



Scottish Annex: requirements relating to living donation

Introduction

The Scottish Ministers and the Human Tissue Authority (HTA) have agreed that the HTA will act on the Scottish Ministers' behalf in relation to cases of living donation involving Scotland, in order to promote consistency of approach across the UK. The general arrangements set out in the HTA's Codes of Practice on the Donation of organs, tissues and cells for transplantation and the Donation of allogeneic bone marrow and peripheral blood stem cells (PBSC) for transplantation therefore apply to Scottish cases. There are, however, some important differences, relating mainly to the types of Scottish cases which can be considered by the HTA. These restrictions, which stem from the extension to the living donation arrangements of the principles of Scots law relating to children and adults with incapacity, are described in more detail in this Annex.

The Scottish Legal Framework

The legal framework for living donation and transplantation is set out in section 17 of the [Human Tissue \(Scotland\) Act 2006](#) (herewith referred to as the (HT) Scotland Act), and in general applies to a part of the body which can be removed from a living person for the purpose of transplantation. The provisions of section 17 are supplemented by those in the [Human Organ and Tissue Live Transplants \(Scotland\) Regulations 2006](#) (herewith referred to as the Scottish Live Transplants Regulations). Although the (HT) Scotland Act and these Regulations refer to 'the Scottish Ministers', this has been done for technical legal reasons and in practical terms should be understood as meaning the HTA.

There are 3 broad categories of potential donors: adults who have the capacity to make their own decisions; adults who lack that capacity; and children. There are restrictions on each in terms of living donation, and the Scottish Live Transplants Regulations set out the circumstances in which those restrictions can be lifted by the HTA. The common requirements are that the HTA has to be satisfied that:

- no reward has been or is to be given in contravention of section 20 of the (HT) Scotland Act, which prohibits commercial dealings in parts of a human body for transplantation;
- there is no evidence of duress or coercion affecting the donor's decision; and
- the relevant requirements of the Scottish Live Transplants Regulations under the (HT) Scotland Act have been met.

For adults with capacity, the position is as described in these Codes, bearing in mind that someone becomes an adult in Scotland when they reach the age of 16. The Scottish Live Transplants Regulations do not apply to the donation of regenerative tissue by adults with capacity, but such cases involving an adult in Scotland are subject to the administrative arrangements set out in the Code of Practice on the donation of allogeneic bone marrow and PBSC.

For adults with incapacity (AWI), the (HT) Scotland Act applies the principles embodied in the [Adults with Incapacity \(Scotland\) Act 2000](#). The only types of donation open to AWI are (1) regenerative tissue, and (2) an organ or part of an organ in the circumstances where it has to be removed from the AWI as part of a domino organ transplant operation. In relation to the donation of regenerative tissue, the Scottish Live Transplants Regulations include additional protections for the AWI based on the 2000 Act. A form has to be completed certifying that the adult does not have the capacity to understand what is involved in the donation of regenerative tissue. The form is prescribed in the [Schedule to the Adults with Incapacity \(Removal of Regenerative Tissue for Transplantation\) \(Form of Certificate\) \(Scotland\) \(No. 2\) Regulations 2006](#). The Scottish Live Transplants Regulations also stipulate that there is no other adult who could act as a donor, that removal of the regenerative tissue involves at most a minimal foreseeable risk and no more than minimal discomfort to the donor, and that the AWI has not indicated unwillingness to be a donor. With this last point in mind, the Scottish Live Transplants Regulations provide that the adult's nearest relative, principal carer or proxy should be included in the interview process wherever possible, so that account can be taken of any views the adult might have expressed before losing capacity.

The position regarding children is broadly similar to that for AWI. In Scots law, a child is a person who has not yet reached the age of 16. The provisions of the (HT) Scotland Act and the associated Regulations apply to all children in Scotland. The only forms of donation open to them are an organ or part of an organ which has to be removed as part of a domino organ transplant operation, or regenerative tissue. It is not possible for children to take these decisions themselves, even though they may be thought capable of understanding the issues involved. In those cases, their views can be taken into account, but the decisions must be taken by the HTA. In reaching its decision, the HTA can also take account of the views of those with parental rights and responsibilities for the child, though a local authority in that position is excluded from the process.

Because the Scottish Live Transplants Regulations are couched in terms of 'the Scottish Ministers', it has not been possible within them to make the distinction which exists in the equivalent English Regulations¹ between decisions which can be taken by the HTA itself or those decisions which have to be taken by a panel of no fewer than 3 members of the HTA. In practical terms, however, that distinction will be applied to Scottish cases in the same way as it is to equivalent cases in the rest of the UK.

The Scottish Live Transplants Regulations provide for reconsideration of decisions by the HTA, but contain an additional provision allowing for anyone who is involved in a case and is aggrieved by the HTA's decision in that case to appeal to the Court of Session.

¹ Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.