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.

Changes to legislation:
There are currently no known outstanding effects for the The Human Tissue (Permitted Material) Regulations (Northern Ireland) 2023.