NATIONAL REGULATIONS

Sweden

01. 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 our Tissue 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 products Agency.

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.

05. Requirements for the consent from minor donors

B6.2.6

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

06. Certification of laboratories for donor testing

B6.3.6

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.

07. Additional testing for allogeneic HPC donors

B6.4.9

	Testing required	Risk assessment require	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

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.

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

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

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

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.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

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

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

We use the other warnings labels according to JACIE, and that is allowed by law.
Those required by law according to SOSFS2009:31

12. Others

C7.4.3

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.