

- (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

	<i>Name</i>
Address	Parliamentary Under Secretary of State
Date	Department of Health and Social Care

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.

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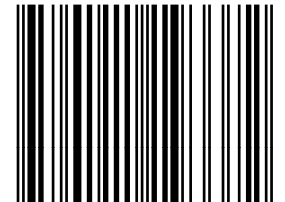
(a) S.I. 2012/1916, as prospectively amended by S.I. 2019/775 from IP completion day. “IP completion day” is defined in Schedule 1 to the Interpretation Act 1978 (c. 30).

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