

Guidelines for the Blood Transfusion Services

22.1: Introduction

<http://www.transfusionguidelines.org/red-book/chapter-22-haemopoietic-progenitor-cells/22-1>

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Cellular therapy is now covered by a variety of legislation. The EU Directive on Tissues and Cells (2004/23/EC) and its associated Commission Directives (2006/17/EC and 2006/86/EC) have been transposed into UK law as the Human Tissue (Quality and Safety for Human Application) Regulations, 2007 as amended. The Human Tissue Act 2004, Human Tissue (Scotland) Act 2006 and Directions or Codes of Practice issued by the Human Tissue Authority also apply. In addition, there are a number of key international standards for haemopoietic stem cells, notably the FACT-JACIE and the NetCord-FACT Standards and the WMDA standards. The lists of publications in sections 22.1.1 and 22.1.2 have been grouped according to their origins.

The guideline references in this chapter apply to the donation, collection, testing, processing, cryopreservation, storage and distribution of haemopoietic progenitor cells (HPC) and mononuclear cells (MNC) within the UK. These guidelines are applicable to stem cell donor registries and to bone marrow, peripheral blood and cord blood collection and processing facilities, and importing facilities, hereafter mentioned as establishments.

22.1.1: UK Regulation/Guidelines

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. HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment (current edition), available at www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance
3. Human Tissue Act 2004 (except Scotland). Available at www.legislation.gov.uk
4. Human Tissue (Scotland) Act 2006. Available at www.show.scot.nhs.uk
5. Human Tissue Authority Codes of Practice. Available at www.hta.gov.uk
 1. Guiding principles and the fundamental principle of consent (Code A)
 2. Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation (Code G).
6. Human Tissue Authority Guidance document for establishments working with Umbilical cord blood. Available at www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/establishments-involved-cord-blood
7. Data Protection Act 2018. Available at www.gov.uk/data-protection
8. BSHI Guidelines for HLA matching and donor selection for haematopoietic progenitor cell transplantation. Available at www.bshi.org.uk
9. Joint UKBTS Professional Advisory Committee's (JPAC) Donor Selection Guidelines for either cord blood donors or bone marrow/peripheral blood stem cell donors. Available at www.transfusionguidelines.org
10. Joint UKBTS Professional Advisory Committee's (JPAC) Geographical Disease Risk Index (GDRI). Available at: www.transfusionguidelines.org

11. Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Microbiological Safety Guidelines. Available at www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation

22.1.2: European & International Directives/Guidelines

1. EDQM Guide to the quality and safety of tissues and cells for human application. Available at www.edqm.eu/en/guide-to-the-quality-and-safety-of-tissues-and-cells-for-human-application1
2. EC Guidelines to Good Manufacturing Practice (Eudralex) Manufacture of Sterile Medicinal Products. Available at ec.europa.eu/health/medicinal-products/eudralex_en
3. International Standards for Cellular Therapy Product Collection, Processing, and Administration. From the Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee of ISCT-Europe and EBMT (JACIE). Available at www.ebmt.org/accreditation/jacie-standards
4. International Standards for Cellular Therapy Product Collection, Processing, and Administration Accreditation Manual. Available at www.jacie.org
5. NetCord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration. Available at www.factwebsite.org
6. NetCord-FACT Cord Blood Accreditation Manual. Available at www.factweb.org/forms/store/CommercePlusFormPublic/search?action=Publications
7. World Marrow Donor Association (WMDA) International Standards for Unrelated Haematopoietic Stem Cell Donor Registries - promotes a range of standards, guidelines and recommendations to facilitate the exchange of haematopoietic stem cells across international borders. Available at www.wmda.info
8. European Federation for Immunogenetics (EFI) 'Standards for histocompatibility testing'. Available at efi-web.org
9. National Marrow Donor Program (USA) Standards. May be helpful in benchmarking for equivalent UK standards. Available at www.marrow.org
10. WMDA Donor Medical Suitability Recommendations. Available at share.wmda.info/display/DMSR/WMDA+Donor+Medical+Suitability+Recommendations+Main+page