

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 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>