NATIONAL REGULATIONS
Austria

01. Requirement for JACIE

JACIE is **voluntary**. JACIE facilitates transplant centres to participate in clinical studies (e.g. CAR-T cell trials) but is not a requirement. In the national health-structure-plan there are requirements for autologous and allogeneic BMT units but do not include a quality accreditation programs. CAR-Ts are mainly infused in allogeneic HCT centres but this is not a requirement.

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:

Hospitals require official permits for operation. This also includes autologous and allogeneic BMT units. The respective state government is responsible for issuing licenses.
The respective regulations can be found in the Hospitals and Health Resorts Act (Krankenanstalten und Kuranstaltengesetz des Bundes; §§3), detailed regulations in the respective state Hospitals Act (Landeskrankenanstaltenge-setz; e.g. §§ 4 ff Vienna Hospitals Act 1987).

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

Hospitals have a respective “decision document”

Bone Marrow Collection Units

Apheresis Collection Units

Cell Processing units

Governmental authority that registers, authorises or certifies:

Austrian federal office for safety in health care (Bundesamt für Sicherheit im Gesundheitswesen)

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

Certificate from the Austrian federal office for safety in health care.

03. cGxP training requirements

CM3.3.4 C4.4.2.5 D4.4.2.5

The National law requires staff to receive annual training in current GxP: Annual hygiene training for cell and tissue establishments and GMP processes.

04. Physicians’ licensing / qualifications

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

Physicians hold a Specialist Certificate.

05. Requirements for the consent from minor donors

B6.2.6

There are no specific requirements regarding who can obtain informed consent.
This is not further defined in the tissue regulation, but it is relevant under civil law: Before the age of 14, the legal representative must give consent. After the age of 14, donors can also consent themselves. The decisive factor here is whether the person is capable of understanding and judgment, i.e. whether the minor donor understands the consequences of giving consent.

06. Certification of laboratories for donor testing

B6.3.6

For IDMs the Austrian federal office for safety in health care (Bundesamt für Sicherheit im Gesundheitswesen) certifies the laboratories for donor testing.

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

Always depending on the risk (e.g. travel in an endemic aera).

From a Registry point of view, HTLV is required for all US donations.

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128 is used in Collection and Processing facilities.

09. Approval of Investigational treatment protocols & patient consent forms

B8.1, B8.2

Most importantly, a positive vote from the ethics committee would demonstrate that a centre complies with the applicable national laws and regulations.

10. Distribution before completion of donor eligibility

D7.4.7, C7.4.7, CM7.4.6

The law in Austria allows products to be distributed prior to completion of donor eligibility under specific circumstances.
In principle, distribution of cell & tissue products is only possible once all the specified requirements have been met (see national tissue safety regulation §15 section 1). This means that the assessment of donor suitability (according to §3 section 1 tissue procurement regulation) must also be completed.

The selection criteria must be determined based on a risk assessment that takes into account the use of a specific donor (e.g. specific selection criteria of §3 of the tissue procurement regulation) – responsible for that is the Responsible Person (as defined in the law). The release of tissue/cells must be carried out by the Responsible Person in accordance with §9 tissue safety regulation before tissues/cells are distributed for use in humans. With an appropriate risk assessment, including a risk-benefit assessment in relation to the treatment of the patient concerned, the cells may be released under the responsibility of the responsible person before specific test results are available.

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]	✓	

Required [by law]

The national requirements are laid down in several documents including the Gewebesicherheitsgesetz (Tissue safety law), §§ 8 and 9 of the Gewebeentnahmereinrichtungs-Verordnung ("tissue-procurement directive";) and §13 of the Gewebebankenverordnung (tissue establishment directive). It is defined to label either the product, transport container or give in the acompaning documents the following information: State "Results of IDM tests of the donor", state "Warning of potential hazards" if applicable, and if a product has been tested positive for a relevant infectious disease marker, add: "BIOLOGICAL HAZARD"