EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE ACT 2004 (ETHICAL APPROVAL, EXCEPTIONS FROM LICENSING AND SUPPLY OF INFORMATION ABOUT TRANSPLANTS) (AMENDMENT) REGULATIONS 2008

2008 No. 3067

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 These Regulations amend regulation 3 of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 (S.I. 2006/1260) by replacing the words, "a licence under section 16(2)" in regulation 3(4)(b)(i) and (iii) with "a licence for the purposes of section 16(2)", in order to reflect more accurately, that section 16(2) does not authorise the granting of a licence.

3. Matters of special interest to the Joint Committee on Statutory Instruments

SI 2006 No. 1260 was reported for defective drafting by the JCSI. This SI corrects the drafting defect.

4. Legislative Context

4.1 Enabling Powers: section 16(3) and 52(1) of the Human Tissue Act 2004.

5. Territorial Extent and Application

5.1 This instrument applies to England, Wales and Northern Ireland.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 These Regulations amend regulation 3 of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 (S.I. 2006/1260) by replacing the words, "a licence under section 16(2)" in regulation 3(4)(b)(i) and (iii) with "a licence for the purposes of section 16(2)", in order to reflect more accurately, that section 16(2) does not authorise the granting of a licence.

8. Consultation outcome

8.1 As this is a drafting correction with no implications for policy or practice, no consultation has been carried out.

9. Guidance

9.1 No guidance is necessary to support this drafting correction.

10. Impact

10.1 The impact on business, charities or voluntary bodies is nil.

10.2 The impact on the public sector is nil.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 As this is a technical drafting correction no monitoring or review is necessary.

13. Contact

Peter Jones at the Department of Health (email: peter.jones@dh.gsi.gov.uk) can answer any queries regarding the instrument.