SCOTTISH STATUTORY INSTRUMENTS

2021 No. 110

HUMAN TISSUE

The Human Tissue (Authorisation) (Specified Type B Procedures) (Scotland) Regulations 2021

Made - - - - 25th February 2021

Coming into force in accordance with regulation 1

The Scottish Ministers make the following Regulations in exercise of the powers conferred by section 16C(1) and (2) of the Human Tissue (Scotland) Act 2006(**1**) and all other powers enabling them to do so.

In accordance with section 16C(3) of that Act the Scottish Ministers consider that it is appropriate for the procedures specified in these Regulations to be subject to provision mentioned in section 16C(2)(a)(i) to (iv).

In accordance with section 16C(4) of that Act they have consulted such persons as they consider appropriate.

In accordance with section 59(3)(ad)(**2**) of that Act a draft of this instrument has been laid before and approved by resolution of the Scottish Parliament.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Tissue (Authorisation) (Specified Type B Procedures) (Scotland) Regulations 2021 and come into force on the day on which section 23 of the Human Tissue (Authorisation) (Scotland) Act 2019(**3**) comes into force for all purposes.

(2) In these Regulations—

"the 2006 Act" means the Human Tissue (Scotland) Act 2006,

"relevant time" has the same meaning as in section 16K(2) of the 2006 Act.

Type B Procedures

2. The pre-death procedures specified in the second column of the table in the schedule are specified as Type B procedures for the purposes of sections 16D and 16E of the 2006 Act(**4**).

(**1**) 2006 asp. 4. Section 16C was inserted by section 23(1) of the Human Tissue (Authorisation) (Scotland) Act 2019 asp 11 ("the 2019 Act").
(**2**) Section 59(3)(ad) was inserted by section 23(2) of the 2019 Act.
(**3**) 2019 asp 11.
(**4**) Sections 16D and 16E were inserted by section 23(1) of the 2019 Act.

Circumstances in which Type B procedures may be carried out

3.—(1) A Type B procedure may be carried out only if—

(a) in the view of two registered medical practitioners, the conditions in paragraph (2) are met, and

(b) the procedure is authorised in accordance with regulation 4.

(2) The conditions referred to in paragraph (1)(a) are that—

(a) the requirements of section 16E(2)(c), (d) and (e) of the 2006 Act are met, and

(b) no Type A procedure could provide the necessary information for either of the purposes described in section 16E(3) of the 2006 Act.

(3) For the purposes of paragraph (1)(a)—

(a) one of the registered medical practitioners must be the health worker primarily responsible for the person's medical treatment, and

(b) neither registered medical practitioner may be a member of the clinical team or teams primarily responsible for carrying out the removal and use of a part of the person's body after the person's death for transplantation.

(4) The views of the registered medical practitioners referred to in paragraph (1)(a) must be recorded in writing.

Authorisation of Type B procedures

4.—(1) The carrying out of a Type B procedure is authorised in relation to a person ("A") if—

(a) A has expressly authorised the carrying out of the procedure,

(b) A is an adult who, at the relevant time, has not expressly authorised the carrying out of the procedure and A's nearest relative authorises the carrying out of the procedure in accordance with paragraph (2), or

(c) A is a child who, at the relevant time, has not expressly authorised the carrying out of the procedure, and either—

(i) there is a person ("B") who has parental rights and parental responsibilities in relation to A and B authorises the carrying out of the procedure in accordance with paragraph (3), or

(ii) each person with parental rights and parental responsibilities in relation to A has died or become incapable, but there is a person ("C") who is a person described in section 10A(4) of the 2006 Act and C authorises the carrying out of the procedure in accordance with paragraph (3).

(2) For the purposes of paragraph (1)(b), A's nearest relative may authorise a Type B procedure in relation to A where—

(a) the relative has no actual knowledge that A was unwilling for the procedure to be carried out, and

(b) the relative—

(i) has had regard to A's past wishes and feelings so far as reasonably ascertainable, and

(ii) is satisfied that if A were capable of making a decision about the procedure, A would not be unwilling for the procedure to be carried out.

(3) For the purposes of paragraph (1)(c)(i) or (1)(c)(ii), B or C may authorise a Type B procedure in relation to A where—

(a) B or C has no actual knowledge that A was unwilling for the procedure to be carried out, and

(b) B or C—

(i) has had regard to A's past wishes and feelings so far as reasonably ascertainable, and

(ii) is satisfied that if A were capable of making a decision about procedure, A would not be unwilling for the procedure to be carried out.

(4) An authorisation under paragraph (1)(a), (b) or (c) must be—

(a) in writing, or

(b) given orally to a health worker.

St Andrew's House,
Edinburgh
25th February 2021

JEANE FREEMAN
A member of the Scottish Government

SCHEDULE Regulation 2

Specification of Pre-Death Procedures

Class of procedure	*Type of procedure*
Collection of bodily fluids and microbiological samples	Swabbing or scraping of a bodily orifice other than the mouth, nostril or ear canal
Radiological imaging	Carrying out of a Magnetic Resonance Imaging (MRI) scan
	Carrying out of a Computerised Tomography (CT) scan
	Carrying out of an X-Ray where the person is transferred from their existing location
	Carrying out of ultrasound imaging where the person is transferred from their existing location
	Carrying out of a transthoracic echocardiography where the person is transferred from their existing location
Tissue sampling	Taking of a skin biopsy
Endoscopic procedure	Carrying out of a bronchoscopy

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations specify medical procedures which may be carried out on a person for the purpose of increasing the likelihood of successful transplantation of a part of the person's body after the person's death and which are not for the primary purpose of safeguarding or promoting the physical or mental health of the person, known under the Human Tissue (Scotland) Act 2006 ("the Act") as "pre-death procedures" (see section 16A inserted by section 23 of the Human Tissue (Authorisation) (Scotland) Act 2019).

A pre-death procedure may only be carried out on a person if it has been specified as either a Type A procedure or Type B procedure (see section 16D of the Act).

These Regulations specify the "Type B procedures". Type B procedures are those pre-death procedures which the Scottish Ministers consider are appropriate to be subject to provision about the circumstances in which Type B procedures may be carried out; the way in which the carrying out of Type B procedures can be authorised; the process for authorisation of Type B procedures and the carrying out of Type B procedures.

Regulation 2 states that the Type B procedures are those specified in the schedule.

Regulation 3 describes the circumstances in which Type B procedures may be carried out. Regulation 4 makes provision about the ways in which Type B procedures can be authorised and the process for authorisation.

No business and regulatory impact assessment has been prepared for these Regulations as no impact upon business, charities or voluntary bodies is foreseen.