

NATIONAL REGULATIONS

Finland



JACIE is voluntary.



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



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.



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).

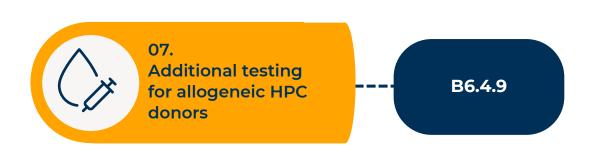
There is no official immunology speciality. Paediatric Hematology/Oncology is an additional training program accepted by medical faculties of the universities in Finland but not an official speciality.



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

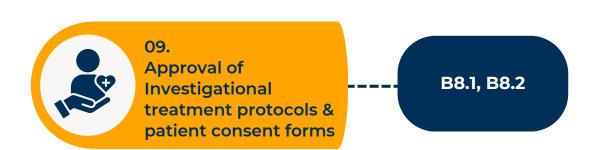


The Regional state administrative agencies certifies the laboratories for donor testing.



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





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.



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.



Biohazard label	Required [by law]	Not allowed [by law]
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.