

Draft Order laid before Parliament under section 150(5) of the Government of Wales Act 2006, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2015 No. XXXX

**CONSTITUTIONAL LAW
DEVOLUTION, WALES
HUMAN TISSUE, ENGLAND AND WALES
HUMAN TISSUE, NORTHERN IRELAND**

The Human Transplantation (Wales) Act
2013 (Consequential Provision) Order 2015

Made - - - - []

Coming into force in accordance with article 1(2)

The Secretary of State makes the following Order in exercise of the powers conferred by sections 150(1) and (2) and 157(2) of the Government of Wales Act 2006⁽¹⁾.

In accordance with section 150(5) of that Act, a draft of this Order was laid before Parliament and was approved by a resolution of each House of Parliament.

Citation and commencement

1.—(1) This Order may be cited as the Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015.

(2) This Order comes into force on the same day that section 16 of the Human Transplantation (Wales) Act 2013 comes fully into force⁽²⁾.

Amendments to the Human Tissue Act 2004

2.—(1) The Human Tissue Act 2004⁽³⁾ is amended as follows.

(2) In section 1 (authorisation of activities for scheduled purposes)—

(a) omit subsection (1A);

(1) 2006 c. 32.

(2) 2013 anaw 5.

(3) 2004 c. 30. Subsection (1A) is inserted by section 16 of the Human Transplantation (Wales) Act 2013 and subsection (9A) by paragraph 22(a) of Schedule 7 to the Human Fertilisation and Embryology Act 2008 (c. 22).

- (b) after subsection (9A) insert—
 - “(9B) Subsection (1) does not apply in relation to—
 - (a) transplantation activities done in Wales; or
 - (b) transplantation activities done outside Wales in relation to relevant material that was removed from a human body in Wales.”;
 - (c) in subsection (10)(c), for “or (8)” substitute “, (8) or (9B)(b)”.
- (3) In section 4 (nominated representatives), after subsection (10) insert—
 - “(11) Where an adult has appointed a person under section 8 of the Human Transplantation (Wales) Act 2013 to represent the adult after death in relation to consent for one or more transplantation activities, the adult is to be treated as also having appointed the person under this section in relation to those activities.”

Amendments to the Quality and Safety of Organs Intended for Transplantation Regulations 2012

- 3. In regulation 3 (interpretation) of the Quality and Safety of Organs Intended for Transplantation Regulations 2012(4), in the definition of “consent”—
 - (a) after “means” insert “, where retrieval of an organ takes place”;
 - (b) in paragraph (a)—
 - (i) for “, Wales and” substitute “or”;
 - (ii) omit the final “or”;
 - (c) after paragraph (b) add—
 - “; or
 - (c) in Wales, express consent where that is required under any of sections 4 to 7 of the Human Transplantation (Wales) Act 2013 or, where express consent is not required, deemed consent under section 4 or 9 of that Act;”.

Date

Name
Secretary of State for Wales

(4) [S.I. 2012/1501](#), to which there are amendments not relevant to this instrument

EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes provision for England and Northern Ireland in consequence of the Human Transplantation (Wales) Act 2013 (the “2013 Act”).

The 2013 Act changes the way in which consent is given to organ and tissue donation for transplantation activities that take place in Wales. The 2013 Act, therefore, amends certain provisions of the Human Tissue Act 2004 (the “2004 Act”) so that they no longer apply in relation to Wales. The 2004 Act continues to apply in cases relating to consent for the purpose of transplantation where the activity takes place in England or Northern Ireland.

This Order makes provision for circumstances in which relevant material from a body comes from Wales into England or Northern Ireland for the purpose of transplantation activities. The Order amends the 2004 Act to provide that a transplantation activity that takes place in England or Northern Ireland, with relevant material that comes from Wales, is lawful without the need for consent under section 1(1) of the 2004 Act.

The Order also provides that where an adult has nominated a representative to deal after death with the issue of consent in relation to a transplantation activity under section 8 of the 2013 Act that nomination is recognised for the purpose of section 4 of the 2004 Act. A similar provision is made in section 8 of the 2013 Act to recognise appointments made under section 4 of the 2004 Act in Wales. This means that a nomination made under either the 2004 or the 2013 Act will have effect no matter whether the transplantation activity takes place in Wales or in England or Northern Ireland.

It also amends the Quality and Safety of Organs Intended for Human Transplantation Regulations 2012 so that “consent” for the purposes of licensing the retrieval of material under those Regulations is defined by reference to deemed and express consent under the 2013 Act where the retrieval takes place in Wales.

The provisions of the Order have effect once section 16 of the Human Transplantation (Wales) Act 2013 comes into force.

An impact assessment has not been prepared for this Order as no costs to the business or voluntary sectors are foreseen.