
STATUTORY INSTRUMENTS

2006 No. 1659

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

PART 2

PERSONS WHO LACK CAPACITY TO CONSENT

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(1).