This survey was initiated in June 2011 and was sent to JACIE National Representatives.

The aim of this survey was to collect basic information on the different national regulations relevant to the JACIE Standards. With the results of the survey, we will be able to provide the inspectors with a list of information that they should expect to see during the inspection. This is especially relevant for when an inspector goes to visit a centre in another country and is unfamiliar with local regulations.

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1. Country

Austria

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - BM für Arbeit, Soziales und Gesundheit (Ministry of health)
Collection BM (C1.2) - BM für Arbeit, Soziales und Gesundheit (Ministry of health)
Collection Apheresis (C1.2) - BM für Arbeit, Soziales und Gesundheit (Ministry of health)
Cell Processing (D1.2) - BM für Arbeit, Soziales und Gesundheit (Ministry of health)

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - Betriebsbewilligung (licence)
Collection BM (C1.2) - Betriebsbewilligung (licence)
Collection Apheresis (C1.2) - Betriebsbewilligung und Herstellungsgenehmigung (licence)
Cell Processing (D1.2) - Herstellungsgenehmigung (licence)

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

Facharztzeugnis (certificate of specialisation) Zusatzfach i.S. des Facharztzeugnisses (certificate of (sub-)specialisation)

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

none

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate English translation)? If there is no regulatory requirement, please write “none”.

BM A.S.G. / AGES ministry of health / agency of regulatory affairs

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Betriebsbewilligung / Herstellungsgenehmigung certificate

8. What are the requirements for these diseases under the laws and regulations in your country?
<table>
<thead>
<tr>
<th>Testing</th>
<th>Risk assessment</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6.6.2.1 Human T cell lymphotrophic virus I.</td>
<td></td>
<td>X</td>
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<tr>
<td>B6.6.3.2 Human T cell lymphotrophic virus II</td>
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<td>X</td>
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<tr>
<td>B6.6.2.3 West Nile Virus.</td>
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<td></td>
</tr>
<tr>
<td>B6.6.2.4 Trypanosoma cruzi (Chagas’ Disease)</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

### AGES

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

### Betreibsbewilligung / herstellungsgenehmigung

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

### Betreibsbewilligung / herstellungsgenehmigung

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

### Betreibsbewilligung / herstellungsgenehmigung

13. Other relevant information

No Response
Belgium

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write "none".

<table>
<thead>
<tr>
<th>Unit</th>
<th>Certification/Registration Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Units (B1.3.1)</td>
<td>none</td>
</tr>
<tr>
<td>Collection BM (C1.2)</td>
<td>Federal Agency for Medicine and Health Products (FAGG/AFMPS)</td>
</tr>
<tr>
<td>Collection Apheresis (C1.2)</td>
<td>Federal Agency for Medicine and Health Products (FAGG/AFMPS)</td>
</tr>
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<td>Cell Processing (D1.2)</td>
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</tr>
<tr>
<td>Medical Licence by the Ministry of Health</td>
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</table>

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write "none".

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<td>FAGG/AFMPS licence</td>
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</tr>
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</tr>
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</table>

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write "none".

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write "none".

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate English translation)? If there is no regulatory requirement, please write "none".

<table>
<thead>
<tr>
<th>Laboratory for donor testing</th>
<th>Certification/Registration Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minister van Volksgezondheid - Minister of Health</td>
<td></td>
</tr>
</tbody>
</table>

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write "none".

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<tbody>
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<tr>
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<td>X</td>
</tr>
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<td>B6.6.2.4 Trypanosoma cruzi (Chagas’ Disease)</td>
<td>X</td>
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9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write "none".

FAGG/AFMPS

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write "none".

licence by FAGG/AFMPS

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write "none".

licence by FAGG/AFMPS

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write "none".

licence by FAGG/AFMPS

13. Other relevant information

1. Country

Finland

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - FIMEA, Finnish Medical Agency

Collection BM (C1.2) - FIMEA

Collection Apheresis (C1.2) - FIMEA

Cell Processing (D1.2) - FIMEA

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - licence

Collection BM (C1.2) - licence

Collection Apheresis (C1.2) - licence

Cell Processing (D1.2) - licence

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

written document
5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate English translation)? If there is no regulatory requirement, please write “none”.

FINAS (Finnish Accreditation Service)

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

8. What are the requirements for these diseases under the laws and regulations in your country?

<table>
<thead>
<tr>
<th>Disease</th>
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</tr>
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</tr>
<tr>
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<td></td>
<td></td>
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<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

FIMEA

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

None exactly for this purpose

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

None- general document

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

6/22
13. Other relevant information

No Response
1. Country

**Germany**

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

**Clinical Units (B1.3.1)** - None

**Collection BM (C1.2)** - Regional Governments and Paul Ehrlich Institute (PEI)

**Collection Apheresis (C1.2)** - Regional Governments and Paul Ehrlich Institute

**Cell Processing (D1.2)** - Regional Governments and Paul Ehrlich Institute

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

**Clinical Units (B1.3.1)** - None

**Collection BM (C1.2)** - Herstellungserlaubnis, PEI-Genehmigung

**Collection Apheresis (C1.2)** - Herstellungserlaubnis, PEI-Genehmigung

**Cell Processing (D1.2)** - Herstellungserlaubnis, PEI-Genehmigung

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

Facharzturkunde Hematology/Oncology Certificate of DAG-KBT to be an approved transplant physician

Certificate of an experienced transplant physician who supervised the training in transplant medicine

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

None. In general informed consent by the father and the mother of the minor donor will suffice. The term "Sorgerecht" (legal right to care) is essential, if there is no marriage or divorce.

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate) English translation? If there is no regulatory requirement, please write “none”.

Laboratories have to take part in external quality control provided by a number of institutions (e.g. INSTAND Ringversuche)
7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Certificate of participation in the external quality control system, normally on an annual basis

8. What are the requirements for these diseases under the laws and regulations in your country?

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<tr>
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</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

Paul Ehrlich Institut (PEI), Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

Genehmigung der klinischen Prüfung by PEI or BfArM

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Genehmigung der klinischen Prüfung by PEI or BfArM

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Zulassung des Produktes

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Certificate for participation in external quality testing, in general renewed on an annual basis

13. Other relevant information

No Response
1. Country

**Hungary**

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

**Clinical Units (B1.3.1)** –
1. Nemzeti Erőforrás Minisztérium (Ministry of National Resources): law;
2. Állami Népegészségügyi és Tisztiorvosi Szolgálat (National Public Health and Medical Officer Service (NPHMOS)): business licence;
3. Országos Egészségbiztosítási Pénztár (National Health Insurance Fund): number of cases financed /year

**Collection BM (C1.2)** –
1. Nemzeti Erőforrás Minisztérium (Ministry of National Resources): law;
2. Állami Népegészségügyi és Tisztiorvosi Szolgálat (National Public Health and Medical Officer Service (NPHMOS)): business licence;
3. Országos Egészségbiztosítási Pénztár (National Health Insurance Fund): number of cases financed /year

**Collection Apheresis (C1.2)** –
1. Nemzeti Erőforrás Minisztérium (Ministry of National Resources): law;
2. Állami Népegészségügyi és Tisztiorvosi Szolgálat (National Public Health and Medical Officer Service (NPHMOS)): business licence;
3. Országos Egészségbiztosítási Pénztár (National Health Insurance Fund): number of cases financed /year

**Cell Processing (D1.2)** –
1. Nemzeti Erőforrás Minisztérium (Ministry of National Resources): law;
2. Állami Népegészségügyi és Tisztiorvosi Szolgálat (National Public Health and Medical Officer Service (NPHMOS)): business licence;
3. Országos Egészségbiztosítási Pénztár (National Health Insurance Fund): number of cases financed /year

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - law, business licence,
Collection BM (C1.2) - law, business licence,
Collection Apheresis (C1.2) - law, business licence,
Cell Processing (D1.2) - business licence,

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

10/22
Certificate of specialisation (exam of Hematology..)
Certificate of functioning (where and what kind of job and how long she/he worked)

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

ALLOGENEIC MINOR DONORS: informed consents of parents (or legal guardian in the absence of parents) + hospital ethical committee + permission of Pediatric or Adult (depending on the recipient) Transplantation Committee are needed
AUTOLOGOUS MINOR DONOR: informed consents of parents (or legal guardian in the absence of parents), only

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate) English translation)? If there is no regulatory requirement, please write “none”.

Licence

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

8. What are the requirements for these diseases under the laws and regulations in your country?

<table>
<thead>
<tr>
<th>Disease</th>
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<tr>
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</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

Local regulation (at hospital), only

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Licence of National Public Health and Medical Officer Service (NPHMOS)

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Állami Népegészségügyi és Tisztiorvosi Szolgálat (National Public Health and Medical Officer Service) (NPHMOS)
12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Licence of National Public Health and Medical Officer Service (NPHMOS) + hospital ISO certificate

13. Other relevant information

No Response
1. Country

Italy

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - Gruppu Italiano di Midollo osseo e terapie Cellulari (GITMO) on behalf of Centro nazionale trapianti (CNT)

Collection BM (C1.2) - Centro Nazionale Trapianti (CNT)

Collection Apheresis (C1.2) - Centro Nazionale Sangue (CNS)

Cell Processing (D1.2) - Centro Nazionale Trapianti (CNT)

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - GITMO code: “CIC number of the Transplant Centre”

Collection BM (C1.2) - Italian Bone Marrow Donor Registry code, CNT/CNS accreditation award

Collection Apheresis (C1.2) - Italian Bone Marrow Donor Registry code, CNT/CNS accreditation award

Cell Processing (D1.2) - CNT/CNS accreditation award

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

Current medical license, specialist certification

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

Civil code article 414: the informed consent for minor donors must be obtained from the legal guardian.

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate) English translation)? If there is no regulatory requirement, please write “none”.

The HLA laboratory must be EFI certified.

All the other tests must be performed in a laboratory authorised by the Regional Authorities

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

13/22
EFI accreditation award for the HLA lab
Institutional accreditation and Regional code number assignment for the other labs

8. What are the requirements for these diseases under the laws and regulations in your country?

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<td></td>
</tr>
</tbody>
</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

Local Ethical Committee on behalf of Agenzia Italiana del Farmaco (AIFA)

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Ethical Committee approval

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

CE marking

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

CE marking of all reagents and kits used

13. Other relevant information

1. Country

Slovakia

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

- Clinical Units (B1.3.1) - Ministry of Health of Slovak Republic (SR)
- Collection BM (C1.2) - Ministry of Health of Slovak Republic (SR)
- Collection Apheresis (C1.2) - Ministry of Health of Slovak Republic (SR)
- Cell Processing (D1.2) - Ministry of Health of Slovak Republic (SR)

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

- Clinical Units (B1.3.1) - Štátny ústav pre kontrolu liečív (State Institute for Drug Control - ŠÚKL)
- Collection BM (C1.2) - ŠÚKL
- Collection Apheresis (C1.2) - ŠÚKL
- Cell Processing (D1.2) - ŠÚKL

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

Responsible person (Guarrantor) must have an appropriate medical specialisation - gained after examination at the accredited University after appropriate training (usually > 5 years). Person without this specialisation must work under supervision of an experienced person.

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

Donor’s parents or legal guardian in accordance with applicable laws and regulations and shall be documented

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate) English translation)? If there is no regulatory requirement, please write “none”.

Send this question, please, to dr. Maria Kusikova, e-mail kusikova@pe.unb.sk.
7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Send this question, please, to dr. Maria Kusikova, e-mail kusikova@pe.unb.sk.

8. What are the requirements for these diseases under the laws and regulations in your country?

<table>
<thead>
<tr>
<th>Disease</th>
<th>Testing</th>
<th>Risk assessment</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6.6.2.1 Human T cell lymphotrophic virus I.</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>B6.6.3.2 Human T cell lymphotrophic virus II</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>B6.6.2.3 West Nile Virus.</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>B6.6.2.4 Trypanosoma cruzi (Chagas’ Disease)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

*Other (please specify):* Send this question, please, to dr. Maria Kusikova, e-mail kusikova@pe.unb.sk.

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

ŠÚKL

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Confirmation from ŠÚKL

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

ŠÚKL

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

ŠÚKL

13. Other relevant information

All the fields you asked about are regulated in Slovakia and must be approved by competent authorities which are in most cases the Ministry of Health and the State Institute for Drug Control.
1. Country

Sweden

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

<table>
<thead>
<tr>
<th>Unit Type</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Units (B1.3.1)</td>
<td>The hospital but not the unit</td>
</tr>
<tr>
<td>Collection BM (C1.2)</td>
<td>The hospital but not the unit</td>
</tr>
<tr>
<td>Collection Apheresis (C1.2)</td>
<td>Socialstyrelsen (Board of health)</td>
</tr>
<tr>
<td>Cell Processing (D1.2)</td>
<td>Socialstyrelsen (Board of health)</td>
</tr>
</tbody>
</table>

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

<table>
<thead>
<tr>
<th>Unit Type</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Units (B1.3.1)</td>
<td>None</td>
</tr>
<tr>
<td>Collection BM (C1.2)</td>
<td>None</td>
</tr>
<tr>
<td>Collection Apheresis (C1.2)</td>
<td>Författningssamling: regulation</td>
</tr>
<tr>
<td>Cell Processing (D1.2)</td>
<td>Swedish law and regulations</td>
</tr>
</tbody>
</table>

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

Board certification

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

Swedish law.

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate) English translation? If there is no regulatory requirement, please write “none”.

SWEDAC (accreditation board)

ISO standard. Voluntary for the laboratories

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

ISO certificate
8. What are the requirements for these diseases under the laws and regulations in your country?

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Testing</th>
<th>Risk assessment</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6.6.2.1 Human T cell lymphotrophic virus I.</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B6.6.3.2 Human T cell lymphotrophic virus II</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>B6.6.2.3 West Nile Virus.</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>B6.6.2.4 Trypanosoma cruzi (Chagas’ Disease)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Other (please specify): HIV, HBV, HCV, syphilis</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

Regional Ethical Review Board

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Decision from the board

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

The basis is in the law. The MPA has published regulations

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

SWEDAC

13. Other relevant information

No Response
1. Country

**Turkey**

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - T.C. Saglik Bakanligi Tedavi Hizmetleri Genel Müdürlügü/Ministry of Health General Directorate of Curative Services

Collection BM (C1.2) - T.C. Saglik Bakanligi Tedavi Hizmetleri Genel Müdürlügü/

Collection Apheresis (C1.2) - T.C. Saglik Bakanligi Tedavi Hizmetleri Genel Müdürlügü/

Cell Processing (D1.2) - T.C. Saglik Bakanligi Tedavi Hizmetleri Genel Müdürlügü/

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - Certificate of Competence (one certificate is required for a stem cell transplantation center and covers all the below headings)

Collection BM (C1.2) - Certificate of Competence

Collection Apheresis (C1.2) - Certificate of Competence

Cell Processing (D1.2) - Certificate of Competence

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

Diploma from the University or MoH Education and Training Hospital + document showing that he/she had training for 1 year in a SCT Unit after sub-specialty education.

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

MoH Clinical Trials Bylaw states that informed consent and assent is required from children as stated above.

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate English translation)? If there is no regulatory requirement, please write “none”.

Saglik Bakanligi/Ministry of Health

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.
Certificate of Competence

8. What are the requirements for these diseases under the laws and regulations in your country?

<table>
<thead>
<tr>
<th>Disease Description</th>
<th>Testing</th>
<th>Risk assessment</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6.6.2.1 Human T cell lymphotrophic virus I.</td>
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<td>X</td>
</tr>
</tbody>
</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

MoH General Directorate of Pharmaceuticals and Pharmacy

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Ethical Committee approval and MoH approval letters

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

Certificate from MoH

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

None

13. Other relevant information

The new bylaw (regulation) in the writing process will be in concordance with JACIE requirements.
1. Country

United Kingdom

2. Which governmental authorities in your country register, authorise or certify the following units? Please provide the name in original language and (approximate) English translation. If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - None
Collection BM (C1.2) - Human Tissue Authority
Collection Apheresis (C1.2) - Human Tissue Authority
Cell Processing (D1.2) - Human Tissue Authority

3. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis If there is no regulatory requirement, please write “none”.

Clinical Units (B1.3.1) - None
Collection BM (C1.2) - Human Tissue Authority Licence
Collection Apheresis (C1.2) - Human Tissue Authority Licence
Cell Processing (D1.2) - Human Tissue Authority Licence

4. How can physicians demonstrate that they have specialist certification or training? If there is no regulatory requirement, please write “none”.

Completion Certificate of Specialist Training

5. For minor donors, does the national law have specific requirements concerning who can obtain informed consent? (e.g. consent must be obtained by a legal adviser) If there is no regulatory requirement, please write “none”.

Yes - and Specialist Assessors can be appointed by the HTA

6. Which governmental authorities in your country register, authorise or certify the Laboratory for donor testing (please provide the name in original language and approximate) English translation? If there is no regulatory requirement, please write “none”.

CPA

7. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

CPA Certificate

8. What are the requirements for these diseases under the laws and regulations in your country?
<table>
<thead>
<tr>
<th></th>
<th>Testing</th>
<th>Risk assessment</th>
<th>None</th>
</tr>
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<td></td>
<td>X</td>
<td></td>
</tr>
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</table>

9. What is the name of the appropriate governmental authority, if any? If there is no regulatory requirement, please write “none”.

None

10. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

None

11. What document(s) would demonstrate that a centre complies with the applicable national laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

HTA Licence

12. What document(s) would demonstrate that a centre is performing communicable disease testing according to applicable laws and regulations? Indicate the type of document and name e.g. licence, Herstellungserlaubnis. If there is no regulatory requirement, please write “none”.

CPA Certificate and HTA Licence

13. Other relevant information

No Response