NATIONAL REGULATIONS

UK

0.1 Requirement for JACIE

JACIE is a **requirement for reimbursement**. NHS England specified in their service specification that a centre must be JACIE accredited.

02. Authorisation and licencing

B1.3.1, CM1.3.1, C1.3.1, D1.2.1

Clinical Units

Governmental authority that registers, authorises or certifies:

NHS England, Scotland or Wales is the responsible commissioner of services.
The Care Quality Commission acts as the independent regulator and inspects hospital trusts
Human Tissue Authority as it pertains to testing, storage of cellular therapy products.

Document that demonstrates that the unit complies with the national laws and regulations:

- **England: Care Quality Commission reports (not specific to cell therapy)**
  - https://www.cqc.org.uk/care-services
- **Wales: Welsh Health Specialist Services Committee (not specific to cell therapy)**
  - https://whssc.nhs.wales/
- **HTA Inspection reports**
  - https://www.hta.gov.uk/guidance-professionals/latest-inspection-reports

Bone Marrow Collection Units

Apheresis Collection Units

Cell Processing units

Governmental authority that registers, authorises or certifies:

Human Tissue Authority (England and Wales)

Document that demonstrates that the unit complies with the national laws and regulations:

- **HTA Inspection reports**
  - https://www.hta.gov.uk/guidance-professionals/latest-inspection-reports

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

National law requires staff to receive annual training in current GxP, and up-to-date GCP training is required for staff involved in clinical research. However, the only mention of GxP in the HTA standards is the requirement for processing labs to follow European GMP Volume 4 Annex 1 standards when conducting open processing. There is nothing specific in the question regarding research.

04. Physicians' licensing / qualifications

B3.1.1, B3.2.1 CM3.1.1 , C3.2.1, D3.2.1

This is managed by the GMC (General Medical Council). A doctors registration can be checked on the GMC website and this includes: Haematology, Medical Oncology, Clinical, Oncology, Paediatrics (subspecialisation – Paed Oncology).
Paediatric Haematology is not recognised separately and most Paediatric Haematologists are registered as Haematology.

05. Requirements for the consent from minor donors

B6.2.6

National law has specific requirements concerning who can obtain informed consent for minor donors. This is managed according to the regulations set down in the Human Tissue Act 2004. Children under 16 need to be assessed to determine whether they are Gillick competent:

Gillick competence means that a child is considered to be legally competent to make their own decisions on medical treatment matters when that child has sufficient understanding and intelligence to fully understand what is proposed. If a child has this level of understanding and intelligence for the proposed treatment, the child can give or refuse consent.

If 16-17 they are presumed to be Gillick Competent unless there is evidence to the contrary.
If a child is not Gillick competent then they have to be assessed by an independent Accredited Assessor and this report is submitted to the HTA who then approves (or not) the BM or PBSC collection.

06. Certification of laboratories for donor testing

B6.3.6

Human Tissue Authority has legal status with respect to all cellular therapy including testing requirements. Testing labs will be UKAS certified to ISO 15189 (2022) not HTA licensed.
UKAS (https://www.ukas.com/) accredits all laboratory services in the UK.

07. Additional testing for allogeneic HPC donors

B6.4.9

	Testing required	Risk assessment required	None
Human immunodeficiency virus, type 1	✓		
Human immunodeficiency virus, type 2	✓		
Hepatitis B virus	✓		
Hepatitis C virus	✓		
Treponema pallidum (syphilis)	✓		
Human T cell lymphotropic virus I		✓	
Human T cell lymphotropic virus II		✓	
West Nile Virus		✓	
Trypanosoma cruzi (Chagas' Disease)		✓	

Additional comments
HTA - Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment.

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128 is used in Collection and Processing facilities.

HTA includes a standard:

GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a. There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

The document that demonstrates a center's compliance with applicable national laws and regulations is the HTA license.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law allows products to be distributed prior to the completion of donor eligibility.

11. Biohazard and warning labels

D7.4.4.1/C7.4.4.1/ CM7.4.3.1

The only regulations are Gov.UK requirements for transportation of biological substances, UN3373. No specific mention of biohazard in the HTA Guide to Quality and Safety or the Human application licensing standards.

12. Others

Important information to share

Responsibility for healthcare is devolved to the separate nations in the UK, ie England, Scotland, Wales and Northern Ireland so there are national variations. In some situations there are overarching national bodies such as the Human Tissue Authority but in others it is country specific. Northern Ireland is more complex still as the devolved assembly has been suspended since Brexit due to the complexities around Northern Ireland and this resulted in reversion to direct rule from Westminster. As of 2024 the Northern Ireland assembly is now re-established.