POLICY NOTE

THE HUMAN TISSUE (SUPPLY OF INFORMATION ABOUT TRANSPLANTS) (SCOTLAND) REGULATIONS 2025

SSI 2025/139

The above instrument was made by the Scottish Ministers in exercise of the powers conferred by section 19(1) of the Human Tissue (Scotland) Act 2006 and all other powers enabling them to do so. The instrument is subject to negative procedure.

Summary Box

These Regulations create a duty for relevant clinicians to notify the Human Tissue Authority if they are made aware that their patient has received a transplant outside the United Kingdom, or have a reasonable suspicion that specified offences under human tissue or modern slavery legislation may have been committed.

Policy Objectives

Overview

The Human Tissue (Scotland) Act 2006 regulates the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue from the deceased, for specified health related purposes. The Act also creates offences in relation to the commercial dealings in organs for human transplantation.

The introduction of section 32A to the Human Tissue Act 2004 and section 20A to the Human Tissue (Scotland) Act 2006 by the Health and Care Act 2022 expanded the prohibition on commercial dealings in organs for human transplantation to acts done outside the United Kingdom.

Since the introduction of these sections there has been an increase in suspicious activity being flagged in other parts of the United Kingdom to the police and the Human Tissue Authority, the regulator whose responsibilites include living organ donation approvals. These Regulations seek to address uncertainty in what information can be reported, and when, by creating a duty to report those suspicions to the Human Tissue Authority.

The creation of a new statutory requirement to report specified information to the Human Tissue Authority applies to relevant clinicians, who are defined as the doctors and nurses involved in the care and treatment of patients who need an organ transplant, who are receiving an organ transplant, or who have already received an organ transplant.

The duty will apply to these doctors and nurses practising in transplant and non-transplant centres to ensure the duty applies to clinicians who may come across these patients.

The Regulations will mirror the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024, which extend to England, Wales and Northern Ireland and came into force in April 2024. Another policy aim, therefore, is to stay aligned with the rest of the United Kingdom, given the common approach to organ donation and transplantation currently in place in the United Kingdom.

Background

Following the coming into force of section 32A of the Human Tissue Act 2004 and section 20A of the Human Tissue (Scotland) Act 2006, arrangements for what clinicians should do if they suspected that these new offences were taking place or had been committed were put in place. In Scotland, it was agreed that clinicians should report their concerns to the Human Tissue Authority, who would then consider whether, in their view, an offence had taken place. If so, they would report their findings to Police Scotland, who would investigate further and then pass the details to the Crown Office and Procurator Fiscal Service, if appropriate. Guidance was issued to clinicians in Scotland to explain the procedures.

In recent years the Human Tissue Authority has become aware of an increase in unlawful activities in England. This activity relates to both transplants when a recipient has travelled outside of the United Kingdom as well as when potential donors have been brought into or were already in the United Kingdom. However, while it was always open to clinicians to report suspected offences, it became clear that clinicians had concerns about how reporting suspicions might interact with the duties of confidence they owe patients. To address this concern, the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024 ("the 2024 Regulations") were made and came into force on 1 April 2024. The 2024 Regulations extend and apply to England, Wales, and Northern Ireland. They created a statutory requirement for relevant clinicians to report specified information to the Human Tissue Authority if they are made aware that a patient has received an organ transplant outside the United Kingdom or they have a reasonable suspicion that specified offences under human tissue and modern slavery legislation in England, Wales, and Northern Ireland may have been committed.

Since the 2024 Regulations came into force an increasing number of reports have been made to the Human Tissue Authority, and from the Human Tissue Authority to the police, in England, Wales, and Northern Ireland.

While there have been no reports so far to the Human Tissue Authority of suspected offences under section 20A of the Human Tissue (Scotland) Act 2006, given the increasing number of reports in the rest of the United Kingdom under the 2024 Regulations, these Regulations introduce similar reporting duties in Scotland.

The Regulations will give clinicians in Scotland clarity around when and to whom they should report suspected offences and transplants outside the United Kingdom and should increase the safety of those under threat of being victims of transplant-related offences.

A statutory duty to report organ transplants which have taken place outside the United Kingdom was considered the most effective way to capture data on where UK nationals and residents are receiving transplants.

Legisative context

Section 20 of the Human Tissue (Scotland) Act 2006 creates offences prohibiting commercial dealings in parts of a human body for transplantation. Section 20A of that Act extends the application of the offences in section 20 to actions that take place outside the United Kingdom in certain circumstances. These circumstances are where the person who does the action (such as paying for or arranging another form of reward for an organ) is habitually resident in Scotland or is a UK national not habitually resident in Northern Ireland, and the action relates to a human organ. Section 17 creates offences in relation to the removal or use of organs for transplant from living donors unless certain criteria are met and the donation is approved by the Human Tissue Authority.

Section 1 of the Human Trafficking and Exploitation (Scotland) Act 2015 creates an offence where a person takes a relevant action with a view to another person being exploited. A "relevant action" includes the recruitment, transportation, transfer, harbouring, receiving, or exchange or transfer of control over another person, or the arrangement or facilitation of any of these actions. Section 3(6) provides that exploitation includes circumstances where a person is encouraged, required or expected to do anything which involves the commission of an offence under Part 1 of the Human Tissue (Scotland) Act 2006, or which would involve the commission of the offences in that Part if it were done in Scotland. Sections 17, 20 and 20A are in Part 1 of the Human Tissue (Scotland) Act 2006.

Section 19(1) of the Human Tissue (Scotland) Act 2006 provides a regulation-making power for the Scottish Ministers to require specified persons to supply certain information with respect to transplants to a specified authority. These Regulations are made under this regulation-making power.

These Regulations introduce statutory duties for relevant clinicians to report information, which is specified in the schedules of the Regulations, to the Human Tissue Authority in the following circumstances:

1. where a relevant clinician has reasonable suspicion that one or more of the offences in section 17, 20 or 21 of the Human Tissue (Scotland) Act 2006 or section 1 of the Human Trafficking and Exploitation (Scotland) Act 2015 (where section 3(6) of that Act applies) may have been committed, and

2. where a relevant clinician becomes aware of an organ transplant that has taken place outside the United Kingdom, and the recipient is habitually resident in Scotland, or is otherwise a United Kingdom national.

These duties only apply where the clinician's reasonable suspicion or knowledge arose in the course of their profession. These duties do not apply where a clinician has reason to believe

that another clinician has previously supplied the required information to the Human Tissue Authority, in relation to the same suspected offence or organ transplant.

Failure to comply with the duties created by this instrument, without reasonable excuse, is an offence under section 19(4)(a) of the Human Tissue (Scotland) Act 2006. A person guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Knowingly or recklessly supplying information which is false or misleading in a material respect, in purported compliance with this instrument, is an offence under section 19(4)(b) of the Human Tissue (Scotland) Act 2006. A person guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

UN Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 Compatibility

The Scottish Ministers have made the following statement regarding children's rights.

In accordance with section 23(2) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 (the Act), the Scottish Ministers certify that, in their view, the Human Tissue (Supply of Information about Transplants) (Scotland) Regulations 2025 are compatible with the UNCRC requirements as defined by section 1(2) of the Act.

EU Alignment Consideration

This instrument is not relevant to the Scottish Government's policy to maintain alignment with the EU. However, it is worth noting that no EU member states permit payments for organs from either living or deceased donors; this is prohibited under Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation[1].

Consultation

The content of these Regulations has been subject to consultation and engagement with external stakeholders. A number of meetings and conversations were conducted with officials from the UK Government's Department of Health and Social Care and from the other devolved nations in the course of development of this policy. Consultations were also carried out with the Human Tissue Authority, Police Scotland, the Crown Office and Procurator Fiscal Service, and colleagues within the Scottish Government, including those dealing with professional regulation and criminal justice issues. The policy was discussed at the Scottish Donation and Transplant Group, which brings together key stakeholders in this field, including clinicians and patient representatives.

An online consultation event was hosted by the Scottish Government with key stakeholders on 4 June 2024. Attendees at the stakeholder event included representatives from the Human

[1] In particular Article 13 of the Directive - Directive - 2010/53 - EN - EUR-Lex

Tissue Authority, the Department of Health and Social Care, the General Medical Council, Police Scotland, the Crown Office and Procurator Fiscal Service, the Scottish National Blood Transfusion Service, NHS Blood and Transplant, representatives from several NHS Scotland Boards, and the following organisations representing patients: the British Liver Trust Scotland, Kidney Research UK, and Kidney Care UK.

Following points made at the consultaton event, it was considered whether it would be possible to put the duty onto health boards, rather than directly onto clincians, in Scotland. However, it was decided to mirror the arrangements in the rest of the United Kingdom in order to provide clarity across the United Kingdom donation system, and also for reasons of workability.

Impact Assessments

The Scottish Government has considered a series of impact assessments related to these Regulations and concluded that an Equality Impact, a Data Protection, and a Child Rights and Wellbeing Impact Assessment should be completed. The Scottish Government is satisfied that there are no significant additional equality, children's, or privacy impact issues. No changes to the Regulations have therefore been required as a result of these impact assessments.

Fairer Scotland Duty – The Scottish Government is satisfied a full assessment is not required. An initial screening assessment concluded that these Regulations do not introduce any differential socio-economic disadvantages in relation to this duty.

Islands Communities – After initial consideration, the Scottish Government is satisfied that the Regulations will not result in a disadvantage for any island communities compared to the mainland or compared to another island groups. A full assessment has therefore not been required.

Strategic Environment Assessment (SEA) – the Scottish Government is satisfied that no environmental effects are anticipated as a result of these Regulations and no SEA is required.

Financial Effects

The Minister for Public Health and Women's Health confirms that no BRIA is necessary as the instrument has no financial effects on the Scottish Government, local government, or on business.

Scottish Government
Population Health Directorate

April 2025