Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK

19. Tissue banking: general principles

Last updated on 13 February 2023

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 and Safety Regulations. 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 applies throughout the UK with the exception of Scotland, where the Human Tissue (Scotland) Act 2006 applies, and Wales, where the Human Transplantation Act (Wales) 2013 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 and Codes of Practice to Tissue Establishments. HTA expected standards are contained in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment 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 Human Tissue Act 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.

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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 chapter 19, chapter 20 and chapter 21 apply to tissue banking activities within the UK Blood and Tissue Services. 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 Tissue (Deceased Donors) Donor Selection Guidelines and the Tissue (Live Donors) Donor Selection Guidelines.

Other key documents relating to tissue banking are:

- Guide to the quality and safety of tissues and cells for human application produced by the European Directorate for the Quality of Medicines and Healthcare (EDQM)
- Microbiological safety guidelines produced by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors *[MHRA, 2022]*
- EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines (2008 revision)
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices
- The Retention and Storage of Pathological Records and Specimens *[RCPath and IBMS, 2015]*

References

MHRA (2022). Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2022. London: Pharmaceutical Press.

Royal College of Pathologists (RCPath) and the Institute of Biomedical Science (IBMS) (2015). The Retention and Storage of Pathological Records and Specimens, fifth edition.

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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 2018 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.