

Guidelines for the Blood Transfusion Services

20.1: General considerations

<http://aws-lon-jpac.targetservers.uk/red-book/chapter-20-tissue-banking-selection-of-donors/20-1-general-considerations>

20.1: General considerations

The overall responsibility for applying the policies for the selection and care of tissue donors lies with the Tissue Establishment authorised clinician, who must have relevant clinical experience and will be familiar with the various legal statutes and relevant documents which apply to tissue banking (see Chapter 19). The Tissue Establishment authorised clinician must consult with relevant specialist advisors as appropriate.

The authorised clinician will rely on procedures and documentation that enable the appropriate medical and behavioural history to be acquired, to prevent microbial infection and transmission of disease (for example neurodegenerative disease) to the recipient^{1,2}. Decisions on donor assessment should be consistent with JPAC *Donor Selection Guidelines*.³

Tissues must be procured, transported, processed, stored, and distributed according to the regulatory requirements specified in Chapter 19 of these guidelines.

Procedures must be in place to document a complete audit trail from donor to recipient. Tissue Establishments must ensure that tissues can be traced from the donor to the point of issue. It is the responsibility of the hospital to ensure procedures are in place to document the fate of the tissue from its receipt to its use or discard. Tissue Establishments should have end user agreements in place with all hospitals to whom they provide tissue to ensure hospitals are aware of these requirements and have agreed to comply with them, and systems in place, such as periodic audit, to ensure this is being done. Evidence of such checks should be retained by Tissue Establishments. This will ensure that the audit trail can be followed in both directions. Clinicians caring for the recipients of tissues associated with risks identified following the issue of tissue must be informed where pertinent. Mechanisms should be in place to ensure that confidentiality is maximised.

UK Blood Transfusion Services Tissue Establishments may collect tissues from donors referred to them by Specialist Nurse Practitioners for Organ or Tissue Donation or another Tissue Establishment and may also refer donors to other Tissue Establishments. Whenever information regarding donor medical and behavioural history and/or consent for donation is obtained by, or on behalf of, a third party this must be subject to a written agreement between the parties involved. The agreement must specify what information is required regarding the medical and behavioural history of the donor and consent for donation, the standards for obtaining this information and the responsibilities of both parties in ensuring that the information is accurate and properly documented. The information should, as a minimum, be provided in accordance with the guidance in this document, regulatory requirements and the current JPAC *Donor Selection Guidelines*.³ It is the responsibility of the designated clinician to determine the Tissue Establishment's policy for the referral of donors. Donors must be excluded from donation if any of the criteria defined in Annex A of the HTA's Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment⁴ apply, unless the donation is justified on the basis of a documented risk assessment process approved by the establishment's Designated Individual.