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

2020 No. 0000

HUMAN TISSUE, ENGLAND

The Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020

Made - - - -	***
Coming into force - -	*20th May 2020*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 3(9) and 52(1) of the Human Tissue Act 2004(**a**).

In accordance with section 52(10)(**b**) of that Act, the Secretary of State has consulted such persons as the Secretary of State considers appropriate.

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

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and come into force on 20th May 2020.

(2) These Regulations extend to England and Wales only.

(3) These Regulations apply in relation to activities done in England for the purpose of transplantation(**c**).

Relevant material that is not permitted material

2.—(1) Paragraphs (2) to (5) specify types of relevant material(**d**) for the purposes of the definition of "permitted material" in section 3(9) ("appropriate consent": adults) of the Human Tissue Act 2004.

(2) Subject to paragraphs (3) and (4), the whole or any part of the following is specified—

(a) arm;

(b) brain;

(**a**) 2004 c. 30 ("the 2004 Act"); subsection (9) was inserted into section 3 by section 1(1) and (5) of the Organ Donation (Deemed Consent) Act 2019 (c. 7) ("the 2019 Act").
(**b**) Section 52(10) was amended, so far as relevant, by section 2(1) and (7) of the 2019 Act.
(**c**) *See* section 54(3) of the 2004 Act as to references to transplantation in that Act.
(**d**) *See* section 53 of the 2004 Act for the meaning of "relevant material".

(c) face;

(d) finger;

(e) foot;

(f) forearm;

(g) hand;

(h) leg;

(i) lower leg;

(j) mouth;

(k) nose;

(l) spinal cord;

(m) thigh;

(n) toe;

(o) trachea;

(p) upper arm;

(q) cervix;

(r) clitoris;

(s) embryo (inside the body)(**a**);

(t) fallopian tube;

(u) foetus;

(v) labia;

(w) ovary;

(x) penis;

(y) perineum;

(z) placenta;

(aa) prostate;

(bb) testicle;

(cc) umbilical cord;

(dd) uterus;

(ee) vagina;

(ff) vulva.

(3) The following is not specified in so far as it is disaggregated from any of the relevant material specified in sub-paragraphs (a) to (p) of paragraph (2)—

(a) artery;

(b) bone;

(c) muscle;

(d) nervous tissue;

(e) skin;

(f) tendon.

(4) The whole or part of the trachea is not specified in so far as it is attached to a lung.

(5) The following types of cells are specified only in so far as all or part of the cells is for use in, or as, an advanced therapy medicinal product—

(**a**) *See* section 54(6) of the 2004 Act for the meaning of "embryo". That subsection was substituted by paragraph 24 of Schedule 7 to the Human Fertilisation and Embryology Act 2008 (c. 22).

(a) limbal stem cells;

(b) liver cells;

(c) lung epithelial cells;

(d) pancreatic cells;

(e) renal epithelial cells.

(6) In this regulation, "advanced therapy medicinal product" has the same meaning as in the Human Medicines Regulations 2012(**a**).

Signatory text

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

Address
Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under the Human Tissue Act 2004 (c.30) ("the 2004 Act"). Section 3 of the 2004 Act makes provision for the interpretation of "appropriate consent". This term is used in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult.

Section 3(6) provides that, in relation to certain activities done in England, in certain circumstances, appropriate consent means deemed consent. Certain of those activities involve the removal, storage or use, for the purpose of transplantation, of "permitted material". Section 3(9) defines "permitted material" as "relevant material" (as defined by section 53 of the 2004 Act) other than relevant material of a type specified in regulations. These Regulations specify types of relevant material that will not be "permitted material". Permitted material is not subject to deemed consent.

Regulation 2(2) specifies the whole or any part of certain relevant material, for example the arm, brain and face.

Regulation 2(3) provides that the types of relevant material listed in that paragraph, which are component parts of relevant material specified in regulation 2(2)(a) to (p), are not specified when detached from the latter.

Regulation 2(4) provides that the whole or part of the trachea, which is listed in paragraph (2), is not specified if it is connected to a lung.

Regulation 2(5) specifies certain types of cells as relevant material, for example limbal stem cells, in so far as all or part of the cells is for use for the purpose of transplantation in the form of an advanced therapy medicinal product. Regulation 2(6) provides that in regulation 2(5), "advanced therapy medicinal product" has the same meaning as it does in the Human Medicines Regulations 2012 (S.I. 2012/1916).

A full impact assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

(**a**) S.I. 2012/1916, as prospectively amended by S.I. 2019/775 from IP completion day. "IP completion day" is defined in Schedule 1 to the Interpretation Act 1978 (c. 30).

£4.90

UK202002241015 02/2020 19585

http://www.legislation.gov.uk/id/ukdsi/2020/9780111193372

ISBN 978-0-11-119337-2

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