NATIONAL REGULATIONS

Norway

01. Requirement for JACIE

JACIE accreditation is **voluntary** but strongly recommended (JACIE approval is seen as a prerequisite for ATMP production and use)

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**
- **Cell Processing units**

Governmental authority that registers, authorises or certifies:

1. The Norwegian Directorate of Health (Norw: “Helsedirektoratet”)
2. “Manufacturing Authorisation for Medicinal Products” from “The Norwegian Medical Products Agency” (Norw: “Direktoratet for medisinske produkter”) is required for ATMPs.

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

1. From the Norwegian Health Directorate: “Licence according to regulation of 7th of December 2015 on tissues and cells” (Norw: “Godkjenning etter forskrift 7. desember 2015 nr. 1430 om håndtering av celler og vev”)
2. From the Norwegian Medical Products Agency (where relevant): “Manufacturer’s Authorisation for Medicinal Products” (Norw: “Tilvirkertillatelse for legemidler”)

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

The law does not require regular competency checks and recertification programs, although this might be required by regulatory agencies for specific parts of their approval.

04. Physicians’ licensing / qualifications

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

The Norwegian Directorate of Health issues medical specialist approval certificates to Medical Doctors after completion of their training, and this is based on recommendations from their approved training organisations (ATOs) and independent individual application to the same Directorate.

05. Requirements for the consent from minor donors

B6.2.6

Patients are considered paediatric patients up to 18 years of age. However, from the age of 16, donors and patients are legally entirely independent from their parents and decide for themselves whether they will consent to any form of treatment or donation. Before that age, the parents decide, although the child's opinion should be increasingly heard and taken into account depending on their chronological age and maturity. A system of appointed legal advisors who replace the parents does not exist, although two doctors must handle the donor and patient side independently of each other, and each doctor should represent the interest of their respective client.

06. Certification of laboratories for donor testing

B6.3.6

The Norwegian Directorate of Health (Norw: "Helsedirektoratet"): Regulated by the law on medical specialist services (Norw: "Spesialisthelsetjenesteloven" and the regulation concerning medical laboratories and radiology departments (Norw: forskrift om medisinsk laboratorie- og røntgenvirksomhet).

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

West Nile Virus and Tryponosoma only by indication if the medical history reveals it. Testing for Treponema pallidum and Toxoplasma gondii is also compulsory.

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128 is used in Collection & Processing facilities.

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

There is no approval of each research centre per se. However, an “Organisation-centric approach” with a CTIS “High Level Administrator” as required by EMA gives an overview over clinical trials within each organisation.
Each clinical research project or trial involving medical products (CTPs in this case) must be approved by The Norwegian Medical Product Agency, which is fully based on EMA’s Clinical Trial Information System (CTIS).
For Gene Modified Organisms (GMOs) a separate approval must also be obtained from The Norwegian Environment Agency. Each agency will issue an approval document specific for each study, and each trial has to be registered in the EU Clinical Trials Register and in the clinicaltrials.gov database.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

Donor eligibility approval post distribution is neither specifically prohibited, nor specifically allowed by Norwegian law. JACIE-requirements have been practiced since 2017, although this kind of distribution is almost never practiced.

11. Biohazard and warning labels

D7.4.4.1/C7.4.4.1/ CM7.4.3.1

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

The regulation regarding handling of human cells and tissues (Norw: “Celleforskriften” §38f) requires products with positive test results to be labelled “smittefarlig materiale”. Otherwise, there is no specific law requirements for the remaining warning labels mentioned under this point.