NATIONAL REGULATIONS
Finland

1. 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:

Sosiaali- ja terveysalan lupa- ja valvontavirasto (Valvira) National supervisory authority for welfare and health.

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

Bone Marrow Collection Units

Apheresis Collection Units

Cell Processing units

Governmental authority that registers, authorises or certifies:

Lääkealan turvallisuus- ja kehittämiskeskus (Fimea) Finnish Medicines Agency.

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

The National law requires staff to receive adequate training and requirements according to the Directive 2006/86/EC Annex I, B Personnel, point 3.

04. Physicians' licensing / qualifications

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

The professional qualifications of social welfare and health care professionals (incl. physicians) can be verified in the public information service maintained by Valvira for the registers of social welfare and health care professionals (JulkiSuosikki and JulkiTerhikki, respectively).
There is no official immunology speciality. Paediatric Hematology/Oncology is an additional training program accepted by medical faculties of the universities in Finland but not an official speciality.

05. Requirements for the consent from minor donors

B6.2.6

The donor’s personal physician must contribute to the decision to donate.

06. Certification of laboratories for donor testing

B6.3.6

The Regional state administrative agencies certifies the laboratories for donor testing.

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

ISBT128 is used in Collection and Processing facilities.

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

For stem cell transplantation or medicinal product, a licence issued by Finnish medicines agency (for tissue establishment or clinical trial, respectively). For clinical trials also a statement form ERB is necessary.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in Finland does not allow products to be distributed prior to completion of donor eligibility. According to directive 2006/86/EC: There must be a system of inventory hold for tissues and/or cells to ensure that they cannot be released until all requirements laid down in this Directive have been satisfied. Only in an extreme situation, the donor can be used before eligibility is completely.

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]

Requirements according to the Directive 2006/86/EC, Annex II, E. Final labelling for distribution.