STATUTORY RULES OF NORTHERN IRELAND

2023 No. 26

HUMAN TISSUE

The Human Tissue (Permitted Material) Regulations (Northern Ireland) 2023

Made - - - - 1st March 2023
Coming into operation in accordance with regulation 1(2)

The Department of Health makes the following Regulations in exercise of the powers conferred by sections 3(9A) and 52(4B) and (4C) of the Human Tissue Act 2004(**1**).

In accordance with section 52(11)(**2**) of that Act, the Department of Health has consulted such persons as it considers appropriate.

Citation, commencement and application

1.—(1) These Regulations may be cited as the Human Tissue (Permitted Material) Regulations (Northern Ireland) 2023.

(2) These Regulations come into operation on 1st June 2023.

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

Permitted material

2.—(1) All relevant material (within the meaning given by section 53 of the Human Tissue Act 2004) is specified as permitted material for the purposes of section 3(6AA) of that Act; but this is subject to paragraphs (2) and (5).

(2) Except as provided by paragraphs (3) and (4), the whole or any part of the following is not permitted material—

(a) arm;

(b) brain;

(**1**) 2004 c. 30 ("the 2004 Act"); sections 3(9A) and 52(4B) and (4C) were inserted into the 2004 Act by section 1(1), (4) and (6) of the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 (c. 10) ("the 2022 Act"); section 52(4B) of the 2004 Act was amended by section 2 of the Northern Ireland (Executive Formation and Organ Tissue Donation) Act 2023 (2023c.)

(**2**) Section 52(11) was inserted by section 1(6)(b) of the 2022 Act

(**3**) See section 54(3) of the 2004 Act as to references to transplantation in that Act

(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)(**4**);
(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 tissue does not fall within paragraph (2) in so far as it is disaggregated from any of the relevant material specified in sub-paragraphs (a) to (p) of that paragraph (and, accordingly, such tissue is permitted material)—

(a) artery;
(b) bone;
(c) muscle;
(d) nervous tissue;
(e) skin;

(**4**) 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)

(f) tendon.

(4) The whole or part of the trachea does not fall within paragraph (2) in so far as it is attached to a lung (and, accordingly, such tissue is permitted material).

(5) The following types of cells are not permitted material in so far as all or part of the cells is for use in, or as, an advanced therapy medicinal product—

(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(**5**).

Sealed with the Official Seal of the Department of Health on 1st March 2023

(L.S.)

Ryan Wilson
A senior officer of the Department of Health

(**5**) S.I. 2012/1916

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 Northern Ireland, 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(9A) defines "permitted material" as relevant material of a type specified in regulations made by the Department of Health in Northern Ireland, but the regulations may not make provision dealing with a matter falling within a description specified in Schedule 3 to the Northern Ireland Act 1998 (reserved matters).

Regulation 2(2) specifies the whole or any part of certain relevant material, for example the arm, brain and face that are not permitted material.

Regulation 2(3) provides that the listed tissue does not fall within paragraph (2) in so far as it is disaggregated from any of the material specified in sub-paragraphs (a) to (p) of that paragraph and is therefore such tissue is permitted material.

Regulation 2(4) provides that the whole or part of the trachea, does not fall within paragraph (2), as it is attached to the lung and therefore such tissue is considered permitted material.

Regulation 2(5) specifies certain types of cells are not permitted material in so far as all or part of the cells is for use in, or as, an advanced therapy medicinal product for example limbal stem cells.

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.