

*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.*

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DRAFT WELSH STATUTORY  
INSTRUMENTS

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**2015 No. (W. )**

**HUMAN TISSUE, WALES**

**The Human Transplantation  
(Persons who Lack Capacity to  
Consent) (Wales) Regulations 2015**

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations are made under section 9 of the Human Transplantation (Wales) Act 2013. This section applies where a living adult lacks capacity to consent to organ donation and no decision is in force.

These Regulations make provision as to the circumstances in which that living adult who lacks capacity is deemed to consent to the storage and use for transplantation of relevant material that has come from a human body. The circumstances in which consent is deemed to have been given are where storage and use are in the best interest of the living adult who lacks capacity.

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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**The Human Transplantation  
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Consent) (Wales) Regulations 2015**

*Made*

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*Coming into force*

*1 December 2015*

The Welsh Ministers in exercise of their powers in sections 9(2) and 20(1) and (2) of the Human Transplantation (Wales) Act 2013<sup>(1)</sup> 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 and application**

**1.**—(1) The title of these Regulations is the Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015 and they come into force at 00:01 on 1 December 2015.

(2) These Regulations apply in relation to Wales.

**Deemed consent to storage and use of relevant material**

**2.**—(1) This regulation applies in any case falling within paragraphs (a) and (b) of section 9(1) of the Human Transplantation (Wales) Act 2013 (storage and

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use involving material from adults who lack capacity to consent).

(2) An adult (“P”) who lacks capacity to consent to an activity of a kind mentioned in section 3(2)(c) or (d) of that Act (storage or use of relevant material from a human body for the purpose of transplantation) which involves material from P’s body, is deemed to have consented to the activity where the activity is done by a person who is acting in what they reasonably believe to be P’s best interests.

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

Date