NATIONAL REGULATIONS
The Netherlands

01. Requirement for JACIE

JACIE is a requirement to perform the procedures. JACIE accreditation is a requirement for a permit to perform SCT procedures by local law.

02. Authorisation and licencing

B1.3.1, CM1.3.1, C1.3.1, D1.2.1

Clinical Units

Bone Marrow Collection Units

Apheresis Collection Units

Governmental authority that registers, authorises or certifies:

Health and Youth Care Inspectorate (or IGJ), part of the Ministry of Health, Welfare and Sport (VWS)
(Inspectie Gezondheidszorg en JEUGD (IGJ), onderdeel van Ministerie van Volksgezondheid, Welzijn en Sport (VWS)). https://english.igj.nl/about-us

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

Medical Center license (issued bij VWS).

Cell Processing units

Governmental authority that registers, authorises or certifies:

Health and Youth Care Inspectorate (or IGJ), part of the Ministry of Health, Welfare and Sport (VWS)
(Inspectie Gezondheidszorg en JEUGD (IGJ), onderdeel van Ministerie van Volksgezondheid, Welzijn en Sport (VWS)). https://english.igj.nl/about-us

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

Medical Centers' license (issued bij IGJ/VWS)
Admission by IGJ of compliance with local legislation (Wvkl) and status: 'tissue establishment' or 'organ bank'.
https://www.igj.nl/zorgsectoren/bloed-weefsels-en-organen/toezicht-op-cellen-en-weefsels
https://www.igj.nl/zorgsectoren/bloed-weefsels-en-organen/erkenning-of-vergunning

For ATMP: GMP license (issues bij IGJ/VWS)
https://www.igj.nl/zorgsectoren/geneesmiddelen/productie-gmp/gmp-inspecties-en-certificaat

03. cGxP training requirements

CM3.3.4
C4.4.2.5
D4.4.2.5

National legislation doesn't have specific requirements for staff to receive annual training on current GxP. There are requirements for GCP and GMP training once every 3 years, not annually. Ref GCP-WMO registration for medical research (WMO = Wet medisch-wetenschappelijk onderzoek met mensen). No requirement for annual (re)training for all GxP. There are requirements for proof of competence by health care providers.

04. Physicians' licensing / qualifications

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

Healthcare provider expertise:
To gain expertise, healthcare providers undergo training.
In case of a profession registered in the BIG Act the law also states for that profession:

- the training requirements;
- the area of expertise (for example, for a doctor, oncology is an area of expertise).

Every person who is a healthcare provider and meets these requirements may use the legally protected title associated with that profession and is registered in the BIG database: https://www.bigregister.nl/registratie
The BIG requirement is applicable for: pharmacist, doctor, physiotherapist, healthcare psychologist, clinical technologist, educational psychologist-generalist, physician assistant, psychotherapist, dentist, nurse and midwife.

05. Requirements for the consent from minor donors

B6.2.6

Artikel 5 van de wet op orgaandonatie;
Minor donors are only to donate for closely related patient in danger of life, after consent from:

- Donor <12yrs of age: the donors parents or parental power, and juvenile judge
- Donor 12-18 years of age: the donors parents or parental power and from the minor donor

06. Certification of laboratories for donor testing

B6.3.6

Farmatec, part of the Ministry of Health, Welfare and Sport (VWS) authorises the Laboratory to test donors. https://www.farmatec.nl/vergunningen/vergunning-donortestlaboratorium

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)		✓	

Additional comments

Not regulated by law, but indicated by the national blood supply org based on international standards.

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128 is used in Collection and Processing facilities, in combination with SEC (NL legislation).

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

In addition to the approval of a Medical Ethical Assessment Committee (METC) recognized in the Netherlands by the Central Committee on Human Research (CCMO), centers may require permission from the centers' Board of Management for the local feasibility of the research (feasibility test).
The researcher is responsible for the complete and correct completion of all assessment documents, including the abbreviated application form. The researcher submits this to the science office before the deadline of the meeting.
This could be demonstrated by medical ethical committee approval letter.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in The Netherlands allows products to be distributed prior to completion of donor eligibility. Status of donor eligibility determination to be stated in the accompanying documentation. Results to be communicated to transplant center.

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] According to the applicable EU regulation, Biohazard warning label is required (if applicable).
(ref Eisenbesluit lichaamsmateriaal 2006)

12. Others

C7.4.2

C7.4.2
According to the European privacy law (General Data Protection Regulation AVG, see below), privacy of donor and recipient should be maintained throughout the whole process. Personal information of the recipient should not be shared with donor, vice versa.
Thus applying label with all information in the proximity of the donor is prohibited by law.

Directive 95/46/EC (General Data Protection Regulation)
Algemene Verordening Gegevensbescherming voor de zorgsector | Ministerie van Volksgezondheid, Welzijn en Sport | Rijksoverheid.nl