APPENDIX 3

SUMMARY OF LOCKHART RECOMMENDATIONS AND HOW THESE ARE ADDESSED IN THE PATTERSON BILL

	Lockhart Review recommendation	**How the issue is addressed in the Bill**
1	Clinical practice and scientific research involving assisted reproductive technologies (ART) and the creation and use of human embryos for research purposes should continue to be subject to specific national legislation.	The national legislative scheme will continue to exist.
2	Reproductive cloning should continue to be prohibited.	Proposed clauses 9 and 14 continue to ban the development of a human embryo clone for longer than 14 days and the implantation of such a clone in a human or animal. Amended section 20 also bans the development and implantation of **any** embryo that does not result from the fertilisation of a human egg by human sperm.
3	Implantation into the reproductive tract of a woman of a human embryo created by any means other than fertilisation of an egg by a sperm should continue to be prohibited.	This is banned in proposed clause 20 of the PHC Act.
4	Development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited.	This is banned in proposed clause 14 of the PHC Act.
5	Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue be prohibited.	This is banned in proposed clause 20 of the PHC Act.
6	Development of a human–animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17.	Creation of chimeric embryos is banned in proposed clause 17 of the PHC Act. The creation and development of hybrid embryos is banned by proposed clause 23B, unless authorised by licence. The only licences that may be issued are ones giving effect to recommendations 17 and 24. Development of hybrid embryos beyond 14 days is banned in all cases by proposed clause 18.
7	Placing a human embryo into an animal or into the body of a human apart from into a woman's reproductive tract, or placing an animal embryo into the body of a human, for any period of gestation, should all remain prohibited.	This is banned in proposed clause 19 of the PHC Act.
8	Implantation into the reproductive tract of a woman of an embryo created with genetic material provided by more than two people should continue to be prohibited.	This is banned in proposed clause 20 of the PHC Act.
9	Implantation into the reproductive tract of a woman of an embryo created using precursor cells from a human embryo or a human fetus should continue to prohibited.	This is banned in proposed clause 20 of the PHC Act.

10	Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to prohibited	This is banned in proposed clause 20 of the PHC Act.
11	Collection of a viable human embryo from the body of a woman should continue to be prohibited.	This is banned in proposed clause 16 of the PHC Act.
12	Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.	This will continue to be the case (proposed clause 12 of the PHC Act).
13	Creation of human embryos by fertilisation of human eggs by human sperm to create embryos for the purposes of research should continue to be prohibited except in the situation described in Recommendation 15.	This is banned in proposed clause 12 of the PHC Act, which makes it an offence to create a human embryo by fertilisation of human egg with human sperm for any purpose other than achieving pregnancy.
14	Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.	Use of excess ART embryos in research will continue to be permitted, under licence (proposed amended section 20 of the RIHE Act).
15	Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART.	The proposed amendments to section 20 of the RIHE Act allow a person to apply to the Licensing Committee to undertake research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division. Such activity not authorised by a licence is banned under proposed clause 10B of the RIHE Act.
16	Testing of human oocytes for maturity by fertilisation up to, but not including, the first cell division or by parthenogenetic activation should be permitted for research, training and improvements in clinical practice of ART.	Testing by fertilisation up to the first mitotic division will be permitted under licence (proposed clauses 10B and 20 of the RIHE Act). Parthenogenic activation will be also be permitted under licence in accord with recommendation 25 (amended clause 20 of the RIHE Act allows a person to apply for a licence to create an embryo by any means other than fertilisation of human egg by human sperm).
17	Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice.	Proposed paragraph 20(1)(f) enables the granting of a licence to permit this.
18	The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.	No legislative change required.
19	Consideration should be given to the use of cytoplasmic transfer (including transfer of mitochondrial DNA), under licence, for research on mitochondrial disease and other uses to improve ART treatment.	Proposed amended section 20(1) of the RIHE Act will permit, under licence, certain types of research that may be useful in relation to cytoplasmic transfer. However, an embryo containing genetic material from more than two people (and created by the fertilisation of human egg and sperm) will not be able to be created for research purposes.
20	An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.	The new definition of "unsuitable for implantation" in subsection 7(1) of the RIHE Act provides for this.

21	Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice.	New subclause 24(8) in the RIHE Act enables the Licensing Committee to modify the requirements for "proper consent" in relation to use of such embryos. This will enable the current 14 day cooling-off period to be shortened, so as to allow the use of fresh embryos.
22	Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under licence, for research, training and improvements in clinical practice.	New subsection 24(8) in the RIHE Act (described immediately above) will enable this.
23	Human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	Section 22 of the PHC Act bans the creation or development of a human embryo by a process other than fertilisation unless this is licensed. Section 20 of the RIHE provides for the licensing of the creation and use of such embryos. This has the effect of allowing SCNT under licence. The PHC Act also bans the development of any human embryo (including a human clone) outside the body of a woman beyond 14 days (clause 14), and the implantation of a human embryo clone (or any embryo that has not been created using sperm and egg) (clauses 9 and 20(3)).
24	In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	Paragraph 20(1)(g) of the RIHE Act enables the granting of a licence to permit this. Section 18 of the PHC Act bans the development of such embryos for more than 14 days.
25	Creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	Proposed clause 22 of the PHC Act bans such activity, except under licence. Proposed clause 20 of the RIHE provides for the granting of licences. Clause 9 of the PHC Act bans the implantation of such embryos and proposed clause 14 of the PHC Act bans their development for longer than 14 days.
26	Creation of human embryos using the genetic material from more than two people, or including heritable genetic alterations, should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	The combined effect of proposed clauses 13 and 23 of the PHC Act and clause 20(1) of the RIHE Act is that the Licensing Committee may licence the creation of embryos that include genetic material from more than two people provided that the embryo is created by means other than fertilisation of a human egg by human sperm. Fertilisation studies may also be undertaken, under licence, up to (but not including) the first mitotic division.

27	Creation of embryos using precursor cells from a human embryo or a human fetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	Proposed clause 23A of the PHC Act bans such activity, except under licence. Proposed clause 20 of the RIHE provides for the granting of licences. Clause 20 of the PHC Act bans the implantation of such embryos and clause 14 of the PHC Act bans their development for longer than 14 days.
28	The definition of a 'human embryo' in both Acts should be changed to: 'A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either: (i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or (ii) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, 14 days and has not yet reached eight weeks of development.'	This was the NHMRC's draft definition at the time the Lockhart Report was written. The final NHMRC definition differed slightly from the draft definition. The proposed new definition in the PHC Act and the RIHE Act is the final NHMRC definition.
29	The National Health and Medical Research Council (NHMRC) should review its guidelines in relation to consent to research on excess ART embryos, in order to clarify the consent process in relation to the following issues: • the circumstances, if any, where those who choose to donate excess ART embryos to research may be able to choose not to be contacted at some later stage to give consent to a particular research proposal • the circumstances, if any, where a human research ethics committee can determine that the researcher need not ask for further consent to use embryos already declared 'excess' • the development of an appropriate form of consent that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess • the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used, once the embryo is declared excess.	For consideration by the NHMRC - No changes to the legislation required.

30	The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice (see Recommendations 20–22).	For consideration by the NHMRC - No changes to the legislation required.
31	The current principles of consent for participation in medical research must apply to sperm, egg and embryo donors, so as to ensure that decisions are freely made.	The proposed amendments to the RIHE Act make it clear that proper consent must be gained for any research involving human eggs or human embryos.
32	The NHMRC should develop guidelines for egg donation.	For consideration by the NHMRC - No changes to the legislation required.
33	The present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted.	Proposed clause 21 of the PHC Act is the same as the existing prohibition.
34	The Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) should continue to be the regulatory body responsible for assessing licence applications, issuing licences and monitoring compliance, as under current arrangements.	This continues to be the case – no changes to the legislation required.
35	The role of the Licensing Committee should be extended to include assessment of licensing applications and issuing licences for any additional activities permitted, under licence (see Recommendations 14–27).	Proposed amendments to subclause 20(1) of the RIHE Act will enable the Licensing Committee to do this.
36	The Australian Parliament and the Council of Australian Governments should give urgent attention to the problem of delays in the filling of vacancies on the Licensing Committee.	Proposed amendments to clause 16 of the RIHE Act (new subsections (7) and (8)) address this recommendation.
37	There should be no attempt to recover the cost of administration, licensing, monitoring and inspection activities associated with the legislation from researchers at this point in time.	This continues to be the case.
38	The Licensing Committee should continue to perform its functions in relation to licences and databases for research permitted by licences under the Research Involving Human Embryos Act.	This continues to be the case.
39	Licensing Committee inspectors should be given powers, under the Prohibition of Human Cloning Act and the Research Involving Human Embryos Act, of entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation, if such powers do not clearly exist.	Proposed clauses 37A, 37B, 37C and 37D in the RIHE Act provide for these powers.

40	There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.	No changes to legislation required.
41	The import or export of a patient's reproductive material, including ART embryos, for the purpose of that person's ongoing ART treatment should not require any regulation other than that required under existing quarantine regulation.	Regulation 7 of the *Customs (Prohibited Exports) Regulations 1958* is proposed to be repealed by virtue of Schedule 4 of the Bill.
42	The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.	Section 23C of the PHC Act requires the Minister for Customs to take all reasonable steps to ensure that regulations are made permitting this.
43	The existing requirements for the import and export of human biological materials are satisfactory and, for ethically derived human embryonic stem cells, no further restrictions are necessary.	No changes to legislation required.
44	Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.	This continues to be the case under proposed clause 21 of the PHC Act.
45	Donors of tissue that is going to result in an immortal stem cell line should be informed by means of processes monitored by human research ethics committees about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments.	The proposed changes to the Act ensure that there must be proper consent (in accordance with NHMRC guidelines) in relation to any use or creation of embryos.
46	The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.	No changes to legislation required.
47	A national stem cell bank should be established.	Proposed clause 47B of the RIHE Act requires the Minister to report to Parliament (within 6 months) regarding the establishment of a national register of donated excess ART embryos.
48	Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.	No changes to legislation required.
49	A national register of donated excess ART embryos should be established.	Proposed clause 47B of the RIHE Act requires the Minister to report to Parliament (within 6 months) regarding the establishment of a national register of donated excess ART embryos.
50	The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings.	Proposed clause 12A avoids constitutional issues associated with binding rulings, but addresses the basic concern of the Lockhart Committee which appeared to be the potential liability of researchers where they are acting in good faith in accordance with a licence but where the NHMRC Licensing Committee in fact had no power to issue the licence.

51	The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NHMRC and to parliament on any rulings it gives, or any licences it grants, in that way.	Proposed clause 12A (as described above).
52	A researcher who conducts research on the basis of a ruling or a licence should be protected from liability under the legislation, provided that they act in accordance with the relevant ruling or licence.	Proposed clause 12A (as described above).
53	In view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.	The Bill includes a new clause 25A (in the PHC Act) and a new clause 47A (in the RIHE Act) that requires that a review be undertaken.
54	There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.	No changes to legislation required.

Source: Senator the Hon Kay Patterson, Senate Hansard, 19 October 2006, pp.14-19.