

DISCUSSION PAPER

**NON-CONSENSUAL
GENETIC TESTING**

Model Criminal Law Officers' Committee of the
Standing Committee of Attorneys-General

November 2008

This Discussion Paper was prepared by the Model Criminal Law Officers' Committee. It does not necessarily represent the views of the Standing Committee of Attorneys-General or an individual Attorney-General.

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1 Introduction

1.1 *The impetus for developing a non-consensual genetic testing offence*

In 2003, the Australian Law Reform Commission (ALRC) and Australian Health Ethics Committee released its report, *Essentially Yours: The Protection of Human Genetic Information in Australia*, Report No 96. The Inquiry focussed on issues arising out of the rapid development of human genetic technology. The Inquiry was prompted by concerns about

- privacy and discrimination, especially in the context of insurance and employment, and
- ethical and other oversight of clinical practice, medical and scientific research, and the use and collection of genetic databases.

Recommendation 12 of the ALRC's report stated that:

The Standing Committee of Attorneys-General (SCAG) 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.

In April 2007, SCAG requested that the Model Criminal Law Officers Committee (MCLOC) consider the merits of a draft model offence to criminalise non-consensual genetic testing. SCAG asked MCLOC to give special consideration to health and law enforcement matters in developing the model offence.

In this Discussion Paper, MCLOC examines the issue of non-consensual genetic testing and proposes draft model offences to criminalise it.

MCLOC encourages interested people or organisations to provide their views on this discussion paper. These comments will be used to assist MCLOC in preparing its final report.

Comments should be sent to:

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Submissions will be published on the Commonwealth Attorney-General's Department website. Please advise if you do not wish to have your submission published.

1.2 *Model Criminal Law Officers' Committee*

On 28 June 1990, SCAG placed the question of the development of a national Model Criminal Code for Australian jurisdictions on its agenda. To advance the concept, SCAG established the Criminal Law Officers Committee consisting of an officer from each Australian jurisdiction with expertise in criminal law and criminal justice matters. That Committee's name was changed in November 1993 to the Model Criminal Code Officers Committee (MCCOC). MCCOC released several Discussion Papers and Reports on criminal law topics.¹

¹ MCCOC and MCLOC discussion papers and reports can be found at the Australian Government Attorney-General's Department website at <http://www.ag.gov.au/www/agd/agd.nsf/Page/Model_criminal_code>.

In July 2006, SCAG decided to rename the committee as the Model Criminal Law Officers Committee to reflect the Committee's broader role of advising on criminal law issues that have been referred to it by SCAG and the fact that development of the Model Criminal Code is largely complete.

1.3 Committee's previous work on related issues

Non-consensual genetic testing may be captured by some theft and fraud offences. The Committee has previously reported on the law dealing with these offences in its Final Report on *Chapter 3: Theft, Fraud, Bribery and Related Offences* (Dec 1995). The Committee has also reported on model forensic procedures and non fatal offences against the person.

2 What is non-consensual genetic testing?

Non-consensual genetic testing occurs when bodily samples are taken and genetically tested without the knowledge or consent of the individual from whom they have been obtained.²

Biomedical technology enables genetic testing to be performed on minute bodily samples. Genetic information may be derived from samples such as hair follicles, saliva left on a glass or cigarette, cheek cells left on a toothbrush and cells deposited on an item of clothing or mucus in a tissue.³

The combination of powerful biomedical technology and the ability to easily access human genetic samples leaves open the potential for non-consensual genetic testing to occur.

² *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003, at paragraph 12.5.

³ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.20.

3 What is the impact of non-consensual genetic testing?

Paragraphs 12.12 to 12.14 of the ALRC Report outline the harm that non-consensual genetic testing can cause.

12.12 The collection of a sample may, in some circumstances, involve a physical harm or a trespass to the person (a battery), as when a person is held down and a bodily sample is taken by force. Collection may also result in emotional harm. Emotional harm may result from situations where, from the perspective of the individual concerned, intimate bodily samples (such as menstrual blood or semen) are taken, or kinship or identity is questioned.

12.13 The most obvious harm arising from testing of the sample is the intrusion on basic human dignity and autonomy. The harm may be also characterised as involving a breach of information privacy. Genetic testing may result in the disclosure of sensitive personal information of many kinds. Testing can reveal information about the present and future health of an individual, an individual's identity, or his or her parentage or kinship. The fact that harm may be caused by the non-consensual disclosure of these kinds of information is recognised by laws that proscribe disclosure in other contexts, including legal and statutory duties of confidentiality, and information and health privacy legislation.

12.14 The possible uses of the information derived from non-consensual testing may also give rise to harm, including harm caused:

- by the use of genetic information by employers, insurers and others for discriminatory purposes;
- to individuals who involuntarily learn about their long-term health prognosis and other physical and behavioural characteristics, in breach of their 'right not to know';
- by media publicity about an individual's genetic characteristics, especially where that individual is a celebrity or otherwise newsworthy;
- by the use of genetic information by police in criminal proceedings or by litigants in civil proceedings; and

- by disruption to family relationships and harmony where parentage or other kinship information is disclosed.

The ALRC Report also noted the increasingly common fear of ‘genetic trophy hunters’. For example, bodyguards of former United States President, Bill Clinton, collected a pint glass after he had drunk from it in a British pub, to ensure that his DNA could not be obtained. Newspapers have also reported a ‘plot’ to obtain a sample of Prince Harry’s DNA.⁴

4 Existing legislative framework

The law in Australia offers some legal protection against harms arising out of non-consensual genetic testing. These protections are outlined below.

4.1 *Tort of trespass to the person and assault*

The tort of trespass to the person is constituted by touching a person’s body without consent. It is a civil tort which would need to be pursued through the courts. Non-consensual touching may also constitute an assault in criminal law.

The offence of assault and the tort of trespass would not apply in cases of ‘discarded’ genetic material where a person has not been touched, such as hair from combs, saliva from a glass, cheek cells from a toothbrush, or mucus from a tissue.⁵

Additionally, police and prosecutors may be reluctant to take action where the touching itself is minor, and no injury or harm is suffered.

⁴ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.6.

⁵ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.20.

4.2 Theft and fraud

As with assault and trespass, it is unlikely that police would investigate the apparently minor theft of a strand of hair or a blood stained tissue. In the case of genetic data, it is the information that can be obtained from these items that raises real issues of concern. Therefore, the relevant question is whether or not a person's genetic information is 'property capable of being stolen'.

The ALRC noted that while current law recognises possessory rights and limited ownership interests in preserved samples of tissue, no proprietary rights are vested in the individual from whom samples are taken, such as might enable that individual to bring an action against others who deal with the samples.⁶

In recent years, however, the definition of property has been expanded to cover intangible property, including things in action. For example, the definition of property in South Australia's *Criminal Law Consolidation Act 1935* includes 'intangible property' (including things in action).

Intangible property describes something which a person or corporation can own and can transfer ownership of to another person or corporation, but has no physical substance. It generally refers to statutory creations such as copyright, trademarks, and patents.

A thing in action is an intangible personal property right recognised and protected by the law, but which has no existence apart from the recognition given by the law, or which confers no present possession of a tangible object. A chose in action, in its more limited meaning, denotes the right of enforcing the payment of a debt by legal proceedings, or obtaining money by way of damages for contract, or as a recompense for a wrong.

Given these developments, information, and DNA information more specifically, may now fall within the definition of property, thereby making it capable of being stolen.

⁶ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.21.

Similarly, many fraud offences have a wide application. For example, the South Australian offence states:

139—Deception

A person who deceives another and, by doing so—

- (a) dishonestly benefits him/herself or a third person; or
- (b) dishonestly causes a detriment to the person subjected to the deception or a third person, is guilty of an offence.

As with assault and trespass, these offences may have no application to discarded material, such as a glass in a public bar, where the person has willingly left the material behind or where there has been no deception of the person whose genetic material has been obtained.

4.4 Breach of information privacy

‘Information privacy’ can be defined as the right of an individual to control the collection, use and disclosure of information relating to him or her.⁷

Privacy legislation at the Commonwealth, State and Territory levels provides some protection against the collection and testing of genetic samples without consent. This protection is limited for the following reasons.

- (a) *Genetic samples vs genetic information* – except in New South Wales, information and health privacy legislation do not currently apply to genetic samples, in contrast with the genetic information derived from them.⁸ The Commonwealth *Privacy Act 1988* (the Privacy Act) was amended in 2006 to extend the definition of ‘health information’ to include genetic information, and to extend the definition of ‘sensitive information’ to include genetic information that is not health information (for example the result of a parentage or kinship test). The amendments do not extend to genetic samples because the then

⁷ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003, at Chapter 7.

⁸ *Privacy and Personal Information Protection Act 1998* (NSW), section 4; *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.22.

Commonwealth Government did not accept the ALRC's recommendation (8-2) to amend the Privacy Act to regulate the handling of genetic samples. Rather, it stated in its response to the ALRC response that:

[t]he 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.

- (b) *Other than in the course of a business* – the application of the Commonwealth Privacy Act is limited because acts done, or practices engaged in, by individuals are exempt if done or engaged in 'other than in the course of a business carried on by the individual'. The example of a journalist who sells information about Y's genetic condition for a news story may be exempt under other provisions of the Privacy Act dealing specifically with media organisations and journalists.⁹

There is also an exemption where the collection, use or disclosure of personal information occurs 'only for the purposes of, or in connection with, his or her personal, family or household affairs'.¹⁰ This would exclude genetic testing for purposes relating to family health, personal identity or parentage testing.

The ALRC considered that the Privacy Act is not the appropriate vehicle to prohibit non-consensual genetic testing. It considered that the focus of the Privacy Act should remain on regulating the practices of government and businesses rather than individuals in their private capacities. It also considered that the enforcement mechanisms for breach of the Privacy Act were inadequate sanction for non-consensual genetic testing.¹¹

⁹ *Privacy Act 1988 (Cth)* section 7B(4).

¹⁰ *Privacy Act 1988 (Cth)* section 16E.

¹¹ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.46.

4.5 Forensic procedures laws

Non-consensual genetic testing is not unlawful under existing forensic procedures legislation. These provisions typically set out when, where and how DNA testing can be conducted for criminal law purposes.

Generally, non-consensual genetic testing is permitted only when an order by a relevant magistrate or judge has been obtained (for example, see Division 5 of Part 1D of the Commonwealth *Crimes Act 1914*).

4.6 New model offences: addressing the gaps in the existing legal framework

After surveying the existing legal framework, MCLOC considers that the harms arising from non-consensual genetic testing are not addressed in Australia.

MCLOC agrees with the ALRC's comments that 'a legislative response is required to address the gaps in existing legislation'.¹²

5 Overseas responses

5.1 United Kingdom

The United Kingdom's Human Genetics Commission reported on the issue of non-consensual genetic testing in its 2002 report, *Inside Information: Balancing Interests in the Use of Personal Genetic Data*. The Commission concluded that there are scenarios where current legal remedies may not offer sufficient protection against breaches of an individual's genetic privacy, for example in the following cases:¹³

¹² *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.26.

¹³ Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, 2002, at page 60. Cited in *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.17.

- X takes Y's beer glass and obtains an analysis of her DNA. X then sells to a newspaper the information that Y has a particular genetic condition.
- X decrypts anonymised genetic information about Y from a research study for some wrongful purpose.
- X obtains a sample from child A, for whom he has no parental responsibility, to ascertain whether he is the father of A.

The Commission recommended that

consideration be given to the creation of a criminal offence of the non-consensual or deceitful obtaining and/or analysis of personal genetic information for non-medical purposes.¹⁴

The UK Government responded to this report in its White Paper on Genetics, *Our Inheritance, Our Future: Realising the potential of genetics in the NHS*.¹⁵ It announced its intention to introduce a new offence of testing an individual's DNA without his/her knowledge or consent. It noted that new offences:

- must not interfere with the use of genetic material by the police or the courts
- must allow doctors or researchers to be sure whether they can order new genetic tests without returning to the patient for consent, and
- must not affect lawful access to private paternity testing.

¹⁴ Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, 2002 at p 62.

¹⁵ A copy of this report can be obtained at <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006538>.

The offence of 'DNA theft' was implemented as part of the UK *Human Tissue Act 2004*.¹⁶ The offence in section 45 commenced on 1 September 2006 and provides that it is an offence to have any bodily material intending:

- that any human DNA in the material be analysed without qualifying consent, and
- that the results of the analysis be used otherwise than for an excepted purpose.

The offence carries a maximum penalty of three years imprisonment.

The definition of qualifying consent and excepted purposes are set out in Schedule 4. Excepted purposes include general purposes such as medical treatment and criminal justice. A copy of the text of section 45 and Schedule 4 Part 1 and 2 are at **Attachment A**.

5.2 *International Declaration on Human Genetic Data*

On 16 October 2003, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the International Declaration on Human Genetic Data.¹⁷ This recognised that human genetic data have a special status because:

- they can be predictive of individual genetic predispositions
- they may have a significant impact on the family, including offspring, extending over generations
- they may contain information of a significance that is not necessarily known at the time of the collection of biological samples, and,
- they may have cultural significance for persons or groups.

¹⁶ A copy of this Act can be obtained at http://www.opsi.gov.uk/ACTS/acts2004/ukpga_20040030_en_1.

¹⁷ A copy of this declaration can be obtained at <http://unesdoc.unesco.org/images/0013/001342/134217e.pdf>.

Relevant provisions of the Declaration are outlined below. A complete copy of the Declaration is at **Attachment B**.

- Article 1(c) provides that the Declaration applies to the collection, processing, use and storage of human genetic data ... except in the investigation, detection and prosecution of criminal offences and in parentage testing that is subject to domestic law that is consistent with the international law of human rights
- Article 7(a) provides that every effort should be made to ensure that human genetic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatisation of an individual, a family, a group or communities
- Article 8 requires that consent be obtained before any collection of human genetic data
- Article 12 provides for the collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings, and
- Article 14 sets out privacy and confidentiality considerations.

6 Model non-consensual genetic testing offences

6.1 Conceptual framework

As outlined above, the objective of the model offences is to address the harms arising out of non-consensual genetic testing. The offences are not intended to:

- override existing legislation and settled case law on consent and other relevant issues, or

- make unlawful currently lawful medical practices.

The model provisions allow for the continued operation of existing legislation and case law where the law is settled. For example, 'consent' is not defined in the model provisions because there is a settled body of case law about consent (both the physical contact and the conduct of medical procedures, including administering diagnostic and other tests) and how it is established (see discussion on section 5.3.2 for further information).

The model provisions also provide a defence of lawful authority to protect currently lawful genetic testing practices (see discussion on section 5.3.5 for further information).

6.2 The offenders

The MCLOC model offences apply to individuals as well as bodies corporate that conduct the testing, such as laboratories and their employees, agents or officers.

Where the offender is a body corporate, the physical elements of the offence would be attributed to the body corporate where committed by an employee, agent or officer acting within the actual or apparent scope of his/her employment, or within his or her actual or apparent authority.¹⁸

The MCLOC model offences are aligned with the ALRC's views about the application of the offences to individuals and bodies corporate.

6.3 The model provisions

MCLOC proposes draft model offences for consideration. The proposed offences would form part of Chapter 5 (offences against the person) of the Model Criminal Code. A complete version of the MCLOC model offences is set out at the end of this section.

¹⁸ This is the approach adopted in sections 12.1 and 12.2 of the *Criminal Code Act 1995 (Cth)*; see discussion at *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.55.

The MCCOC Forensic Procedures Report¹⁹ has been used as a model for drafting the non-consensual genetic testing provisions. The offence, penalty provisions and defences for the proposed unlawful genetic testing offences are aligned with similar provisions in the Forensic Procedures Report.

The model provisions apply standard fault elements used in Chapter 2 of the Model Criminal Code – the general principles of criminal responsibility. The operation of the fault elements in each provision is explained below.²⁰

Model provisions

5.3.1 Definitions

(1) In this Division:

bodily material means any part of a human body or anything produced by a human body, including human organs, cells, ova and foetal tissue, hair, nails, skin tissue, saliva, blood, semen and other bodily fluids.

genetic test means a test or procedure in which the bodily material of a person is used to reveal genetic information about that person.

obtain bodily material includes remove or collect bodily material.

(2) In this Division, a reference to bodily material of a person includes a reference to bodily material that no longer forms part of the person's body but previously formed part of, or was produced by, the person's body.

(3) In this Division, a reference to a person incapable of giving consent is a reference to a living person who is:

- (a) a child under 18 years of age, or
- (b) incapable of understanding the general nature and effect of the action for which consent is required, or
- (c) incapable of indicating whether or not he or she consents or does not consent to the action for which consent is required.

(4) In this Division, a reference to the consent of a person who is deceased is a reference to consent given (and not subsequently revoked) during the person's lifetime.

¹⁹ MCCOC Report - Model Forensic Procedures Bill 2000 and the proposed national DNA database - May 1999.

²⁰ The standard Model Criminal Code fault elements are set out at the beginning of the MCCOC Report - Chapters 1 and 2 of the Model Criminal Code *The General Principles of Criminal Responsibility*.

(5) In this Division, a reference to causing a genetic test to be conducted includes a reference to conducting a genetic test.

5.3.2 Obtaining bodily material for genetic test

(1) A person who obtains any bodily material of another person:

- (a) with the intention of causing a genetic test to be conducted using that bodily material, and
- (b) without the consent to the genetic test of that other person, and
- (c) knowing about or being reckless as to that lack of consent,

is guilty of an offence.

Maximum penalty: Imprisonment for 2 years.

(2) It is not an offence to attempt to commit an offence against this section.

5.3.3 Use of bodily material for genetic test

A person who causes a genetic test to be conducted using the bodily material of another person:

- (a) without the consent to the genetic test of that other person, and
 - (b) knowing about that lack of consent,
- is guilty of an offence.

Maximum penalty: Imprisonment for 2 years.

5.3.4 Disclosure or use of results of genetic test

(1) A person who discloses or uses any information obtained as a result of a genetic test conducted using the bodily material of another person:

- (a) without the consent of that other person to that disclosure or use, and
 - (b) knowing about or being reckless as to that lack of consent,
- is guilty of an offence.

Maximum penalty: Imprisonment for 2 years.

(2) This section does not apply to the disclosure or use of information that does not identify any person.

5.3.5 Application of offences if person incapable of giving consent

A person who obtains or uses bodily material of a person who is incapable of giving consent at the time the bodily material is obtained or used, or discloses or uses information obtained as a result of a genetic test conducted using bodily material of a person who is incapable of giving consent at the time of the disclosure or use of the information:

- (a) is to be treated as having acted without the consent of the person incapable of giving consent, and
- (b) is to be treated as having known about that lack of consent if it is proved that the person knew that the other person was, or was reckless as to the other person being, a person incapable of giving consent.

5.3.6 Defences

(1) A person is not criminally responsible for an offence against this Division in respect of the following:

(a) the obtaining or use of any bodily material, or the disclosure or use of any information, if the person is a public official (within the meaning of Part 3.6) acting in the course of his or her duty as a police officer, prison officer or other law enforcement officer and the conduct of the person is reasonable in the circumstances for the purpose of performing that duty,

(b) the disclosure or use of information in connection with proceedings for an offence or any legal proceedings arising out of a contravention of a law of the Commonwealth, a State or a Territory,

(c) the obtaining or use of bodily material of a deceased person, or the disclosure or use of any information obtained as a result of a genetic test conducted using bodily material of a deceased person, if the person obtaining or using the bodily material or disclosing or using the information is *[description of person or persons entitled to consent to testing of bodily material of deceased person]* or is acting with the consent of that person,

(d) the obtaining or use of bodily material of a person who is incapable of giving consent, or the disclosure or use of any information obtained as a result of a genetic test conducted using bodily material of a person who is incapable of giving consent, if the person is *[description of person or persons entitled to consent to testing of bodily material on behalf of person incapable of giving consent]* or is acting with the consent of that person.

(2) This Division does not affect the obtaining or use of bodily material, or the disclosure or use of information obtained as a result of a genetic test conducted using bodily material, if the obtaining or use of the bodily material is authorised by or under another law of the State [or Territory] or a law of the Commonwealth.

Note: It is for each jurisdiction to decide who is to be authorised to give consent to a genetic test, or to the disclosure or use of information about a genetic test, in the case of bodily material obtained from a deceased person or a person incapable of giving consent. This extends to the question of whether a genetic test using bodily material of a child must be consented to by one parent or by both parents and to the question of who should be able to

consent to the testing of bodily material of a deceased person if the deceased person cannot be identified.

If a decision is made to require a parent (or both parents) to consent to a genetic test using bodily material of a child, section 5.1.8 of the Code contains a definition of “parent”.

In the case of a bodily material of a deceased person, the person entitled to give consent could be defined in line with laws of the jurisdiction relating to donations of tissue or organs. For example, in NSW the legislation could enable the “senior available next of kin” (within the meaning of the Human Tissue Act 1983) to consent to a genetic test.

Section 5.3.1 - Definitions

(1) In this Division:

bodily material means any part of a human body or anything produced by a human body, including human organs, cells, ova and foetal tissue, hair, nails, skin tissue, saliva, blood, semen and other bodily fluids.

genetic test means a test or procedure in which the bodily material of a person is used to reveal genetic information about that person.

obtain bodily material includes remove or collect bodily material.

(2) In this Division, a reference to bodily material of a person includes a reference to bodily material that no longer forms part of the person’s body but previously formed part of, or was produced by, the person’s body.

(3) In this Division, a reference to a person incapable of giving consent is a reference to a living person who is:

- (a) a child under 18 years of age, or
- (b) incapable of understanding the general nature and effect of the action for which consent is required, or
- (c) incapable of indicating whether or not he or she consents or does not consent to the action for which consent is required.

(4) In this Division, a reference to the consent of a person who is deceased is a reference to consent given (and not subsequently revoked) during the person’s lifetime.

(5) In this Division, a reference to causing a genetic test to be conducted includes a reference to conducting a genetic test.

Subsection 5.3.1(1) – definition of bodily material

The definition of bodily material covers parts of a human body or anything produced by a human body. This includes bodily material obtained from a deceased person.

The three model offences apply to genetic testing conducted on the bodily material of deceased persons because the following harms could arise as a result of genetic testing on deceased persons:

- revealing an illness with a genetic component, thus affecting surviving family members, and
- revealing something that is embarrassing or damages the deceased's reputation, causing distress to surviving family members.

Subsection 5.3.1(1) – definition of genetic test

MCLOC considers that 'genetic test' should be defined generally to be a test or procedure that uses bodily material of a person to reveal information about their genes. The definition of genetic test does not list the tests described in the ALRC Report,²¹ as the terms used in that definition are of a technical or scientific nature and are therefore at odds with the style of other provisions in the Model Criminal Code (which are capable of being generally understood). Also, the definition is technologically neutral because the types of genetic tests that can be undertaken are likely to change as technology develops.

This definition captures all types of genetic testing, including testing of non-coding regions of DNA (this includes the Profiler Plus genetic testing system).

²¹ Chapter 10 of the ALRC Report discusses forms of genetic testing, and defines genetic testing to be scientific tests that are conducted to reveal genetic information, including but not limited to DNA or RNA tests, tests using DNA chip technology, testing the biological products of particular genes, biochemical tests, medical imaging processes and assessments of morphological characteristics of certain cells.

Subsection 5.3.1 (2)

This subsection provides that a reference to bodily material in the offence provisions includes bodily material obtained from the body of another person. When read with the other offence provisions, the effect of this section is that the requirement to obtain consent still applies in relation to testing bodily material that has become detached from a person's body. This will extend to cases in which the bodily material is mixed with the bodily material of another person.

Subsection 5.3.1 (3)

This subsection defines the categories of person who are 'incapable of giving consent'. This term as defined then appears in section 5.3.5 which deals with how the concept of consent to a genetic test (which can render the offences inapplicable) operates in the case of such a person. The listed categories of such people are:

- children
- people incapable of understanding the general nature and effect of the action for which consent is required
- people incapable of indicating whether or not they consent to the action for which consent is required.

Subsection 5.3.1(4)

The subsection, read with the offence provisions, allows the deceased person to consent during their lifetime to the use of their bodily material or disclosure of genetic testing results once they have died.

Subsection 5.3.1(5)

This subsection defines the terms 'causing a genetic test to be conducted'. Causing a genetic test to be conducted includes situations where a person

- conducts a genetic test themselves, or
- arranges for genetic testing to occur through a third party (for example, by sending bodily material to a laboratory for testing).

Section 5.3.2 - Obtaining bodily material for genetic test

(1) A person who obtains any bodily material of another person:

(a) with the intention of causing a genetic test to be conducted using that bodily material, and

(b) without the consent to the genetic test of that other person, and

(c) knowing about or being reckless as to that lack of consent,

is guilty of an offence.

Maximum penalty: Imprisonment for 2 years.

(2) It is not an offence to attempt to commit an offence against section 5.3.2.

This proposed offence criminalises the taking of bodily material for genetic testing when the person from whom bodily material has been obtained did not consent to having that specific sample of bodily material genetically tested.

There are differing views about whether criminalising the taking of bodily material is appropriate. The ALRC considered that criminalising the taking of the bodily material was inappropriate given the ubiquity of material from which genetic samples can be taken.²² However, the New South Wales Legal Aid Commission expressed the view, in a submission to the ALRC, that the conduct constituting the offence should include the taking of bodily material.²³

MCLOC considers both views can be addressed by criminalising the taking of bodily material where the intention of submitting it for genetic testing exists. By including the element of intention, a person cannot be charged for merely

²² *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.52.

²³ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.50.

taking bodily material without the required consent. MCLOC considers that this addresses the ALRC's concern about the ubiquity of genetic samples.

The United Kingdom has used intention in a similar way. The UK 'DNA theft' offence is based on the possession of genetic material with intent to test that material. That is, it is an offence to have any bodily material *intending* -

(a) that any human DNA in the material be analysed without qualifying consent, and

(b) that the results of the analysis be used otherwise than for an excepted purpose.

Elements of the offence and penalty

The fault elements²⁴ and physical elements of the offence are outlined in the following table. Under the Model Criminal Code 'default' fault elements are supplied where no fault element is specified. These are indexed in the table below.²⁵

Offence	Fault element	Physical	Penalty
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²⁴ Section 203 of the Model Criminal Code (found in Chapters 1 and 2 - *The General Principles of Criminal Responsibility*) defines the standard fault elements as follows.

- A person has intention with respect to conduct when he or she means to engage in that conduct. A person has intention with respect to circumstance when he or she believes that it exists or that it will exist. A person has intention with respect to a result if he or she means to bring it about or is aware that it will occur in the ordinary course of events.
- A person has knowledge of a circumstance or a result if he or she is aware that it exists or will exist in the ordinary course of events.
- A person is reckless with respect to a circumstance if:
 - (a) he or she is aware of a substantial risk that the circumstance exists or will exist, and
 - (b) having regard to the circumstances known to him or her, it is unjustifiable to take the risk.

²⁵ Section 203.5 of the Model Criminal Code (found in Chapters 1 and 2 - *The General Principles of Criminal Responsibility*) provides that the default fault element under the Model Criminal Code is recklessness.

		element	
Obtaining bodily material for genetic material testing	A intends (means) to obtain the material. (default fault element)	A obtains the material.	2 years
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable risk) that the material is bodily material. (default fault element)	The material is bodily material.	
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable risk) that the material belongs to B. (default fault element)	The bodily material belongs to B.	
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable risk) that B does not consent.	The bodily material is obtained without the consent of B.	
	A's intention is to have the material genetically tested (ulterior fault element).	N/A	

The maximum penalty proposed for this offence is two years imprisonment.

MCLOC considered this penalty reflects:

- the seriousness of the harm to a victim's personal autonomy, wellbeing and bodily integrity, and
- the likelihood that the commission of the offence would result in long-term consequences for the victim's family members and the general community.

Consent

A physical element that appears in all three MCLOC model offences is that the individual from whom the bodily material was taken did not consent to such testing.

Section 5.3.3 - Use of bodily material for genetic test

A person who causes a genetic test to be conducted using the bodily material of another person:
(a) without the consent to the genetic test of that other person, and
(b) knowing about that lack of consent,
is guilty of an offence.

Maximum penalty: Imprisonment for 2 years.

This proposed offence criminalises the use of bodily material for genetic testing when the person from whom bodily material has been obtained did not consent to having that specific sample of bodily material genetically tested.

Elements of the offence and penalty

The elements of the offence are outlined in the below table.

Offence	Fault element	Physical element	Penalty
Use of bodily material for genetic testing	A intends (means) the test to be conducted. (default fault element)	A causes a genetic test to be conducted	2 years
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable risk) that the material is bodily material. (default fault element)	The test is conducted using bodily material.	
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable	The bodily material belongs to B.	

	risk) that the material belongs to B. (default fault element)		
	A knows that B does not consent to the conduct of the test.	B does not consent to the conduct of the test.	

The penalty is consistent with penalties assigned to similar offences. For example, the Model Criminal Code offence of possession of identification information with the intention of committing an indictable offence carries a penalty of three years imprisonment.²⁶ Similarly, the *Health Records and Information Privacy Act 2002* (NSW) offence of the intentional disclosure or use of any health information about an individual carries a penalty of two years imprisonment.²⁷ The MCLOC model offence is comparable in kind and seriousness to these offences – because they all result in a violation of an individual’s personal autonomy and privacy.

Section 5.3.4 - Disclosure or use of results of genetic test

(1) A person who discloses or uses any information obtained as a result of a genetic test conducted using the bodily material of another person:
(a) without the consent of that other person to that disclosure or use, and
(b) knowing about or being reckless as to that lack of consent,
is guilty of an offence.

Maximum penalty: Imprisonment for 2 years.

(2) This section does not apply to the disclosure or use of information that does not identify any person.

This proposed offence criminalises using or disclosing the results of another person’s genetic test, knowing about or being reckless as to whether that person has given consent to use the information for that purpose.

MCLOC considers an offence of improper use or disclosure provides further protection to individuals by requiring genetic testing laboratories and other

²⁶ *Model Criminal Code* section 6.3(3).

²⁷ *Health Records and Information Privacy Act 2002* (NSW), section 68.

persons to obtain consent before using or disclosing information derived from a genetic test.

Some submissions to the ALRC Inquiry, including from the South Australian Department of Human Services, submitted that the offending conduct should specifically include the 'publication' or 'use' of an identified individual's results.²⁸

The ALRC pointed to the significant difficulties involved in defining the unauthorised uses, given the range of information that could be derived from samples and the spectrum of possible uses. Some of these uses would be proscribed by existing law, such as where the publication of genetic information is defamatory.²⁹

The offence provision is restricted to the use and disclosure of genetic information that identifies the specific individual from whom the sample was obtained. MCLOC considers that in many cases there may be benefits in allowing disclosure of genetic information that does not identify a person; for example, this may occur for the purposes of medical or scientific research; and that the potential harms in this are minimal.

Proposed subsection (2) provides the offence does not apply to the disclosure or use of information that does not identify any person.

Subsection (2) has been drafted in line with subsection 86(3) in the MCCOC Model Forensic Procedures Report.³⁰ Section 86 provides:

86 Access to and disclosure of information on DNA identification databases (former cl 66B)

(1) A person must not access, or disclose to any person, information stored on a DNA database unless the information

²⁸ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.51.

²⁹ *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC Report No 96, 2003 at paragraph 12.53.

³⁰ MCCOC Report - Model Forensic Procedures Bill 2000 and the proposed national DNA database - May 1999.

is accessed or disclosed for one or more permissible purposes.

Maximum penalty: 2 years imprisonment.

...

(3) Nothing in this section applies in relation to information that does not identify any person.

Elements of the offence and penalty

The elements of the offence are outlined in the below table.

Offence	Fault element	Physical element	Penalty
Disclosure or use of results of genetic test	A intends (means) to disclose or use the information. (default fault element)	A discloses or uses information.	2 years
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable risk) that the information was obtained as a result of a genetic test. (default fault element)	The information was obtained as a result of a genetic test.	
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable risk) that the material is from B. (default fault element)	The test was conducted on bodily material from B.	
	A knows (is aware) or is reckless (aware of a substantial and unjustifiable risk) that B does not consent to the	The information was disclosed or used without the consent of B.	

	disclosure or use.		
Exception: The information does not identify any person.			

The disclosure offence in the draft is similar to the 'disclosure of information' offence in the MCCOC Model Forensic Procedures Report (section 81). The disclosure of information offence carries a penalty of two years. Accordingly, the penalty in the disclosure offence is aligned with the penalty of the disclosure of information offence.

Section 5.3.5 - Application of offences if person incapable of giving consent

A person who obtains or uses bodily material of a person who is incapable of giving consent at the time the bodily material is obtained or used, or discloses or uses information obtained as a result of a genetic test conducted using bodily material of a person who is incapable of giving consent at the time of the disclosure or use of the information:

- (a) is to be treated as having acted without the consent of the person incapable of giving consent, and
- (b) is to be treated as having known about that lack of consent if it is proved that the person knew that the other person was, or was reckless as to the other person being, a person incapable of giving consent.

The genetic testing of bodily material taken from persons incapable of giving consent, and the disclosure of that information, is addressed in section 5.3.5. Section 5.3.5 is a deeming provision that applies to the offences in sections 5.3.2-5.3.4.

It governs how the exemptions from those offences relating to consent operate in the case of a person incapable of giving consent (as defined in subsection 5.3.1(3)).

Only a person authorised to provide consent on their behalf (as provided by the relevant legislation) may do so. The question of who may give consent on the behalf of a person incapable of giving consent has been left for each jurisdiction to determine.

MCLOC recognises that in most jurisdictions, arrangements for determining who may consent on behalf of a person incapable of giving consent are dealt with by specific legislation or through a settled body of case law. Generally, legislation and case law addresses the question of who may provide consent on behalf of a person incapable of giving consent for the following procedures:

- the removal of tissue from the body
- medical treatment, and
- parentage testing.

Human tissue legislation in most jurisdictions establishes how consent to the removal of tissue from the body is determined. Section 7 of the *Human Tissue Act 1983* (NSW), for instance, provides that an adult may consent to the removal of regenerative tissue for transplantation into another living person, therapeutic purposes, medical purposes, and scientific purposes. Section 10 provides that a parent may consent to the removal of regenerative tissue from a child if it is for certain purposes. Similarly, section 7 of the *Human Tissue Act 1982* (Vic) provides that an adult may consent to the removal of regenerative tissue for transplantation into another living person, therapeutic purposes, medical purposes, and scientific purposes. Section 15 of that Act provides that tissue is only to be removed from a child for the purposes of transplantation into the body of a parent, brother or sister.

Guardianship legislation in most jurisdictions establishes the circumstances in which legal guardians may consent to the medical treatment of a person in their care. For example, section 59 of the *Guardianship and Administration Act 1993* (SA) provides a guardian may consent to the medical or dental treatment of a mentally incapacitated person. Similarly, the *Guardianship and Administration Act 1986* (Vic) provides that a 'person responsible' for a person may consent to medical treatment in section 39 of that Act. A 'person responsible' is defined under section 37 of the Act.

Issues of consent relating to parentage testing are determined under family law legislation in most jurisdictions. For example, subsection 28(2) of the

Status of Children Act 1996 (NSW) deals with how consent is obtained when a court orders that parentage testing must be conducted on a person less than 18 years of age. This section states that the procedure or act must not be carried out in relation to the child without the consent of a parent or guardian of the child.

Similar provisions relating to consent in parentage testing can be found in Commonwealth, Tasmanian and Northern Territory legislation.³¹

Therefore, MCLOC considers that it would be inappropriate (and unnecessary) for the model non-consensual genetic testing offences to seek to regulate the means by which consent may be given on behalf of a person incapable of giving consent when established principles and precedents already exist in each jurisdiction. The model offences are not intended to change existing consent principles. MCLOC recommends that, for the purpose of the model offences, consent on behalf of a person incapable of giving consent should be established by:

- a) inserting provisions in the model offences which mirror existing legislation and common law that deals with consent in that jurisdiction, or
- b) amending existing legislative provisions that define consent in each jurisdiction to ensure these provisions extend to consent for genetic testing.

Section 5.3.6 - Defences

(1) A person is not criminally responsible for an offence against this Division in respect of the following:

(a) the obtaining or use of any bodily material, or the disclosure or use of any information, if the person is a public official (within the meaning of Part 3.6) acting in the course of his or her duty as a police officer, prison officer or other law enforcement officer and the conduct of the person is reasonable in the circumstances for the purpose of performing that duty,

³¹ *Family Law Act 1975* (Cth) section 69Z(2), *Status of Children Act 1974* (TAS) section 15, and *Status of Children Act* (NT) section 13.

(b) the disclosure or use of information in connection with proceedings for an offence or any legal proceedings arising out of a contravention of a law of the Commonwealth, a State or a Territory,

(c) the obtaining or use of bodily material of a deceased person, or the disclosure or use of any information obtained as a result of a genetic test conducted using bodily material of a deceased person, if the person obtaining or using the bodily material or disclosing or using the information is [*description of person or persons entitled to consent to testing of bodily material of deceased person*] or is acting with the consent of that person,

(d) the obtaining or use of bodily material of a person who is incapable of giving consent, or the disclosure or use of any information obtained as a result of a genetic test conducted using bodily material of a person incapable of giving consent, if the person is [*description of person or persons entitled to consent to testing of bodily material on behalf of person incapable of giving consent*] or is acting with the consent of that person.

(2) This Division does not affect the obtaining or use of bodily material, or the disclosure or use of information obtained as a result of a genetic test conducted using bodily material, if the obtaining or use of the bodily material is authorised by or under another law of the State [or Territory] or a law of the Commonwealth.

MCLOC considers it important to limit the scope of the model offences by inserting defences that protect legitimate and accepted non-consensual genetic testing practices or the disclosure of genetic information.

In framing the defences, MCLOC considered the issue of onus of proof. The defences and the onus of proof issue are discussed below.

Paragraph 5.3.6(1)(a) - defence for law enforcement activities

It is important that the proposed offences not preclude lawful and legitimate law enforcement activities. Accordingly, paragraph 5.3.6(1)(a) includes a defence applicable to 'reasonable conduct' by a police officer, prison or other law enforcement officer in the course of duty.

At a minimum, the defence should apply to law enforcement conduct that is expressly authorised by law eg DNA testing powers under relevant legislation. Such conduct could be preserved simply by application of the lawful authority defence that forms part of the Model Criminal Code.

MCLOC lawful authority defence

*A person is not criminally responsible for an offence if the person's conduct constituting the offence is justified or excused by any Act or law.*³²

However, MCLOC has included a broader defence at paragraph 5.3.6(1)(a). That is because the lawful authority defence does not preserve the lawfulness of law enforcement conduct that would otherwise contravene the proposed genetic testing offences, and that is currently neither authorised nor prohibited by law. Such conduct is currently lawful because there is no offence prohibiting it; however it would not be protected by the lawful authority defence because there is no law authorising it. Depending on the jurisdiction, conduct falling into this grey area may include taking a crime scene sample or covertly obtaining genetic material.

The effect of the proposed offences would be to outlaw such conduct, unless covered by a defence of the kind proposed. An alternative approach would be for jurisdictions to legislatively authorise all law enforcement conduct relating to genetic material they viewed as legitimate, and to enact the narrower 'lawful authority' defence to apply where these laws provided authority.

MCLOC has proposed a broad 'reasonable conduct' type of defence in a different context previously.

MCLOC 'reasonable conduct' defence

A person is not criminally responsible for an offence against this Part if the person is, at the time of the offence, a public official (within the meaning of Part 3.6) acting in the course of his or her duty as a police officer, prison officer, or other law

³² Model Criminal Code – Chapter 5 Non Fatal Offences against the Person at page 138.

*enforcement officer and the conduct of the person is reasonable in the circumstances of performing the duty.*³³

MCLOC seeks comments on the merits of these two approaches.

Paragraph 5.3.6(1)(b)

MCLOC considers that it would be undesirable for the offences to apply to non-consensual genetic testing practices occurring in the context of legal proceedings.

This paragraph provides a defence for the disclosure or use of information in connection with proceedings for an offence or any legal proceedings arising out of a contravention of a law of the Commonwealth, a State or Territory.

Paragraph 5.3.6(1)(c)

This paragraph provides a defence for situations where a person authorised to consent on behalf of a deceased person provided consent for

- genetic testing of the bodily material of the deceased person or
- the use or disclosure of results of genetic testing conducted on the deceased person.

As discussed above, the definition of a person authorised to consent on behalf of a deceased person is to be determined under each jurisdiction's existing arrangements.

Paragraph 5.3.6(1)(d)

This paragraph provides a defence for situations where a person authorised to consent on behalf of a person incapable of giving consent provided consent for

- genetic testing of the bodily material of the person incapable of giving consent, or
- the use or disclosure of results of genetic testing conducted on the person incapable of giving consent.

³³ Model Criminal Code – Chapter 5 Non Fatal Offences against the Person at page 138.

As discussed above, the definition of a person authorised to consent on behalf of a person incapable of giving consent is to be determined under each jurisdiction's existing arrangements.

Subsection 5.3.6(2) – the lawful authority defence

MCLOC intends to protect currently lawful practices in the medical context through the defence of lawful authority. A general defence of lawful authority is contained in Chapter 2 of the Model Criminal Code.³⁴ The defence is set out below.

Lawful authority

A person is not criminally responsible for an offence if the person's conduct constituting the offence is justified or excused by any Act or other law.

A modified defence of lawful authority, adjusted to the non-consensual genetic testing context, is set out in subsection 5.3.5(2).

The proposed lawful authority defence applies to genetic testing practices that are specifically authorised by existing legislation in Australian jurisdictions. For example, the Privacy Act was amended in 2006 to permit the disclosure of genetic information to a genetic relative where the disclosure is necessary to prevent a serious threat to the life, health or safety of that genetic relative. (National Privacy Principles 2.3(ea)). This disclosure would not be an offence under the proposed model offence provisions.

However, in some cases, a genetic testing practice may currently be considered 'legitimate' but there may be no legislation actually authorising it. Persons engaging in unauthorised practices may be at risk of being charged under the model offence provisions, because the lawful excuse defence would not apply to these practices. Therefore, before enacting the model offence provisions, States and Territories should review genetic testing practices that

³⁴ The lawful authority defence is set out at page 138 of Chapter 5 of the Model Criminal Code Report on Non Fatal Offences Against the Person. In this Report, MCCOC proposed that the lawful authority defence should be added to Chapter 2 of the Code.

are not currently underpinned by legislative authority and consider whether these practices need to receive legislative support.

MCLOC seeks comments from stakeholders/interested parties on activities that may be unintentionally caught by the model offences.

Onus of Proof

If the circumstances described in proposed section 5.3.6 (ie the defences) apply, the genetic testing offences in proposed sections 5.3.2 –5.3.4 will not be made out.

A question for consideration is where the onus of proof should lie for establishing the absence of these matters. As drafted, they are evidential burden defences. The defendant must adduce some evidence to put the defence in issue, and then the onus passes to the prosecution to prove the absence of the defence as part of its case.³⁵

An alternative approach would be to treat the absence of the matters in the defences as an element of the offence so that in every case, the prosecution must prove the absence of each of these matters as part of its case.

MCLOC seeks comments on this alternative approach.

³⁵ Model Criminal Code – Chapters 1 and 2: The General Principles of Criminal Responsibility at page 114.

ATTACHMENT A

UK 'DNA Theft' offence

Human Tissue Act 2004

45 Non-consensual analysis of DNA

(1) A person commits an offence if—

(a) he has any bodily material intending—

(i) that any human DNA in the material be analysed without qualifying consent, and

(ii) that the results of the analysis be used otherwise than for an excepted purpose,

(b) the material is not of a kind excepted under subsection (2), and

(c) he does not reasonably believe the material to be of a kind so excepted.

(2) Bodily material is excepted if —

(a) it is material which has come from the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death,

(b) it is an existing holding and the person who has it is not in possession, and not likely to come into possession, of information from which the individual from whose body the material has come can be identified, or

(c) it is an embryo outside the human body.

(3) A person guilty of an offence under this section—

(a) is liable on summary conviction to a fine not exceeding the statutory maximum;

(b) is liable on conviction on indictment—

(i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or

(iii) to both.

(4) Schedule 4 (which makes provision for the interpretation of "qualifying consent" and "use for an excepted purpose" in subsection (1)(a)) has effect.

(5) In this section (and Schedule 4)—

- "bodily material" means material which—

(a) has come from a human body, and

- (b) consists of or includes human cells;
- “existing holding” means bodily material held immediately before the day on which this section comes into force.

Section 45

Introductory

1 This Part of this Schedule makes provision for the interpretation of “qualifying consent” in section 45(1)(a)(i).

Qualifying consent

2 (1) In relation to analysis of DNA manufactured by the body of a person who is alive, “qualifying consent” means his consent, except where sub-paragraph (2) applies.

(2) Where—

(a) the person is a child,

(b) neither a decision of his to consent, nor a decision of his not to consent, is in force, and

(c) either he is not competent to deal with the issue of consent or, though he is competent to deal with that issue, he fails to do so,

- “qualifying consent” means the consent of a person who has parental responsibility for him.

(3) In relation to analysis of DNA manufactured by the body of a person who has died an adult, “qualifying consent” means—

(a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;

(b) if paragraph (a) does not apply, the consent of a person who stood in a qualifying relationship to him immediately before he died.

(4) In relation to analysis of DNA manufactured by the body of a person who has died a child, “qualifying consent” means—

(a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;

(b) if paragraph (a) does not apply—

(i) the consent of a person who had parental responsibility for him immediately before he died, or

(ii) where no person had parental responsibility for him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time.

Application to Scotland

3 (1) In its application to Scotland, paragraph 2 has effect with the following amendments.

(2) In sub-paragraphs (2) and (4)(b)(i) and (ii), for “parental responsibility for” there is substituted “parental responsibilities in relation to”.

(3) At the end there is inserted—

“(5) In this paragraph—

- “adult” means a person who has attained the age of 16 years;
- “child” means a person who has not attained the age of 16 years;
- “parental responsibilities” has the meaning given by section 1(3) of the Children (Scotland) Act 1995 (c. 36).”

PART 2 USE FOR AN EXCEPTED PURPOSE

Introductory

4 This Part of this Schedule makes provision for the interpretation of “use for an excepted purpose” in section 45(1)(a)(ii).

Purposes of general application

5 (1) Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose—

(a) the medical diagnosis or treatment of the person whose body manufactured the DNA;

(b) purposes of functions of a coroner;

(c) purposes of functions of a procurator fiscal in connection with the investigation of deaths;

(d) the prevention or detection of crime;

(e) the conduct of a prosecution;

(f) purposes of national security;

(g) implementing an order or direction of a court or tribunal, including one outside the United Kingdom.

(2) For the purposes of sub-paragraph (1)(d), detecting crime shall be taken to include—

(a) establishing by whom, for what purpose, by what means and generally in what circumstances any crime was committed, and

(b) the apprehension of the person by whom any crime was committed;

and the reference in sub-paragraph (1)(d) to the detection of crime includes any detection outside the United Kingdom of any crime or suspected crime.

(3) In sub-paragraph (1)(e), the reference to a prosecution includes a prosecution brought in respect of a crime in a country or territory outside the United Kingdom.

(4) In this paragraph, a reference to a crime includes a reference to any conduct which—

- (a) constitutes one or more criminal offences (whether under the law of a part of the United Kingdom or a country or territory outside the United Kingdom),
 - (b) is, or corresponds to, conduct which, if it all took place in any one part of the United Kingdom, would constitute one or more criminal offences, or
 - (c) constitutes one or more offences of a kind triable by court-martial under the Army Act 1955 (3 & 4 Eliz. 2 c. 18), the Air Force Act 1955 (3 & 4 Eliz. 2 c. 19) or the Naval Discipline Act 1957 (c. 53).
- (5) Sub-paragraph (1)(g) shall not be taken to confer any power to make orders or give directions.

Purpose of research in connection with disorders, or functioning, of the human body

6 (1) Use of the results of an analysis of DNA for the purpose of research in connection with disorders, or the functioning, of the human body is use for an excepted purpose if the bodily material concerned is the subject of an order under sub-paragraph (2).

(2) The Secretary of State may by regulations specify circumstances in which the High Court or the Court of Session may order that this paragraph apply to bodily material.

Purposes relating to existing holdings

7 Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose if the bodily material concerned is an existing holding—

- (a) clinical audit;
- (b) determining the cause of death;
- (c) education or training relating to human health;
- (d) establishing after a person's death the efficacy of any drug or other treatment administered to him;
- (e) obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
- (f) performance assessment;
- (g) public health monitoring;
- (h) quality assurance;
- (i) research in connection with disorders, or the functioning, of the human body;
- (j) transplantation.

Purposes relating to material from body of a living person

8 Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose if the bodily material concerned is from the body of a living person—

- (a) clinical audit;

- (b) education or training relating to human health;
- (c) performance assessment;
- (d) public health monitoring;
- (e) quality assurance.

9 (1) Use of the results of an analysis of DNA for the purpose of obtaining scientific or medical information about the person whose body manufactured the DNA is use for an excepted purpose if—

- (a) the bodily material concerned is the subject of a direction under sub-paragraph (2) or (3) or an order under sub-paragraph (4) or (5), and
- (b) the information may be relevant to the person for whose benefit the direction is given or order is made.

(2) If the Authority is satisfied—

- (a) that bodily material has come from the body of a living person,
- (b) that it is not reasonably possible to trace the person from whose body the material has come (“the donor”),
- (c) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the donor, and
- (d) that there is no reason to believe—
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse consent to the use of the material for that purpose is in force, or
 - (iii) that the donor lacks capacity to consent to the use of the material for that purpose,

it may direct that this paragraph apply to the material for the benefit of the other person.

(3) If the Authority is satisfied—

- (a) that bodily material has come from the body of a living person,
- (b) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the person from whose body the material has come (“the donor”),
- (c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the material for that purpose,
- (d) that there is no reason to believe—
 - (i) that the donor has died,
 - (ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or
 - (iii) that the donor lacks capacity to consent to the use of the material for that purpose, and

(e) that the donor has been given notice of the application for the exercise of the power conferred by this sub-paragraph,

it may direct that this paragraph apply to the material for the benefit of the other person.

(4) If the Court of Session is satisfied—

(a) that bodily material has come from the body of a living person,

(b) that it is not reasonably possible to trace the person from whose body the material has come (“the donor”),

(c) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the donor, and

(d) that there is no reason to believe—

(i) that the donor has died,

(ii) that a decision of the donor to refuse consent to the use of the material for that purpose is in force, or

(iii) that the donor is an incapable adult within the meaning of the Adults with Incapacity (Scotland) Act 2000 (asp 4),

it may order that this paragraph apply to the material for the benefit of the other person.

(5) If the Court of Session is satisfied—

(a) that bodily material has come from the body of a living person,

(b) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the person from whose body the material has come (“the donor”),

(c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the material for that purpose,

(d) that there is no reason to believe—

(i) that the donor has died,

(ii) that a decision of the donor to refuse to consent to the use of the material for that purpose is in force, or

(iii) that the donor is an incapable adult within the meaning of the Adults with Incapacity (Scotland) Act 2000, and

(e) that the donor has been given notice of the application for the exercise of the power conferred by this sub-paragraph,

it may order that this paragraph apply to the material for the benefit of the other person.

10 Use of the results of an analysis of DNA for the purpose of research in connection with disorders, or the functioning, of the human body is use for an excepted purpose if—

- (a) the bodily material concerned is from the body of a living person,
- (b) the research is ethically approved in accordance with regulations made by the Secretary of State, and
- (c) the analysis is to be carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the individual from whose body the material has come can be identified.

Purpose authorised under section 1

11 Use of the results of an analysis of DNA for a purpose specified in paragraph 7 is use for an excepted purpose if the use in England and Wales, or Northern Ireland, for that purpose of the bodily material concerned is authorised by section 1(1) or (10)(c).

Purposes relating to DNA of adults who lack capacity to consent

12 (1) Use of the results of an analysis of DNA for a purpose specified under sub-paragraph (2) is use for an excepted purpose if—

- (a) the DNA has been manufactured by the body of a person who—
 - (i) has attained the age of 18 years and, under the law of England and Wales or Northern Ireland, lacks capacity to consent to analysis of the DNA, or
 - (ii) under the law of Scotland, is an adult with incapacity within the meaning of the Adults with Incapacity (Scotland) Act 2000 (asp 4), and
- (b) neither a decision of his to consent to analysis of the DNA for that purpose, nor a decision of his not to consent to analysis of it for that purpose, is in force.

(2) The Secretary of State may by regulations specify for the purposes of this paragraph purposes for which DNA may be analysed.

Power to amend paragraphs 5, 7 and 8

13 The Secretary of State may by order amend paragraph 5, 7 or 8 for the purpose of—

- (a) varying or omitting any of the purposes specified in that paragraph, or
- (b) adding to the purposes so specified.

International Declaration on Human Genetic Data

16 October 2003

The General Conference,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Economic and Social Council resolutions 2001/39 on Genetic Privacy and Non-Discrimination of 26 July 2001 and 2003/232 on Genetic Privacy and Non-Discrimination of 22 July 2003, the ILO Convention (No. 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 and the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system,

Recalling more particularly the Universal Declaration on the Human Genome and Human Rights which it adopted, unanimously and by acclamation, on 11 November 1997 and which was endorsed by the United Nations General Assembly on 9 December 1998 and the Guidelines for the implementation of the Universal Declaration on the Human Genome and Human Rights which it endorsed on 16 November 1999 by 30 C/Resolution 23,

Welcoming the broad public interest worldwide in the Universal Declaration on the Human Genome and Human Rights, the firm support it has received from the international community and its impact in Member States drawing upon it for their legislation, regulations, norms and standards, and ethical codes of conduct and guidelines,

Bearing in mind the international and regional instruments, national laws, regulations and ethical texts relating to the protection of human rights and fundamental freedoms and to respect for human dignity as regards the collection, processing, use and storage of scientific data, as well as of medical data and personal data,

Recognizing that genetic information is part of the overall spectrum of medical data and that the information content of any medical data, including genetic data and proteomic data, is highly contextual and dependent on the particular circumstances,

Also recognizing that human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups,

Emphasizing that all medical data, including genetic data and proteomic data, regardless of their apparent information content, should be treated with the same high standards of confidentiality,

Noting the increasing importance of human genetic data for economic and commercial purposes,

Having regard to the special needs and vulnerabilities of developing countries and the need to reinforce international cooperation in the field of human genetics,

Considering that the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine, for their applications and for the use of such data for non-medical purposes,

Also considering that the growing amount of personal data collected makes genuine irretrievability increasingly difficult,

Aware that the collection, processing, use and storage of human genetic data have potential risks for the exercise and observance of human rights and fundamental freedoms and respect for human dignity,

Noting that the interests and welfare of the individual should have priority over the rights and interests of society and research,

Reaffirming the principles established in the Universal Declaration on the Human Genome and Human Rights and the principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and expression, including freedom of research, and privacy and security of the person, which must underlie the collection, processing, use and storage of human genetic data,

Proclaims the principles that follow and **adopts** the present Declaration.

A. General provisions

Article 1 – Aims and scope

(a) The aims of this Declaration are: to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived, referred to hereinafter as “biological samples”, in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research; to set out the principles which should guide States in the formulation of their legislation and their policies on these issues; and to form the basis for guidelines of good practices in these areas for the institutions and individuals concerned.

(b) Any collection, processing, use and storage of human genetic data, human proteomic data and biological samples shall be consistent with the international law of human rights.

(c) The provisions of this Declaration apply to the collection, processing, use and storage of human genetic data, human proteomic data and biological samples, except in the investigation, detection and prosecution of criminal offences and in parentage testing that are subject to domestic law that is consistent with the international law of human rights.

Article 2 – Use of terms

For the purposes of this Declaration, the terms used have the following meanings:

(i) Human genetic data: Information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis;

(ii) Human proteomic data: Information pertaining to an individual’s proteins including their expression, modification and interaction;

(iii) Consent: Any freely given specific, informed and express agreement of an individual to his or her genetic data being collected, processed, used and stored;

(iv) Biological samples: Any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual;

(v) Population-based genetic study: A study which aims at understanding the nature and extent of genetic variation among a population or individuals within a group or between individuals across different groups;

(vi) Behavioural genetic study: A study that aims at establishing possible connections between genetic characteristics and behaviour;

(vii) Invasive procedure: Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe;

(viii) Non-invasive procedure: Biological sampling using a method which does not involve intrusion into the human body, such as oral smears;

(ix) Data linked to an identifiable person: Data that contain information, such as name, birth date and address, by which the person from whom the data were derived can be identified;

(x) Data unlinked to an identifiable person: Data that are not linked to an identifiable person, through the replacement of, or separation from, all identifying information about that person by use of a code;

(xi) Data irretrievably unlinked to an identifiable person: Data that cannot be linked to an identifiable person, through destruction of the link to any identifying information about the person who provided the sample;

(xii) Genetic testing: A procedure to detect the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change;

(xiii) Genetic screening: Large-scale systematic genetic testing offered in a programme to a population or subsection thereof intended to detect genetic characteristics in asymptomatic people;

(xiv) Genetic counselling: A procedure to explain the possible implications of the findings of genetic testing or screening, its advantages and risks and where applicable to assist the individual in the long-term handling of the consequences; It takes place before and after genetic testing and screening;

(xv) Cross-matching: Matching of information about an individual or a group contained in various data files set up for different purposes.

Article 3 – Person's identity

Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom.

Article 4 – Special status

(a) Human genetic data have a special status because:

(i) they can be predictive of genetic predispositions concerning individuals;

(ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned

belongs;

(iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;

(iv) they may have cultural significance for persons or groups.

(b) Due consideration should be given to the sensitivity of human genetic data and an appropriate level of protection for these data and biological samples should be established.

Article 5 – Purposes

Human genetic data and human proteomic data may be collected, processed, used and stored only for the purposes of:

(i) diagnosis and health care, including screening and predictive testing;

(ii) medical and other scientific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as “medical and scientific research”;

(iii) forensic medicine and civil, criminal and other legal proceedings, taking into account the provisions of Article 1(c);

(iv) or any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and the international law of human rights.

Article 6 – Procedures

(a) It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavour to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints.

(b) Independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.

(c) When the collection, processing, use and storage of human genetic data, human proteomic data or biological samples are carried out in two or more States, the ethics committees in the States concerned, where appropriate, should be consulted and the review of these questions at the appropriate level should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.

(d) It is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and this should entail neither a disadvantage nor a

penalty for the person concerned.

Article 7 – Non-discrimination and non-stigmatization

(a) Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.

(b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.

B. Collection

Article 8 – Consent

(a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights.

(b) When, in accordance with domestic law, a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative should have regard to the best interest of the person concerned.

(c) An adult not able to consent should as far as possible take part in the authorization procedure. The opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

(d) In diagnosis and health care, genetic screening and testing of minors and adults not able to consent will normally only be ethically acceptable when they have important implications for the health of the person and have regard to his or her best interest.

Article 9 – Withdrawal of consent

(a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.

(b) When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.

(c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed.

Article 10 – The right to decide whether or not to be informed about research results

When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons

who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.

Article 11 – Genetic counselling

It is ethically imperative that when genetic testing that may have significant implications for a person's health is being considered, genetic counselling should be made available in an appropriate manner. Genetic counselling should be non-directive, culturally adapted and consistent with the best interest of the person concerned.

Article 12 – Collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings

When human genetic data or human proteomic data are collected for the purposes of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, the collection of biological samples, in vivo or post-mortem, should be made only in accordance with domestic law consistent with the international law of human rights.

C. Processing

Article 13 – Access

No one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security.

Article 14 – Privacy and confidentiality

(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, family or, where appropriate, group, in accordance with domestic law consistent with the international law of human rights.

(b) Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.

(c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.

(d) Human genetic data, human proteomic data and biological samples collected for medical and scientific research purposes can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law.

(e) Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.

Article 15 – Accuracy, reliability, quality and security

The persons and entities responsible for the processing of human genetic data, human proteomic data and biological samples should take the necessary measures to ensure the

accuracy, reliability, quality and security of these data and the processing of biological samples. They should exercise rigour, caution, honesty and integrity in the processing and interpretation of human genetic data, human proteomic data or biological samples, in view of their ethical, legal and social implications.

D. Use

Article 16 – Change of purpose

(a) Human genetic data, human proteomic data and the biological samples collected for one of the purposes set out in Article 5 should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned is obtained according to the provisions of Article 8(a) or unless the proposed use, decided by domestic law, corresponds to an important public interest reason and is consistent with the international law of human rights. If the person concerned lacks the capacity to consent, the provisions of Article 8(b) and (c) should apply mutatis mutandis.

(b) When prior, free, informed and express consent cannot be obtained or in the case of data irretrievably unlinked to an identifiable person, human genetic data may be used in accordance with domestic law or following the consultation procedures set out in Article 6(b).

Article 17 – Stored biological samples

(a) Stored biological samples collected for purposes other than set out in Article 5 may be used to produce human genetic data or human proteomic data with the prior, free, informed and express consent of the person concerned. However, domestic law may provide that if such data have significance for medical and scientific research purposes e.g. epidemiological studies, or public health purposes, they may be used for those purposes, following the consultation procedures set out in Article 6(b).

(b) The provisions of Article 12 should apply mutatis mutandis to stored biological samples used to produce human genetic data for forensic medicine.

Article 18 – Circulation and international cooperation

(a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to these data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning human genetic data and human proteomic data and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.

(c) Researchers should endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters and, subject to the provisions of Article 14, should encourage the free circulation of human genetic data and human proteomic data in order to foster the sharing of scientific knowledge, provided that the principles set out in this Declaration are observed by the parties concerned. To this end, they should also endeavour to publish in due course the results of their research.

Article 19 – Sharing of benefits

(a) In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the

following forms:

- (i) special assistance to the persons and groups that have taken part in the research;
 - (ii) access to medical care;
 - (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research;
 - (iv) support for health services;
 - (v) capacity-building facilities for research purposes;
 - (vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;
 - (vii) any other form consistent with the principles set out in this Declaration.
- (b) Limitations in this respect could be provided by domestic law and international agreements.

E. Storage

Article 20 – Monitoring and management framework

States may consider establishing a framework for the monitoring and management of human genetic data, human proteomic data and biological samples based on the principles of independence, multidisciplinary, pluralism and transparency as well as the principles set out in this Declaration. This framework could also deal with the nature and purposes of the storage of these data.

Article 21 – Destruction

- (a) The provisions of Article 9 apply *mutatis mutandis* in the case of stored human genetic data, human proteomic data and biological samples.
- (b) Human genetic data, human proteomic data and the biological samples collected from a suspect in the course of a criminal investigation should be destroyed when they are no longer necessary, unless otherwise provided for by domestic law consistent with the international law of human rights.
- (c) Human genetic data, human proteomic data and biological samples should be available for forensic purposes and civil proceedings only for as long as they are necessary for those proceedings, unless otherwise provided for by domestic law consistent with the international law of human rights.

Article 22 – Cross-matching

Consent should be essential for the cross-matching of human genetic data, human proteomic data or biological samples stored for diagnostic and health care purposes and for medical and other scientific research purposes, unless otherwise provided for by domestic law for compelling reasons and consistent with the international law of human rights.

F. Promotion and implementation

Article 23 – Implementation

- (a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with the international law of human rights. Such measures should be supported by action in the

sphere of education, training and public information.

(b) In the framework of international cooperation, States should endeavour to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge concerning human genetic data and the related know-how.

Article 24 – Ethics education, training and information

In order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large. In this regard, States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 25 – Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out therein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, inter alia, on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.

Article 26 – Follow-up action by UNESCO

UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of the life sciences and their applications through technologies, based on respect for human dignity and the exercise and observance of human rights and fundamental freedoms.

Article 27 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.