Draft Regulations laid before the National Assembly for Wales under section 20(4) of the Human Transplantation (Wales) Act 2013 for approval by resolution of the National Assembly for Wales.

# DRAFT WELSH STATUTORY INSTRUMENTS

## 2015 No. (W.)

### **HUMAN TISSUE, WALES**

The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015

#### EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under the Human Transplantation (Wales) Act 2013 ("the Act").

Section 7(4) of the Act provides that express consent must be obtained for the removal of excluded relevant material for the purposes of a transplantation activity.

Regulation 2 makes provision as to the definition of excluded relevant material for the purposes of section 7 of the Act.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained at the Department of Health and Social Services, Welsh Government, Cathays Park, Cardiff CF10 3NQ.

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## 2015 No. (W.)

### **HUMAN TISSUE, WALES**

The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015

Made \*\*\*

Coming into force

1 December 2015

The Welsh Ministers in exercise of their powers in sections 7(2) and 20(1) and (2) of the Human Transplantation (Wales) Act 2013(1) and having carried out such public consultation as they consider appropriate in accordance with section 20(3) of that Act make the following Regulations.

In accordance with section 20(4) of that Act, a draft of these Regulations has been laid before and approved by a resolution of the National Assembly for Wales.

# Title, commencement, application and interpretation

- 1.—(1) The title of these Regulations is the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 and they come into force at 00:01 on 1 December 2015.
  - (2) These Regulations apply in relation to Wales.
  - (3) In these Regulations—

"the Act" ("y Ddeddf") means the Human Transplantation (Wales) Act 2013.

#### **Excluded relevant material**

- **2.**—(1) This regulation is subject to the exceptions in paragraph (4).
- (2) For the purposes of section 7(2) of the Act the whole or part of the following composite tissues ("excluded composite tissues") are specified as excluded relevant material—
  - (a) brain;
  - (b) spinal cord;
  - (c) face;
  - (d) nose;
  - (e) mouth;
  - (f) arm;
  - (g) upper arm;
  - (h) forearm;
  - (i) hand;
  - (j) finger;
  - (k) leg;
  - (l) thigh;
  - (m) lower leg;
  - (n) foot: or
  - (o) toe.
- (3) For the purposes of section 7(2) of the Act the whole or part of any of the following is specified as excluded relevant material—
  - (a) ovary;
  - (b) uterus;
  - (c) penis;
  - (d) testicle;
  - (e) foetus;
  - (f) placenta;
  - (g) umbilical cord; or
  - (h) embryo (inside the body).
- (4) The whole or part of any of the following that forms part of any excluded composite tissues is not excluded relevant material—
  - (a) eye;
  - (b) nervous tissue;
  - (c) artery;
  - (d) bone;
  - (e) muscle;
  - (f) tendon; or
  - (g) skin,

in so far as they are not being used for the transplantation of any excluded composite tissues.

Minister for Health and Social Services, one of the Welsh Ministers Date