Chapter 19: Tissue banking: general principles

19.1: Regulatory environment in the UK

The whole process of tissue banking is now covered by legislation. The EU Directive on Tissues and Cells (2004/23/EC)\(^1\) and its associated Commission Directives (2006/17/EC and 2006/86/EC)\(^2,3\) have been transposed into UK law as the Human Tissue (Quality and Safety for Human Application) Regulations 2007.\(^4\) These regulations lay down standards of quality and safety for all aspects of banking of human tissues and cells intended for human applications. In addition, the Human Tissue Act 2004\(^5\) applies throughout the UK with the exception of Scotland, where the Human Tissue (Scotland) Act 2006\(^6\) applies.

All Tissue Establishments need to be licensed by the ‘Competent Authority’, which in the case of the UK is the Human Tissue Authority (HTA). Under the Human Tissue Act the HTA issues its expected standards in the form of ‘Directions’\(^7\) and ‘Codes of Practice’\(^8\) to Tissue Establishments. HTA expected standards are contained in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment,\(^7\) which is implemented via Directions and is periodically updated.

Every Tissue Establishment must designate a responsible person (termed the Designated Individual\(^4\)) who shall be responsible for ensuring that all activities relating to human tissues and cells intended for human application are in accordance with the laws in force in the UK. It is therefore the responsibility of the Designated Individual to ensure that all the requirements of the HTA are met in a timely and comprehensive manner.

19.2: Reference documents for tissue banking

The advice contained in these guidelines is believed to represent acceptable practice at the time of writing. It is policy to revise these guidelines as new developments occur. However, it may not be possible to do so at the time of such change and the guidelines should therefore be used with due regard to current acceptable practice.

The guidelines in Chapters 19–21 apply to tissue banking activities within the Transfusion Services of the UK. They must be read in conjunction with the other sections of the guidelines including regulatory environment in the UK, quality in Blood and Tissue Establishments, microbiology tests for donors and donations and labelling of human tissue products.

Reference should be made to the current version of the JPAC Donor Selection Guidelines\(^9\) available at www.transfusionguidelines.org.uk.

Other key documents relating to tissue banking are listed in the references at the end of this chapter.\(^10,11,12,13,14,15,16\)
19.3: Data protection and confidentiality

Living donors and families of deceased donors must be told that information relating to the donation will be stored in accordance with the Data Protection Act (DPA)1998 and may be shared with relevant health professionals.

Tissue Establishments shall take the necessary measures to ensure that all data, collated within the scope of all their banking activities and to which third parties have access, have been rendered anonymous so that neither donor nor recipients remain identifiable.

19.4: References

7. Human Tissue Authority: Directions given under the Human Tissue Act 2004 to establishments licensed under the Quality and Safety Regulations, available at www.hta.gov.uk /legislationpoliciesandcodesofpractice/htalegaldirections.cfm:
   • 003/2010 implementing the ‘Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment’
8. Human Tissue Authority: Codes of Practice, available at www.hta.gov.uk:
   • Code 1. Consent
   • Code 2. Donation of solid organs for transplantation
   • Code 5. Disposal of human tissue
   • Code 8. Import and export of human bodies, body parts and tissue
   • Code 9. Research
9. Joint UKBTS/NIBSC Professional Advisory Committee’s (JPAC) Donor Selection Guidelines. Available at www.transfusionguidelines.org.uk:
   • Tissue donor selection guidelines: living donors (TDSG-LD)
   • Tissue donor selection guidelines: deceased donors (TDSG-DD).
12. Royal College of Ophthalmologists (2008). Standards for retrieval of human ocular tissue used in transplantation, research and training. Available at www.rcophth.ac.uk


