Chapter 20: Tissue banking: selection of donors

20.1: General considerations

The overall responsibility for applying the policies for the selection and care of tissue donors lies with the tissue bank designated 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 bank designated clinician must consult with relevant specialist advisors as appropriate.

The designated 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 (including malignant or neurodegenerative disease) to the recipient. Decisions on donor assessment should be consistent with JPAC Donor Selection Guidelines.¹

Tissues must be procured, transported, processed, stored and distributed according to the requirements stated in these guidelines (the Red Book).

Procedures must be in place to document a complete audit trail from donor to recipient. Tissue banks must ensure that tissues can be traced from the donor to the point of issue. It is the responsibility of the hospital to document the fate of the tissue from its receipt to its use or discard. 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 banks may collect tissues from donors referred to them by a third party such as a donor transplant coordinator or another tissue bank and may also refer donors to other tissue banking agencies such as a cornea or research bank. 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 and the current JPAC Donor Selection Guidelines.¹ It is the responsibility of the designated clinician to determine the bank’s policy for the referral of donors.

20.2: Consent

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 must be applied during the consent procedure. The statutory requirements for consent are detailed in the relevant national legislation, the
Human Tissue Act (2004)\textsuperscript{2} and the Human Tissue (Scotland) Act 2006.\textsuperscript{3} Further detailed guidance is laid out in the current version of the Human Tissue Authority Code of Practice on Consent\textsuperscript{4} and in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.\textsuperscript{5}

Living donors must be competent to give consent before donations can be accepted. Where donors are not competent, 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 to donation of organs and tissues then that consent is sufficient for the activity to be lawful. Where the wishes of the deceased are unknown, the Human Tissue Acts rank persons in a qualifying relationship for the purpose of obtaining consent to organ and tissue donation. The consent of the nominated representative or the highest ranking person at the time of death should be sought. In circumstances where this person does not wish to deal with the issue of consent, or is unable to do so, the next person in the ranking order is approached, but it is advisable to record this in the notes.

Consent must cover retrieval, testing, storage, discard and access to medical records. If the tissue may be used for research and development, or teaching, specific consent must be obtained for this as well. Explicit information must be given if tissues are to be retrieved for specific commercial use. 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 (1998)\textsuperscript{6} 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
- explicit information on which tissue is to be retrieved and the clinical purpose to which it is to be put
- 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 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.

### 20.3: Medical and behavioural history

The information noted in the following two subsections for living and deceased donors should be reviewed by the designated clinician who is familiar with the relevant standards in the field of tissue banking (see Chapter 19).

#### 20.3.1: For living donors

Medical and behavioural history must be sought by appropriately trained professionals and in compliance with the following guidance.
• Information may be obtained from the donor by either face-to-face interview or by recorded telephone interview by appropriately trained tissue bank staff. This must allow for the exclusion of lifestyle infectious risks. During interviews, a mechanism should be in place to ensure that confidentiality is maximised.

• The interview must be conducted while the donor is free from the effect of anaesthetic, hypnotic or narcotic medication. The donor must be mentally competent to give an accurate history.

• If the medical interview is not done at the time of admission for surgery, a system must be in place to capture any relevant medical and behavioural history changes that may occur in the interval between interview and donation.

• A standard questionnaire to elicit the medical and behavioural history must be used.

• Donors should be selected according to the JPAC Donor Selection Guidelines.¹

• The completed questionnaire must be retained as part of the tissue bank donor record.

• The medical records, if available, must be consulted to review the medical and behavioural history and the medical examination.

Further medical history may be sought, where appropriate, from:

• the general practitioner

• any other relevant medical personnel.

20.3.2: For deceased donors

The cause of death and the medical and behavioural history should elicit whether the donor meets the selection criteria outlined in the JPAC Donor Selection Guidelines.¹ Modifications for the behavioural and medical history questions may be needed when accepting paediatric donors. Where the deceased donor is less than 18 months of age, or breast fed within the 12-month period prior to donation, the mother’s risk for transmissible disease must also be evaluated. Information must be sought from the following sources by appropriately trained professionals and must be documented using a standard form:

• The donor’s next of kin or other person identified as the most likely to be in possession of relevant information.

• The medical notes if the donor was admitted to hospital prior to death.

• The general practitioner.

• The post-mortem (where one is undertaken). If no post-mortem is undertaken, the cause of death of the donor, as ascertained from the medical notes, must be documented in the tissue bank donor record.

A record must be made of how the donor was identified (e.g. toe tag, wristband) and by whom.

The deceased donor’s external appearance should be thoroughly examined at the time of retrieval. The appearance must be documented with respect to the donor’s medical and behavioural history, including the presence of any obvious medical intervention, scars, tattoos, skin or mucosal lesions, jaundice, infection, trauma or needle tracks.
The date and time of death must be documented, and where applicable the time the body was refrigerated.

20.4: Tissue-specific donor considerations

Reference must be made to the JPAC Donor Selection Guidelines document for ages and other specific donor requirements for different tissues.

20.5: Donor testing

The general principles of microbiological testing and the specific testing requirements for tissue donors are covered in Chapter 9. Testing must be completed in a licensed Tissue Establishment or under a third party agreement between the testing laboratory and the licensed Tissue Establishment. If a third party laboratory is used to perform any aspect of donor testing, the specific requirements and responsibilities of both parties in achieving them must be defined in a written agreement. Such testing should, as a minimum, be performed in accordance with the guidance in this document. There should be protocols for assuring the veracity and security of the sample, labelling, and supporting documentation. The time from sample acquisition to testing or freezing of the sample should be minimised and must be consistent with test kit manufacturers’ recommendations or validated for the purpose. Due consideration should be given to dilution of the sample (see section 20.7).

Additional discretionary testing may be required (e.g. for malaria, Chaga’s disease or West Nile Virus), dependent on the donor’s travel history. RhD testing may be required on donors if the retrieved tissues will contain residual red cells or red cell membranes at the time of implantation.

The tissue bank should have a documented policy to follow in the case of donors with reactive screening tests. There should be protocols for alternative or confirmatory testing and acceptance or rejection of donations.

A positive result should be notified urgently to the source bank, Specialist Nurse Organ Donation or supplier of the tissue or cells so that clinicians in all centres that have received material from the same donor can be informed and take appropriate action. Where tissue or cells from a donor have been sent to other banks or centres, these banks or centres must be told about the positive result. Reports of positive tests should be included in the routine donor surveillance programmes and notified to the HTA (see section 21.8).

20.6: Living donor samples

All blood samples from living donors must be acquired using positive donor identification by an individual trained to ensure the security of the sample and supporting documentation. Living donors can be tested by either a single sample taken at the time of donation where testing includes a nucleic acid amplification technique (NAT) or by two samples including a post-quarantine sample where additional NAT testing is not required.

Where only a single sample is tested the ‘donation sample’ must be obtained at the time of donation or, if not possible, within 7 days post-donation.

Where two samples are tested the ‘post-quarantine sample’ is required after an interval of at least 180 days from the date of donation. In these circumstances of repeat testing, the donation sample can be taken up to 30 days prior to and 7 days after donation. When the donation blood sample is taken prior to the date of tissue donation a system must be in place to ensure that the pre-quarantine sample reflects the risk status at the time of donation.
For amnion donation only a maternal sample is required, i.e. a cord blood sample is not required.

### 20.7: Deceased donor samples

Appropriate mechanisms must be in place to ensure:

- The secure identification of samples obtained from hospital laboratories. Where there is doubt about the identity of a blood sample from a tissue donor (inadequate labelling), DNA profiling may be accepted as an accurate method for confirming the identity of the blood sample.

- Documentation of the date and time the sample was taken, the name of the individual and laboratory supplying the sample and sample storage conditions.

An ante-mortem blood sample, up to 7 days preceding death, is always preferable to a post-mortem sample for testing. Where no ante-mortem sample is available, then a post-mortem sample can be used. Samples for testing must not be taken more than 24 hours post-mortem and the time from sampling to testing or freezing of the sample should be minimised and must be consistent with the test kit manufacturer’s recommendations or validated for the purpose.

The anatomical site from which the post-mortem sample was obtained must be documented. The sample appearance should be documented. If the sample appears dilute or grossly haemolysed, a repeat sample, preferably from an alternative site, should be obtained if possible. Tissue banks should have a protocol for post-mortem sampling, clearly defining preferred sites for sampling (e.g. cardiac puncture or femoral vessel puncture and avoiding sites close to intravenous lines).

Where a deceased donor with significant blood loss has received ante-mortem transfusions, a pre-transfusion sample should be used whenever possible for testing. If a pre-transfusion sample is not available, tissue banks must employ an algorithm incorporating the timing, nature and volume of the fluids infused and the donor’s own blood volume to assess any resultant plasma dilution (see the JPAC Donor Selection Guidelines for an example of a deceased donor intravenous fluid report form). Samples of blood estimated to be more than 50% dilute are not suitable for testing.

For post-mortem samples, concluded test results other than negative will debar tissues from release unless a superior sample can be obtained (e.g. obtained ante-mortem or closer to the time of death), and this sample is tested and negative results are obtained. The acquisition of the ‘superior’ sample must be subject to the same requirements given above.

In the case of deceased neonatal or infant tissue donors the following blood samples are required:

- A maternal sample is required when an infant is less than 18 months of age or when an older child has been breast fed within the 12-month period prior to donation.

- For still births and neonates less than 48 hours after birth, no sample is required.

- For neonates between 48 hours and 28 days after birth, a sample is only required if there are identifiable risks of possible viral transmission, e.g. receiving blood components/products or undergoing a surgical procedure.

- For infants more than 28 days after birth, a sample is always required.

### 20.8: Follow-up
There is a duty of care to the donor and/or donor’s family. For donors who on confirmatory testing have positive or indeterminate results, there should be protocols in place for contacting, counselling and referring the donor, or relevant contacts of the deceased donor, for further investigation and treatment as appropriate.

For living donors this should be at a local level where the donor was recruited. Confidentiality must be ensured and the donor’s permission sought prior to referral for further medical follow-up and assessment.

In the case of a deceased donor, the initial contact should be by the medical team who provided clinical care at the time of death, or if death occurred outside a healthcare facility by the Specialist Nurse Organ Donation or the Tissue Establishment. They should ensure that those close contacts of the deceased donor for whom results may have health implications are appropriately informed and counselled. Appropriate specialist referral should be offered.

20.9: Autologous tissue donation

The designated clinician should decide the policy in relation to the provision of an autologous service.

Autologous donors should be tested for the same microbiological markers as for an allogeneic living donor. Microbiological testing must include bacteriological culture where tissue does not undergo a validated terminal antimicrobial treatment. The medical history may be less relevant than for allogeneic donation of tissues. The rationale for any exceptions must be documented.

Separate storage must be used to avoid inappropriate issue. Autologous tissue must be securely segregated from allogeneic tissue at all stages from collection to issue. Autologous donations may not be transferred to the allogeneic bank.

A system must be in place to enable the hospital to recognise that the tissue is autologous. The autologous tissue must be labelled with the donor/recipient name, hospital number and date of birth.

20.10: Archiving of donor samples

An archive blood sample should be kept for look-back investigations in the event of an adverse reaction. This must be for a minimum of 11 years after the expiry date of the tissue with the longest storage life.

Tissues can be held for a number of years prior to issue. During this period in storage there may be changes to the mandatory microbiology test requirements and improvements in screening assays for mandatory or other markers. Consideration should be given for an additional blood sample archive for tissues with a long expiry for possible future testing that is not currently available.

A policy regarding the need for re-testing of the tissue inventory needs to be established. Any policy adopted must be operationally feasible and will depend on both the maximum storage period of the tissue and the probability of the tissue being issued. When new, or significantly improved, mandatory tests are introduced consideration should be given to the re-testing of archive samples from the donors of tissue still in issuable stock. Where there is no archive sample available to test, a risk assessment must be performed. It should include factors such as the seriousness of the infection, any viral inactivation procedures performed on the tissue, the effect on inventory of discarding such tissues and the severity of impact of possible tissue shortages on recipients.

20.11: Release criteria
For allogeneic donors the concluded result of all microbiological assays, with the exception of syphilis and anti-HBc, must be negative for a tissue to be released from quarantine for issue. For donors who are found to be ‘repeat reactive’ in any screening assay but for whom subsequent testing confirms lack of infection, the initial reactivity in the screening assay is due to non-specific reactivity and any tissue products from this donation may be safely released for clinical use.

In the case of a deceased infant donor where a maternal sample is found to be positive for any mandatory marker of infection, the donation must not be used irrespective of the test result for the infant.

Donors with a positive anti-HBc may be considered as eligible provided an anti-HBs has been documented at more than 100 IU/L at some time.

Donors with reactive confirmatory tests for the presence of treponemal infection should be fully assessed, taking into account the results of confirmatory (reference) testing and medical history. The presence of current (active) infection will exclude the use of tissues from such donors. Where the assessment leads to the conclusion that the risk of active infection is remote, then non-cardiovascular tissues may be used. The presence of serological marker patterns of treponemal infections (e.g. IgM positivity) should not be used as a sole criterion to determine the presence of active infection (and therefore their eligibility). Any reactive results obtained on confirmatory testing should be discussed with staff experienced in interpreting treponemal test results, before a decision is made to use tissues.

For autologous donors positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and reimplanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts and/or no risk of mix-ups at issue.

### 20.12: References