NATIONAL REGULATIONS
Turkey

01. Requirement for JACIE

JACIE is **voluntary**.

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:
Hematopoetik kök hücre nakli merkezleri yönetmeliği.
Regulation on haematopoietic stem cell transplantation centers.

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

Apheresis Collection Units

Governmental authority that registers, authorises or certifies:
Terapötik Aferez Merkezleri ve Üniteleri Hakkında Yönetmelik.
Regulation on Therapeutic Apheresis Centers and Units.

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

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

There are no specific requirements

04. Physicians' licensing / qualifications

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

Physicians should have a specialty registration in haematology or oncology and at least six months of training in an active transplant center.

05. Requirements for the consent from minor donors

B6.2.6

The consent must be obtained by an appointed legal adviser.

06. Certification of laboratories for donor testing

B6.3.6

The authorities in our country register, authorise, or approve the laboratory for all tests.

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)			✓

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

There is no specific system definition for labeling in Turkey. ISBT128 is routinely used.

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

It must be authorised per the Regulation on Clinical Trials of Medicinal Products for Human Use.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in Turkey does not allow products to be distributed prior to completion of donor eligibility, except in very specific circumstances and with a risk assessment previously done.

11. Biohazard and warning labels

D7.4.4.1/C7.4.4.1/ CM7.4.3.1

	Required [by law]	Not allowed [by law]
Biohazard label	✓	
Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"	✓	
Statement "WARNING: Advise Patient of Communicable Disease Risks"	✓	
Statement "WARNING: Reactive TestResults for [name of disease agent or disease]	✓	

Additional comments

Required [by law]

There is a definition in Hospital Service Standards.