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STATUTORY INSTRUMENTS

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**2006 No. 1659**

**The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006**

**PART 1**

**PRELIMINARY**

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

(2) These Regulations shall come into force on 1st September 2006.

(3) Subject to paragraphs (4) to (8), these Regulations apply in relation to England and Wales and Northern Ireland.

(4) This regulation applies in relation to Scotland as well as to England and Wales and Northern Ireland.

(5) Regulation 2 applies in relation to Scotland as well as to England and Wales and Northern Ireland but paragraph (b) of the definition of the clinical trials regulations applies only to England and Wales.

(6) Regulations 3 and 5 apply in relation to England and Wales only.

(7) Regulations 4 and 6 apply in relation to Northern Ireland only.

(8) Regulation 7 applies in relation to Scotland only.

**Interpretation**

2. In these Regulations—

“the Act” means the Human Tissue Act 2004;

“the Authority” means the Human Tissue Authority;

“the clinical trials regulations” means—

(a) the Medicines for Human Use (Clinical Trials) Regulations 2004<sup>(1)</sup> and any other regulations replacing those regulations or amending them, and

(b) any other regulations relating to clinical trials and designated by the Secretary of State as clinical trials regulations for the purposes of section 30(5) of the Mental Capacity Act 2005<sup>(2)</sup> (research);

“donor” and “recipient” have the meaning given by regulation 11;

“intrusive research” means research of a kind that would be unlawful if it was carried out

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(1) S.I.2004/1031.

(2) 2005 c. 9.

- (a) on or in relation to a person who had capacity to consent to it, but
- (b) without his consent;

“organ” means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

“relevant commencement date”, in relation to any particular research, means—

- (a) the date on which section 30 of the Mental Capacity Act 2005 comes into force, but
- (b) if different dates are appointed for different purposes, means the date on which that section, in its application to that research, comes into force; and

“transplantable material” has the meaning given by—

- (a) regulation 9 for the purposes of section 34 of the Act (information about transplant operations), and
- (b) regulation 10 for the purposes of section 33 of the Act (restrictions on transplants involving a live donor).