

## NATIONAL REGULATIONS

## Spain



01.
Requirement for JACIE

JACIE is a requirement to perform some procedures: It is currently mandatory for all activities (Collection, Processing and Clinical) in allo SCT centres (URD and RD) and highly recommended for CAR-T (in practice it is mandatory). It is not required for autologous.

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02. Authorisation and licencing B1.3.1, CM1.3.1, C1.3.1, D1.2.1



**Clinical Units** 



**Apheresis Collection Units** 



**Bone Marrow Collection Units** 



Governmental authority that registers, authorises or

**Cell Processing units** 



**certifies:** National and Regional. The National Competent Authoriy (ONT) manages the National and European Centre´s Registry



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

Specific document from each authority, there are 17 different regions in Spain.



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

There are no specific requirements.



04.
Physicians'
licensing /
qualifications

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

Hematology, Pediatrics, oncology or immunology residency are official training by the Health Autorithy of Spain with specific programs and regulations. There are no formal subspecialization in transplant.



05. Requirements for the consent from

minor donors

B6.2.6

The law has specific requirements concerning who can obtain informed consent: Legal representation and an ethical committee must give approval.



06.
Certification of laboratories for donor testing

B6.3.6

Regional transplantation authority authorises the Laboratory for donor testing by means of a license.

|                                      | Testing required | Risk<br>assessment<br>required | None |
|--------------------------------------|------------------|--------------------------------|------|
| Human immunodeficiency virus, type 1 | $\otimes$        | •                              |      |
| Human immunodeficiency virus, type 2 | <b>⊗</b>         |                                |      |
| Hepatitis B virus                    | Ø                |                                |      |
| Hepatitis C virus                    | <b>⊗</b>         |                                |      |
| Treponema pallidum (syphilis)        | <b>⊗</b>         |                                |      |
| Human T cell lymphotropic virus I    |                  | ⊗                              |      |
| Human T cell lymphotropic virus II   |                  | ⊗                              |      |
| West Nile Virus                      |                  | <b>⊗</b>                       |      |
| Trypanosoma cruzi (Chagas' Disease)  |                  | 8                              |      |

## **Additional comments**

CMV, T. cruzi, toxoplasma, malaria, Dengue, VEB, depending on donor history or cell characteristics



ISBT128 is used in Collection and Processing facilities, and SEC.



A document from the regional Health authority accrediting the unit to perform transplants (official document). Also, an ethical committee approval may be required depending on the institution.



Statement "WARNING: Advise Patient

"WARNING:

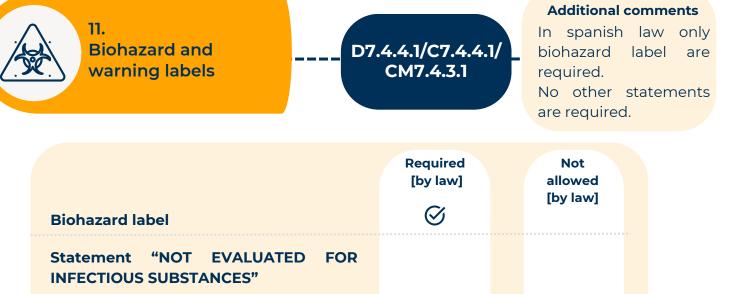
TestResults for [name of disease agent

of Communicable Disease Risks"

Statement

or disease]

Spanish legislation doesn't allow for the distribution of products before the donor eligibility process has been completed. This can be done in specific cases, but there are minimum requirements.



Reactive