STATUTORY INSTRUMENTS

2006 No. 1659

HUMAN TISSUE

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

Made - - - -	*22nd June 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.

(4) This regulation applies in relation to Scotland as well as 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.

(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 out 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, and

(iii) which is carried out 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 asp4.
(**6**) S.I. 2006/1260.

(a) the whole or part of any of the following organs if it is to be used for the same purpose as the entire organ in the human body—

(i) kidney,

(ii) heart,

(iii) lung or a lung lobe,

(iv) pancreas,

(v) liver,

(vi) bowel,

(vii) larynx;

(b) face, or

(c) limb.

Meaning of transplantable material for the purposes of section 33 of the Act

10.—(1) Subject to paragraphs (2) and (3), for the purposes of section 33 of the Act (restriction on transplants involving a live donor), "transplantable material" means—

(a) an organ, or part of an organ if it is to be used for the same purpose as the entire organ in the human body,

(b) bone marrow, and

(c) peripheral blood stem cells,

where that material is removed from the body of a living person with the intention that it be transplanted into another person.

(2) The material referred to in paragraph (1)(a) is not transplantable material for the purposes of section 33 of the Act in a case where the primary purpose of removal of the material is the medical treatment of the person from whose body the material is removed.

(3) The material referred to in paragraph (1)(b) and (c) is transplantable material for the purposes of section 33 of the Act only in a case where the person from whose body the material is removed is—

(a) an adult who lacks the capacity, or

(b) a child who is not competent,

to consent to removal of the transplantable material.

Cases in which restriction on transplants involving a live donor is disapplied

11.—(1) Section 33(1) and (2) of the Act (offences relating to transplants involving a live donor) shall not apply in any case involving transplantable material from the body of a living person ("the donor") if the requirements of paragraphs (2) to (6) are met.

(2) A registered medical practitioner who has clinical responsibility for the donor must have caused the matter to be referred to the Authority.

(3) The Authority must be satisfied that—

(a) no reward has been or is to be given in contravention of section 32 of the Act (prohibition of commercial dealings in human material for transplantation), and

(b) when the transplantable material is removed—

(i) consent for its removal for the purpose of transplantation has been given, or

(ii) its removal for that purpose is otherwise lawful.

(4) The Authority must take the report referred to in paragraph (6) into account in making its decision under paragraph (3).

(5) The Authority shall give notice of its decision under paragraph (3) to—

(a) the donor of the transplantable material or any person acting on his behalf,

(b) the person to whom it is proposed to transplant the transplantable material (" the recipient") or any person acting on his behalf, and

(c) the registered medical practitioner who caused the matter to be referred to the Authority under paragraph (2).

(6) Subject to paragraph (7), one or more qualified persons must have conducted separate interviews with each of the following—

(a) the donor,

(b) if different from the donor, the person giving consent, and

(c) the recipient,

and reported to the Authority on the matters specified in paragraphs (8) and (9).

(7) Paragraph (6) does not apply in any case where the removal of the transplantable material for the purpose of transplantation is authorised by an order made in any legal proceedings before a court.

(8) The matters that must be covered in the report of each interview under paragraph (6) are—

(a) any evidence of duress or coercion affecting the decision to give consent,

(b) any evidence of an offer of a reward, and

(c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

(9) The following matters must be covered in the report of the interview with the donor and, where relevant, the other person giving consent—

(a) the information given to the person interviewed as to the nature of the medical procedure for, and the risk involved in, the removal of the transplantable material,

(b) the full name of the person who gave that information and his qualification to give it, and

(c) the capacity of the person interviewed to understand—

(i) the nature of the medical procedure and the risk involved, and

(ii) that the consent may be withdrawn at any time before the removal of the transplantable material.

(10) A person shall be taken to be qualified to conduct an interview under paragraph (6) if—

(a) he appears to the Authority to be suitably qualified to conduct the interview,

(b) he does not have any connection with any of the persons to be interviewed, or with a person who stands in a qualifying relationship to any of those persons, which the Authority considers to be of a kind that might raise doubts about his ability to act impartially, and

(c) in the case of an interview with the donor or other person giving consent, he is not the person who gave the information referred to in paragraph (9)(a).

Decisions of the Authority: procedure for certain cases

12.—(1) In any case to which paragraph (2), (3) or (4) applies, the Authority's decision as to the matters specified in regulation 11(3) shall be made by a panel of no fewer than 3 members of the Authority.

(2) A case falls within this paragraph if—

(a) the donor of the transplantable material is a child, and

(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(3) A case falls within this paragraph if—

(a) the donor of the transplantable material is an adult who lacks capacity to consent to removal of the material, and

(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(4) A case falls within this paragraph if—

(a) the donor of the transplantable material is an adult who has capacity to consent to removal of the material, and

(b) the case involves—

(i) paired donations,

(ii) pooled donations, or

(iii) a non-directed altruistic donation.

(5) In this regulation—

"non-directed altruistic donation" means the removal (in circumstances not amounting to a paired or pooled donation) of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him;

"paired donations" means an arrangement under which—

(a) transplantable material is removed from a donor ("D") for transplant to a person who is not genetically related or known to D, and

(b) transplantable material is removed from another person for transplant to a person who is genetically related or known to D; and

"pooled donations" means a series of paired donations of transplantable material, each of which is linked to another in the same series (for example, transplantable material from D is transplanted to the wife of another person ("E"), transplantable material from E is transplanted to the partner of a third person ("F") and transplantable material from F is transplanted to D's son).

Right to reconsideration of Authority's decision

13.—(1) The Authority may reconsider any decision made by it under regulation 11(3) if it is satisfied that—

(a) any information given for the purpose of the decision was in any material respect false or misleading, or

(b) there has been any material change of circumstances since the decision was made.

(2) A specified person may in any case require the Authority to reconsider any decision made by it under regulation 11(3).

(3) "Specified persons", in relation to such a decision, are—

(a) the donor of the transplantable material or any person acting on his behalf,

(b) the recipient of the material or any person acting on his behalf, and

(c) the registered medical practitioner who caused the matter to be referred to the Authority under regulation 11(2).

(4) The right under paragraph (2) is exercisable by giving to the Authority, in such manner as it may direct, notice of exercise of the right.

(5) A notice under paragraph (4) shall contain or be accompanied by such other information as the Authority may reasonably require.

(6) On receipt of the information required by paragraph (5), the Authority shall provide to the person requiring the reconsideration—

(a) a copy of each report made under regulation 11(6) of the interviews that were conducted in the case, and

(b) a statement of the Authority's reasons for its decision.

(7) Paragraphs (1) to (6) do not apply to a decision made by the Authority on reconsideration in pursuance of a notice under this regulation.

Procedure on reconsideration

14.—(1) Reconsideration shall be by way of fresh decision made at a meeting of the Authority.

(2) The meeting shall take place as soon as reasonably practicable after the provision of the reports and statement required by regulation 13(6), having regard to the need to allow time for the information contained in that material to be taken into account.

(3) Where a member of the Authority has taken part in the making of a decision subject to reconsideration (whether under regulation 12 or otherwise), he is disqualified from participating in the Authority's reconsideration of it.

(4) On reconsideration under regulation 13(2)—

(a) the person ("A") by whom the reconsideration is required under regulation 13(2) shall be entitled to require that he or his representative be given an opportunity to appear before and be heard at the meeting of the Authority at which the decision is reconsidered, and

(b) the members of the Authority in attendance at the meeting at which the decision is reconsidered shall consider any such written representations and comments.

(5) The Authority shall give a notice of its decision to A.

(6) If on reconsideration the Authority upholds the previous decision, the notice under paragraph (5) shall include a statement of the reasons for the Authority's decision.

(7) "Reconsideration" means reconsideration in pursuance of a notice under regulation 13.

Rosie Winterton
Minister of State,
22nd June 2006 Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision as to the circumstances in which certain activities may be carried out in relation to material from the body of a person who lacks capacity to consent for the purposes of certain provisions of the Human Tissue Act 2004 (c. 30) ("the Act"). Provision is also made in connection with the restrictions on transplants involving a live donor in section 33 of the Act. This covers the definition of the transplantable material to which those restrictions apply and the circumstances in which live donor transplants are permitted.

Regulations 3, 4 and 8 make provision as to the circumstances in which an adult who lacks capacity is deemed to consent to the storage and use of relevant material for the purposes in Part 1 of Schedule 1 to the Act. Separate provision is made for England and Wales, and for Northern Ireland. In both cases the circumstances in which consent is deemed to have been given include any case where storage and use are in the best interests of the adult who lacks capacity and any case where those activities are carried out for the purpose of an authorised clinical trial. In addition, consent is deemed to have been given where the activities are carried out for the purpose of certain approved research. Different provisions apply in England and Wales depending on whether the research is carried out before or after section 30 of the Mental Capacity Act 2005 comes into force (see regulation 3(2)(c) to (e) and regulation 8). That section makes provision as to research that may be carried out involving, or in relation to, persons who lack capacity and applies to England and Wales only. Before the commencement of section 30, the research must be approved by a research ethics authority. For Northern Ireland, the research must be approved by a research ethics authority (see regulation 4(2)(c) and regulation 8).

Regulations 5 to 7 prescribe the excepted purposes for which the results of DNA analysis may be used where the analysis is of DNA that has been manufactured by the body of an adult who lacks capacity to consent. Separate provision is made for England and Wales, for Northern Ireland and for Scotland. The results of DNA analysis are permitted to be used in specified circumstances that are equivalent to those specified for the purposes of regulations 3 and 4 (use in best interests of person who lacks capacity, use for the purpose of an authorised clinical trial and use for the purpose of certain approved research).

Regulation 9 provides a definition of "transplantable material" for the purposes of section 34 and regulation 10 provides a definition of "transplantable material for the purposes of section 33 of the Act. Regulation 11 specifies the circumstances in which transplants of such material from the body of a live donor may be carried out without contravening the restrictions set out in that section. The restrictions are disapplied if the matter has been referred to the Human Tissue Authority and if, after certain required interviews have taken place, the Authority is satisfied that certain specified conditions have been met. These relate to consent, information given to the donor and lack of reward for the donor of transplantable material.

Regulation 12 provides that a panel of at least three members of the Human Tissue Authority must make the decision on transplants from live donors in any case of organ donation where a child is involved, where the donor is an adult who lacks the capacity to consent or where the donor is an adult who has capacity to consent but where there are paired donations, pooled donations or altruistic donation.

Regulations 13 and 14 provide a right of reconsideration of the Authority's decision as to the matters specified in regulation 11(3). This right may be exercised by the Authority (where it is satisfied that there has been a material change in the circumstances since the decision was made or that any

information given to it was in a material respect false or misleading), the donor, the recipient or the registered medical practitioner who referred the matter to the Authority. Regulation 14 makes provision about the procedure to be followed for reconsideration.

A Regulatory Impact Assessment was prepared for the Human Tissue Act 2004 and a copy has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment are published on the Department of Health's website (www.dh.gov.uk) and can be obtained from room 611, 6th Floor North, Wellington House, Waterloo Road, London SE1 8UG.