





 **1. Requirement for JACIE** — JACIE is voluntary.

 **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:**
National Transplantation Organization (EOM)


 **Document that demonstrates that the unit complies with the national laws and regulations:**
National Certificate for Transplantation

 **03. cGXP training requirements** — **CM3.3.4** — There are no specific requirements.

 **04. Physicians' licensing / qualifications** — **B3.1.1, B3.2.1** — Physicians hold a license.

 **05. Consent from minor donors** — **B6.2.6**

The national law specifically requires that informed consent must be obtained from a legally authorized representative.

 **06. Laboratory testing of all donors including autologous** — **B6.3.6** — The Ministry of Health authorises the Laboratory for donor testing by means of a license.

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) | | ✓ | |

08. Product labelling and coding system

D7.1.2, C7.1.2, CM7.1.2

ISBT128/ Eurocode – no specific requirement is used in Collection and Processing facilities, and SEC.

09. Investigational treatment protocols and patient consent forms

B8.1, B8.2

The Hospital's Scientific Committee gives approval that a facility complies with applicable national legislation and regulations.

10. Distribution before completion of donor eligibility

D4.7.4, C7.4.7, CM7.4.7

Greek legislation allows for the distribution of products before the donor eligibility process has been completed.

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]" | ✓ | |