

## **EXECUTIVE NOTE**

### **The Adults with Incapacity (Removal of Regenerative Tissue for Transplantation) (Form of Certificate) (Scotland) (No. 2) Regulations 2006 SSI/2006/368**

The above instrument is being made in exercise of the powers conferred by section 18(2) of the Human Tissue (Scotland) Act 2006 (“the 2006 Act”). The instrument is subject to the negative resolution procedure.

This instrument revokes and replaces The Adults with Incapacity (Removal of Regenerative Tissue for Transplantation) (Form of Certificate) (Scotland) Regulations 2006/343 (S.S.I. 2006/343) which makes an erroneous reference in the form of certificate of incapacity contained in its Schedule to revocation of the certificate; this instrument is therefore made without such a reference.

#### **Policy Objective**

The policy on donation by living adults with incapacity, as set out in the 2006 Act, seeks to apply the general principles set out in the Adults with Incapacity (Scotland) Act 2000 (“the 2000 Act”). The only forms of donation which are open to adults with incapacity (AWI) under the 2006 Act are an organ, but only in the context of a domino organ transplant operation (which is defined in section 17(10) of the 2006 Act), and regenerative tissue.

Sections 17(1)(c) of the 2006 Act provides that it is an offence to remove any tissue from an AWI for transplantation, whilst section 17(2)(c) makes it an offence to use any tissue from an AWI for transplantation. These offences of removal or use may be disapplied by the Scottish Ministers by means of regulations under section 17(4) where the tissue is regenerative tissue and where certain other requirements that may be specified in the regulations are met. The Scottish Ministers have disapplied the offences relating to removal and use of regenerative tissue from an AWI in certain circumstances by the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006, which are being made under sections 17(3), (4), (5) and (7), 18(2) and 59(1)(b) of the 2006 Act; those draft regulations have been laid and are currently lying before the Parliament. In keeping with the requirements of the 2000 Act, it is necessary to show that the adult from whom it is proposed to remove the regenerative tissue is incapable (within the meaning of the 2000 Act) to make his or her own decision about the proposed removal and use of the regenerative tissue in question for transplantation.

Section 18(2) of the 2006 Act requires that the Scottish Ministers issue a certificate confirming that they are of the opinion that the adult is incapable in relation to a decision about the removal from the adult of regenerative tissue for transplantation, and that the certificate should be in a form prescribed in Regulations by the Scottish Ministers. The form used in these Regulations is modelled on that in the Schedule to the Adults with Incapacity (Medical Treatment Certificates) (Scotland) Regulations 2002, made under section 47(5) of the 2000 Act. It has been modified, however, to refer to ‘the Scottish Ministers’ whereas the previous form placed the responsibility on a Registered Medical Practitioner.

In practical terms, the Human Tissue Authority will act on behalf of the Scottish Ministers in such cases under arrangements to be made for the Human Tissue Authority to assist the Scottish Ministers with certain of their functions; section 54 of the 2006 Act enables the Scottish Ministers to make such arrangements. The Department will work with the Authority to put in place the practical arrangements needed, and these will be reflected in the guidance for practitioners which the HTA is developing.

No such certificate is needed for the removal or use of organs for transplantation from an AWI, as the only context in which organs may be removed is as part of an domino organ transplant operation. For such operations, the adult would already have been assessed for capacity for the operation itself as this falls within “medical treatment” of the adult for the purposes of section 47 of the 2000 Act. The certificate issued by a registered medical practitioner for the operation will therefore serve, by virtue of section 17(b) of the Act as evidence of the adult’s incapacity.

### **Financial Effects**

The instrument itself has no financial effects on the Scottish Executive or any other organisation.

### **Regulatory Impact Assessment**

The draft Regulations have no impact on businesses, charities or voluntary bodies. The of donation of regenerative tissue by AWI will be extremely small, not least because of the protections included in the Regulations being made under section 17 of the 2006 Act, and the arrangements for their scrutiny will form part of the systems of scrutiny being set up by the Human Tissue Authority for living donation in general. There is strong support across all sectors for the regulation of living donation, as it protects the interests and safety of potential donors and recipients. Using the HTA to undertake this function for Scotland avoids the need to create a regulatory body specifically for Scottish cases of living donation.

Health Department: Healthcare Planning Division  
June 2006