## **Guidelines for the Blood Transfusion Services**

## 19.4: References

http://www.transfusionguidelines.org/red-book/chapter-19-tissue-banking-general-principles/19-4-references

## 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 <a href="https://www.legislation.gov.uk">www.legislation.gov.uk</a>
- 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
- Human Transplantation (Wales) Act 2013. Available at http://www.legislation.gov.uk/anaw/2013/5 /contents/enacted
- 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/legaldirections
  - 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 <a href="https://www.transfusionguidelines.org">www.transfusionguidelines.org</a>:
  - 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
- 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
- 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