POLICY NOTE

THE HUMAN TISSUE (AUTHORISATION) (SPECIFIED TYPE B PROCEDURES) (SCOTLAND) REGULATIONS 2021

SSI 2021/XXX

The above instrument was made in exercise of the powers conferred by section 16C(1) and (2) of the Human Tissue (Scotland) Act 2006, as inserted by the Human Tissue (Authorisation) (Scotland) Act 2019 ("the 2019 Act"). The instrument is subject to affirmative procedure.

Summary Box

The purpose of this instrument is to specify medical procedures that are Type B pre-death procedures; how they may be authorised and what conditions must be met in order for them to be carried out.

Pre-death procedures are medical procedures 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. Type B procedures are those medical procedures which Ministers consider are appropriate to be carried out subject to further provision as to the circumstances of carrying out, authorisation or manner of carrying out to those included in the provisions of the 2019 Act.

Policy Objectives

The overall aim of the 2019 Act seeks to facilitate, as part of a wider package of measures, an increase in the number of successful organ and tissue donations in Scotland. As part of this, it is important to ensure that the processes which support donation and transplantation work well and are underpinned by a clear legal framework. This instrument is necessary to specify Type B procedures which are permitted, and the associated authorisation requirements and conditions to be met, in order to give practical effect to the legal framework in the 2019 Act.

Without certain pre-death procedures, donation will unlikely to be able to proceed in cases of donation following circulatory death. Currently, around 40% of deceased donation in Scotland happens after a person has died following circulatory death (DCD)[1]. This is where the donor has been pronounced dead following cessation of the heart and respiratory activity. Some Type A procedures[2] will be required for all of these donors, for example blood tests and urine samples; Type B procedures are those procedures which will be carried out less frequently. Donation after diagnosis of death by neurological criteria (also known as donation after brain death, or DBD), where the donor has been pronounced dead using neurological criteria, accounts for the rest of deceased donation.

[1] https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/20250/nhsbt-scotland-summary-report-sep-20.pdf
[2] https://www.legislation.gov.uk/ssi/2020/80/contents/made

The statutory framework

The 2019 Act sets out a dedicated statutory framework in relation to pre-death procedures and provides that Scottish Ministers may, by regulation, specify pre-death procedures as either Type A or Type B.

Before a pre-death procedure can be carried out the requirements of the statutory framework set out in the 2019 Act must be met. This includes that it must be necessary to carry out the procedure, either for the purpose of ascertaining whether a part of the person's body is suitable for transplantation, or for the purpose of increasing the likelihood of successful transplantation; the procedure must be authorised and there must be no suggestion that the person would have objected to the procedure being carried out, following the carrying out of the duty to inquire, provided for in the Act. The framework also only permits a procedure to be carried out in certain circumstances and, particularly, not prematurely and not if it is likely to cause more than minimal discomfort or likely to harm the patient.

Type B regulations

The medical procedures set out in this instrument as Type B reflect procedures are those which, unlike Type A procedures, are not routinely required to facilitate deceased donation and increase the likelihood of successful transplantation, but may be required on occasion to enable further investigation to check for infection or malignancy. These include imaging procedures carried out away from the bedside, bronchoscopy, small skin biopsy (for example on a skin lesion) and swabbing or scraping certain areas of the body.

The regulations specify that these procedures may be authorised either by the donor, or by their nearest relative[3], or person with parental rights and responsibilities in the case of a child[4]. In practice, authorisation from such a family member will be the authorsation route taken in the vast majority of cases, particularly given the circumstances in which deceased donation takes place.

The regulations also specify conditions for a specified Type B procedure to be carried out. The conditions are that two Registered Medical Practitioners (RMPs) must be of the view that:

- the conditions set out in section 16E (2) (c) to (e)[5] of the 2019 Act are met, and
- it is not possible to obtain the required information by carrying out a Type A procedure.

One of these RMPs must be the health worker primarily responsible for the person's medical treatment. Neither of the RMPs can be part of the clinical team or teams involved in the removal or use of a part of the person's body after the person's death for the transplantation. The views of the RMPs must be recorded in writing.

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[3] For the purposes of the 2006 Act, the Nearest Relative is the person who, at the relevant time, is highest in the list of relations at section 50.

[4] Authorisation may be given on behalf of a child by a person with parental rights and responsibilities in relation to them, including a local authority. Where there is no person with parental rights and responsibilities or that person is incapable of providing authorisation, section 10A of the 2006 Act sets out who is permitted to authorise donation on behalf of a child.

[5] These are that the procedure is necessary, that it is not likely to cause more than minimal discomfort to the patient, and that it is not likely to harm the patient.

Consultation

The Scottish Government carried out a public consultation on the proposed content of the draft regulations from 9 October to 20 November 2020. The consultation was publically available and was also sent directly to NHS Boards, NHS Organ Donation Committees, NHS Blood and Transplant (NHSBT), Scottish National Blood Transfusion Service (SNBTS), Clinical Leads for Organ Donation, relevant clinical representative organisations such as the Scottish Intensive Care Society as well as faith organisations. 15 responses were received which were all from individuals and organisations with experience of the deceased organ and tissue donation and transplantation pathway.

The majority of respondents were generally content with the proposed list of procedures, authorisation methods and conditions. A small number of responses suggested that it should be made clear in the regulations that those involved in the transplantation process should be prevented from making the assessment. As a result the regulations include certain requirements as to which RMPs may be involved, as set out above.

In addition, comments or suggestions made in the consultation to amend the list of procedures were further considered in discussion with clinical advisors and representatives from the Scottish Intensive Care Society, NHSBT and SNBTS to ensure that the list represents the Type B procedures which might be used at this time. As a result the list of procedures is unchanged from that which was consulted upon.

Where agreement to publish responses to the public consultation has been provided these have now been published on the Scottish Government consultation hub website, where an analysis of responses is also accessible: https://consult.gov.scot/population-health/consultation-specified-type-b-procedures/.

Impact Assessments

An Equality Impact Assessment (EQIA) has been completed for this instrument. There are no negative impacts arising from this instrument.

There is no impact on business (the legislation does not apply to activities that are undertaken by businesses) charities or voluntary bodies.

Financial Effects

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

Scottish Government
Directorate for Population Health

January 2021