

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

[AS AMENDED AT STAGE 2]

REVISED EXPLANATORY NOTES

INTRODUCTION

1. As required under Rule 9.7.8A of the Parliament's Standing Orders, these revised Explanatory Notes are published to accompany the Human Tissue (Authorisation) (Scotland) Bill (which was introduced in the Scottish Parliament on 8 June 2018) as amended at Stage 2. Text has been added or amended as necessary to reflect the amendments made to the Bill at Stage 2 and these changes are indicated by sidelining in the margin.

2. These Explanatory Notes have been prepared by the Scottish Government in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by the Parliament.

3. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a section, or a part of a section, does not seem to require any explanation or comment, none is given.

THE BILL

4. The primary purpose of the Human Tissue (Authorisation) (Scotland) Bill ("the Bill") is to introduce a 'soft' opt-out system of organ and tissue donation for the purposes of transplantation. It amends the Human Tissue (Scotland) Act 2006 ("the 2006 Act"), to add to existing provisions in that Act which provide for authorisation of removal and use of parts of the body of a deceased person for the purposes of transplantation and other specified purposes (research, education, training and audit).

5. It introduces "deemed" authorisation for deceased organ and tissue donation which will apply to most adults. This means that where an adult potential donor has not expressed any objections to donation for the purpose of transplantation, the adult's authorisation may in some circumstances be deemed to have been given and the donation could proceed. It also builds on existing provision in the 2006 Act for express authorisations, introduces statutory opt-out declarations and continues to enable authorisation by nearest relatives in certain circumstances.

6. The Bill also contains some new provisions to supplement the existing statutory framework to ensure it continues to work effectively including introducing more flexibility in the timing of the authorisation process, as well as clarity about authorisation for pre-death procedures (PDPs) - medical procedures which may be carried out in order to increase the likelihood of successful transplantation of donated organs and tissue. Provisions for authorisation by and on behalf of children (people who are under the age of 16 years) are also updated, and additional circumstances in which authorisation may be given for children are included. A more detailed explanation of the Bill's purpose can be found in the Policy Memorandum, which also explains the thinking and policy intentions that underpin it.

THE STRUCTURE AND SUMMARY OF THE BILL

7. The Bill is in 4 Parts, with Part 1 providing an overview of the Bill's structure.

Part 2 – Duties of the Scottish Ministers

8. Part 2 adds to the existing duties of Scottish Ministers under the 2006 Act as regards transplantation and donation of body parts, to include promotion of information and awareness about authorisation of transplantation and the nature of pre-death procedures and how these may be authorised. Duties are also added for the Scottish Ministers to make arrangements to establish and maintain a register of information about donation decisions and provision is made about the persons to whom and the purposes for which information from that register can be disclosed. This puts the existing organ donor register, maintained by NHS Blood and Transplant¹ (NHSBT), on a statutory basis in Scotland. There is a power for Ministers to delegate the running of the Register to another person. It is envisaged that the Scottish Ministers will delegate the function to NHSBT so that the Organ Donor Register will continue to operate as it does at present.

Part 3 – Authorisation of removal and use of part of body of deceased person

9. Part 3 (which is in six Chapters) amends the existing provisions contained in the 2006 Act for authorisation of removal and use of part of the body of deceased persons. Chapter 1 contains section 4 on timing of authorisations. Under the existing authorisation system in the 2006 Act, an authorisation may be given on behalf of a potential donor only after the potential donor's death. Section 4 provides flexibility around when authorisations may be given by the nearest relative or person with parental rights and parental responsibilities ("PRRs")² so that authorisation may be given shortly before the potential donor's death. This will allow donation to proceed more quickly after the potential donor's death.

10. Chapter 2 adds to existing provision about authorisation by or on behalf of an adult in the 2006 Act. In particular, it provides for the circumstances where an adult may be deemed to have authorised donation for the purposes of transplantation of commonly donated types of organ and tissue. Deemed authorisation will not apply to adults who lack capacity and adults resident in

¹ NHS Blood and Transplant is a Special Health Authority established under the National Health Service Act 1977.

² Section 60 of the 2006 Act defines "parental responsibilities" as having the meaning given by section 1(3) of the Children (Scotland) Act 1995 (c.36) and "parental rights" as having the meaning given by section 2(4) of that Act. The 2006 Act also includes headings which refer to "parental rights and responsibilities" to refer to parental rights and parental responsibilities.

Scotland for less than 12 months (“excepted categories”). Chapter 2 also provides for the circumstances in which authorisation may be given by a nearest relative.³ It also includes provisions which enable an adult to record a declaration that the adult does not wish to become an organ or tissue donor after death, i.e. “opt-out”, and specifies how and to whom a valid oral authorisation, opt-out declaration, or authorisation by nearest relative or person with PRRs may be given.

11. Changes are also made to include requirements to take into account the potential donor’s most recent view about donation. Chapter 2 also provides that the removal and use of less commonly donated types of organ and tissue, or the removal of commonly donated types for purposes other than transplantation from a potential donor who is subject to deemed authorisation, can only be carried out with authorisation by a nearest relative.

12. Chapter 3 includes provisions about authorisation by or on behalf of a child⁴ to align some of the provisions on authorisation with those relating to adults, and reflecting the requirements of the United Nation Convention on Rights of the Child.⁵ These provide–

- a child 12 years of age or over but under 16 years may record a decision not to become an organ or tissue donor after death i.e. “opt-out”;
- for a change of mind by a child who had previously recorded a donation decision;
- local authorities may authorise donation for children for whom they hold PRRs, in consultation with relevant parties;
- for alignment of the method of communicating decisions for children with that for adults;
- for a requirement that those persons with PRRs who may authorise donation on behalf of a child under 12 years must consider if the child may have been unwilling to donate and, if so, donation may not be authorised;
- another person with a relationship with the child to be able to authorise donation in cases where there is nobody with PRRs for a child or the person with PRRs is incapacitated.

13. Chapter 4 includes some general provisions about authorisation for donation, and enables Ministers to make further provision about the manner in which decisions may be communicated. It also includes provisions about how an authorisation or opt-out declaration may be withdrawn where a person is blind or unable to write and adds that authorisation can also be given for the purpose of quality assurance under section 3(1) of the 2006 Act. Amendments are also made to section 11 of the 2006 Act which sets out various requirements which must be satisfied before a body part may be removed and used in accordance with the Act.

³ “Nearest relative” is defined in section 50 of the 2006 Act. Section 50(4) also provides that the list is ranked in order so it provides for a hierarchy of decision makers.

⁴ “Child” is defined in section 60(1) of the 2006 Act as a person who is under the age of 16 years.

⁵ Further background is included in the Children’s Rights and Wellbeing Impact Assessment published by the Scottish Government.

14. A framework for authorisation of pre-death procedures (PDPs) relating to transplantation is set out in Chapter 5, and Chapter 6 includes duties on health workers to inquire as to whether there is an opt-in or opt-out decision in place; the potential donor's most recent views about donation and pre-death procedures, and whether the potential donor is in an excepted category.

Part 4 – General and Final Provisions

15. Part 4 makes general and final provisions, including adding an interpretation section to the 2006 Act and consequential amendments.

PART 1 – OVERVIEW OF THE BILL

Section 1 – Overview of the Bill

16. Section 1 sets out that the Bill is arranged in four parts.

PART 2 – DUTIES OF THE SCOTTISH MINISTERS

Section 2 – Information and awareness about authorisation of transplantation and about pre-death procedures

17. Section 1 of the 2006 Act places duties on the Scottish Ministers to promote, support and develop programmes of transplantation and promote information and awareness about donation for transplantation. Section 2 of the Bill adds into section 1 of the 2006 Act two additional duties on Scottish Ministers. The first is to promote information and awareness of the authorisation process for transplantation of organs and tissue; including what deemed authorisation for transplantation means. The second is to promote information and awareness about PDPs, the timing of the use of those procedures and how authorisation for PDPs may be given. Section 2(3) outlines that as part of these duties, the Scottish Ministers must promote a campaign of awareness and information at least every year on how authorisation may be deemed and how to expressly authorise and opt-out of donation of body parts for transplantation. The duty in section 1 of the 2006 Act is currently met in a number of ways, including high profile media campaigns which are supplemented by targeted information, including social media activity and information being provided at public events. New public information will be developed to ensure that the public understands the implications of the system, and this will also include information which meets the needs of different people, or groups of people.

Section 3 – Establishment and maintenance of register

17. The existing NHS Organ Donor Register (ODR) is a confidential, computerised database – maintained by NHSBT - that is used to help establish whether a person in the UK wants to donate organs and tissue after death for the purposes of transplantation. More information about the ODR can be found via the Organ Donation Scotland website.⁶ The aim of section 3 of the Bill, which

⁶ <https://www.organdonationscotland.org/>

inserts sections 2A to 2D into the 2006 Act, is to give the ODR a statutory basis in Scotland, and to enable the management of the ODR to continue to be delegated to NHSBT.

Section 2A – Establishment and maintenance of register

18. Section 2A(1) requires the Scottish Ministers to put in place arrangements to establish and maintain a register (referred to in the Bill and these explanatory notes as “the Register”)—

- a) to facilitate the carrying out of their duty under section 1(a) of the 2006 Act to promote, support and develop programmes of transplantation, and
- b) to facilitate the removal of organs and tissue for the purposes of transplantation which is authorised in terms of the 2006 Act as amended by the Bill.

19. This reflects the existing purposes of the ODR: the ODR currently holds information that facilitates organ and tissue donation only for the purposes of transplantation. If the practical operation of the ODR changes in future so that it can facilitate donation for the other purposes in section 3(1) of the 2006 Act (research, education, training, audit and – as added by section 20 of the Bill - quality assurance), the Scottish Ministers can use the regulation making power in section 2D(1) to allow the Register to be used for the purpose of facilitating organ and tissue donation for those purposes.

20. Section 2A(2) sets out the information which must be held on the Register. This includes details of people who authorise or do not authorise removal and use of a part of their body for transplantation after death. The information should be sufficient to identify those people (for example name, address and date of birth) and should record whether a person wants to donate organs or tissue and, if so, which organs or tissue. If the ODR changes in future so that it can facilitate donation for research, education, training, audit or quality assurance, the Scottish Ministers may make regulations under section 2D(1) which modify section 2A(1) to add these purposes to the list of information which the Register must hold.

21. Section 2A(3) provides that the Register is not open to public inspection or search, and subsection (4) allows the Scottish Minister to determine the form the information on the register is to be kept in, for example electronically.

Section 2B – Delegation of function of establishing and maintaining Register

22. New section 2B enables the Scottish Ministers to authorise another organisation to establish and maintain the Register. The current arrangements under which NHSBT manages the ODR will be able to continue by the Scottish Ministers exercising the power to delegate their functions under this section. There is also a requirement that information about any arrangement is made public by the Scottish Ministers.

23. Section 2B(2) sets out that “register organisation” means the Scottish Ministers or, if the Scottish Ministers exercise the power in section 2B(1) to delegate the maintenance of the Register to another person, that person. In practice, it is anticipated that the register organisation will be NHSBT. The Bill provides that persons who wish to expressly authorise, or opt-out of, organ and tissue donation for transplantation may communicate that decision to the register organisation. See paragraphs 37, 38 and 45 for further explanation.

Section 2C – Disclosure of information

24. For the donation and transplantation process to work, information about a person in the ODR needs to be disclosed in certain circumstances. New section 2C(1)(a) of the 2006 Act provides that such information may be shared with certain people within Scotland, as long as it is to allow or help them to carry out transplantation functions under Part 1 of that Act.

25. The people within Scotland with whom information from the ODR can be shared are:

- a registered medical practitioner,
- a person (or person within a description) authorised under section 11(1)(b) of the 2006 Act,
- a health worker who is acting in accordance with section 16H or 16I of the 2006 Act.

26. These people are empowered to share information amongst themselves and with those listed in section 2C(4) where this will allow or assist them to carry out tasks relating to transplantation. The people listed in section 2C(4) include the nearest relative⁷ of an adult who is a potential donor, or someone who has information about the potential donor's last known view. In addition, it includes, where the potential donor is a child, the person with PRRs, or a person who has or recently had a significant involvement in the child's upbringing, a close relative or friend of the child (new section 10A, inserted by section 16 of the Bill, sets out who this includes) or any other person consulted in relation to the potential donor's decision on organ and tissue donation.

27. Information from the ODR needs to be shared with these people as part of the donation process to ensure, amongst other things, that the decision on the Register reflects the latest decision of an adult or child (if aged 12 or over and under 16 years). The ODR information also may be shared in cases where a nearest relative or person is asked to authorise donation for purposes other than transplantation or for the transplantation of less common types of organs and tissue.

28. New section 2C(1)(b) of the 2006 Act permits information to be disclosed to a person operating outwith Scotland to help or allow them to exercise transplantation functions. For example, if a person is outside Scotland and becomes a potential donor, information about them from the ODR could be disclosed to assist in discussions with their nearest relatives.

Section 2D – Power to make provision about Register

29. Section 2D gives the Scottish Ministers the power to make provision about the Register by regulations subject to affirmative procedure.⁸ This includes amending the types of information to be held under section 2A(2). For example, if the ODR changes in future so that it can facilitate organ donation for research, education, training, audit or quality assurance, the Scottish Ministers may make regulations under section 2D(1) to allow information from the Register to be disclosed to facilitate donation for those purposes. The power in Section 2D also allows Ministers to modify

⁷ Nearest relative is defined in section 50 of the 2006 Act.

⁸ Laid in draft and approved by a resolution of the Scottish Parliament before regulations are made; section 29 of Interpretation and Legislative Reform (Scotland) Act 2010 (c.10) (“ILRA”).

the list of persons in section 2C(2) to whom information may be disclosed, and the purposes for which information may be disclosed.

Section 2E – Duty to promote opportunities to consider register status

30. New section 2E places the Scottish Ministers under a duty to promote regular opportunities for people to consider and review an express authorisation, as well as to consider making an opt-out declaration. The Scottish Ministers are to give consideration to how these opportunities can be provided in the context of healthcare services.

PART 3 - AUTHORISATION OF REMOVAL AND USE OF PART OF BODY OF DECEASED PERSON

Chapter 1 - Timing of authorisation

Section 4 – Timing of authorisation

31. Under the current authorisation system in the 2006 Act, organ and tissue donation may only be authorised on behalf of a potential donor once the potential donor has died. Section 4 will adjust the current authorisation system by amending sections 7, 9, 10, 11, 22 and 50 of the 2006 Act to include reference to “relevant time”. This will allow authorisation to be given by the nearest relative or person with PRRs shortly before death or after the potential donor’s death and will allow flexibility in the timing of authorisation so authorisation can be given just before death. In particular, this takes account of circumstances where a person may donate after circulatory death and due to time constraints in the organ donation process there is very little time to speak to a person’s family and loved ones after death is diagnosed. It will also align with the provisions for authorisation for pre-death procedures to ensure that authorisation for donation is in place before these may be carried out (Chapter 5).

32. A definition of “relevant time” is in the new section 16K(2) (Interpretation)⁹, which is inserted into the 2006 Act by section 26 of the Bill. In relation to a living potential donor, the “relevant time” is when—

- a) in the view of the health worker (defined in new section 16J of the 2006 Act) who is primarily responsible for the potential donor’s physical or mental medical treatment, the potential donor is likely to die imminently (including as a result of the withdrawal of life sustaining treatment),
- b) where the potential donor is receiving life-sustaining treatment, there has been a decision to withdraw that treatment, and
- c) the potential donor is incapable of making a decision about donation.

33. Where the potential donor is deceased, the “relevant time” means immediately before death.

⁹ Section 16K is added to the 2006 Act by section 26(2) of the Bill and applies to sections 1 to 16K, as amended.

34. Section 4(9) of the Bill amends section 50(1) and (2) of the 2006 Act (definition of nearest relative) to enable the hierarchy provided in for section 50(4) to be applied both in circumstances where the nearest relative is to be identified before the person's death, and in the circumstances where the nearest relative is to be identified after the person's death.

Chapter 2 – Authorisation by or on behalf of adult

Section 5 – Express authorisation by adult

35. Section 5 of the Bill amends section 6 of the 2006 Act, which sets out that an adult may authorise removal and use of part of the adult's body after the adult's death for one or more of the purposes in section 3(1) of the 2006 Act (e.g. transplantation, research), so that this section will be relevant to circumstances where the adult records an express decision to authorise the removal and use of a part of the adult's body after death, thereby distinguishing this express authorisation from "deemed authorisation". Section 5 also adds a new section 6A to the 2006 Act about withdrawal of express authorisation.

36. Section 5(2), which inserts new subsection (1A) into section 6 of the 2006 Act, provides the way in which an express authorisation can be made.

37. If the decision is for the purpose of transplantation, this can be made—

- a) to the register organisation orally or in writing (this reflects the current methods of joining the ODR e.g. via NHSBT's website, the Organ Donation Scotland website, the Driver and Vehicle Licensing Agency (DVLA) website, phoning NHSBT, completing a GP registration or Boots Advantage card registration form or by phoning NHSBT, filling in NHSBT's online form or sending NHSBT a completed registration form by post), or
- b) otherwise in writing (e.g. by carrying a completed donor card)

38. If the decision is for other purposes listed in section 3(1), - research, education and training, or audit or quality assurance¹⁰ - authorisation can be given in writing. Currently, there is not a facility to record on the ODR an express authorisation decision for these other purposes.

Section 6A – Withdrawal of express authorisation: adult

39. Section 5(4) of the Bill inserts new section 6A into the 2006 Act. Section 6A(1) provides that an express authorisation may be withdrawn by the adult in writing or if express authorisation was given to the register organisation, then withdrawal may be given orally or in writing to the register organisation. Section 6A(2) provides that if an express authorisation is given by the adult for the removal and use of a part (or parts) for a purpose (or purposes) under section 3(1) and the adult subsequently makes a declaration to opt out of removal and use of the same part (or parts) for the same purpose (or purposes) then the express authorisation is withdrawn for that part or purpose and the remainder of the authorisation stays in place. New section 6A(2) and (3) means—

- where the express authorisation and the opt-out declaration have the same extent (or the opt-out declaration has a wider extent), the express authorisation will be treated as withdrawn in full, and

¹⁰ Quality assurance is added as a purpose by section 20.

- where the express authorisation has a wider extent than the opt-out declaration, the express authorisation will be treated as partially withdrawn (and otherwise remain in force).

40. For example, if a person who had opted in to donate their heart, lungs and liver for transplantation, and subsequently changed their mind and made a decision to opt-out of donating their heart for transplantation, then the authorisation for donation of the heart is treated as withdrawn. The remainder of the express authorisation remains in force for the other parts or purposes contained in the authorisation.

41. New section 6A(4) and (5) provides that an express authorisation is treated as withdrawn by the adult in relation to removal and use of a part (or parts) for a purpose under section 3(1) of the 2006 Act if another person (for example a relative or friend) provides evidence to a health worker (defined in new section 16J, inserted by section 26(1A) of the Bill) about the adult's most recent view, which would lead a reasonable person to conclude that the adult was unwilling for the part to be removed and used for that purpose. Similarly, if a person provides evidence to a health worker that would lead a reasonable person to conclude that the adult would have been unwilling because of the circumstances of their death for the part to be removed, for example if donation in the particular circumstances of death are not compatible with a person's faith,¹¹ the express authorisation is treated as withdrawn. Subsection (5)(b) provides that the authorisation will remain in force for the parts and purposes to which the withdrawal does not apply.

42. Section 6A(5)(c) provides that it is the part of the authorisation that remains in force that is to be taken into account for establishing whether authorisation may be deemed, or whether the adult's nearest relative may give an authorisation on the adult's behalf.

Section 6 – Opt-out declaration by adult

Section 6B – Opt-out declaration: adult

43. Section 6 of the Bill inserts a new section 6B into the 2006 Act.

44. Section 6B(1) provides that an adult may make a declaration that they do not authorise the removal and use of part of their body for a purpose in section 3(1) of the 2006 Act (an "opt-out declaration"). Section 6B(2) provides that while an opt-out declaration is in force for the removal and use of a part of the body for a purpose under section 3(1) of the 2006 Act, which includes transplantation, research, education or training or audit or quality assurance, the part must not be removed and used for that purpose.

45. Section 6B(3) provides the way in which an opt-out declaration can be made. This is the same as for express authorisations (see paragraphs 36 - 38). If for transplantation, it can be made to the register organisation orally or in writing, also reflecting the current method of opting-out on the ODR. It can also be otherwise in writing, but in practice opt-out declarations will continue not to be able to be made via the DVLA, GP practices or similar. If the declaration relates to one of

¹¹ Some faiths will only regard a person as dead when their heart ceases to function. Therefore a diagnosis of death using neurological criteria may not be regarded as cessation of life and in those circumstances it may be that the person would not wish donation to proceed.

the other purposes in section 3(1) of the 2006 Act it must be in writing, as, similar to express authorisations, the facility to allow this to be recorded is not currently available on the ODR.

Section 6C - Withdrawal of opt-out declaration: adult

46. Section 6 of the Bill also adds new section 6C to the 2006 Act. Section 6C(1) provides that an opt-out declaration may be withdrawn by the adult in writing or if an opt-out declaration was given to the register organisation, then withdrawal may be given orally or in writing to the register organisation. Section 6C(2) provides that an opt-out declaration is treated as withdrawn if, after an opt-out declaration is made by the adult, the adult subsequently makes an express authorisation in respect of the same part, or parts, for the same purpose (or purposes). The opt-out declaration is then treated as withdrawn for that part or purpose. The remainder of the opt-out declaration stays in place. Subsections (2) and (3) mean—

- where the opt-out declaration and the express authorisation have the same extent (or the express authorisation has a wider extent), the opt-out declaration will be treated as withdrawn to its full extent, and
- where the opt-out declaration has a wider extent than the express authorisation, the opt-out declaration will be treated as partially withdrawn (and otherwise remain in force).

47. An example is where a person who had opted out of donation for organ and tissue transplantation subsequently changed their mind, deciding to donate their heart for transplantation. The opt-out declaration would effectively be withdrawn for their heart. The remainder of the opt-out declaration remains in force for the other parts or purposes.

48. Similar to the provisions about withdrawal of an express authorisation, new section 6C(4) to (7) provides the circumstances in, and extent to which, an opt-out declaration may be treated as withdrawn by the adult for a part or parts or purpose under section 3(1). If another person (for example a relative or friend) provides evidence to a health worker about the adult's most recent view, which would lead a reasonable person to conclude that the adult was willing for the part to be removed for the purpose, the opt-out declaration is treated as withdrawn to that extent.

49. Subsection (4)(b)(ii) also provides for cases where a person provides evidence to a health worker that would lead a reasonable person to conclude that the adult would have been willing because of the circumstances of death for the part to be removed. For example, if in the particular circumstances of death removal and use of the part would be compatible with a person's faith,¹² the provisions would allow evidence that the person was in fact willing to donate in those circumstances, to be taken into account. Subsection (5)(a) provides that the opt-out declaration is withdrawn to the extent that it relates to the removal and use of the part or parts for that purpose, and subsection (5)(b) provides that the opt-out declaration will otherwise remain in force.

50. Subsection (6) accordingly provides that the adult is treated as having authorised the removal and use of the part in respect of which the opt-out declaration is treated as withdrawn, for the purpose in question.

¹² See also paragraph 41, above.

Section 7 – Deemed authorisation for transplantation as respects adult

Section 6D – Deemed authorisation for transplantation: adult

51. Section 7 of the Bill inserts new section 6D into the 2006 Act and enables authorisation for transplantation to be deemed for certain adults (people 16 years of age or over¹³). New section 6D(1) provides that where there is no express authorisation by an adult of removal and use of any part for transplantation, and no opt-out declaration in place in respect of the removal and use of the part of the body in question for transplantation then the adult is deemed to have authorised the removal and use of that part for the purpose of transplantation (“deemed authorisation”). Deemed authorisation specifically does not extend to the other purposes in section 3(1) of the 2006 Act (research etc.) for which authorisation may be given.

52. Section 6D(2) sets out the circumstances in which deemed authorisation does not apply.

Non- resident adult

53. Deemed authorisation does not apply to a person who was not ordinarily resident in Scotland for a period of at least 12 months immediately before the relevant time (a “non-resident adult”). The Bill does not define what is meant by “ordinarily resident”, however the term has been subject to extensive and recent case law which gives it its meaning. Whether a person has been ordinarily resident in a place will be a question of degree in each case, but is not achieved by extraordinary, occasional or temporary residence. This suggests that living in a place or country has been done voluntarily and for a settled purpose and as part of the regular order of the person’s life for the time being, whether for short or long duration. A settled purpose could include education, business, employment, health or family. “Relevant time” is defined in new section 16K and clarifies the point at which authorisation may be given.¹⁴

54. This provision will also mean that a period of time where a person was ordinarily resident in Scotland immediately before the age of 16 may be included in the calculation of the 12 months to determine whether deemed authorisation will apply.

Adult incapable of understanding deemed authorisation

55. An adult who is not capable of understanding the nature and consequences of deemed authorisation will not be deemed to have authorised donation. Section 6D(3) sets out that this includes where the person was incapable of understanding both that they may be deemed to authorise donation and that this means organs and/or tissue may be removed after death for transplantation. It also makes clear that the person must have been incapable of understanding over a significant period of time up to the point at which they may be a donor. This is intended to include situations where capacity has fluctuated, but would apply when it is considered that the incapacity is such that over the period the person would not have been capable of understanding the nature and consequences of deemed authorisation. It is also intended to take into account that whether a period is considered significant will vary from case to case and will depend on the person’s individual circumstances, and will also take into account any evidence provided e.g. by family and friends. An example of when an adult will be considered incapable of understanding is if there is

¹³ Adult is defined in section 60(1) of the 2006 Act as a person who is 16 years of age or over.

¹⁴ See paragraphs 31 to 33.

evidence available to a health worker which would lead a reasonable person to conclude that the adult is so incapable (section 6D(4)).

Excepted body parts

56. Authorisation of donation for transplantation by an adult for an excepted body part will not be deemed. Section 6D(5) enables Ministers to specify in regulations what is an excepted body part. The intention is that excepted body parts will be those parts of the body which would not be considered to be commonly donated types of organ and tissue and therefore should not be included in deemed authorisation. This could include, for example, the face or limbs. Ministers would only be able to set these out after consultation, and the regulations are subject to affirmative procedure.¹⁵ Authorisation for these less common types of organ and tissue will still be able to be given by a nearest relative where authorisation is deemed (see section 6G inserted into the 2006 Act by section 10 of the Bill, as described below).

Evidence of unwillingness

57. Section 6D(2)(d)(i) provides that deemed authorisation does not apply in relation to a non-excepted part of an adult's body if another person (for example, a relative or friend) provides evidence to a health worker about the adult's most recent view, which would lead a reasonable person to conclude that the adult was unwilling for the part to be used for transplantation. Section 6D(2)(d)(ii) provides that deemed authorisation does not apply in relation to a non-excepted part of an adult's body where a person provides evidence to a health worker that would lead a reasonable person to conclude that, if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be used for transplantation.

Section 8 – Non-resident adult: authorisation for transplantation by nearest relative

58. Section 8 of the Bill inserts section 6E into the 2006 Act. New section 6E(1) provides that the nearest relative¹⁶ of a non-resident adult may authorise the removal and use of a part of the adult's body after the adult's death for transplantation. This is only where there is not an express authorisation by the adult for the removal and use of any part of the adult's body for transplantation, and no opt-out declaration by the adult as respects removal and use of the part for transplantation, in force at the relevant time.¹⁷

59. Authorisation may only be given by a nearest relative under subsection (1) where the nearest relative has no actual knowledge that the adult's most recent view was that the adult was unwilling for the part to be removed and used for transplantation, or if the adult were capable of making a decision about removal and use of the part, the adult would be unwilling in the circumstances for the part to be removed and used for transplantation.

60. In addition, subsection (1)(c) of new section 6E provides that an authorisation may be given where the nearest relative is satisfied that the adult was not unwilling for the part to be removed

¹⁵ Laid in draft and approved by a resolution of the Scottish Parliament before regulations are made; section 29 of ILRA.

¹⁶ Nearest relative is defined in section 50(1) of the 2006 Act.

¹⁷ New section 16K, inserted by section 26 of the Bill.

and used for transplantation and if the adult were capable of making a decision about removal and use of the part, the adult would not be unwilling in the circumstances for the part to be removed and used for transplantation. The nearest relative has to have had regard to any evidence referred to in new section 16H(6)(a) and (b) (information about the adult's views given by a person who has said they want to provide this).

61. The fact that there is in force no express authorisation by the adult is not to be regarded as unwillingness by the adult (subsection (2)). The authorisation by the nearest relative must be in writing and signed, or given orally to a health worker and after the authorisation is given it may not be withdrawn (subsections (3) and (4)).

Section 9 – Adult incapable of understanding deemed authorisation: authorisation for transplantation by nearest relative

62. Section 9 of the Bill inserts section 6F into the 2006 Act which makes similar provision to new section 6E, enabling a nearest relative to authorise removal and use of part of an adult's body for transplantation where the adult is incapable of understanding the nature and consequences of deemed authorisation.

63. There is an additional requirement in new section 6F that the nearest relative must have regard to the adult's past wishes and feelings, so far as reasonably ascertainable (subsection (3)). This further enables the views of the adult to be taken into account even where this may not have been an express view on donation.

Section 10 – Excepted body parts: authorisation for transplantation by nearest relative

64. Section 10 of the Bill inserts new section 6G into the 2006 Act. The new section applies where deemed authorisation applies under new section 6D(1) and enables nearest relatives to authorise removal and use of an excepted body part subject to similar requirements in new section 6E (authorisation for transplantation by a nearest relative of a non-resident adult).

Section 11 – Authorisation for purposes other than transplantation by nearest relative

65. The 2006 Act allows authorisation for removal and use of parts of the body of a deceased adult to be used for the purposes of research, education and training and audit or quality assurance. Quality assurance is added to the purposes for which authorisation may be given under section 6 of the 2006 Act (see paragraph 97).

66. Under the current system, authorisation can be given by the adult (section 6(1) of the 2006 Act) or by an adult's nearest relative (section 7 of the 2006 Act) for any of the purposes in section 3(1).

67. Under the new system of authorisation introduced by the Bill, section 6(1) of the 2006 Act (as amended by the Bill) will continue to allow an adult to authorise expressly for any of the section 3(1) purposes. Deemed authorisation only applies to authorisation for the removal and use of body parts for transplantation (new section 6D inserted by section 7 of the Bill). Section 11 of the Bill adds new section 6H into the 2006 Act which will allow the nearest relative of an adult to authorise removal and use of a part of the adult's body for one or more of the purposes in section 3(1)(b) to

(d) but only where there is not an express authorisation in force for removal and use of any part for the purpose in question, there is no opt-out declaration in force for the removal and use of the part for the purpose in question and there is no opt-out declaration in force for the removal and use of the part for transplantation. This will allow authorisation by a nearest relative for these purposes where authorisation for the purpose of transplantation is deemed, and also where there is in place an express authorisation e.g. for the purpose of transplantation but not for the purpose in question. It also makes clear that if there is an opt-out declaration in force for transplantation, removal would not take place for the other purposes.

68. The nearest relative may also only authorise where the relative has no actual knowledge that the adult would be unwilling for the part to be removed for the purpose in question or that, if the adult were capable of making a decision, the adult would not have been unwilling in the circumstances for the part to be removed. The nearest relative is also required when taking the decision to authorise removal to be satisfied that the adult was not unwilling (or would not have been unwilling in the circumstances), having regard to any evidence referred to in new section 16H(6)(a) and (b) (information about the adult's views given by a person who has said they want to provide this).

69. An authorisation by a nearest relative under new section 6H may be withdrawn, and the withdrawal must be in writing and signed or given orally to a health worker (subsections (5) and (6)).

70. Section 7 of the 2006 Act, which makes provision about nearest relative authorisation for adults, including for transplantation, is repealed by section 11(3). This will be commenced at the same time as the provisions introducing deemed authorisation.

Chapter 3 – Authorisation by or on behalf of child

71. Chapter 3 includes provisions which amend the 2006 Act and make changes to the existing provisions, along with including specific new provisions, in relation to authorisation by or on behalf of a child. These include aligning some of the provisions with those relating to authorisation by adults and introducing requirements that a child's most recent view is taken into account where authorisation is given by a person with parental rights and parental responsibilities ("PRRs").

Section 12 – Authorisation by child 12 years of age or over

Section 8 of the 2006 Act – Authorisation: child 12 years of age or over

72. Section 12 of the Bill amends section 8 of the 2006 Act and also inserts new section 8A. Section 8 enables a child aged 12 years or over to authorise the removal and use of parts of the child's body after death for one or more of the purposes in section 3(1) of the 2006 Act. The amendments made by section 12 include provision the same as those for adults in section 6 of the 2006 Act about how an authorisation may be given and to whom.

73. Section 12(2) inserts subsection (1A) which provides that an authorisation by a child aged 12 years or over for transplantation must be in writing or, if given to the register organisation, be given orally or in writing. This is similar to the provisions for adults (see paragraphs 36 - 38). New subsection (1A)(b) provides that if it is for another of the purposes listed in section 3(1) it

must be in writing. Section 12(2) also inserts new subsection (1B) which provides that an authorisation by a child under section 8(1) is to be treated as an express authorisation made by an adult under section 6(1) once the child becomes an adult. Section 8(2) of the 2006 Act, which currently makes provision about the way an authorisation is to be given by a child (12 years of age or over), is repealed.

Section 8A - Withdrawal of authorisation: child 12 years of age or over

74. New section 8A is inserted after section 8 of the 2006 Act by section 12(4) of the Bill. This, again, makes similar provision to adults in relation to authorisation by a child 12 years of age or over. Section 8A enables an authorisation made by the child under 8(1) of the 2006 Act to be withdrawn in writing or if authorisation was given to the register organisation, then withdrawal may be given orally or in writing to the register organisation. If there is in force an authorisation under section 8(1) for removal and use of a part of the child's body for a purpose referred to in section 3(1), and the child subsequently makes a declaration under new section 8B(1) (opt-out declaration, see paragraph 76) with regard to removal and use of the part for that purpose, then the authorisation is treated as withdrawn so far as it relates to removal and use of the part for that purpose. It otherwise remains in force.

75. Where there is an authorisation in force by virtue of section 8(1) and evidence is provided by a person to a health worker that would lead a reasonable person to conclude that the child's most recent view was that the child was unwilling for the part to be removed and used for that purpose, or that if the child was capable of making a decision the child would be unwilling in the circumstances¹⁸ for the part to be removed and used for that purpose, then the authorisation is treated as being withdrawn so far as it relates to removal and use of the part for that purpose. It otherwise remains in force (so far as other body parts are concerned for example) and is treated as being in force at the relevant time for the purpose of section 8D(1)(a)(i) (authorisation by person with parental rights and responsibilities) so would not permit an authorisation by a person with PRRs, and section 16I(2)(a)(ii) (duty to inquire). It would also remain in force for the purposes of authorising pre-death procedures in terms of section 16F(1)(e) (see Chapter 5 – paragraphs 101 to 115).

Section 13 – Opt-out declaration: child 12 years of age or over

Section 8B – opt-out declaration: child 12 years of age or over

76. Section 13 of the Bill inserts sections 8B and 8C after section 8A of the 2006 Act (inserted by section 12 of the Bill). Subsection (1) of inserted section 8B provides that a child aged 12 years or over may make a declaration that the child does not authorise removal and use of part of the child's body for one or more of the purposes in section 3(1) of the 2006 Act ("opt – out declaration"). This, again, is similar to the provisions for adults. Subsection (2) provides that if such a declaration is in force, the part must not be removed and used for that purpose. New section 8B(3) makes provision about how and to whom an opt-out declaration may be made. If it is for transplantation, it must be in writing or given to the register organisation orally or in writing. Subsection (3)(b) provides that if it is for another of the purposes listed in section 3(1) it must be in writing.

¹⁸ See paragraph 41 for an example of circumstances.

77. Similar to an authorisation under section 8 (see paragraph 73), subsection (4) makes it clear that a declaration made by a child under new section 8B(1) is to be treated as an opt-out declaration made by an adult under section 6B(1) once the child becomes an adult.

Section 8C - Withdrawal of opt-out declaration: child 12 years of age or over

78. New section 8C provides that a declaration made by virtue of section 8B(1) (opt-out declaration) may be withdrawn by the child in writing or if the opt-out declaration was given to the register organisation, then withdrawal may be given orally or in writing to the register organisation. Subsections (2) and (3) provide that if there is in force a declaration by virtue of section 8B(1) with regards to removal and use of a part of the child's body for a purpose referred to in section 3(1), and the child subsequently makes an authorisation by virtue of 8(1) for removal and use of the part for that purpose then the declaration is treated as withdrawn so far as it relates to removal and use of the part for that purpose and otherwise remains in force.

79. Subsections (4) and (5) provide that where there is an opt-out declaration in force and evidence is provided by a person to a health worker that would lead a reasonable person to conclude that the child's most recent view was that the child was willing for the part to be removed and used for that purpose, or that if the child was capable of making a decision the child would be willing in the circumstances of death for the part to be removed and used for that purpose, then the declaration is treated as being withdrawn so far as it relates to removal and use of the part for that purpose. It otherwise remains in force and is treated as being in force at the relevant time for the purpose of section 8D(1)(a)(ii) and (iii) (authorisation by person with PRRs) so would preclude authorisation for the matters still covered by the declaration and section 16I(2)(a)(ii) (duty to inquire – whether there is an opt-out declaration in force).

80. Subsections (6) and (7) provide that, to the extent that the child's declaration is treated as withdrawn by virtue of subsection (5) then the child is treated as having authorised removal and use of the part for that purpose and that authorisation is treated as being in force at the relevant time for the purpose of section 8D(1)(a)(i) (authorisation by person with PRRs) so would also preclude authorisation in these circumstances, and section 16I(2)(a)(i) (duty to inquire). The authorisation would also be in force for the purposes of authorising pre-death procedures in terms of section 16F(1)(e) (see Chapter 5 – paragraphs 101 to 115).

Section 14 – Authorisation by person with parental rights and responsibilities: child 12 years of age or over

81. Section 14 of the Bill adds new section 8D to the 2006 Act. It provides that a person who, at the relevant time, has PRRs in relation to a child may authorise the removal and use of a part of the child's body after the child's death for one or more of the purposes referred to in section 3(1) of the 2006 Act (e.g. transplantation, research etc.). This is subject to certain conditions set out in new section 8D(1)(a) to (c). It replaces the current provisions in the 2006 Act which enable a person with PRRs to authorise removal and use of body parts for a child 12 years of age or over (section 9 of the 2006 Act is therefore repealed by section 14(3)). Amended section 8 and new sections 8A to 8C operate to enable a decision to be in place by a child aged 12 or over, and new section 8D will only apply if there is no authorisation or declaration in place by virtue of section 8(1) or 8B.

82. New section 8D(1)(a) of the 2006 Act provides that authorisation by a person with PRRs can be given where there is in force at the relevant time no authorisation by virtue of section 8(1) of the 2006 Act by the child of removal and use of any part for the purpose in question. There also has to be no declaration by virtue of section 8B(1) (“opt-out declaration”) by the child as respects removal and use of the part for the purpose in question or if transplantation is not the purpose in question, no declaration by the child by virtue of section 8B(1) of the 2006 Act by the child as respects removal and use of the part for transplantation.

83. New section 8D(1)(b) and (c) also provide that for a person with PRRs to give authorisation the person must have no actual knowledge that the child’s most recent view was that the child was unwilling for the part to be removed and used for the purpose in question, or if the child were capable of making a decision about removal and use of the part, the child would be unwilling in the circumstances of death for the part to be removed and used for the purpose in question¹⁹. The person with PRRs, having had regard to any evidence referred to in section 16I(4)(a) and (b) (evidence from a person who has indicated to a health worker that the person wishes to provide evidence about the child’s most recent views on willingness or willingness in the particular circumstances) must also be satisfied that the child was not unwilling for the part to be removed and used for the purpose in question and if the child were capable of making a decision the child would not be unwilling in the circumstances for the part to be removed and used for the purpose in question.

84. Subsection (2) of new section 8D of the 2006 Act provides that, for the purposes of subsection (1)(b) and (c), the mere fact that there is in force no authorisation by virtue of section 8(1) by the child of removal and use of any part of the child’s body for the purpose in question is not to be regarded as unwillingness by the child. Subsection (3) makes provision about how an authorisation may be given and to whom. Subsection (4) provides that an authorisation given by a person with PRRs under new section 8D(1) may be withdrawn in writing by the person who gave the authorisation. However, to the extent that an authorisation by virtue of subsection (1) is for the purposes of transplantation, it may not be withdrawn (subsection (6)).

Section 15 – Authorisation by person with parental rights and responsibilities: child under 12 years of age

85. Section 10 of the 2006 Act (as amended by section 4 of the Bill) enables a person with PRRs at the relevant time²⁰ in relation to a child (who is under 12 years of age also at the relevant time) to authorise removal and use of a part of the child’s body for one or more purposes in section 3(1) of the 2006 Act (e.g. transplantation, research etc.). Section 15 of the Bill amends section 10 of the 2006 Act to provide that the child’s view, where known, should be taken into account where authorisation is given for a child aged under 12 years of age. This aligns, and makes similar provisions on authorisation for children under 12 years of age with those 12 years of age or over, and adults. An authorisation may be withdrawn, apart from for the purposes of transplantation (section 10(3) of the 2006 Act prevents this). Section 15(4) of the Bill also repeals section 10(2) of the 2006 Act which is superseded by new provisions in amended section 10 of the 2006 Act

¹⁹ See paragraph 41 for an example of circumstances.

²⁰ Section 10 is amended by section 4(5) of the Bill to include reference to “relevant time”; defined in new section 16K(2) inserted by section 26(2) of the Bill.

about how and to whom authorisations and withdrawal of authorisations may be given and withdrawn.

Section 16 – Authorisation by other persons: children

86. Section 16 of the Bill inserts new section 10A into the 2006 Act. This enables people other than those with PRRs to authorise removal and use of a child’s body parts after death where there is no one with PRRs due to death or where the person with PRRs is incapacitated. For example, if parents and child are all critically ill and expected to die as a result of a car accident. New section 10A(4) lists the people who would be able to authorise in these circumstances, including a person who has been recently involved in the upbringing of the child, a sibling or a grandparent. In common with the nearest relative hierarchy provided in the 2006 Act,²¹ the people who may authorise in these circumstances rank in the order listed in subsection (4) (subsection (9)).

87. Similar conditions apply to authorisation by a person under new section 10A to those which apply where a person with PRRs is authorising both for a child aged under 12 years and 12 years or over. This includes only enabling authorisation where there is no authorisation or opt-out declaration in force (child 12 years of age or over); and ensuring that the child’s view should be taken into account before authorisation is given (section 10A(1)(c) and (d) and (3)).

88. Subsection (11) provides that for the purposes of authorisation a person’s relationship with the child is to be left out of account if the person is under 16 years of age, the person does not wish or is unable to make a decision about authorisation or it is not reasonably practicable to communicate with the person in the time available.

Section 17 – Functions of local authority with parental rights and responsibilities

89. Section 17(2) amends the 2006 Act to repeal the words “but who is not a local authority” in section 10(1) of the 2006 Act. This, along with the repeal of section 9²², removes the restriction on local authorities being able to authorise donation and means a local authority²³ which holds PRRs in relation to a child is able to authorise the removal and use of a part of that child’s body after death.

90. New section 10B is added by subsection (3) and places duties on a local authority to consult in relation to decisions about authorisation. Where there is in place an authorisation or an opt-out declaration by a child and a local authority is consulted about the child’s most recent views, the local authority must (so far as reasonably practicable) seek the views of the child’s parents and other people who were involved in the child’s life.

91. Duties are also placed on a local authority with PRRs who may be authorising donation, (so far as reasonably practicable) to find out the views of the child, the child’s parents and other

²¹ Section 50(1) and (4) of the 2006 Act.

²² Section 9 is repealed by section 14(3) of the Bill.

²³ Section 60 of the 2006 Act defines local authority as a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994.

people who were involved in the child's life, and have regard to these when deciding whether to authorise (new section 10B(4) and (5)).

Chapter 4 – Authorisations: general

92. Chapter 4 includes some general provision about decisions about authorisation for donation.

Section 18 – Power to make provision about decisions

93. Section 18 of the Bill amends the 2006 Act by inserting section 10C after section 10B (inserted by section 17 of the Bill). New section 10C(1) enables the Scottish Ministers to make provision in regulations about the manner in which decisions are given and to whom. The decisions to which the regulations may relate are authorisations for the removal and use of body parts for purposes set out in section 3(1) of the 2006 Act, declarations that authorisation is not given (opt-out declarations) and authorisation for pre-death procedures relating to transplantation (see Chapter 5).

94. The Bill makes changes to the provisions in the 2006 Act which currently set out how decisions about authorisation may be given, and to whom. For example, that express authorisations for transplantation may be in writing or given to the register organisation orally or in writing, or if the express authorisation is for another purpose it must be in writing (section 5(2) which inserts new section 6(1A) into the 2006 Act). This is not only to make clear how and to whom decisions about authorisation may be given, but also to reflect current practice and processes which are available to give effect to decisions including how the ODR operates. This has changed since the 2006 Act came into force, including the addition of the option to “opt-out”. Regulations under section 10C(1) will enable the requirements about the way in which decisions may be made to keep pace with developments in practice and processes.

95. Section 10C(2) provides that regulations under subsection (1) may modify this Act. Section 18(3) of the Bill provides that regulations made under 10C(1) are subject to affirmative procedure.

Section 19 – Withdrawal by person who is blind or unable to write

96. The 2006 Act includes provisions in relation to withdrawal of authorisations by people who are blind or unable to write. Section 19 of the Bill adds provision to the 2006 Act in relation to how a person who is blind or unable to write may withdraw an authorisation or an opt-out declaration made by virtue of the new provisions included in this Bill. In light of these changes section 19(3) and (4) of the Bill repeals the current provisions in sections 6 and 8 of the 2006 Act which provide for withdrawal of authorisation by people who are blind or unable to write.

Section 20 – Removal and use of part of body for quality assurance purposes

97. Section 20 of the Bill adds the words “or quality assurance” after the word “audit” in section 3(1)(d) of the 2006 Act. This makes it clear that the purposes for which a person may authorise removal and use of body parts includes quality assurance.

Section 21 – Removal of part of body of deceased person: further requirements

98. Section 21 of the Bill amends section 11 of the 2006 Act to clarify the role of the registered medical practitioner in cases where another person has been authorised to remove tissue and reflect the changes made in relation to authorisation of removal and use of part of a body of deceased person by the Bill. Subsection (4) is amended to continue to ensure that the person who proposes to carry out the removal of the body part is satisfied that the removal is appropriately authorised.

99. Section 21(1), (1A), (1C) and (2) of the Bill amends section 11(1) and (2) of the 2006 Act to make it clear that a part of the body of a deceased person may be removed by a person authorised to do so in accordance with regulations, that the regulations may authorise a description of persons and that the regulations can also enable a registered medical practitioner to give such a general authorisation of a person or description of persons. Section 11(3)(b) is repealed, removing the implication that authorisations must only be given on a case by case basis. Section 11(4) ensures that it is only the person who proposes to remove the body part who is required to be satisfied that the requirements of section 11(4) are met.

100. New subsections (4A) to (4C) are added and set out what is sufficient for the person who proposes to carry out the removal of the body parts to be satisfied that the correct authorisation for the purposes of removal is in place. New subsection (4B) sets out that the person, must be satisfied that there is an appropriate record of various matters relevant to the authorisation, and new subsection (4C) provides that the person, must also be satisfied that they have no reason to believe that appropriate and correct authorisations are not in place to allow them to proceed with removal of the part of the body in question.

Chapter 5 - Pre-death procedures relating to transplantation

101. Chapter 5 sets out a system of authorisation for “pre-death procedures”, which are medical procedures carried out primarily for the purpose of increasing the likelihood of successful transplantation of a part of a person’s body after death.

Section 22 – Pre-death procedures relating to transplantation

102. Section 22 of the Bill adds sections 16A to 16G to the 2006 Act.

Section 16A – Meaning of “pre-death procedure”, “Type A procedure” and “Type B procedure”

103. New section 16A defines “pre-death procedure” as a medical procedure which is (a) 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 (b) which is not for the primary purpose of safeguarding or promoting the physical or mental health of the person. This makes it clear that it is not a procedure which would be carried out as part of the usual care of a person, and which may incidentally benefit transplantation. Further provision is made in subsection (2) to categorise pre-death procedures as “Type A” and “Type B” procedures, which are procedures or types of procedure specified in regulations made by the Scottish Ministers.

Section 16B – Type A procedures

104. New section 16B enables the Scottish Ministers to specify “Type A procedures” in regulations subject to affirmative procedure,²⁴ and only after consultation. Subsection (1A) enables the regulations to specify the manner in which a procedure must be performed in order for it to be categorised as a Type A procedure. Subsection (2) restricts Type A procedures to those in respect of which the Scottish Ministers consider it appropriate that the carrying out of the procedure or the category of procedure should be in accordance with new section 16E (which includes that the procedure is authorised if there is an authorisation in place for removal and use of body parts for transplantation (express or deemed)).

Section 16C – Type B procedures

105. Section 16C enables the Scottish Ministers to specify a pre-death procedure or category of procedure (other than one specified as a Type A procedure) as a “Type B procedure” in regulations, after consultation and subject to affirmative procedure. Subsection (2) provides that regulations made under subsection (1) may also make provision about (i) the circumstances in which Type B procedures may be carried out, (ii) the way in which the carrying out of Type B procedures may be authorised, (iii) the process for authorisation of Type B procedures, and (iv) the carrying out of Type B procedures. Different provision may be made for different procedures or categories of procedure. Subsection (3) provides that regulations under subsection (1) may specify a pre-death procedure (or category of procedure) as a Type B procedure only if the Scottish Ministers consider that it is appropriate that the procedure or, as the case may be, the category of procedure should be subject to provision mentioned in subsection (2)(a)(i) to (iv).

106. A distinction is made between Type A and Type B procedures in the respective enabling powers. The Bill sets out the minimum standards as to authorisation and pre-conditions, and procedures will be prescribed as Type A only where Ministers are of the view that the requirements set out in the Bill are sufficient in light of the nature of the procedure in question and also how it is performed i.e. minimally invasive or routine, and which people may be expected to readily understand (on the basis of public information campaigns) to be undertaken in order for donation and transplantation to be successful. Where Ministers are not of this view in relation to a particular procedure but are content that the procedure may be carried out subject to appropriate safeguards, including requirements as to authorisation, the procedure may be prescribed as a Type B procedure.

New section 16D – Restrictions on carrying out of pre-death procedures

107. Section 16D restricts the carrying out of pre -death procedures to those which are Type A or Type B procedures and, therefore, subject to the provisions of Part 5.

New section 16E – Carrying out of Type A and Type B procedures

108. Subsection (1) sets out the circumstances in which Type A or Type B procedures may be carried out. This includes that the health worker who is to carry out the procedure, or who has authorised a person to carry out the procedure, has no actual knowledge that the person was unwilling for the procedure to be carried out, has had regard to the person’s past wishes and

²⁴ Laid in draft and approved by a resolution of the Scottish Parliament before regulations are made; section 29 of ILRA.

feelings so far as reasonably ascertainable (having had regard, in particular, to any evidence about the adult or child's most recent views on the carrying out of a pre-death procedure), and is satisfied that if the person were capable of making a decision about authorisation of the procedure, the person would not be unwilling for the procedure to be carried out. Authorisation for removal and use of a part of a body for transplantation also has to be in place.

109. In the case of a Type A procedure, the carrying out of the procedure is authorised under new section 16F, which includes that it can be expressly authorised, authorised by a nearest relative (for an adult) or person with PRRs (for a child) or it is authorised where there is in place an express authorisation for donation by an adult or authorisation by a child aged 12 or over. It may also be authorised in the case of an adult where authorisation for transplantation is deemed (under new section 6D). For a Type B procedure, the carrying out of the procedure may be authorised only in accordance with any provision made under section 16C(1) in relation to that procedure (or category of procedure).

110. Subsection (2) sets out requirements which have to be met before a pre-death procedure may be carried out (Type A or Type B). These are met if— (a) in the view of the health worker primarily responsible for the person's medical treatment, the person is likely to die imminently (including as a result of the withdrawal of life-sustaining treatment), (b) where the person is receiving life-sustaining treatment, the decision to withdraw that treatment has been taken by that health worker, and (c) the carrying out of the procedure is necessary to ascertain the suitability of the organ/tissue for transplantation or to increase the likelihood of successful transplantation. It is also a requirement that the carrying out of the procedure is not likely to cause more than minimal discomfort to the person, and the carrying out of the procedure is not likely to harm the person.

Section 16F – Authorisation of Type A procedures

111. Section 16F sets out how Type A procedures are authorised for the purposes of section 16E (authorisation being a pre-condition of the procedure being able to be carried out). The procedure may be expressly authorised by the person, authorised by a nearest relative (adult) or person with PRRs (child). It is also authorised where there is in place an express authorisation for donation by an adult or an authorisation by a child aged 12 or over, or in the case of an adult where authorisation for transplantation is deemed (under section 6D).

112. The nearest relative of an adult may not authorise the carrying out of a Type A procedure if the relative has actual knowledge that the adult was unwilling for the pre-death procedure to be carried out or unless the relative has had regard to the person's past wishes (so far as reasonably ascertainable having regard to any evidence provided by a person under section 16H(6)(c)) and is satisfied that if the adult had been capable of making a decision about the authorisation of the procedure, the person would not be unwilling for it to be carried out.

113. Section 16F(3) provides that for the purpose of subsection (1)(c) (authorisation for a child) a person may not give authorisation (a) if the person has actual knowledge that the child was unwilling for the procedure to be carried out or (b) unless the person has had regard to the child's past wishes and feelings (so far as reasonably ascertainable having regard to any evidence provided by another person under section 16I(4)(c)) and is satisfied that if the child were capable of making a decision about authorisation the child would not have been unwilling for the procedure to be carried out.

114. Where a person has expressly authorised the carrying out of one or more Type A procedures under subsection (1)(a), subsection (1)(f) does not authorise the carrying out of a Type A procedure not mentioned in that authorisation. An authorisation under subsection (1)(a), (b) or (c) must be in writing or given orally to a health worker.

New section 16G – Authorisation of Type A procedures: transitory provision

115. In the event that the provisions introducing pre-death procedures come into force before the provisions introducing deemed authorisation (new section 6D inserted by section 7 of the Bill) come into force, new section 16G provides that authorisation for pre-death procedures may be given expressly by an adult or given by a child aged 12 or over, or may be given by a nearest relative who is entitled to authorise the removal and use of a part of the adult's body for transplantation or, in the case of a child, a person who would be entitled to authorise the removal and use of a part of the child's body for transplantation. This is subject to the requirements in section 16F(2) and (3), though the duty to have regard to evidence obtained by a health worker in sections 16H and 16I about the person's views on pre-death procedures does not apply as these will apply in the context of introduction of "deemed authorisation", so will be commenced along with those provisions.

Chapter 6 – Duty to inquire

116. Chapter 6 includes provisions for duties on health workers to inquire into the views of the potential donor in relation to the removal and use of parts of the person's body for the purposes set out in section 3(1) of the 2006 Act (e.g. transplantation, research) and in relation to the carrying out of pre-death procedures.

Section 23 – Duty to inquire

117. Section 23 of the Bill adds new sections 16H and 16I to the 2006 Act.

Section 16H – Duty to inquire: adult

118. New section 16H(1) requires that a health worker (defined in new section 16J, added by section 26 of the Bill) must carry out the inquiries specified in section 16H(2) before the earlier of the carrying out of a pre-death procedure in relation to an adult or the removal of part of the body of a deceased adult for any of the purposes referred to in section 3(1).

119. The health worker must take reasonable steps to inquire as to whether there is in force an express authorisation or an opt-out declaration by the adult. Where neither is in force at the relevant time (relevant time is defined in new section 16K(2)), subsection (2)(b) requires the health worker to inquire into whether the adult is a non-resident adult or an adult who is incapable of understanding the nature and consequences of deemed authorisation. In making inquiries as to whether an adult is incapable (in these circumstances), the health worker must consult (so far as reasonably practicable) any person who has indicated that they wish to provide evidence in relation to the adult's capacity (subsection (4)). Where it is established that an adult is incapable of understanding the nature and consequences of deemed authorisation an inquiry must also be made into the adult's past wishes and feelings so far as reasonably ascertainable (paragraph (c) of subsection (2)).

120. In any case the health worker must inquire, so far as reasonably practicable, into the adult's most recent views in relation to carrying out pre-death procedures and the removal and use of part of an adult's body for a purpose in section 3(1) (subsection (2)(d)). These inquiries are to be made with the nearest relative of the adult. In addition, subsection (5)(b) and (c) also requires that inquiries are to include consulting any person who has indicated to a health worker that they wish to provide evidence mentioned in subsection (6) (the adult's views on willingness or unwillingness for removal and use of a part of their body for the purposes in section 3(1), including in the particular circumstances and on the carrying out of pre-death procedures). Inquiries must also be made with such other person as the health worker considers appropriate, which could include another person who the health worker is aware of and may have evidence about the adult's view, but this is only if it is reasonably practicable to do so.

Section 16I – Duty to inquire: child

121. New section 16I (Duty to inquire: child) is added after new section 16H and makes provision about inquiries which must be made in relation to a child. These are similar to the requirements which apply in relation to an adult and include that a health worker must carry out the inquiries before the earlier of the carrying out of a pre-death procedure in relation to a child or the removal of part of the body of a deceased child for any of the purposes referred to in section 3(1).

122. Subsection (2)(a) provides that the health worker must take reasonable steps to inquire as to whether there is in force an authorisation by virtue of section 8(1) or a declaration by virtue of section 8B(1) by the child. Subsection (2)(b) provides that the health worker must inquire into the child's most recent views in relation to the carrying out of pre-death procedures in relation to the child and the removal and use of a part of the child's body for a purpose referred to in section 3(1) by consulting, so far as is reasonably practicable, the persons referred to in subsection (3).

123. Subsection (3) provides that the persons referred to in subsection (2)(b) are a person who, at the relevant time, has PRRs in relation to the child; if a person is entitled to authorise removal and use of a part of the child's body by virtue of section 10A, that person (person authorised where people with PRRs have died or are incapable of authorising); any person who has indicated to a health worker a wish to provide evidence mentioned in subsection (4) and such other persons as the health worker considers appropriate.

124. Subsection (4) provides that the evidence referred to in subsection (3)(c) is evidence that the child's most recent view was that the child was willing, or as the case may be, unwilling for a part of the child's body to be removed and used for a purpose referred to in section 3(1); that if the child were capable of making a decision about removal and use of a part, the child would be willing, or as the case may be, unwilling in the circumstances for part of the child's body to be removed and used for a purpose referred to in section 3(1); about the child's views in relation to the carrying out of a pre-death procedure in relation to the child.

PART 4 – GENERAL AND FINAL PROVISIONS

Section 24 – Meaning of “the 2006 Act”

125. Section 24 provides that in this Bill “the 2006 Act” means the Human Tissue (Scotland) Act 2006.

Section 25 – Ancillary provision

126. Section 25 enables the Scottish Ministers by regulations to make any incidental, supplementary, consequential, transitional, transitory or saving provision they consider appropriate for the purposes of, in connection with or for giving full effect to this Act or any provision made under it. Subsection (2) provides that regulations under this section may modify any enactment (including this Act) or make different provision for different purposes. Subsection (3) provides that regulations under subsection (1) which contain provision adding to, replacing or omitting any part of the text of an Act are subject to the affirmative procedure. Subsection (4) provides that otherwise, regulations under subsection (1) are subject to the negative procedure.

Section 26 – Interpretation

127. Section 26(2) of the Bill adds an interpretation section to the 2006 Act (new section 16K) which will apply to sections 1 to 16K of the 2006 Act.

128. Subsection (1A) inserts new section 16J which sets out the meaning of “health worker” for the purposes of carrying out the functions within the Act, which include the duty to inquire, the carrying out of pre-death procedures and receiving authorisation and evidence of views in relation to the authorisation process. Subsection (1) provides that a health worker is a registered medical practitioner,²⁷ a registered nurse,²⁸ or a person (or person within a description) authorised to exercise the functions of a health worker. Subsections (2) to (7) set out who may make such an authorisation, the parameters or conditions of such an authorisation and how such an authorisation may be revoked.

129. The persons who may authorise a person to exercise the functions are listed in subsection (2) and are a registered medical practitioner, a registered nurse, a Health Board, a Special Health Board and the Common Services Agency for the Scottish Health Service. Subsection (3) provides how such an authorisation may be applied, namely that a person or description of person may exercise some or all of the functions; may exercise functions in relation to particular cases or classes of case and may be made in relation to different persons or classes of person to exercise different functions. In practice this enables general authorisations to be made, rather than requiring that they are given individually to relevant persons. Subsection (4) provides that an authorisation may only be given if the authoriser considers that the person or description of person has the appropriate skills, qualifications and experience to carry out the function(s) in question. Subsection (5) provides that if an authorisation is given to a description of person by a person other than a registered medical practitioner or registered nurse then it may be revoked only by the person who gave the authorisation; in all other cases it may be revoked by any person listed in subsection (2). Subsections (6) and (7) provide that Scottish Ministers may give general or specific directions to persons listed in subsection (2) in relation to such authorisations and those directions must be complied with, which could for example be in relation to specific skills, qualifications or expertise

²⁷ “Registered medical practitioner” means a fully registered person within the meaning of the Medical Act 1983 (see schedule 2 of The Scotland Act 1998 (Transitory and Transitional Provisions) (Publication and Interpretation etc. of Acts of the Scottish Parliament) Order 1999).

²⁸ “Registered”, in relation to nurses, means registered in the register maintained by the United Kingdom Council for Nursing, Midwifery and Health Visiting by virtue of qualifications in nursing (see schedule 2 of The Scotland Act 1998 (Transitory and Transitional Provisions) (Publication and Interpretation etc. of Acts of the Scottish Parliament) Order 1999).

a person must have in order to be authorised. Subsection (8) provides that Scottish Ministers may make regulations to modify who is a health worker or who may make authorisations.

130. A definition of “relevant time” is also provided (subsection (2)). This applies to sections 1 to 16K, and section 50 (nearest relative). In relation to a living person it is when, in the view of the health worker who is primarily responsible for the medical treatment of the person (i.e. any procedure or treatment designed to safeguard or promote the person’s physical or mental health, see the definition in section 16K(1)), the person is likely die imminently (including as a result of withdrawal of life-sustaining treatment), the decision has been taken to withdraw that treatment (if the person is receiving treatment) by that health worker and, if the person is 12 years of age or over, the health worker is of the opinion that the person is incapable by reason of ill health of making a decision about the removal and use of a part of the person’s body for a purpose referred to in section 3(1).

131. If the person is deceased, relevant time means immediately before the person’s death.

132. Subsection (3) repeals sections 6(6), 8(7) and 15(2) of the 2006 Act which provide definitions of “writing” now updated in new section 16K(1). Subsection (4) repeals the definitions of “Health Board” and “Special Health Board” in section 13(5) as the definitions are now included in section 16K(1).

Section 27 – Minor and consequential modifications

133. Section 27 makes a number of minor and consequential amendments to the Anatomy Act 1984, the Adults with Incapacity (Scotland) Act 2000 and the 2006 Act.

Section 27A – Review and report on operation of Act

134. Section 27A provides for Scottish Ministers to review and report on the operation of the Act 5 years beginning the date of Royal Assent. The report must set out the objectives to be achieved by deemed authorisation for transplantation, the extent to which the objectives have been delivered and remain appropriate and an assessment of the support provided to relatives of donors before and after transplantation.

Section 28 – Commencement

135. Subsection (1) of section 28 provides that this section and sections 24, 25 and 29 come into force on the day after Royal Assent. Subsection (2) provides that the rest of this Act comes into force on such day as the Scottish Ministers may by regulations appoint. Subsection (3) provides that regulations under this section may appoint different days for different purposes. Subsection (4) provides that regulations under this section may include transitional, transitory or saving provision and may make different provision for different purposes.

Section 29 – Short title

136. Section 29 provides that the short title of this Act is the Human Tissue (Authorisation) (Scotland) Act 2019.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32A) as amended at Stage 2

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

REVISED EXPLANATORY NOTES

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