

NATIONAL REGULATIONS

Sweden



Requirement for **JACIE**

JACIE is **voluntary**. It is not a requirement for any type of therapy



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:

These are not individually authorized or certified in any way. However, the hospital is under the authority of Socialstyrelsen (National Board of Health)



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

The hospital licence to provide health care. No specific licence is required for Transplant or cellular therapy clinical units.



Bone Marrow Collection Units



Apheresis Collection Units



Governmental authority that registers, authorises or certifies:

Collection of cells is under the authority of Socialstyrelsen (National Board of Health) and SOSFS2009:30



regulations.

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

Authorisation document (tillstånd) granted by IVO.



Cell Processing units



Governmental authority that registers, authorises or certifies:

Handling of cells in Tissue our establishment (vävnadsinrättning) requires authorisation from National Board of Health (Socialstyrelsen) and Health and Social Care Inspectorate (IVO) that follows the Swedish law 2008:286 9§ and SOSFS 2009:31 regulations.

Handling of cells for production of medicines requires authorisation from Swedish Medical Products Agency (Läkemedelsverket) that follows the Swedish Law 2008:286 9§ and LVFS2008:12 regulations.



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

Authorisation document (tillstånd) granted by IVO.

Authorisation document (tillstånd) granted by the Swedish medical



03. cGxP training requirements CM3.3.4 C4.4.2.5 D4.4.2.5

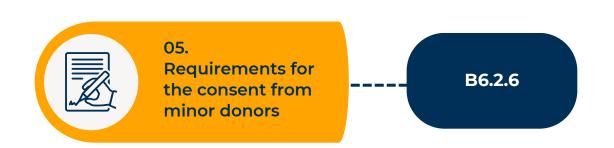
There are no specific requirements. The Swedish law requires applicable training without specifications of type or interval. Some centers have annual GMP training for processing in their SOPs.



04. Physicians' licensing / qualifications

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

It is given out by the National board of Health. It is only Oncology meaning both radiation and medical oncology. There is no subspecialisation within the oncology speciality.



It varies depending on age. The child can sign for him/herself from 16 although the age limit for being a minor is 18.



Laboratory for donor testing is accredited by SWEDAC, which is Sweden's national accreditation body. In addition, donor testing is CE-marked, according to EU-legislation.



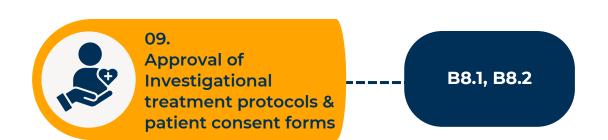
	Testing required	Risk assessment require	None
Human immunodeficiency virus, type 1	⊗		
Human immunodeficiency virus, type 2	Ø		
Hepatitis B virus	\otimes		
Hepatitis C virus	\otimes		
Treponema pallidum (syphilis)	⊗		
Human T cell lymphotropic virus I	\otimes		
Human T cell lymphotropic virus II	\otimes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

Additional comments

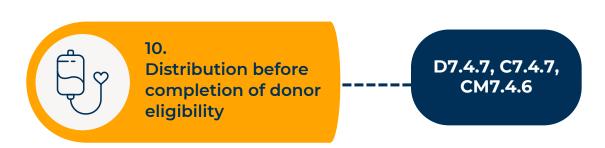
For HBV test includes HBsAg and anti-HBc. Other not required but after risk assessment are: Chikungunya, Leishmaniasis, Toxoplasmosis, EBV, CMV, Tuberculosis according to SOSFS2009:30 regulation.



ISBT128 is used according to SOSFS2009:31 and LVFS2008:12 Swedish regulations (as well as SEC).



It depends on the type of protocol. All research has to be approved by the national ethical review board. They also have to follow the biobank law. If an individual patient is treated on an investigational protocol with no research aim (publication is not planned), there is no national oversight. Each institution deals with this situation independently.



It is allowed for exceptional cases according to the Swedish regulations in SOSFS2009:31 (9 kap 7§).



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]	8	

Additional comments

We use the other warnings labels according to JACIE, and that is allowed by

Those required by law according to SOSFS2009:31



Product labelling. The Swedish law requires for allogenic product intended for specific recipient labelling of primary container with Recipient name and personal identification (AF) according to Swedish system (personal number or reserve number). In partial labelling allows information as AC. Regulation SOSFS2009:31.