INTRODUCTION

1. These explanatory notes relate to the Commons Amendments to the Human Fertilisation and Embryology Bill [HL], as brought from the House of Commons on 23rd October 2008. They have been prepared by the Department of Health in order to assist the reader of the Bill and the Commons Amendments and to help inform debate on the Commons Amendments. They do not form part of the Bill and have not been endorsed by Parliament.

2. These notes, like the Commons Amendments themselves, refer to Bill 70, the Bill as first printed for the Commons.

3. These notes need to be read in conjunction with the Commons Amendments and the text of the Bill. They are not, and are not meant to be, a comprehensive description of the effect of the Commons Amendments.

4. All the Commons Amendments were in the name of the Minister.

COMMENTARY ON COMMONS AMENDMENTS

Commons Amendment 1

5. Commons Amendment 1 would make a drafting change to new section 4A of the Human Fertilisation and Embryology Act 1990 (“the 1990 Act”), inserted by clause 4 of the Bill, to ensure consistency in the use of the phrase "keeping or using".

Commons Amendments 2 and 27

6. Commons Amendment 2 would introduce a new regulation-making power to section 4A of the 1990 Act (inserted by clause 4 of the Bill) to enable the circumstances in which a human admixed embryo can be kept or used to be restricted. This power could be used, for
example, if it became necessary to shorten, in some circumstances, the 14-day time limit for
which human admixed embryos may be kept. This mirrors an existing power in relation to
human embryos in section 3(3)(c) of the 1990 Act. Commons Amendment 27 would make
this new regulation-making power subject to the affirmative resolution procedure.

**Commons Amendments 3, 5, 27, 29, 30 and 49 to 52**

7. Commons Amendment 3 would remove the regulation-making power at new section
4A(5)(e) of the 1990 Act (inserted by clause 4 of the Bill), which enables “such other thing as
may be specified in regulations” to be brought within regulation under the 1990 Act as a
human admixed embryo. The amendment would replace this power with a provision that
would bring embryos containing both human DNA and animal DNA within regulation as
human admixed embryos, but only if the animal DNA is not predominant.

8. Commons Amendment 5 would make an amendment consequential on Commons
Amendment 3 to ensure that the power under new section 4A(10)(a) of the 1990 Act to amend
the categories of human admixed embryos under section 4A(5) would extend to the new
category added by Commons Amendment 3.

9. Commons Amendments 27, 29, 30 and 49 to 52 would make amendments to clauses
30 and 31 and Schedule 2 consequential on the insertion of new section 4A(4A) or on the
removal of the regulation-making power at new section 4A(5)(e).

**Commons Amendment 4**

10. Commons Amendment 4 would make a drafting correction, bringing new section
4A(9) of the 1990 Act (inserted by clause 4 of the Bill) into line with new subsection (4)(a) of
section 1 of that Act (inserted by clause 1(4)). The amendment would ensure that in new
section 4A(8) of the 1990 Act the reference to an egg is capable of including an egg in the
process of fertilisation.

**Commons Amendments 6, 7, 10 to 12, 105, 107 and 114 to 116**

11. Commons Amendments 6, 7, 10, 11, 12, 105, 107, 114, 115 and 116 relate to the
requirements of Directive 2004/23/EC\(^1\), laying down standards of quality and safety for
human tissues and cells intended for human application, and Commission Directives
2006/17/EC\(^2\) and 2006/86/EC\(^3\), laying down technical requirements in relation to Directive

of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of
human tissues and cells (OJ L No. 102, 7.4.2004, p. 48).

Parliament and of the Council as regards certain technical requirements for the donation, procurement and

Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and
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2004/23/EC. They would ensure implementation of certain of those requirements in a case where embryos are created under a research licence with a view to embryonic stem cells from them being used for human application.

**Commons Amendments 8, 9 and 13**

12. Commons Amendments 8, 9 and 13 would make minor drafting corrections to clauses 14 and 24.

**Commons Amendments 14 to 23**

13. Commons Amendment 14 would replace paragraphs (g) to (j) of new section 33A(2) of the 1990 Act (inserted by clause 25 of the Bill) with new paragraphs (g) and (h). New paragraph (g) would continue to exempt from the prohibition on disclosure, contained in new section 33A(1), the disclosure of information where no individual can be identified from the information. New paragraph (h) of section 33A(2) would exempt from the prohibition the disclosure of identifying information, other than “identifying donor information”, where the necessary consents have been obtained. Provision about disclosure with consent is currently made by paragraphs (h) to (j) of subsection (2) of new section 33A and by subsections (4), (5) and (9) of that section.

14. Commons Amendment 22 would insert into new section 33A a definition of “identifying donor information”. The definition is based on the existing wording of new section 33A(7)(a). Commons Amendment 18 would make a consequential amendment to new section 33A(7)(a), replacing the words used in the definition of “identifying donor information” with that phrase. The exclusion of “identifying donor information” from new paragraph (h) of new section 33A(2) ensures that the provision could not be used to enable the Human Fertilisation and Embryology Authority (“the Authority”), or licensed clinics, or others to whom the prohibition on disclosure in new section 33A(1) applies, to disclose identifying information about donors on the basis of the donor’s consent. The disclosure of such information is dealt with by the new provisions being inserted into the 1990 Act by clause 24.

15. New paragraph (h) of new section 33A(2) should be read together with new section 33AB of the 1990 Act, which would be inserted by Commons Amendment 23. This would set out whose consent is needed in order for a disclosure to fall within new paragraph (h). New paragraph (h), read together with new section 33AB, would potentially allow researchers more access to the data about treatments on the Authority’s register where the relevant consents have been obtained.

16. New section 33AB would provide that the consent of each individual who can be identified from the information is required in order for disclosure to fall within the exemption

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events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L294, 25.10.2006, p.32).
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set out in new paragraph (h). Where such an individual is under the age of 18 and is not competent to consent, the consent of a person having parental responsibility for them must be obtained. Where such an individual is under that age but is competent to consent, their consent must be obtained.

17. Subsection (6) of new section 33A currently prevents the exemptions relating to disclosure with consent (paragraphs (h) to (j) of subsection (2)) from being used to disclose information to a person under the age of 18. Commons Amendment 17 would remove subsection (6). Disclosure with consent to those under the age of 18 of identifying information, other than “identifying donor information”, would be governed by new section 33AB.

18. Commons Amendment 16 would remove subsections (4) and (5), which make supplemental provision about disclosure with consent, from new section 33A. The provision made by these subsections (with the exception of that made by paragraph (b) of subsection (4)) is reflected in new section 33AB. New section 33AB also reflects the provision made by subsection (9), which would be removed by Commons Amendment 19.

19. Commons Amendment 15 would insert a new paragraph into new section 33A(2), replacing subsections (8) and (9) of new section 33A, which would be removed by Commons Amendment 19. This amendment would provide that the Authority, and others to whom the prohibition on disclosure in new section 33A(1) applies, are not prohibited from disclosing information relating to the provision of treatment services to an identifiable individual where certain conditions are met. Those conditions are that: (1) the person disclosing the information is satisfied that the disclosure is necessary to avoid imminent danger to a person’s health; (2) it is not reasonably practicable to obtain the person’s consent to the disclosure; and (3) it would be possible either to disclose the information to others, by virtue of new sections 33A(2)(h) and 33AB, if the person’s consent had been obtained or to disclose the information to that person, relying on subsection (10) of section 33A(2) (as amended by Commons Amendment 20). As noted above, the provision made by subsection (9) is reflected in new section 33AB.

20. Subsection (10) of section 33A(2) currently provides that the prohibition on disclosure in new section 33A(1) does not apply to the disclosure to an individual of information falling within section 31(2)(a) to (e) of the 1990 Act (see clause 24) that relates only to that individual or only to that individual and the person they were treated together with. Commons Amendment 20 would amend subsection (10) so that the prohibition would also be prevented from applying if the information related only to the individual and the person in respect of whom the individual had given a notice under clause 37 or 44. This would ensure that people who enter into fatherhood or parenthood agreements will not be prevented, by new section 33A(1), from receiving identifying information about the other party to the agreement, even if the other party does not consent, provided that the information relates only to the two of them.
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21. Commons Amendment 21 would remove from new section 33A(11) the definition of “relevant individual”. The definition is currently used in paragraph (j) of new section 33A(2) but that paragraph would be removed by Commons Amendment 14.

Commons Amendments 24 to 26 and 117 and 118

22. Commons Amendments 24 to 26 would make amendments to clause 29 of the Bill. Commons Amendments 24 and 26 would together replace the repeal of section 41(7) of the 1990 Act with an amendment of that provision. In the 1990 Act as it stands, section 41(7) makes it an offence for a person, without reasonable excuse, to fail to comply with a requirement imposed under regulations made under section 10(2)(a) of the 1990 Act. Section 10(2)(a) of the 1990 Act enables regulations to be made giving a licence committee (or the Authority itself on an appeal from such a committee) power to require people to give evidence or to produce documents. In the 1990 Act as amended by the Bill, equivalent powers to make provision about the summoning of witnesses or the production of documents will be contained in new sections 19B(3)(a) and 20B(3)(e) of the 1990 Act, inserted by clauses 19 and 21 respectively. Commons Amendment 24 would replace the reference to section 10(2)(a) of the 1990 Act in section 41(7) with a reference to sections 19B(3)(a) and 20B(3)(e). Commons Amendment 25 would make a consequential change in order to preserve the reference to section 41(7) in section 41(9).

23. Commons Amendments 117 and 118 would make amendments to Schedule 8 to the Bill, which contains repeals, consequential on these changes to clause 29.

Commons Amendment 28

24. New sections 20A(3) and 20B(2) of the 1990 Act (inserted by clause 21 of the Bill) introduce regulation-making powers relating to membership and proceedings of appeals committees and procedure in relation to reconsideration of licensing decisions. Under the Bill as it stands, these powers would be subject to the negative resolution procedure. Commons Amendment 28 would add these powers to the list in new section 45(4A) of the 1990 Act (inserted by clause 30 of the Bill), so making them subject to the affirmative resolution procedure.

Commons Amendments 31 and 34

25. Under clause 37, for a man to fulfil the agreed fatherhood conditions both he and the woman to be treated must give notice in writing of consent to the man being treated as the father of any child born from the treatment. Notice must also be given in writing of any withdrawal of consent. Equivalent provision is made for second female parents under clause 44. Under subsection (2) of clauses 37 and 44 these written notices must also be signed. Commons Amendments 31 and 34 would provide that if any of the persons involved were unable to sign because of illness, injury or physical disability, the requirement as to signature could be satisfied by someone else signing the notice, at the direction of the person involved, in that person’s presence and in the presence of an attesting witness. These changes would be consistent with provision made in new paragraph 1(2) of Schedule 3 to the 1990 Act (inserted by Schedule 3 to the Bill) in relation to consents given under that Schedule.
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Commons Amendments 32, 33, 35, 37, 40 and 95 to 103
26. Commons Amendments 32, 33, 35, 37, 40 and 95 to 103 would make minor drafting corrections to Part 2 of the Bill (including Schedule 6). Commons Amendments 96, 97, 101 and 102 would convert references to the date or time of a civil partnership into references to the date or time of the formation of a civil partnership. This is because a civil partnership is defined (by section 1 of the Civil Partnership Act 2004) as the relationship not the ceremony.

Commons Amendments 36 and 38
27. Commons Amendment 36 would correct an anomaly in the Bill (as it applies to England and Wales and Northern Ireland). The amendments made by Schedule 6 already treat children born to female civil partners in the same way as children born to married couples for the purposes of Acts which draw a distinction between married and unmarried parents. Under the provisions of the Bill (paragraph 15 of Schedule 6) a child, born to a female same-sex couple who later entered into a civil partnership, would also be treated as legitimate in law for other purposes. However, a child born to female civil partners would not be treated as legitimate in law for all purposes. Although the concept of legitimacy has less legal significance than in the past, it remains possible (for example) for a disposition of property to refer to a person’s legitimate children. This amendment would remove the anomaly by amending clause 48 of the Bill. Commons Amendment 38 would also extend the effect of this to children born to female parents in a void civil partnership, if either or both parties reasonably believed the civil partnership to be valid at the time they registered as civil partners. Such a belief is to be presumed, in the absence of evidence to the contrary. This is consistent with the treatment of void civil partnerships and marriages for the purposes of the rest of Part 2 of the Bill.

Commons Amendments 39, 47 and 94
28. Commons Amendment 94 would make consequential amendments to the Schedule to the Population (Statistics) Act 1938 to reflect the changes made by clauses 42 and 43 of the Bill in relation to female same-sex couples and parenthood. The amendment would enable the statistical data collected at birth registration, where a child is born to female same-sex parents, to include information relating to the age of the second female parent and the date of formation of any civil partnership. Commons Amendment 39 would add the Schedule to the 1938 Act to the list in clause 53(5) of enactments which make express provision for a child having a parent by virtue of clause 42 or 43. Commons Amendment 47 would amend clause 67 concerning extent to reflect the fact that some of the amendments made to the Schedule to the 1938 Act would not extend to Scotland. The reason for this is that the Scottish Ministers intend to make other amendments to the 1938 Act shortly to reflect the abolition of the status of illegitimacy in Scotland under the Family Law (Scotland) Act 2006.

Commons Amendments 41 to 45
29. Commons Amendments 41 to 45 would amend the amendments made to the Surrogacy Arrangements Act 1985 by clause 59 to ensure that when non-profit making bodies charge for the activities that they are no longer prohibited from charging for (in relation to facilitating surrogacy arrangements, as a result of changes made by the Bill), they can only
recoup the reasonable costs attributable to those activities, and may not inflate their charges to
cover costs incurred in relation to other activities.

30. Commons Amendment 45 would provide that any reference to “reasonable payment”
is to a payment which does not exceed the body’s costs reasonably attributable to the doing of
the act. This could include overheads attributable to the activities and not just the costs of
carrying out the activities. This would prevent cross-subsidisation between the activities they
are no longer prohibited from charging for and those for which they are still prohibited from
charging for, since the costs of doing the latter would not be ‘reasonably attributable’ to the
costs of doing the former.

31. Commons Amendments 41, 42, 43 and 44 would convert references in new section
2(2A) and (2B) of the 1985 Act (inserted by clause 59) to “payment” into references to
“reasonable payment”.

Commons Amendment 46
32. Commons Amendment 46 relates to clause 64, which confers power on the Secretary
of State to make, by order, supplementary, incidental, consequential, transitional or saving
provision, including provision modifying other enactments, in consequence of, or to give full
effect to, the Bill’s provisions. The power is subject to certain consultation requirements as
set out in that clause. It does not currently provide for modification of the provisions of the
Bill itself (other than modification pending the coming into force of another provision of the
Bill).

33. Clause 53(2) deals with the interpretation of references to the father of a child, in any
enactment, deed or any other instrument or document, so that, following on from the
provision made by Part 2 of the Bill, references to fathers can be read as references to second
female parents. Clause 53(3) makes provision about the interpretation of references to
evidence of paternity. Clause 53(5) prevents these general rules of interpretation from
applying to the enactments there listed, which, by virtue of the amendments contained in
Schedule 6, make express provision about second female parents.

34. Commons Amendment 46 would allow the list in clause 53(5) to be updated if an
order was made under clause 64 modifying other enactments by making express provision for
the possibility of there being a second female parent.

Commons Amendment 48
35. Commons Amendment 48 would remove the privilege amendment inserted by the
House of Lords.

Commons Amendments 53, 62 to 71 and 73 to 88
36. Commons Amendments 53, 62 to 71 and 73 to 88 would make changes to the
terminology used in Schedule 3 to the Bill (which amends Schedule 3 to the 1990 Act).
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Commons Amendment 53 would replace the phrase “the incapacitated person”, used in new paragraph 1(2) of Schedule 3 to the 1990 Act, with the phrase “person unable to sign” in order to distinguish a person who is incapacitated due to illness, injury or physical disability, from a person who lacks capacity to consent.

37. Commons Amendments 62 to 71 and 73 would replace the phrase “the child donor” in new paragraph 9 of Schedule 3 to the 1990 Act with the letter “C”. This would avoid any confusion about referring to a “donor” where a child’s gametes will be stored for their use alone. Commons Amendments 74 to 88 would change the word “patient” in new paragraph 10 of Schedule 3 to “P”, so that the Schedule is consistent in the labels used. These amendments would also make minor drafting changes so as to refer to P “having” rather than “regaining” capacity.

**Commons Amendment 54**

38. Commons Amendment 54 would make new paragraph 2(1A) of Schedule 3 to the 1990 Act (inserted by Schedule 3 to the Bill) consistent with paragraph 2(1)(c) of that Schedule to that Act. It would clarify that a person could consent to the use of a human admixed embryo, created using their cells, for the purposes of any project of research. There was a concern that the existing reference to “a” project of research suggested, incorrectly, that express consent would be required to each individual project.

**Commons Amendments 55, 57 to 61, 72, 89 to 93, 106 and 108 to 113**

**Existing cell lines**

39. Commons Amendment 92 would insert new paragraphs 15F and 15G into Schedule 3 to the 1990 Act (by amending Schedule 3 to the Bill). These would provide an exception to the general requirement for an effective consent (found in paragraphs 6, 13 and 14 of Schedule 3 to the 1990 Act - paragraphs 13 and 14 are inserted by Schedule 3 to the Bill) for the use of a person’s “human cells” (as defined - see paragraph 14 of Schedule 3 to the Bill) to bring about the creation in vitro of an embryo or human admixed embryo for research purposes and for the subsequent storage and use for those purposes of any resulting embryo. This exception to the requirement for consent would only apply to cells lawfully stored for research purposes before the commencement of the provision in Schedule 3 to the Bill that introduces a reference to “human cells” into paragraph 6(1) of Schedule 3 to the 1990 Act. In addition, the exception would only apply if the Authority was satisfied that either:

i. the person responsible under the licence could not reasonably identify the donor;

ii. the donor had died, or was reasonably believed to be dead, and consent from a family member or close friend had been obtained, working on the basis of a hierarchy established by the Human Tissue Act 2004 (person in a qualifying relationship); or
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iii. the donor was not reasonably traceable or, if there was reason to believe the donor was dead, a person in a qualifying relationship was not reasonably traceable.

40. In each case, there must not be any information available to the person responsible under the licence to suggest that the donor would have objected to the research. In addition the Authority would have to be satisfied there were reasonable grounds for believing that scientific research would be adversely affected to a significant extent if the only human cells that could be used were those for which consent had been obtained (or which fell within the exception to consent for adults lacking capacity detailed below).

41. Commons Amendment 106 would insert new section 15(5) into the 1990 Act to make it a condition of any research licence, which relies on the exception to consent under new paragraph 15F of Schedule 3, that any embryos or human admixed embryos created must be anonymised so that they cannot be linked back to the donor.

Adults who lack capacity

42. Commons Amendment 92 would also insert new paragraphs 15B to 15E into Schedule 3 to the 1990 Act. New paragraph 15B would create an exception to the requirement for an effective consent, found in paragraphs 6, 13 and 14 of Schedule 3, for the use of human cells from a person who has attained 18 years of age (or, in Scotland, 16 years of age) to bring about the creation in vitro of an embryo or human admixed embryo for research purposes and for the subsequent storage and use for those purposes of any resulting embryo. Reliance on this exception would be subject to the conditions set out in new paragraphs 15C and 15D. The Authority would have to be satisfied that:

i. the adult lacked capacity to consent and was unlikely to have capacity at some time in the future;

ii. the adult suffered from, or was likely to develop, a serious disease, serious disability or other serious medical condition;

iii. the proposed embryonic research was intended to increase knowledge about that disease/ disability/ condition (or one similar to it) or about its treatment (or the treatment of a similar condition) or about care for persons affected by it (or by a similar condition);

iv. there was no evidence that the adult had refused consent at any time in the past when they may have had capacity;

v. there were reasonable grounds for believing research of comparable effectiveness could not be carried out using the human cells of a person who could consent themselves;

vi. the person responsible under the licence had taken reasonable steps to identify a carer for the adult who could be consulted or had nominated someone if such a carer could not be found;

vii. the carer or nominee had been provided with information and consulted as to their opinion of what the adult lacking capacity’s wishes or feelings...
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would be likely to be about the proposed use of their cells – if the carer or nominee indicated they did not think that the adult lacking capacity would want their cells to be used then the researcher could not use the cells.

43. In addition new paragraph 15E of Schedule 3 to the 1990 Act would make provision so that if the adult donor acquired capacity they could give notice that their cells were not to be used to create any further embryos, or that any existing embryos which had not yet been used for research purposes could not be used for those purposes.

44. Amendment 57 would make a consequential change to paragraph 6 of Schedule 3 to the 1990 Act, which relates to consent to the creation and use of embryos, by inserting new sub-paragraph (3ZD). This would make it clear that in the circumstances covered by new paragraphs 15B and 15F of Schedule 3 to the 1990 Act, embryos can be created and used without consent. Amendment 90 would make equivalent provision for human admixed embryos by inserting new paragraph 13(7) into Schedule 3 to the 1990 Act.

45. Amendment 61 would make a consequential change to paragraph 8 of Schedule 3 to the 1990 Act, which relates to consent to storage, to make it clear that in the circumstances covered by new paragraphs 15B and 15F of Schedule 3 to the 1990 Act embryos can be stored without consent. Amendment 91 would make equivalent provision for human admixed embryos by inserting new paragraph 14(4) into Schedule 3 to the 1990 Act.

46. Amendments 110 to 112 would make consequential amendments to the amendments made to the Human Tissue Act 2004 by Schedule 7 to the Bill to ensure that it was clear that the requirements of the 2004 Act would not apply, not only where an effective consent is required for activities under the 1990 Act, but also where the exception to consent under new paragraphs 15B and 15F of Schedule 3 applies.

47. Amendment 113 would make consequential changes to the Mental Capacity Act 2005 to ensure that research that involves the use of a person’s human cells to create an embryo or human admixed embryo in vitro and the storage and use of such embryos would not fall within regulation under section 30 of the 2005 Act.

Cells from children

48. Commons Amendments 57 and 59 would amend paragraphs 6 and 8 of Schedule 3 to the 1990 Act, to allow the use of human cells from a child under the age of 18 years (or, in Scotland, 16 years) to create an embryo in vitro for research purposes, and the subsequent storage and use for those purposes of such embryos, without the child’s consent. Consent would have to be given by a person having parental responsibility for the child and a number of other safeguards would have to be satisfied (see below). Commons Amendments 90 and 91 would make equivalent provision for the use of a child’s human cells to create human admixed embryos in vitro for research purposes and for the storage and use for those purposes of such embryos by amending new paragraphs 13 and 14 of Schedule 3 to the 1990 Act (inserted by Schedule 3 to the Bill). These amendments would also ensure that if a child
attained the age of 18, or became competent to consent before that time, they would be able to vary or withdraw any consent given by a person with parental responsibility (subject to the usual limits on varying and withdrawing consent set out in paragraph 4 of Schedule 3 to the 1990 Act). These provisions could not be relied on unless the Authority was satisfied that certain conditions were met. Commons Amendment 92 would insert new paragraph 15A into Schedule 3 to the 1990 Act to set out these “parental consent conditions”. The Authority would need to be satisfied that:

i. the child lacked capacity, or was not competent, to consent;
ii. the child suffered from, or was likely to develop, a serious disease, serious disability or any other serious medical condition;
iii. the research the embryos would be used for was intended to increase knowledge about the disease/ disability/ condition (or one similar to it) or about its treatment (or the treatment of a similar condition) or about care for persons affected by it (or by a similar condition);
iv. there were reasonable grounds for believing research of comparable effectiveness could not be carried out using the human cells of a person who could consent themselves.

49. Commons Amendment 55 would replace paragraph 2(2) of Schedule 3 to the 1990 Act to clarify that where consent was given to the use of a child’s human cells to create an embryo or human admixed embryo \textit{in vitro} and for the storage of that embryo the consent would have to state what should happen to the embryo if the child died. In addition, the amendment would clarify that any consent by a person to the use of their human cells to create an embryo or human admixed embryo \textit{in vitro} is to endure their death, unless otherwise stated.

50. Commons Amendments 58 and 60 would make consequential amendments to paragraphs 6 and 8 of Schedule 3 to the 1990 Act to ensure that the definition of a “relevant person” for the purposes of those paragraphs applies to the new provisions enabling a person with parental responsibility to consent to the use of their child’s cells.

51. Commons Amendments 72, 89 and 93 would reorganise and expand the definitions used in Schedule 3 to the 1990 Act by inserting at the end of that Schedule, in the new paragraph 16 inserted by Schedule 3 to the Bill, definitions of “parental responsibility” and “capacity”. Provision would also be included for references in the Schedule to 18 years to be read, in relation to Scotland, as references to 16 years.

52. Commons Amendment 108 would amend the Age of Legal Capacity (Scotland) Act 1991. The effect of the change would be that a child under the age of 16 has capacity to consent to the use of his or her human cells in accordance with Schedule 3 to the 1990 Act where the child is capable of understanding the nature of the research.
53. Commons Amendment 109 would add a new provision to the Adults with Incapacity (Scotland) Act 2000. This would ensure that the use of human cells to bring about the creation of an embryo or human admixed embryo without the adult’s consent where the adult is incapable is treated as an intervention for the purpose of that Act so that the overarching principles in section 1 and various procedural mechanisms in that Act apply.

**Commons Amendment 56**

54. Commons Amendment 56 would ensure consistency in situations when consent is required under Schedule 3 to the 1990 Act. The amendment would be consequential on the provision in paragraph 2 of Schedule 2 to the Bill, which enables embryologists to train using donated embryos. Provisions in the Bill ensure that before an embryo is received by any person an effective consent must be in place for the use of that embryo. Under the Bill, the consent could be to use in treatment or research, or both. This amendment would add that consent could be for use of the embryo in training.

**Commons Amendment 104**

55. Commons Amendment 104 would change the reporting year of the Authority. Currently section 7 of the 1990 Act requires the Authority to produce an annual report based on the anniversary of when the Authority came into operation on 1st August 1991. This amendment would change the reporting period referred to in the 1990 Act to cover the financial year 1st April to 31st March. This is in line with the HM Treasury Financial Reporting Manual, which requires non-departmental public bodies, such as the Authority, to produce an annual report to accompany the annual accounts.

**European Convention on Human Rights**

56. The Government’s view is that the Commons amendments are compliant with Convention obligations. The Government wrote to the Joint Committee on Human Rights on 30th May 2008 outlining in more detail two areas which raise human rights issues. These are set out in summary below.

57. First, the amendments detailed in paragraphs 39 to 53 above, which would create exceptions to the requirement for an effective consent to the use of a person’s human cells to create an embryo or human admixed embryo *in vitro* for research purposes and for the subsequent storage and use for those purposes of such embryos. Although there is no direct case law on this point the Government considers, on balance, that the use of human cells in this way engages Article 8 (right to private and family life). The consent provisions in the 1990 Act and Schedule 3 to the Bill reflect this view. Although removing the requirement for consent would interfere with this right the Government is satisfied that, in the limited cases provided for by the amendments, such interference can be justified on the basis of scientific need. The amendments include significant safeguards to ensure that the exceptions can only be relied on where absolutely necessary and in a manner proportionate to the need. Therefore the Government’s view is that the amendments are compatible with the Convention.
58. Secondly, the amendments detailed in paragraphs 13 to 21 above, which amend the prohibition on disclosure by the Authority of information held on its register (and the prohibition on disclosure by licensed clinics, those subject to a third party agreement and others of information of a kind which the Authority would be required to hold on the register if it held it). The amendments would mean that this prohibition would not apply where a person under the age of 18 years consented to their information being disclosed, or a person with parental responsibility consented on their behalf if the child was not competent to consent or lacked the capacity to consent. The Bill would also be amended so that there is no exception to the prohibition on disclosure for disclosure of information about donors on the basis of the donor’s consent. The Government considers that all these amendments are compatible with Article 8 of the Convention.
These notes refer to the Commons Amendments to the Human Fertilisation and Embryology Bill [HL] as brought from the House of Commons on 23rd October 2008 [HL Bill 83]

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