regarding reliable methods of DNA analysis, statistical calculation, and presentation of evidence in criminal proceedings.

Response

The Government has written to the National Institute of Forensic Science about recommendation 44-3.

Recommendation 44–4
The Commonwealth should amend the *Crimes Act 1914* (Cth) to specify that the prosecution has a duty to provide defendants with reasonable pre-trial notice of all relevant crime scene samples in order to give them an opportunity to have such samples independently analysed.

Response
The issues raised by this recommendation relate to the Review of Part 1D of the Crimes Act. As noted above, the Government has referred relevant recommendations, including recommendation 44-4, to SCAG, which has referred the recommendations to the SCAG and Australasian Police Ministers Council Joint Working Group.

CHAPTER 45 POST-CONVICTION USE OF DNA EVIDENCE

Recommendation 45–1
The Commonwealth should amend the *Crimes Act 1914* (Cth) to require the long-term retention of forensic material found at the scene of serious crimes to facilitate post-conviction analysis.

Recommendation 45–2
The Commonwealth should establish a process to consider applications for post-conviction review from any person who alleges that DNA evidence may exist that calls his or her conviction into question.

Response
As noted in the response to the recommendations in chapters 40, 41, 42 and 43, many of the recommendations in this part of the report overlap with the recommendations in the report of review of Part ID of the Crimes Act. In accordance with the approach outlined in those chapters, recommendations 45-1 and 45-2 dealing with post conviction use of DNA evidence have been referred to the SCAG and Australasian Police Ministers Council Joint Working Group.

CHAPTER 46 CIVIL PROCEEDINGS

Recommendation 46–1
The National Judicial College of Australia and the Law Council of Australia (through its constituent professional associations) should develop and promote continuing legal education programs for judges and legal practitioners, respectively, in relation to the use of genetic information in civil proceedings.

Response
The Government has drawn this recommendation to the attention of the Judicial College of Australia and the Law Council of Australia.