

HUMAN TISSUE (SCOTLAND) ACT 2006

EXPLANATORY NOTES

THE ACT – AN OVERVIEW

Part 3: Tissue Sample Or Organs No Longer Required for Procurator Fiscal Purposes

Section 38 – Tissue sample becoming part of medical records of deceased person

101. **Section 38** provides, in relation to examinations carried out for the purposes of the functions or under the authority of the procurator fiscal on or after the day this section comes into force, that tissue sample retained from such an examination will become part of the medical record of the deceased person once the manager of the relevant establishment (see section 41) receives written notice from the fiscal that the sample is no longer required for the purposes of the functions of the fiscal.

Section 39 – Use of tissue sample which has become part of deceased's medical records

102. **Section 39** provides that where, as a result of receipt of notice under section 38, a tissue sample has become part of the deceased's medical records, it can be used for specified purposes related to diagnosis and audit without authorisation, and for purposes of education, training or research with appropriate authorisation under Part 3, in accordance with section 42, 43, 44, 45 or as the case may be, 46.

Section 40 – Use of organ no longer required for procurator fiscal purposes

103. **Section 40** provides, in relation to examinations carried out for the purposes of the functions or under the authority of the procurator fiscal on or after the day this section comes into force, that an organ removed from the body during such an examination can be retained and used for education, training and research, once the manager of the relevant establishment receives notice from the fiscal that the organ is no longer required for the purposes of the functions of the fiscal; if the subsequent use of the organ for such purposes is authorised in the appropriate manner under Part 3; and if the use is research the research is in addition approved by such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order under the section. The intention is that the order will specify a Research Ethics Committee.

Section 41 – Notice under section 38(2) or 40(2)(a): further provisions

104. **Section 41** sets out the formalities associated with the notification which the fiscal is to send indicating that tissue samples or organs are no longer required for the purposes of the functions of the fiscal. Subsection (1) provides for the ways in which notification may be sent and subsections (2) and (3) provide a definition of the manager of an establishment for the purposes of section 38(2) or 40(2)(a).

Section 42 – Authorisation of use etc after examination: adult

105. **Section 42(1)** provides that an adult may authorise the use of tissue sample, or the retention and use of an organ, which is removed from the adult's body after the adult's death when that sample or organ was removed but is no longer required for the purposes of the functions of the fiscal. The requirement of authorisation applies to use for the purposes of education, training or research. Subsection (2) provides that such authorisation must be in writing and signed by the adult and may be withdrawn in writing signed by the adult. Alternatively, if the adult is blind or unable to write, such authorisation and the withdrawal of such authorisation may be signed by another adult on behalf of the adult who is blind or unable to write. If it is so signed it must be witnessed by one witness. Subsection (3) provides that where a signatory signs authorisation or withdraws authorisation on behalf of an adult in this way, the authorisation or withdrawal must contain a statement signed by the signatory and the witness that the adult expressed the intention to either give or withdraw the authorisation and requested the signatory to sign on his or her behalf. Subsection (4) provides that nothing in the provisions in subsection (2) dealing with authorisation or withdrawal signed by a signatory on the adult's behalf prevents an adult who is blind from giving or withdrawing authorisation without such a signatory under subsection (2).

Section 43 – Authorisation of use etc after examination: adult's nearest relative

106. **Section 43(1)** provides that where no authorisation by the adult of any of the matters referred to in section 42(1) (use of tissue sample or retention and use of an organ which is no longer required for the purposes of the fiscal) is in force immediately before the adult's death, the nearest relative of the deceased adult may authorise one or more of those matters. Authorisation is needed where the use relates to the purposes of education, training or research (sections 39(b)).
107. Subsections (2) and (3) provide that such authorisation by the nearest relative must be in writing, signed by the nearest relative and witnessed by one witness. The authorisation may be withdrawn in writing, signed by the nearest relative and witnessed by one witness. Subsection (2) also provides that, in providing authorisation, the nearest relative must state that they have no actual knowledge that the adult was unwilling for the matter in question to be authorised for the purpose in question.

Section 44 – Authorisation of use etc after examination: child 12 years of age or over

108. **Section 44(1)** provides that a child who is 12 years of age or over may authorise the use of tissue sample, or the retention and use of an organ, which is removed from the child's body after the child's death when that sample or organ was removed but is no longer required for the purposes of the functions of the fiscal. Authorisation is needed where the use relates to the purposes of education, training or research. Subsection (2) provides that such authorisation by the child must be in writing, signed by the child and witnessed by 2 witnesses and may be withdrawn in writing signed by the child. Alternatively, if the child is blind or unable to write, such authorisation and the withdrawal of such authorisation may be signed on behalf of the child. If it is so signed it must be witnessed by one witness. Subsection (3) provides that where a signatory signs authorisation or withdraws authorisation on behalf of a child in this way, the authorisation or withdrawal must contain a statement signed by the signatory and the witness that the child expressed the intention to either give or withdraw the authorisation and requested the signatory to sign on his or her behalf. Subsections (4) and (6) provide that any such authorisation on behalf of a child who is 12 years of age or over who is blind or unable to write must contain or be accompanied by certification from both the signatory and the witness that in their opinion the child understands the effect of the authorisation and is not acting under undue influence in giving it. A similar certification is required from both witnesses to an authorisation which is signed by the child himself or herself under subsection (2). Subsection (5) provides that nothing in the provisions in subsection (2)

dealing with authorisation or withdrawal signed by a signatory on the child's behalf prevents a child who is blind from giving or withdrawing authorisation without such a signatory under subsection (2).

Section 45 – Authorisation of use etc after examination: person with parental rights and responsibilities for child 12 years of age or over

109. **Section 45(1)** provides that if there in force immediately before the death of a child who died 12 years of age or over no authorisation by the child of any of the matters referred to in section 44(1) (use of tissue sample or retention and use of an organ which is no longer required for the purposes of the fiscal) a person who immediately before the child's death had parental rights and responsibilities in relation to the child (but who is not a local authority) may authorise one or more of those matters. Authorisation is needed where the use relates to the purposes of education, training or research.
110. Subsections (2) and (3) provide that such authorisation by the person with parental rights and responsibilities in relation to the child must be in writing, signed by that person and witnessed by 2 witnesses and may be withdrawn in writing, signed by the person who gave the authorisation and witnessed by 2 witnesses. Subsection (2) also provides that, in providing authorisation, the person with parental rights and responsibilities must state that they have no actual knowledge that the child was unwilling for the matter in question to be authorised for the purpose in question.

Section 46 – Authorisation of use etc after examination: person with parental rights and responsibilities for child under 12 years of age

111. **Section 46(1)** provides that where a child dies under 12 years of age, authorisation of one or more of the matters referred to in section 44(1) (use of tissue sample or retention and use of an organ which is no longer required for the purposes of the fiscal) can be given by a person who immediately before the death of the child had parental rights and responsibilities in relation to the child (but who is not a local authority). Authorisation is needed where the use relates to the purposes of education, training or research. Subsection (2) provides that authorisation by the person with parental rights and responsibilities must be in writing, signed by that person and witnessed by 2 witnesses and may be withdrawn in writing, signed by the person who gave authorisation and witnessed by one witness.

Section 47 – Use of tissue sample removed before day on which section 38 comes into force

112. **Section 47** deals with tissue samples removed from the body of a deceased person as a result of an examination carried out for the purposes of the functions or under the authority of the fiscal before section 38 comes into force and held immediately before that day for use for any of the purposes set out in section 39(b) (education, training or research) (whether or not held then also for the purposes of the functions of the fiscal). It provides that such a sample can be retained and used for any of those purposes after the new legislation comes into force without authorisation. Its use for purposes of education, training or research does not preclude its continued use for the purposes of the functions of the fiscal.

Section 48 – Use of organ removed before day on which section 40 comes into force

113. **Section 48** deals with organs removed from the body of a deceased person as a result of an examination carried out for the purposes of the functions or under the authority of the fiscal before section 40 comes into force and held immediately before that day for use for the purposes of existing approved research (whether or not held then also for the purposes of the functions of the fiscal).
114. Subsection (1) provides that such an organ can be retained and used without authorisation for the purposes of the existing approved research or for the purposes of

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education, training or new approved research after the new legislation comes into force. Its use for purposes of education, training or research does not preclude its continued use for the purposes of the functions of the fiscal. Subsection (2) provides that “existing approved research” means research approved before the new legislation (section 40) comes into force by such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order. “New approved research” means research approved after the new legislation (section 40) comes into force by such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order. The intention is that the order will specify that such research is to be approved by a Research Ethics Committee.