

Current Australian regulatory framework— legislative

INTRODUCTION

- 8.1 Previous chapters have focused on the scientific and ethical issues raised by human cloning. The third area of the Committee's inquiry concerned the appropriate regulatory regime to govern human cloning and related research. This chapter introduces the regulatory issues. The approach taken by the AHEC report to these issues will be outlined and the chapter will then discuss the current legislative framework for human cloning and related research in Australia. Chapter 9 will complete the discussion of the current Australian regulatory framework by outlining its non-legislative regulation and presenting the Committee's conclusions concerning Australia's current regulatory framework for dealing with these matters. Chapter 10 will outline some of the principal international developments in recent years in the regulation of human cloning and discuss some of the implications of these developments for Australia. In Chapter 11 the Committee will respond to the recommendations in the AHEC report and consider other options for regulating this area of research. Chapter 12 will present the Committee's suggested framework for the regulation of human cloning and its related research in Australia.

OVERVIEW OF THE CURRENT AUSTRALIAN REGULATORY FRAMEWORK

- 8.2 The discussion in this chapter and Chapter 9 will outline current State and Commonwealth legislative and non-legislative regulation dealing directly or indirectly with research involving human cloning.
- 8.3 Regulation governing human cloning and research or experimentation involving embryos is most relevant to the inquiry. These areas of regulation will be outlined separately. Other legislative and non-legislative regulation is also relevant. Such regulation includes legislation governing the donation of human tissue and the important role played by institutional ethics committees.
- 8.4 There is an important distinction between conducting research using embryos and using cell-based therapies in medical treatment. Cell-based therapies, using adult cells, are of long standing.¹ The use of somatic cell nuclear transfer techniques in the course of therapy or medical treatment in contrast is, as was noted in Chapter 3, some distance into the future. These different techniques affect the kind of regulation that will be applicable in different situations. The legislative and non-legislative regulation discussed below focuses principally on that governing the use of embryos and human tissues in research.
- 8.5 The regulation of human cloning and the use of human embryos in research has evolved as part of the regulation of assisted reproductive technologies. The use of the human embryo in the course of assisted reproductive technologies has been premised on the consent of the genetic parents. There is no comprehensive and consistent approach in Australia to the regulation of human cloning and its related research. This variation between jurisdictions creates frustration and confusion for researchers, practitioners and the general public.
- 8.6 Three States—Victoria, South Australia and Western Australia—regulate human cloning and research involving the use of embryos by means of the legislative frameworks governing assisted reproductive technologies. All three States have a statutory prohibition on cloning. However, as is discussed below, the interpretation of these prohibitions is uncertain.² The recently enacted Commonwealth statutory ban on human cloning in the *Gene Technology Act 2000* can now be added to these statutory prohibitions.
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1 Peter MacCallum Cancer Institute, *Submissions*, p.S888

2 See paragraphs 8.17-8.20 below

- 8.7 New South Wales, Queensland, Tasmania, the Northern Territory and the Australian Capital Territory do not have any legislative prohibition on human cloning or legislative regulation of research involving human embryos. Regulation in these jurisdictions occurs by means of National Health and Medical Research Council (NHMRC) Guidelines and the self-regulation of assisted reproductive technology providers by the Fertility Society of Australia (FSA) through its Reproductive Technology Accreditation Committee (RTAC) Code of Practice. These modes of regulation are discussed in Chapter 9.
- 8.8 Following an outline of the AHEC report's discussion of regulatory issues, the legislative regulation will be discussed. Non-legislative methods of regulation are discussed in the next chapter. Non-statutory methods of regulation, as noted above, occur largely by means of NHMRC Guidelines developed by AHEC. These guidelines must be followed by those in receipt of Commonwealth funding.

THE AHEC REPORT'S DISCUSSION OF REGULATORY ISSUES

- 8.9 An outline of Australian and international regulation relevant to cloning and research involving the use of embryos (as at November 1998) was provided in Chapters 4 and 5 of the AHEC report.
- 8.10 Chapter 4 of the AHEC report canvassed the current legislative and non-legislative regulation of human cloning and embryo experimentation. It noted the absence of legislative regulation of this area in many of the States and Territories and the inconsistent definition of cloning in the legislation in Victoria, Western Australian and South Australia.³ Chapter 4 of the AHEC report also briefly canvassed regulation in the areas of the status of children and the donation of human tissue.⁴
- 8.11 The AHEC report states that substantial limits are placed on research involving embryos in Australia. Specific approval for embryo experimentation is required by legislation in three states (Victoria, Western Australia and South Australia). The effect of those statutory provisions and the NHMRC Statement on Human Experimentation⁵ and

3 AHEC report, Chapter 4, paragraph 4.3

4 The Committee did not address issues relating to the status of children, inheritance or family law as they are at one remove from the focus of the inquiry

5 Superseded now by the *National Statement on Ethical Conduct in Research Involving Humans*—see paragraphs 9.17-9.20 of Chapter 9

the specific NHMRC *Ethical Guidelines on Assisted Reproductive Technology* which deal with embryo experimentation is to allow research involving embryos only in exceptional circumstances. In the case of the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* such exceptional circumstances require a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research, the use of a restricted number of embryos and consent to the specific form of research on the part of the gamete providers and their spouses or partners. In States and Territories other than Victoria, Western Australia and South Australia an institutional ethics committee (IEC) is required to grant approval for such research in accordance with these NHMRC Guidelines.⁶

- 8.12 The AHEC report further commented that embryo splitting and somatic cell nuclear transfer for the specific purpose of cloning an identical human being is either prohibited or against the intention of the regulatory framework established in Victoria, Western Australia and South Australia and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*. Production of embryonic stem cell lines would be in contravention of both the Victorian and Western Australian legislation and the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*.⁷
- 8.13 However, in its conclusion to Chapter 4 of its report, AHEC expresses its concern that:
- ... a private, rather than publicly funded, organisation in a State or Territory other than Victoria, Western Australia or South Australia might consider a venture in cloning of a human being or cloning of human *parts* without the approval of an IEC under NHMRC guidelines. Currently, the NHMRC guidelines are only enforceable against institutions receiving NHMRC funding. The possibility exists that a private institution could decide to undertake such work. Without legislation the NHMRC cannot stop private institutions conducting such work.⁸
- 8.14 In the context of this comment it is worth noting that biotechnology companies are a growth area for investment. It would also appear that most Australian research in this area is occurring in those companies that have managed to recruit the assistance of many of the scientists working

6 AHEC report, Chapter 4, paragraph 4.17. Institutional ethics committee approval may also be required in Victoria and Western Australia

7 AHEC report, Chapter 4, paragraph 4.32

8 AHEC report, Chapter 4, paragraph 4.34. As was noted in Chapter 4 (this report) there is extensive private sector involvement in this research—see paragraphs 4.8-4.10

in this area in our major universities and other publicly funded research institutions.⁹

- 8.15 Chapter 5 of the AHEC report outlined international developments current to November 1998. These included the United Nations Educational, Scientific and Cultural Organisation (UNESCO) *Declaration on the Human Genome and Human Rights* and the Council of Europe *Convention on the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine* and the *Additional Protocol on Human Cloning*. The chapter also canvassed developments in the United Kingdom and the United States of America and Canada. The AHEC report made no comment on the developments or their relevance or application to Australia.¹⁰

CURRENT AUSTRALIAN REGULATORY FRAMEWORK— LEGISLATIVE

- 8.16 The following discussion outlines:
- the legislative provisions prohibiting human cloning at both State and Commonwealth levels;
 - the legislative regulation of research involving the use of embryos in Victoria, South Australia and Western Australia; and
 - other relevant legislation including Commonwealth legislation governing patents and privacy and state and territory human tissue legislation.

9 Mr Robert Klupacs, General Manager and Chief Executive Officer of ES Cell International Pte Ltd, for example, discussed the links between that company and the Monash Institute of Reproduction and Development, *Transcript*, p.169 and *Submissions*, p.S892. Dr Smeaton from BresaGen Ltd also referred to BresaGen's links with the University of Adelaide and the work of Professor Peter Rathjen, *Transcript*, p.150

10 These matters are discussed in more detail in Chapter 10. In contrast to Chapter 3 of the AHEC report, Chapters 4 and 5 elicited little comment in evidence to the inquiry. Mr Peter Eddington criticised both Chapters 4 and 5 for failing to draw any conclusions from the material presented, making weak recommendations in the light of the information (for example, not suggesting ways to remedy the inconsistencies in the definitions of the term 'cloning') and failing to provide any comment on the relative value of overseas models. *Submissions*, pp.S86 and 88

Legislative Provisions Prohibiting Human Cloning

8.17 In Victoria, the *Infertility Treatment Act 1995* (Vic) specifically prohibits human cloning. The Act provides that ‘a person must not carry out or attempt to carry out cloning’.¹¹ The term ‘clone’ is defined in section 3:

“clone” means to form, outside the human body, a human embryo that is genetically identical to another human embryo or person.¹²

8.18 In Western Australia, section 7 of the *Human Reproductive Technology Act 1991* (WA) provides that it is an offence to carry out any procedure directed at human cloning.¹³ It is also an offence to cause or permit a nucleus of a cell of an egg in the process of fertilisation or any embryo to be replaced¹⁴ or to cause or permit the genetic structure of any cell to be altered while the cell forms part of an egg in the process of fertilisation or any embryo.¹⁵ Section 3 defines ‘cloning’ as follows:

“cloning” means the use of reproductive technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical, live born and viable.¹⁶

8.19 In South Australia, the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 made under the *Reproductive Technology Act 1988* (SA) provide that a ‘licensee must not carry out, or cause, suffer or permit to be carried out, the procedure of cloning’.¹⁷ ‘Cloning’ is defined as:

...any procedure directed at producing two or more genetically identical embryos from the division of one embryo.¹⁸

8.20 New South Wales is currently undertaking a review of human tissue legislation. In October 1997, the New South Wales Government issued a

11 Section 47

12 Other provisions such as sections 24 and 25, discussed below, also enhance the prohibition contained in this section. The Infertility Treatment Authority in Victoria has expressed the view that the provisions of the Act do not cover embryonic stem cell research – see paragraphs 8.52-8.53 below.

13 Section 7(1) (d) (i)

14 Section 7(1) (e)

15 Section 7(1) (f)

16 It is also an offence to produce a chimaera—section 7(1)(d)(iii). A chimaera is defined in section 3 as a single living organism which has a mixed genetic origin as a consequence of combining cells derived from different human embryos or the human and other species

17 Regulation 6. Other provisions, outlined below, also enhance the prohibition contained in this section

18 Regulation 1

discussion paper entitled *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*. In the forward to this paper, the then NSW Minister for Health, the Hon. Dr Andrew Refshauge, stated that:

In response to community concern the Government has decided to introduce a law to ensure that two procedures do not develop in New South Wales. The Government has announced the banning of human cloning and trans-species fertilisation involving human gametes or embryos.

The process initiated by the Discussion Paper continues.¹⁹

New Commonwealth provision

8.21 The recently enacted Commonwealth *Gene Technology Act 2000* contains a prohibition on the cloning of whole human beings.²⁰ It also prohibits placing human cells into animal eggs or placing a combination of animal and human cells into a human uterus.²¹ Section 192B of the Act provides:

Cloning of human beings is prohibited

- (1) A person is guilty of an offence if:
 - (a) the person engages in conduct; and
 - (b) the person knows that, or is reckless as to whether, the conduct will result in the cloning of a whole human being.
- (2) In this section:

cloning of a whole human being means the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original.

8.22 The coverage of this provision is limited. Section 13 of the *Gene Technology Act 2000* provides that the Act applies, among other areas, to corporations, to things done in the course of trade and commerce, to things done that

19 AHEC report, Chapter 4, paragraph 4.12 and NSW Minister for Health, *Submissions*, p.866

20 Senator Vanstone (representing the Minister for Health and Aged Care in the Senate) stated, in March 2001, that the provision is an 'interim measure' until each State and Territory has implemented appropriate legislation in this area. She went on to say that the provision is a strong statement of the government's intention that the cloning of whole human beings will not be carried on in Australia. Senator Vanstone also stated that 'it is expected that further clarification of this intent will be provided', Senate, *Hansard*, 26 March 2001, column 22932

21 Sections 192C and 192D

may cause the spread of disease or pests, for purposes relating to statistics and actions by the Commonwealth or Commonwealth authorities.²²

Is cloning prohibited?

8.23 It will be immediately apparent that these definitions of ‘cloning’ are not consistent and that each prohibits slightly different conduct. The AHEC report commented that:

The importance of clearly defining this term will be of great importance in ensuring adequate regulation of this area of science.²³

8.24 The Committee agrees. However, a clear definition of prohibited conduct is not provided by any of the four statutory provisions outlined above.

What are the differences?

8.25 The Victorian definition focuses on the formation of a genetically identical human embryo regardless of its proposed use. It is the formation of the embryo rather than the attempt to replicate a person that is prohibited.²⁴

8.26 The Western Australian legislative prohibition is directed towards the use of reproductive technology for the purpose of producing duplicates or descendants that are ‘genetically identical, live born and viable’. The focus of prohibited conduct is the production of a live born individual. Hence while the Victorian prohibition would apply to the cloning of embryos for any purpose, whether ‘therapeutic’ or ‘reproductive’, the Western Australian prohibition is directed towards ‘reproductive’ cloning.²⁵

8.27 The South Australian definition of cloning appears to prohibit cloning by means of the technique of embryo splitting and not by means of somatic cell nuclear transfer.²⁶ Professor Norman a member of the South Australian Council on Reproductive Technology stated that the Council took the view that the somatic cell nuclear transfer method of cloning was, however, prohibited by regulation 9 of the South Australian Reproductive Technology (Code of Ethical Research Practice) Regulations which states:

22 These areas reflect specific constitutional powers relied on by the Commonwealth to enact the legislation—see section 13 of the Act. This application is subject to any winding back of the operation of the Act under section 14 and concurrent operation of State laws allowed for under section 16 of the Act

23 AHEC report, Chapter 4, paragraph 4.3

24 The provision would also prohibit reproduction of a person if that embryo is implanted in a woman

25 Western Australia further regulates the creation of embryos and this is discussed below

26 AHEC report, Chapter 4, paragraphs 4.28 and 4.3 and footnote 60

A licensee must not replace, or cause, suffer or permit the replacement of, the nucleus of a cell of an embryo, or of an ovum in the process of fertilisation, with any other nucleus.²⁷

South Australian reconsideration of its definition

8.28 Professor Norman explained that the Council readdressed the South Australian definition of cloning as a result of recent scientific advances:

Council noted that the definition in the Codes might imply that cloning experimentation on cells is permissible despite the guidelines of the [NHMRC] that do not allow such research²⁸...While [current] prohibitions were quite satisfactory for the technology currently available,²⁹ the Council was mindful that scientific advances in cloning techniques in the future could alter this. It was particularly noted by the Council that South Australian law does not legislate against the cloning of human organs or tissues.³⁰

8.29 Professor Norman indicated that the Council established a cloning working party whose brief was to develop a new definition of cloning for the Reproductive Technology (Code of Ethical Research Practice) Regulations that would reflect current research.³¹

8.30 The proposed new definition of human cloning would read:

Cloning is defined as the practice of forming an embryo or an entity capable of embryogenesis which is genetically identical to, or substantially identical to, another human being, living or deceased.³²

27 Professor Robert Norman, *Submissions*, p.S718. The somatic cell nuclear transfer method of cloning involves the replacement of the nucleus of an unfertilised ovum (egg/oocyte) not an ovum in the process of fertilisation or an embryo

28 This is a reference to the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* (1996) especially Guideline 11.3. The *Ethical Guidelines* are discussed in Chapter 9, paragraphs 9.9 – 9.16

29 This is a reference to regulation 9 (quoted in paragraph 8.27) and 8 which provide that a licensee must not alter or cause, suffer or permit to be altered, the genetic structure of a cell while the cell forms part of an embryo or an ovum in the process of fertilisation

30 Professor Robert Norman, *Submissions*, p.S718

31 Professor Robert Norman, *Submissions*, p.S718

32 Professor Robert Norman, *Submissions*, p.S719. Any changes to the definition of 'cloning' in the Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 (SA) are still being considered

- 8.31 Professor Norman submitted that ‘the ambit of the Council [only] includes human reproductive technology relating to gametes and embryos’.³³ Hence, while this new definition would:

...therefore exclude the use of human gametes for cloning, it does leave open the possibility of using somatic cells for cloning with methods that do not incorporate human oocytes.³⁴

What about the new Commonwealth definition?

- 8.32 The new Commonwealth definition of human cloning has most in common with that in Western Australia but does not refer to the production of a ‘live born and viable’ person. The reference to ‘duplicates and descendants’ seems to indicate an intention only to prohibit cloning for the purposes of reproduction.³⁵

The problems in using the term ‘genetically identical’

- 8.33 A significant difficulty with all of these legislative definitions of ‘cloning’ is that they rely on the concept of the resulting product being ‘genetically identical’. This is presumably in reliance upon scientific explanations of the process of somatic cell nuclear transfer. However some argue that this description may not be entirely accurate in reality. The process of cloning (described in Chapter 2) involves the replacement of the nucleus of a donated egg with the nucleus of a somatic donor cell. Surrounding the nucleus in the egg is cytoplasm that contains DNA—known as mitochondrial DNA. This DNA will also form part of the genetic inheritance of any offspring and may lead to slight differences from the original donor of the somatic cell. In addition, during each cycle of cell division the DNA within a cell, nuclear and mitochondrial, is replicated. Mutations may occur in this process which means that the product of cell division also is not genetically identical to the cell from which it was produced. These differences may be small, although the product of cloning is likely to be less identical than monozygotic twins. This may lead to argument about whether in fact the cloned entity is entirely ‘identical’.
- 8.34 As the following discussion suggests, the process will probably produce a clone ‘substantially identical’ to, but not completely genetically identical

33 Professor Robert Norman, *Submissions*, p.S719

34 Professor Robert Norman, *Submissions*, p.S719

35 An alternative argument could be made that the use of the term ‘whole human being’ leaves open the possible application of the provision to the creation of embryos for research purposes since it is unclear whether the term ‘whole human being’ should be taken to refer to an embryo, a foetus, a newborn child or an adult

to, the original.³⁶ The possibility that the requirement for ‘genetic identity’ or a ‘genomic copy’ could reduce the effectiveness of provisions prohibiting cloning of human beings was accepted by the NHMRC and AHEC.³⁷ Associate Professor Thomson, the Deputy Chair of AHEC, stated that ‘science has now made it clear that human organisms, although called clones, are not genetically identical’.³⁸ Dr Tobin, a member of AHEC, expressed concern as to how a ban on reproductive cloning expressed in terms of genetic identity could work when ensuring some small genetic variability in the resulting organism could be enough to avoid it.³⁹ This problem has also been acknowledged by Professor Don Chalmers, the former Chair of AHEC.⁴⁰ Senator Vanstone stated that the term ‘genetically identical’ has been ‘deemed to be sufficient from a legal perspective’.⁴¹ In the Committee’s view there must be some doubt about this.

8.35 The Committee is concerned by the narrowness and technicality of the current legislative definitions of cloning and urges that they be replaced by a definition that is broader, more effective and not focused on the requirement of genetic identity.

8.36 It appears to the Committee that the existing legislative definitions of the term ‘cloning’ focus on the final product of the process (that is an embryo or a person) being identical. On the other hand, scientific explanations appear to focus on the process itself not the final product. Hence, in the course of the process of transfer, the genomic content of the nucleus of the somatic cell may remain unchanged but by the time the final product has emerged from the interaction with the cytoplasm and any subsequent mutations, the final product will probably not be strictly identical.

36 This must raise some doubt as to the potential for conviction under section 192B of the *Gene Technology Act 2000* since the scientist presumably would not have engaged in the conduct with the purpose of producing duplicates genetically identical to the original. Although the interpretation of this provision would be a matter for a court, since the penalties for committing this offence are so severe (ten years gaol) the offence will probably be strictly construed

37 Professor Nicholas Saunders, *Transcript*, p.201

38 Associate Professor Colin Thomson, *Transcript*, p.203

39 Dr Bernadette Tobin, *Transcript*, p.203

40 Stephen Brook, ‘Dark Side of the Clone’, *Weekend Australian*, 17 March 2001, p.26

41 Senator Vanstone (representing the Minister for Health and Aged Care in the Senate), 26 March 2001, Senate, *Hansard*, column 22931

The application of the Commonwealth provision

- 8.37 The application of section 192B of the *Gene Technology Act 2000* also complicates the operation of the existing state provisions. Under Section 109 of the Constitution, a law of the Commonwealth on a particular subject that falls within its constitutional power will prevail over an inconsistent State law on the same subject to the extent of the inconsistency. The *Gene Technology Act 2000* does not purport to apply in all areas⁴² (and does permit the concurrent operation of some state laws) but it does apply to corporations.⁴³ As was discussed in Chapter 4 private sector corporations are increasingly engaged in this field of research. If the intention of the Commonwealth is that the definition of cloning in section 192B is to be interpreted so as to permit so called ‘therapeutic cloning’ (and hence an embryo is not a human being for the purposes of section 192B), the status of State provisions, such as that in Victoria which prohibits cloning to produce an embryo, must be an open question.
- 8.38 The intention and operation of the Commonwealth provision and its interaction with existing State provisions prohibiting human cloning must be clarified immediately. This matter is discussed further in Chapter 12. In the Committee’s view the prohibition on human cloning in section 192B of the *Gene Technology Act 2000* is insufficient and inappropriate.

So which would be the best definition?

- 8.39 The proposed South Australian approach to the definition of human cloning does minimise the difficulty caused by the focus in existing provisions on genetic identity by adding the words ‘substantially identical to ...’. The proposed addition of the words ‘an entity capable of embryogenesis’ would also incorporate ‘embryo like’ entities generated by means other than fertilisation. However, this approach does not focus on the intention to produce ‘live born and viable’ whole human beings.
- 8.40 The focus of effective criminal prohibitions on reproductive cloning should be on the intention to produce a whole human being other than by means of existing assisted reproductive technologies. If the retention of some concept of genetic similarity is sought, the inclusion of the words ‘...or substantially identical to...’ would appear to be a worthwhile safeguard against arguments such as those outlined above concerning the

42 See sections 13, 14 and 16 of the *Gene Technology Act 2000*

43 Whether this includes universities is an unresolved question. Universities are commonly constituted as corporations but whether a university is a ‘trading corporation’ by virtue of selling educational services or the results of research is an open question, Department of the Parliamentary Library, Bills Digest No 11 2000-01, *Gene Technology Bill 2000*, footnote 34

weaknesses of the current provisions. However, it may also be necessary to guard against the possibility of the substantial alternation of some DNA in the course of the creation of human embryos by somatic cell nuclear transfer. This could perhaps occur by means of the substitution of sufficient genetic material from another human tissue source so that the result was no longer ‘substantially genetically identical’ to the first donor source and then transferring the resulting embryo to a woman’s uterus.⁴⁴

Legislative Regulation Of Research Involving The Use Of Embryos

Overview

- 8.41 Most of the current sensitivities surrounding cloning research involve research using human embryos, either as a result of creating embryos for research purposes or using surplus embryos from assisted reproductive technology programs to extract embryonic stem cells. The current legislation concerning embryo experimentation applies directly to such research.
- 8.42 The current legislation governing human embryo experimentation reflects a tension between the view that the human embryo (if not a human being) certainly deserves respect, and the view that some experimentation ought to be allowed to gain knowledge that will assist in resolving infertility or improving health outcomes.⁴⁵
- 8.43 None of the three States with statutory regimes totally prohibits research using embryos but substantial limits are placed on any such research. The focus of the legislation is on regulating destructive research, that is research that will harm the embryo or leave it in a condition that will not enable implantation in a woman. The balance in all three pieces of legislation falls in favour of according a special status to the human embryo and ensuring the protection of that status.
- 8.44 It should be noted, however, that non-destructive research does not necessarily equate with research that will have therapeutic benefits for the embryo. Research on an embryo may be harmless without being of any therapeutic benefit to it.⁴⁶

44 Chapter 12 outlines conduct that the Committee considers should be prohibited

45 The AHEC report notes that various reports on the matter in the 1980s also reflect this tension, AHEC report, Chapter 4, paragraph 4.5

46 NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, paragraph 4.2

- 8.45 A cautionary note must be sounded before discussing the current legislative provisions regulating experimentation on human embryos:

The complexities of the concepts being discussed and the limitations of the words and definitions in these Acts make precise interpretation of the legislative effect of the Acts on the application of cloning technology almost impossible.⁴⁷

- 8.46 It is clear that new forms of research arising from cloning technologies, such as the extraction and use of embryonic stem cells, have exposed the problem of trying to apply old definitions to new research.

Victoria

- 8.47 The *Infertility Treatment Act 1995* (Vic) regulates both assisted reproductive technologies and experimentation on embryos. It is administered by the Infertility Treatment Authority. The Act establishes parameters of permitted research utilising human embryos by setting out the conditions under which research on human embryos may be undertaken and prohibiting certain types of research.⁴⁸ The Authority must approve all embryo research. Any scientist or practitioner wanting to undertake such research must be approved and any approved research must be in a place that is licensed by the Authority in accordance with the Act.

- 8.48 Destructive research on embryos as defined in the Act is banned.⁴⁹ Destructive research is research on an embryo if it is unfit for transfer to a woman or, in the case of an embryo that is fit for transfer to a woman, the research would harm the embryo, reduce the likelihood of a pregnancy resulting from the transfer of the embryo or make the embryo unfit for transfer to a woman. The Infertility Treatment Authority may not approve research utilising a human embryo if the research would lead to any of those effects.⁵⁰

- 8.49 The Act is complicated by the technicalities surrounding the definition of the term 'embryo'.⁵¹ The Authority may not grant approval for certain

47 Dr Sandra Webb, Executive Officer, WA Reproductive Technology Council, *Therapeutic Cloning for Tissue Repair: The legal situation in Western Australia and South Australia, Exhibit 2*

48 Section 22

49 Section 24

50 Section 25

51 Section 3 defines an 'embryo' as 'any stage of human embryonic development at and from syngamy'. Syngamy is defined as 'that stage of development of a fertilised oocyte where the chromosomes derived from the male and female pronuclei align on the mitotic spindle'. A zygote is defined as 'the stages of human development from the commencement of penetration of an oocyte by sperm up to but not including syngamy'. The definitions reflect

kinds of research if it involves the ‘formation or use of a zygote if the research proposes that the zygote continue to develop to syngamy’.⁵² Hence destructive research on embryos is prohibited after syngamy. In the case of a zygote (a pre-syngamy embryo) these prohibitions do not apply but an approval for research on zygotes is required under the Act.⁵³

- 8.50 Prohibited practices (in addition to cloning) include forming an embryo outside the body of a woman except for the purposes of a treatment procedure,⁵⁴ importing or exporting a gamete, zygote or embryo into or out of Victoria without the approval of the Authority⁵⁵ and altering the genetic constitution of a gamete intended for use in a fertilisation procedure.⁵⁶
- 8.51 Consent to research involving the formation of a zygote or use of an embryo or zygote must be obtained from each person who produced a gamete to be used in the research and their spouse. The consent must be specific to the particular procedure or research and there are detailed provisions relating to the requirements for informed consent.⁵⁷
- 8.52 Research involving tissue derived from human embryos such as embryonic stem cells would appear to fall outside the Act (although not if an embryo was destroyed in Victoria in order to obtain them). The Infertility Treatment Authority News contained the following statement issued by the Authority:

For the purposes of the *Infertility Treatment Act 1995*, ES cells are neither gametes nor embryos. Therefore they are not within the requirements related to research, nor within the approval processes in relation to import or export of gametes and embryos prescribed in section 56. The Authority, therefore, has no statutory power under the *Infertility Treatment Act 1995* to prescribe certain actions or requirements in relation to the importation of ES cells into Victoria, or in relation to their use in Victoria.⁵⁸

the stages of embryonic development from a zygote through syngamy to an embryo—see Chapter 2, paragraphs 2.9-2.16 for an explanation of this process

52 Section 26

53 Sections 26 and 49

54 Section 49

55 Section 56

56 Section 39

57 Sections 27-32. Part 4 of the Act also contains additional procedures relating to consent

58 ITA News, May 2000. See also Professor Alan Trounson, *Transcript*, p.12; Human Research and Ethics committee of the Monash Medical Centre and Southern Health Care Network, *Submissions*, pp.S138-139 and Rev Dr Norman Ford, *Submissions*, p.S833

- 8.53 It would also appear that stem cells that are derived from embryos created by means of somatic cell nuclear transfer would not fall within the Act. Such embryos are formed without the use of sperm. The definition of the term ‘embryo’ is quite specific and builds on the definitions of ‘zygote’ and ‘syngamy’ (both of which rely on the fertilisation of an egg by sperm). Stem cells derived from reprogrammed adult cells would also fall outside the Act.

South Australia

- 8.54 The *Reproductive Technology Act 1988* regulates both assisted reproductive technologies and experimentation involving embryos. The Act establishes a statutory system of licensing of those who carry out these procedures.
- 8.55 The Act establishes the South Australian Council on Reproductive Technology. Its functions include advising the Minister on questions arising from reproductive technology, promoting informed public debate, advising the Minister on all matters falling under the legislation including the conditions to be included on licences and the establishment of a code of ethical practice.⁵⁹
- 8.56 The Act prohibits carrying out research involving experimentation with ‘human reproductive material’⁶⁰ except in pursuance of a licence.⁶¹ Section 14 of the Act requires that a licence be subject to a condition prohibiting research that may be detrimental to an embryo. The Reproductive Technology (Code of Ethical Research Practice) Regulations 1995 made under the Act⁶² set out the conditions for ethical research practice.⁶³
- 8.57 Research that is prohibited under the Reproductive Technology (Code of Ethical Research Practice) Regulations includes—culturing or maintaining embryos outside the body, research on embryos more than 14 days old, mixing human and animal reproductive material, altering the genetic structure of a cell while that cell forms part of an embryo or an ovum in the process of fertilisation, replacing the nucleus of a cell of an embryo or of an ovum in the process of fertilisation with any other nucleus or placing any cells extracted from an embryo into the body of any person.⁶⁴

59 Section 10

60 Defined in section 3 as ‘a human embryo, human semen, a human ovum’

61 Section 14

62 Section 20(4)

63 These Regulations define an embryo as ‘a human embryo’

64 Regulations 3-13 list research that is prohibited under the Regulations. Regulations 15, 16 and 17 set out consent provisions including the requirement that consent must be given for the

- 8.58 Hence the legislative framework in South Australia is relatively restrictive. However, research involving embryonic stem cells would not be precluded by the Act nor would research involving adult stem cells.⁶⁵
- 8.59 Professor Norman went on to state that the working party established to review the definition of ‘cloning’ in the Reproductive Technology (Code of Ethical Research Practice) Regulations was:
- ...sympathetic to the concept of human embryonic stem cells being established for therapeutic use, either as a generic stem cell line or as a personalised stem cell line. It did not seek to prohibit the use of human somatic cells for this purpose provided that no human gametes were utilised in the production of these stem cell lines.⁶⁶

Western Australia

- 8.60 The *Human Reproductive Technology Act 1991*, like the regulatory regime in South Australia, regulates assisted reproductive technology and research involving embryos and establishes a statutory system of licensing for those who carry out these procedures.
- 8.61 The Act establishes a regulatory structure and Code of Practice. It is administered by the Commissioner of Health who implements the licensing system on advice from the Western Australian Reproductive Technology Council.
- 8.62 Under section 3 of the Act, ‘embryo’ is defined as:
- A live human embryo, in the stage of development which occurs from—
- (a) the completion of the fertilisation of the egg; or
- (b) the initiation of parthenogenesis,
- to the time when, excluding any period of storage, 7 completed weeks of the development have occurred.

particular research to be conducted. Regulation 20 of the Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995 is in similar terms

⁶⁵ Professor Norman noted that the SA Committee was given an opinion that the potential is still open for human somatic cells to be placed in animal oocytes to form human embryonic stem cells or for mature cell lines to be de-differentiated. He stated these would be outside the terms of reference of the Council and not included in the Act, *Submissions*, p.S719

⁶⁶ Professor Robert Norman, *Submissions*, p.S719. Professor Norman also noted that there is a theoretical possibility that cells obtained from the inner cell mass of an embryo could be used to establish ES cell lines without the destruction of the embryo. South Australian regulations prohibit the use of sperm or oocytes for human cloning and also the destruction of embryos to produce cell lines, Professor Robert Norman *Submissions*, p.S719

Prior to that stage the egg is referred to in the Act as an 'egg in the process of fertilisation'.⁶⁷

- 8.63 Section 7 of the Act sets out a range of offences. These include altering the genetic structure of any cell while the cell forms part of an egg in the process of fertilisation or any embryo, conducting unapproved research or diagnostic procedures with an egg in the process of fertilisation or an embryo, replacing the nucleus of a cell of an egg in the process of fertilisation or any embryo and causing or permitting an embryo to be maintained or kept outside the body of a woman after 14 days (excluding any period of storage) from the time the gametes were mixed. Hence nuclear transfer is ruled out but only where that involves an embryonic cell.
- 8.64 Embryo research is strictly regulated. The conditions are such that, in effect, little embryo research can be approved. Section 14(2) directs that such research must be intended to be therapeutic and not likely to harm the embryo, while section 17(b) directs that, as a matter of principle, the Council shall prohibit the development of any egg in the process of fertilisation or any embryo other than with a view to its future implantation into a particular woman.⁶⁸
- 8.65 Hence research involving human cloning for 'therapeutic' purposes is restricted in many ways by the Act although the actual definition of 'cloning' would not rule it out.⁶⁹
- 8.66 The Council must provide specific and general approval for research projects involving gametes obtained in the course of an IVF procedure or intended for use in an artificial fertilisation procedure, an egg in the process of fertilisation or any embryo.⁷⁰ Council may also require that approval also be sought from a specific IEC recognised by the Council.

67 'Parthenogenesis' in 'relation to an embryo means development initiated in the absence of, and other than by, fertilisation'—section 3

68 The definition of 'embryo' means that asexually produced embryos would be included in the restriction on the development of embryos other than for implantation, Dr Sandra Webb, Executive Officer, WA Reproductive Technology Council, *Therapeutic Cloning for Tissue Repair: The legal situation in Western Australia and South Australia, Exhibit 2*. Further, in *Directions given by the Commissioner of Health* to set the standards of practice under the Act for licensees, Direction 8.6 provides that any person to whom the licence applies must not develop, or authorise the development of an embryo other than with a view to its future implantation in a particular woman and the relevant consent should indicate this intention, *WA Gazette*, 171, 3 October 1997, *Exhibit 2*

69 *Exhibit 2*. See the discussion above concerning the various legislative definitions of cloning

70 Section 20

- 8.67 A Western Australian Parliamentary Select Committee reviewed the *Human Reproductive Technology Act 1991* in 1997/98 and reported in 1999.⁷¹ The Select Committee recommended that the prohibition on the development of embryos for research should be retained.⁷² It also recommended that the way be left open for the development of ‘therapeutic cloning’ technology.⁷³

Other Relevant Legislation

Commonwealth

- 8.68 There are Commonwealth statutes that directly impinge upon various aspects of research involving human cloning or research involving the use of embryos but it is important to reiterate the distinction between conducting research and applying the products of the research (such as, for example, cell based therapies) which, as was noted in Chapter 3, is still some distance away. This distinction reflects the regulation to which various matters will be subject.⁷⁴
- 8.69 Imports of biological material or material for use in cloning or related research (such as embryonic stem cells for instance) are regulated by the *Quarantine Act 1908* and administered by the Australian Quarantine and Inspection Service (AQIS).

71 Western Australia, Select Committee on the Human Reproductive Technology Act 1991, *Report*, 1999

72 Report, Recommendation 6f

73 This term is a common one to describe the use of cloning techniques for the development of DNA, cells or tissues for transplantation. The problems arising from the use of the term ‘therapeutic cloning’ were discussed in Chapter 2 and 3 at paragraphs 2.31-2.37 and 3.22. The former Western Australian Government advised that it generally supported the recommendations of the Select Committee but was still considering the recommendations that would bring those parts of the Act relating to embryo research more into line with the NHMRC *Ethical Guidelines on Assisted Reproductive Technology*. Any decision on this matter may affect what sort of ‘therapeutic cloning’ may be permissible in WA since ‘therapeutic cloning’ involves the use of embryos

74 An area of regulation that would arise after the research process that forms the focus of this report is the possible use of stem cells in medical treatment or clinical trials. This, strictly, falls outside the framework of this report which centres on research involving human cloning and research using embryos. The use of cell lines and the conduct of clinical trials would fall within the remit of the *Therapeutic Goods Act 1989* which establishes a national system for controls relating to the safety, quality, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. Essentially any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods before the product can be supplied in Australia. Clinical trials would also involve institutional ethics committees (IECs) the operation of which is discussed in Chapter 9

- 8.70 The grant of a patent for the protection of intellectual property resulting from the research work is regulated by the *Patents Act 1990*. IP Australia submitted that:
- ... issues concerning the patenting of human beings and biological material are often raised in the context of the regulation of human cloning.⁷⁵
- 8.71 Patents ‘cover, generally, any device, substance, method or process that is new, inventive and useful’ and a standard Australian patent has a term of up to 20 years.⁷⁶ IP Australia stated that in Australia patenting is allowed across all technologies provided that the invention fulfils the statutory requirements of the Patents Act. Under section 18(1) of the Patents Act a patentable invention is an invention that is a manner of manufacture, is novel and involves an inventive step and is useful.⁷⁷
- 8.72 However an express exclusion concerns the patenting of human beings. Subsection 18(2) of the Patents Act prohibits patenting ‘human beings, and the biological processes for their generation’.⁷⁸
- 8.73 To date, IP Australia submitted, there has been no judicial consideration of subsection 18(2) and it ‘remains unclear which inventions would be strictly caught by that provision’.⁷⁹ In the absence of such judicial consideration IP Australia notes that it is required to give applicants the benefit of the doubt in relation to the patentability of inventions concerning human material.⁸⁰
- 8.74 Nonetheless, consistent with subsection 18(2) IP Australia states that it will not grant patents for the following: human beings, fetuses, embryos or fertilised ova; or wholly biological processes that begin with fertilisation and end with the birth of a human being.⁸¹

75 IP Australia, *Submissions*, p.S721

76 IP Australia, *Submissions*, p.S723. Some pharmaceutical patents can have their terms extended for a further five years

77 IP Australia, *Submissions*, pp.S723-724

78 IP Australia, *Submissions*, p.S724

79 IP Australia, *Submissions*, p.S724

80 IP Australia cited the High Court decision in the case of *Commissioner of Patents v Microcell* (1959) 102 CLR 232, which held that the Commissioner ought not to refuse acceptance of an application and specification unless it appears practically certain that a patent granted on a specification would be invalid. IP Australia, *Submissions*, p.S724

81 IP Australia, *Submissions*, p.S724. IP Australia submitted (in February 2000) that it had granted 4 patents for cloning processes applicable to non-human mammals and routinely grants patents for both human and animal cell lines, DNA sequences and non-human animal varieties provided the inventions meet the statutory requirements for patentability. IP Australia, *Submissions* p.S724. IP Australia also submitted that it is its understanding that its practice in granting patents for inventions involving human genes, cell lines and tissue is

- 8.75 IP Australia points out that the use of inventions such as human genes, cell lines and tissue ‘would still be subject to other regulatory legislation’. The nature of a patent right is a ‘negative’ right. It does not create a right for a patentee to use their invention, it merely constitutes a right for a patentee to prevent others from using their invention.⁸²
- 8.76 A more contentious issue is the possible application of the regulatory procedures established by the *Gene Technology Act 2000* to research involving cloning techniques applicable to humans. The Act establishes a system of licensing for bodies undertaking genetic modification. The real problem in ascertaining whether the Act may apply to research involving cloning technologies lies in the difficulty of interpreting central terms such as ‘gene technology’ and ‘genetically modified organisms’ as they are defined in section 10. The Committee received evidence supporting both the proposition that the Act would regulate cloning technologies and that it would not.⁸³ The exclusion of somatic cell nuclear transfer from the definition of ‘gene technology’ in section 10⁸⁴ appears to resolve at least some of the uncertainty.⁸⁵

Privacy

- 8.77 Research involving the use of cloning technologies raises many serious issues relating to privacy. These issues concern, among other matters, the

consistent with section 18(2). However, it recognises that there may be ambiguity over what constitutes a human being or the biological process for the generation of a human being. IP Australia, *Submissions*, p.S724

82 IP Australia, *Submissions*, p.S725

83 Dr Nicholas Tonti-Filippini submitted that the Act would regulate producing human embryos by means of somatic cell nuclear transfer. He also argued that the use of human cells to develop specific cells for transplant would be included because the change from being a stem cell to forming cultured cells of a particular tissue type would involve genetic modification and fall within the Act. Dr Nicholas Tonti-Filippini, *Submissions*, pp.S846-847. The inclusion of cloning processes within the processes established by the *Gene Technology Act 2000* was opposed by Professor Roger Short, *Submissions*, p.S867 and the AAS who stated ‘an overlap in the technical language does not imply an overlap in the relevant issues’, AAS, *Submissions*, p.S845

84 Regulation 4, Gene Technology Regulations 2001 SR 106. Regulation 4 provides that for the purposes of section 10 of the Act, the definition of ‘gene technology does not include somatic cell nuclear transfer if the transfer does not involve genetically modified material’

85 Hon Dr Michael Wooldridge, MP, Minister for Health and Aged Care, stated that while cloning of human beings by somatic cell nuclear transfer is not covered by the *Gene Technology Act 2000*, ‘if a person proposed to genetically modify human cells for research or for clinical trials, this would require approval from Gene Technology Regulator and the Therapeutic Goods Administration in the case of clinical trials, *Submissions*, p.S856. The AMA stated that the manipulation of human cells in the laboratory would be regulated under the Act, *Submissions*, p.S841. The Caroline Chisholm Centre for Health Ethics advocated excluding both ES cell lines and human embryo cloning from the Act, *Submissions*, p.S843

collection of genetic data about egg or embryo donors, or the originators of cells, and possible trade in such data. The privacy of the identity of egg and embryo donors is also an issue warranting consideration. Once embryonic stem cells are extracted, the embryonic stem cell would provide the same genetic information about a person as ordinary DNA screens or genetic tests. Thus a complete genetic profile of individuals can be gained from the development of embryonic cell lines as well as from ova, sperm, embryos and other reproductive material. Genetic information (including, for example, predictive information about a person) could also be gained from the examination of the health status or suitability of eggs or cells for use in research.⁸⁶

8.78 The Attorney-General's Department submitted that:

Privacy issues in relation to research involving cloning of human DNA or cells arise in particular where genetic analysis is required to identify the individuals from whom the genetic material used in the research was obtained. This could be necessitated by a need to assess the health status of the tissue by reference to the health and genetic make up of the cell donor and his or her family.⁸⁷

8.79 The *Privacy Act 1988* (Cth) is relevant to the collection, storage, use and disclosure of personal information by Commonwealth agencies. The use of personal information for research is not exempt from the Information Privacy Principles (IPPs) in the Privacy Act. The Attorney-General's Department submitted that under section 95 of the Privacy Act a Commonwealth agency may, in relation to medical research, deal with personal information in ways that may otherwise infringe the (IPPs) if that research conforms to guidelines devised by the NHMRC and approved by the Privacy Commissioner.⁸⁸ Such guidelines have been developed and approved and were published in March 2000.

8.80 Privacy issues in relation to cloning and the use of embryos in research cannot be divorced from genetic information and testing issues generally.

8.81 On 9 August 2000 the Attorney-General and the Minister for Health and Aged Care jointly announced an inquiry to be conducted by the Australian Law Reform Commission and AHEC into the 'human rights, privacy and discrimination issues posed by advances in gene technology'.

86 Dr John Smeaton gave evidence regarding the development of commercial cell lines, *Transcript*, p.149 as well as evidence concerning the assessment of the quality of embryos – *Transcript* p.161

87 Attorney-General's Department, *Submissions*, p.S537

88 Attorney-General's Department, *Submissions*, p.S539. The Privacy Amendment (Private Sector) Act 2000 will extend the Privacy Act to the private sector

The terms of reference, announced on 7 February 2001, are to inquire into whether a regulatory framework is required to:

- protect the privacy of human genetic samples and information;
- provide protection from inappropriate discriminatory use of human genetic information; and
- reflect the balance of ethical considerations relevant to the collection and uses of human genetic samples and information in Australia.

8.82 The Attorney-General and the Minister for Health and Aged Care should ensure that the matters raised above are investigated as part of this inquiry and kept under review pending the report of the inquiry with a view to legislating on these matters if necessary. The final report is due on 30 June 2002.

State and Territory human tissue legislation

8.83 Apart from the legislation discussed above concerning assisted reproductive technology the most relevant legislation at State and Territory level is that regulating the donation and use of human tissue.⁸⁹ The AHEC report notes:

Current human tissue legislation may apply to some aspects of proposed cloning techniques. Where a cloning technique uses material from one body for transplantation to another or for research or other purposes, the consent provisions of the human tissue legislation would apply.⁹⁰

8.84 The importance of the legislation governing the donation and use of human tissue to the issues under discussion in this report lies in the fact that research involving cloning technologies requires embryos (to extract embryonic stem cells), ova (if embryos are to be created specifically for research using somatic cell transfer techniques)⁹¹ and/or human tissue (to gain adult stem cells or somatic cells for cloning purposes).

89 Other State and Territory legislation that may also be relevant regulates access to and use of health information held by authorities, consumer protection and professional conduct (see the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*, p.5). The discussion of such legislation is beyond the scope of this report

90 AHEC report, Chapter 4, paragraph 4.24

91 These have been discussed above in relation to legislative provisions regulating these matters and discussion in the next chapter will outline non-legislative regulation of the use of embryos and ova

- 8.85 All States and Territories have enacted legislation regulating the donation and transplantation of human tissue.⁹² These statutes cover the removal and donation of tissue for transplant, scientific research or therapeutic use and post mortem examination.
- 8.86 The most common definition of 'tissue' is that it includes:
- An organ, or part, of a human body or a substance extracted from, or from a part of, a human body.⁹³
- 8.87 All the State and Territory legislation provides that living adults may consent to donate regenerative tissue for transplantation or for therapeutic, medical or scientific purposes. Adults may consent to donate non-regenerative tissue for transplantation only. Donations may also be made from deceased persons provided consent procedures have been followed.⁹⁴ Regenerative tissue is defined, in general, as 'tissue that, after injury or removal, is replaced in the body of a living person by natural processes of growth or repair'.⁹⁵
- 8.88 These provisions do not extend to foetal tissue, sperm and ova.⁹⁶ In all jurisdictions it is an offence to attempt to buy or sell or trade human tissue.⁹⁷ It is also an offence to remove tissue from a body (living or dead) without consent or authority.⁹⁸

92 ACT: *Transplantation and Anatomy Act 1978*; NSW: *Human Tissue Act 1983*; NT: *Human Tissue Transplant Act 1979*; Queensland: *Transplantation and Anatomy Act 1979*; SA: *Transplantation and Anatomy Act 1983*; Tasmania: *Human Tissue Act 1985*; Victoria: *Human Tissue Act 1982*; WA: *Human Tissue and Transplant Act 1982*

93 See for example: Victoria: s 3; SA: s 5; Tasmania: s 3; NT: s 4. Queensland is the only jurisdiction to use a different definition

94 See for example: Victoria: sections 7 and 8; Tasmania: sections 7 and 8; NT: sections 8 and 9; SA: sections 9 and 10; Qld: sections 10-11. More restrictive rules apply in the case of children. Donations after death require the pre-death consent of the deceased or next of kin after death. Such tissue may be used for transplantation, therapeutic, scientific or medical purposes—see for example—Victoria: s 26; NT: s 18; SA: s 21; Tasmania: s 23. The Human Tissue Amendment Bill 2001, currently before the NSW Parliament would amend some of these procedures in relation to post-mortems in NSW

95 See for example—Queensland: s 4; Victoria: s 3; NT: s 4; SA: s 5 and Tasmania: s 3

96 NSW has special provisions relating specifically to blood or semen donation (part 3A of the Act), the latter applying to semen obtained or received for the purposes of using it for the artificial insemination of a woman. The donor must sign a certificate relating to medical suitability. See also - Victoria: s 5; WA: s 6; Tasmania: s 3; NT: s 5; SA: s 7; Queensland: s 8. The provisions refer to 'foetuses' although they would probably also apply to embryos

97 See for example: Victoria: s 38 and 39; SA: s 35; Queensland: s 40 and 42; Tasmania: s 27

98 See for example: SA: s 38; Tasmania: s 30; WA: s 33

- 8.89 Provisions generally exclude the operation of the legislation from the removal of tissue in the course of medical procedures and the use of tissue so removed.⁹⁹
- 8.90 Also relevant in this context is the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (discussed in Chapter 9) which contains a segment dealing with research utilising human tissue, subject to approval by an institutional ethics committee (IEC).¹⁰⁰ The National Statement provides that:
- Samples collected for diagnostic purposes in the course of treatment¹⁰¹ may also be used for teaching or quality assurance activities and for research. ... Hospitals and pathology laboratories are required by law to retain archival samples for diagnostic or forensic purposes. Accordingly, most hospitals have collections of stored samples, the use of which may lead to important advances in the understanding and treatment of disease.¹⁰²
- 8.91 The National Statement indicates that research involving the use of such human tissue samples may be approved by an IEC in accordance with the National Statement.¹⁰³ Human tissue legislation is currently being reviewed.¹⁰⁴

99 See for example: SA: s 37; NT: s 26; Tasmania: s 28; WA: s 32. Legislation in, for example NSW and Victoria, provide that if there is to be an autopsy no further consent is required to retain and use the tissue, provided it was removed for the purpose of the autopsy and the coroner does not object

100 NHMRC, *National Statement on Ethical Conduct in Research Involving Humans*, pp.43-45

101 As noted above these are excluded from the human tissue legislation

102 *National Statement*, p.43. This excludes foetal tissue, reproductive tissue and tissue from autopsy to which additional guidelines or legislation might apply—*National Statement*, p.43

103 The *National Statement* indicates that in granting such approval IECs should consider issues such as consent, confidentiality, privacy, storage of samples and data, accountability in care and use of such samples. Consent should generally be required for the use of human tissue samples for research and should be specific to the purpose for which the tissue is to be used. However, an IEC may waive consent requirements in accordance with the *National Statement* – *National Statement*, pp.43-45

104 The review of human tissue legislation and procedures in most jurisdictions has arisen in the context of press reports in 2001 of the retention of human tissue and body parts without consent, or following autopsies, for use in research. In NSW, the Minister for Health appointed senior counsel Brett Walker SC to head an inquiry into practices at a Sydney morgue, *Sydney Morning Herald*, 9 March 2001, p.1; Australian Associated Press, 20 March 2001. Mr Walker's report entitled *Inquiry into Matters Arising from the Post-Mortem and Anatomical Examination Practices of the Institute of Forensic Medicine* was publicly released on 17 August 2001. The Western Australian Government ordered an investigation into current state practices for the removal and retention of body parts in WA and pledged to introduce an enforceable code of conduct in relation to such matters. The issue of consent for the use of body parts will be a particular focus of investigation, AAP, 22 March 2001 and *West Australian*, 21 March 2001, p.5. The Victorian Government has set up a working party to review the retention, use and

How does this apply to cloning research?

8.92 Associate Professor Loane Skene summarised the application of human tissue legislation in the context of human cloning:

The law requires, before any tissue or any invasive procedure is undertaken on a person, that they be informed about what is proposed and any material risks associated with that, and in the light of that information they make a choice about whether to undertake that procedure [and give consent].¹⁰⁵

8.93 The situation becomes more complicated, Associate Professor Skene noted, where tissue (such as an ovum):

... had been taken with the woman's consent and was being stored somewhere, another issue arises as to whether there are any property rights in that stored tissue that would prevent the research being undertaken. The law on that in fact is very unclear as to whether you have to go back to that person and ask them for permission again [or whether the initial consent covers any type of unspecified conduct].

Informed consent is:

... adequate to protect the taking of the tissue in the first place, but the use of tissue that has been taken with consent for purposes other than the original purposes for which it was taken is quite unclear.¹⁰⁶

Comment

8.94 The 'ownership' of human tissue is a complex matter and the law, as Associate Professor Skene has stated, is uncertain. It is also not clear at law who, if anyone, 'owns' stored or other genetic material or human tissue. Hence it is unclear who has the right to 'possess' and 'use' it. This uncertainty has posed some difficulties for assisted reproductive technology clinics especially where persons who may be thought to have

disposal of tissue obtained through autopsy from both hospital and coronial morgues and to review the *Human Tissue Act 1982*. This Act remains the legal benchmark in Victoria although the Victorian Institute of Forensic Medicine voluntarily changed its procedures to require consultation with next of kin for both diagnostic and research autopsies, *The Age*, 20 March 2001

¹⁰⁵ Associate Professor Loane Skene, *Transcript*, p.57

¹⁰⁶ Associate Professor Loane Skene, *Transcript*, p.57. Dr Nicholas Tonti-Filippini raised similar issues concerning the status of an ovum (egg): whether it can be owned; if so, by whom and who has the right to consent to its use. The same issues pertain to use of genetic material more generally. Dr Nicholas Tonti-Filippini, *Transcript*, p.57

‘rights’ in relation to stored genetic material, for example donors or couples for whom embryos were formed, cannot or will not express views as to what should be done with such material.¹⁰⁷

- 8.95 The current and potential research involving the use of cloning technologies opens a new series of questions on the donation and use of human tissue. Tissue removed as part of medical procedures, as the result of an autopsy or in other ways could be a source of stem cells or somatic cells for research purposes. Human tissue has potential uses now that are different from those envisaged in the past and the ramifications of the creation of adult or embryonic stem cell lines (or banks of them) from adult cells or embryos are significant. The use of such tissue, both inadvertent and deliberate, needs to be considered. The potential for the identification of the genetic characteristics of human tissue donors is also an issue that requires consideration in this context.
- 8.96 The current framework of human tissue legislation does not easily accommodate these possibilities. The legislation is premised on a once-only ‘donation’ of organs or tissues. As such, it is an unconditional gift and once a person has donated organs or tissues they forfeit any right to attach any conditions to their use.¹⁰⁸
- 8.97 The Committee did not receive evidence that directly canvassed issues arising from the use of human tissue more generally (as opposed to embryonic tissue) in cloning related research. It urges that matters relating to consent to the removal of human tissue and its use in this area of research be examined within any current review of human tissue legislation and taken into account when drafting the legislative provisions relating to consent recommended in Chapter 12.¹⁰⁹
- 8.98 The Committee suggests that the following issues, in particular, be examined in the context of such a review:
- whether it should be required that consent be granted by the individual from whom human material or adult cells originate to the use of the human material or cells in the particular research procedure proposed and to the continued use of the cells or material in the future. It may be necessary that specific consent be granted, not only to ‘research’

107 NSW Government Discussion paper *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, paragraph 6.1

108 NSW Government Discussion Paper, *Review of the Human Tissue Act 1983: Assisted Reproductive Technologies*, paragraph 6.3

109 See Chapter 12, paragraphs 12.68-12.76. The evidence of Dr John Smeaton regarding the proposed development of cell banks indicates the urgent necessity of such a review, *Transcript*, p.150

generally, but to the particular research proposed if human tissue or cells are to be used in research involving the use of cloning technologies. The successful development of adult stem cell therapies may result in adult cell lines becoming a commercial product as some are seeking to do in the case of embryonic stem cell lines.¹¹⁰ Genetic information about the originator of the material may also be acquired from cell lines;

- whether the use of human tissue from deceased persons for this area of research should only be made with the written consent of the originator of the tissue prior to death; and
- whether a person should be able to direct that all human tissue removed from his/her body (for example during medical or surgical procedures) be destroyed.

110 See the evidence of Dr John Smeaton, *Transcript*, pp.149-168 and Mr Robert Klupacs, *Transcript*, p.170