Draft Regulations laid before Parliament under section 52(4) of the Human Tissue Act 2004, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2006 No.

HUMAN TISSUE

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

Made - - - -	*2006*
Laid - - - -	*2006*
Coming into force - -	*1st September 2006*

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred upon her by sections 6, 33(3) and (7) and 52(1) of, and paragraph 12(2) of Schedule 4 to, the Human Tissue Act 2004(**1**).

In accordance with section 52(8) to (10) of that Act she has consulted on the proposal to make the Regulations with the National Assembly for Wales, the relevant Northern Ireland Department(**2**), the Scottish Ministers and such other persons as she considers appropriate.

A draft of this instrument was laid before Parliament in accordance with section 52(4) of that Act and approved by a resolution of each House of Parliament.

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.

(**1**) 2004 c.30.

(**2**) See section 54(1) of the Human Tissue Act 2004 which defines "relevant Northern Ireland department" as the Department of Health, Social Services and Public Safety.

(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(**3**) 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(**4**) (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

(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).

(**3**) S.I. 2004/1031.
(**4**) 2005 c.9.

PART 2

PERSONS WHO LACK CAPACITY TO CONSENT

Storage and use of relevant material

Deemed consent to storage and use of relevant material: England and Wales

3.—(1) This regulation applies in any case falling within paragraphs (a) and (b) of section 6 of the Act (storage and use involving material from adults who lack capacity to consent).

(2) An adult ("P") who lacks capacity to consent to an activity of a kind mentioned in section 1(1)(d) or (f) of the Act (storage or use of material for purposes specified in Schedule 1) which involves material from P's body, is deemed to have consented to the activity where—

(a) the activity is done for a purpose specified in paragraph 4 or 7 of Part 1 of Schedule 1 to the Act (the purposes of obtaining information relevant to another person and of transplantation) by a person who is acting in what he reasonably believes to be P's best interests;

(b) the activity is done for the purpose of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations;

(c) the activity is done on or after the relevant commencement date for the purpose of intrusive research which is carried out in accordance with the requirements of section 30(1)(a) and (b) of the Mental Capacity Act 2005 (approval by appropriate body and compliance with sections 32 and 33 of that Act);

(d) the activity is done on or after the relevant commencement date for the purpose of intrusive research—

(i) section 34 of the Mental Capacity Act 2005 (loss of capacity during research project) applies in relation to that research, and

(ii) the activity is carried on in accordance with regulations made under section 34(2) of that Act; or

(e) the activity is done before the relevant commencement date for the purpose of research which, before that date, is ethically approved within the meaning of regulation 8.

Deemed consent to storage and use of relevant material: Northern Ireland

4.—(1) This regulation applies in any case falling within paragraphs (a) and (b) of section 6 of the Act (storage and use involving material from adults who lack capacity to consent).

(2) An adult ("P") who lacks capacity to consent to an activity of a kind mentioned in section 1(1)(d) or (f) of the Act which involves material from P's body, is deemed to have consented to the activity where—

(a) the activity is done for a purpose specified in paragraph 4 or 7 of Part 1 of Schedule 1 to the Act (the purposes of obtaining information relevant to another person and of transplantation) by a person who is acting in what he reasonably believes to be P's best interests;

(b) the activity is done for the purpose of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations; or

(c) the activity is done for the purpose of research which is ethically approved within the meaning of regulation 8.

Analysis of DNA

Purposes for which DNA may be analysed without consent: England and Wales

5.—(1) This regulation applies for the purposes of paragraph 12 of Schedule 4 to the Act (excepted purposes relating to DNA of adults who lack capacity to consent).

(2) In any case falling within sub-paragraph (1)(a)(i) and (b) of that paragraph (DNA manufactured by the body of a person who under the law of England and Wales lacks capacity to consent), the purposes for which DNA manufactured by the body of a person ("P") who lacks capacity to consent to analysis of the DNA may be analysed are—

(a) any purpose which the person carrying out the analysis reasonably believes to be in P's best interests;

(b) the purposes of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations;

(c) the purposes of intrusive research which is carried out on or after the relevant commencement date in accordance with the requirements of section 30(1)(a) and (b) of the Mental Capacity Act 2005 (approval by appropriate body and compliance with sections 32 and 33 of that Act);

(d) the purposes of intrusive research—

(i) which is carried out on or after the relevant commencement date,

(ii) in relation to which section 34 of the Mental Capacity Act 2005 (loss of capacity during research project) applies in relation to that research, and

(iii) which is carried on in accordance with regulations made under section 34(2) of that Act; or

(e) research which is carried out before the relevant commencement date and which, before that date, is ethically approved within the meaning of regulation 8.

Purposes for which DNA may be analysed without consent: Northern Ireland

6.—(1) This regulation applies for the purposes of paragraph 12 of Schedule 4 to the Act (excepted purposes relating to DNA of adults who lack capacity to consent).

(2) In any case falling within sub-paragraph (1)(a)(i) and (b) of that paragraph (DNA manufactured by the body of a person who under the law of Northern Ireland lacks capacity to consent), the purposes for which DNA manufactured by the body of a person ("P") who lacks capacity to consent to analysis of the DNA may be analysed are—

(a) any purpose which the person carrying out the analysis reasonably believes to be in P's best interests;

(b) the purposes of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations; or

(c) research which is ethically approved within the meaning of regulation 8.

Purposes for which DNA may be analysed without consent: Scotland

7.—(1) This regulation applies for the purposes of paragraph 12 of Schedule 4 to the Act.

(2) In any case falling within sub-paragraph (1)(a)(ii) and (b) of that paragraph (DNA manufactured by the body of a person who under the law of Scotland is an adult with incapacity), the purposes for which DNA manufactured by the body of an adult ("P") with incapacity may be analysed are—

(a) any purpose for which the person carrying out the analysis has obtained the consent of any person who has authority to consent to analysis of P's DNA by virtue of—

(i) a welfare power of attorney within the meaning of section 16(2),

(ii) an intervention order under section 53, or

(iii) a guardianship order under section 58,

of the Adults with Incapacity (Scotland) Act 2000;

(b) a clinical trial which is authorised and conducted in accordance with the clinical trials regulations; or

(c) surgical, medical, nursing, dental or psychological research which is permitted under section 51 of the Adults with Incapacity (Scotland) Act 2000(**5**).

Ethical approval

Ethical approval for the purposes of regulations 3 to 6

8.—(1) Research is ethically approved within the meaning of this regulation if approval is given by a research ethics authority in the circumstances specified in paragraph (2).

(2) The circumstances are that—

(a) the research is in connection with disorders, or the functioning, of the human body,

(b) there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the research has to be confined to, or relate only to, persons who have capacity to consent to taking part in it, and

(c) there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out in circumstances such that the person carrying out the research is not in possession, and not likely to come into possession, of information from which the person from whose body the defined material has come can be identified.

(3) "Defined material"—

(a) in relation to ethical approval for the purposes of regulations 3(2)(e) and 4(2)(c), means the relevant material involved in an activity of a kind mentioned in section 1(1)(d) or (f) of the Act, and

(b) in relation to ethical approval for the purposes of regulations 5(2)(e) and 6(2)(c), means the bodily material in relation to which an analysis of DNA is to be carried out.

(4) "Research ethics authority" has the meaning given by regulation 2 of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006(**6**).

PART 3

TRANSPLANTS

Meaning of transplantable material for the purposes of section 34 of the Act

9. For the purposes of section 34 of the Act (information about transplant operations) "transplantable material" means—

(**5**) 2000 asp 4.
(**6**) S.I. 2006/.