

Guidelines for the Blood Transfusion Services

20.2: Consent

<http://www.transfusionguidelines.org/red-book/chapter-20-tissue-banking-selection-of-donors/20-2-consent>

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Consent must be obtained and documented by appropriately trained professionals competent in the issues and processes of tissue donation. No coercion or inducement to donate can be applied during the consent procedure. The statutory requirements for consent are detailed in the relevant national legislation. Further detailed guidance is laid out in the Human Tissue Authority Codes of Practice: Code A Guiding Principles and the Fundamental Principle of Consent⁵, Codes F part one and two⁶, the Code of Practice on the Human Transplantation (Wales) Act 2013⁷, and in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.⁴

Living donors must be competent to give consent before donations can be accepted, and be provided with the opportunity to consider and receive responses to any questions they may have. Where donors are not competent to provide consent, national legislation and the guidance of the Human Tissue Authority (HTA) must be followed. When a deceased person (while alive and competent) has explicitly consented/given authorisation to donation of organs and tissues then that consent/authorisation is sufficient for the activity to be lawful. Where the decision or wishes of the deceased person are unknown, the Human Tissue Authority Codes of Practice should be followed which reflect the legal requirements in each UK nation.

Consent/authorisation where donated tissue is to be used for transplantation must cover retrieval, testing, storage, discard and access to medical records. If the tissue may be used for non-clinical purposes, as specified in the HTA Code of Practice A, specific consent/authorisation must be obtained for this as well. Living donors and families of deceased donors must be informed that information relating to the donation will be stored in accordance with the Data Protection Act (2018)⁸ and may be shared with relevant healthcare professionals.

For deceased donors, information to be supplied to the next of kin regarding various aspects of tissue donation which forms the basis of consent should include the following:

- that reconstruction will be performed following retrieval
- generic information on which tissue is to be retrieved and the clinical purpose to which it is likely to be used
- if tissue is found to be unsuitable for clinical transplantation it will be discarded via local discard policies or, if permission is granted, it may be used for research or educational purposes
- that the donor will be tested for markers of microbial infection including HIV, hepatitis, HTLV and other infections and after individual case assessment, those relevant contacts will be informed in the event of a relevant confirmed positive result
- that details of medical and behavioural history will be sought from additional professional sources and recorded.

Where the Coroner (the Procurator Fiscal in Scotland) is in legal possession of the body, permission must be requested to undertake the retrieval. It is good practice if this can be done in writing.