Guidelines for the Blood Transfusion Services

Chapter 19: Tissue banking: general principles

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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 and its associated Commission Directives were transposed into UK law as the Human Tissue (Quality and Safety for Human Application) Regulations 2007, (as amended), referred to as the Quality & Safety Regulations.[1] These regulations lay down standards of quality and safety for all aspects of banking of human tissues and cells intended for human applications. The UK retained the same quality and safety standards after 1 January 2021.

In addition, the Human Tissue Act 2004[2] applies throughout the UK with the exception of Scotland, where the Human Tissue (Scotland) Act 2006[3] applies, and the Human Transplantation Act (Wales) 2013[4] applies in Wales.

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'[5] and 'Codes of Practice'[6] to Tissue Establishments. HTA expected standards are contained in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment[5] which is implemented via Directions and is periodically updated.

Every Tissue Establishment must designate a responsible person (termed the Designated Individual) 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. The Designated Individual may if necessary, delegate some of these responsibilities to appropriately trained and qualified individuals (Persons Designate), for example if the Tissue Establishment is located on multiple sites.

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*[7] available at www.transfusionguidelines.org

Other key documents relating to tissue banking are listed in the references at the end of this chapter.[8-13]

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) 2018[14] 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

1. Statutory Instrument 2007 No. 1523 The Human Tissue (Quality and Safety for Human Application) Regulations 2007, and subsequent amendments. Available at www.legislation.gov.uk
2. Human Tissue Act 2004 (except Scotland). Available at www.legislation.gov.uk
3. Human Tissue (Scotland) Act 2006. Available at www.show.scot.nhs.uk
4. Human Transplantation (Wales) Act 2013. Available at http://www.legislation.gov.uk/anaw/2013/5/contents/enacted
5. Human Tissue Authority: Directions given under the Human Tissue Act 2004 to establishments licensed under the Quality and Safety Regulations, available at https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/legal-directions
    - 001/2021 implementing the ‘Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment’
6. Human Tissue Authority: Codes of Practice, available at www.hta.gov.uk:
    - Code A. Guiding principles and the fundamental principle of consent
    - Code F, parts 1 and 2. Donation of solid organs and tissues for transplantation
    - Code E. Research
    - Code of practice on the Human Transplantation (Wales) Act 2013
7. Joint UKBTS/NIBSC Professional Advisory Committee’s (JPAC) Donor Selection Guidelines. Available at www.transfusionguidelines.org:
    - Tissue donor selection guidelines: living donors (TDSG-LD)
    - Tissue donor selection guidelines: deceased donors (TDSG-DD).
8. Council of Europe *Guide to Quality and Safety of Tissues and Cells for Human Application*. European Directorate for the Quality of Medicines and Healthcare. www.edqm.eu

9. SaBTO (2020). Microbiological Safety Guidelines. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876161/SaBTO-microbiological-safety-guidelines.pdf
10. Medicines and Healthcare products Regulatory Agency 11th Edition (2022). *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2022*. London: Pharmaceutical Press.
11. EC Guidelines to Good Manufacturing Practice Volume 4, Annex 1 (2008 revision): Manufacture of Sterile Medicinal Products. Available at https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-4_en
12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Available at: https://eur-lex.europa.eu/eli/reg/2017/746
13. The Royal College of Pathologists and the Institute of Biomedical Science (2015). *The Retention and Storage of Pathological Records and Specimens*, fifth edition.
14. Data Protection Act 2018. Available at https://www.gov.uk/data-protection