EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE ACT 2004 (POWERS OF ENTRY AND SEARCH: SUPPLY OF INFORMATION) REGULATIONS 2006

2006 No. 538

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

2. Description

2.1 These Regulations set out the information to be included in a statement to be issued to the occupier of any premises, when a duly authorised officer executes a warrant under Schedule 5 to the Human Tissue Act 2004.

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

3.1 None

4. Legislative Background

4.1 One of the primary objectives of the Human Tissue Act was to rationalise and update a wide range of existing legislation into one Act of Parliament. The Act sets up a framework for regulating the storage and use of human organs and tissues from the living and the removal, storage and use of tissues and organs from the deceased for specified-health related purposes and public display. It also sets up an independent regulator – the Human Tissue Authority, to regulate activities such as licensing.

4.2 Section 48 and Schedule 5 of the Human Tissue Act 2004 make provision for powers of inspection entry, search and seizures for the purposes of the Act. These regulations require duly authorised officers executing a warrant for entry and search to give the occupier of the premises specified information at the time of entry and search. These Regulations make the first use of the powers afforded to the Human Tissue Authority in Schedule 5(4) (5) of the Act.

5. Extent

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

6. European Convention on Human Rights

6.1 Rosie Winterton, Minister of State for Health Services, has made the following statement regarding Human Rights:

In my view the provisions of the Human Tissue Act 2004 (Powers of Entry and Search: Supply of Information) Regulations 2006 are compatible with the Convention rights.

7. Policy background

7.1 The Human Tissue Act 2004 is a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue from the deceased, for specified health related purposes and public display.

7.2 The existing law on retention and use of organs and tissue was reviewed following public concern into events at Bristol Royal Infirmary and the Royal Liverpool Children's Hospital**.** These inquiries, together with the Isaacs Report, which focussed on retention of adult brains following coroner's post-mortems, showed that storage and use of organs and tissue without proper consent after people had died were commonplace. The legal review showed that the law on tissue retention, both from the living and the deceased, was inadequate and that the law on anatomical examination and transplants needed to be updated.

7.3 The purpose of introducing a regulatory scheme is to help restore public confidence in the proper use of human organs and tissue by ensuring compliance with the consent provisions of the Human Tissue Act 2004, so that tissue donation is encouraged for the public good.

7.4 These regulations intend to provide transparency in the enforcement procedures, and to ensure that there are effective safeguards in Schedule 5 to guard against possible abuse of inspection powers. The intention is that an individual, authorised by the Authority and in possession of an entry warrant, will give the occupier of suspect premises a written statement setting out his own powers under the warrant, together with the rights and obligations of the occupier.

Consultation

7.5 The Department of Health has worked closely with stakeholders, including representatives in Scotland, Wales and NI, patient representative groups, healthcare professionals and interested individuals whilst drafting these regulations.

7.6 These Regulations were the subject of a formal consultation exercise for a period of twelve weeks.

7.7 During the consultation period, respondents did not raise any concerns regarding these regulations, with their aim and intention receiving broad support.

8. Impact

8.1 The Human Tissue Act 2004 (Powers of Entry and Search: Supply of Information) Regulations 2006 do not introduce any additional burdens upon the private or voluntary sectors.

9. Contact

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