Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (Text with EEA relevance)

Article 1 Definitions
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ANNEX I

SELECTION CRITERIA FOR DONORS OF TISSUES AND/OR CELLS (EXCEPT DONORS OF REPRODUCTIVE CELLS) AS REFERRED TO IN ARTICLE 3(a)

Selection criteria for donors are based on an analysis of...

1. Deceased Donors
   - 1.1. General criteria for exclusion
     - 1.1.1. Cause of death unknown, unless autopsy provides information on the...
     - 1.1.2. History of a disease of unknown aetiology.
     - 1.1.3. Presence, or previous history, of malignant disease, except for primary...
     - 1.1.4. Risk of transmission of diseases caused by prions. This risk...
     - 1.1.5. Systemic infection which is not controlled at the time of...
     - 1.1.6. History, clinical evidence, or laboratory evidence of HIV, acute or...
     - 1.1.7. History of chronic, systemic autoimmune disease that could have a...
     - 1.1.8. Indications that test results of donor blood samples will be...
     - 1.1.9. Evidence of any other risk factors for transmissible diseases on...
     - 1.1.10. Presence on the donor’s body of physical signs implying a...
     - 1.1.11. Ingestion of, or exposure to, a substance (such as cyanide,...
     - 1.1.12. Recent history of vaccination with a live attenuated virus where...
     - 1.1.13. Transplantation with xenografts.
   - 1.2. Additional exclusion criteria for deceased child donors
     - 1.2.1. Any children born from mothers with HIV infection or that...

2. Living donors
   - 2.1. Autologous living donor
     - 2.1.1. If the removed tissues and cells are to be stored...
   - 2.2. Allogeneic living donor

2.2.1. Allogeneic living donors must be selected on the basis of...
2.2.2. Selection criteria for allogeneic living donors must be established and...
2.2.3. The same exclusion criteria must be applied as for deceased...

ANNEX II

LABORATORY TESTS REQUIRED FOR DONORS (EXCEPT DONORS OF REPRODUCTIVE CELLS) AS REFERRED TO IN ARTICLE 4(1)

1. Biological tests required for donors
   1.1. The following biological tests must be performed for all donors...
   1.2. HTLV-I antibody testing must be performed for donors living in,...
   1.3. When anti-HBc is positive and HBsAg is negative, further investigations...
   1.4. A validated testing algorithm must be applied to exclude the...
   1.5. In certain circumstances, additional testing may be required depending on...
   1.6. For autologous donors, Annex I, point 2.1.1, applies.

2. General requirements to be met for determining biological markers
   2.1. The tests must be carried out by a qualified laboratory,...
   2.2. The biological tests will be carried out on the donor's...
   2.3. When potential donors have lost blood and have recently received...
   2.4. In the case of a deceased donor, blood samples must...
   2.5. In the case of living donors (except allogeneic bone marrow...
   2.6. If in a living donor (except bone marrow stem-cell and...
   2.7. In the case of bone marrow and peripheral blood stem-cell...
   2.8. In the case of neonatal donors, the biological tests may...

ANNEX III

SELECTION CRITERIA AND LABORATORY TESTS REQUIRED FOR DONORS OF REPRODUCTIVE CELLS AS REFERRED TO IN ARTICLE 3(b) AND ARTICLE 4(2)

1. Partner donation for direct use

2. Partner donation (not direct use)

3. Donations other than by partners

4. General requirements to be met for determining biological markers
   4.1. The tests must be carried out in accordance with Annex...
   4.2. For donations other than by partners, blood samples must be...
   4.3. Sperm donations other than by partners will be quarantined for...

ANNEX IV

CELL AND/OR TISSUE DONATION AND PROCUREMENT PROCEDURES AND RECEPTION AT THE TISSUE ESTABLISHMENT AS REFERRED TO IN ARTICLE 5

1. Donation and procurement procedures
   1.1. Consent and donor identification
      1.1.1. Before the procurement of tissues and cells proceeds, an authorised...

1.1.2. In the case of living donors, the health professional responsible...
1.2. Donor evaluation (this section does not apply to partner donation...
1.2.1. An authorised person must collect and record the donor's relevant...
1.2.2. In order to acquire the appropriate information, different relevant sources...
1.2.3. In addition, in the case of a deceased donor, and...
1.2.4. The complete donor records must be reviewed and assessed for...
1.3. Procurement procedures for tissues and cells
1.3.1. The procurement procedures must be appropriate for the type of...
1.3.2. The procurement procedures must protect those properties of the tissue/cells...
1.3.3. For deceased donation, the area of access must be restricted....
1.3.4. In the case of a deceased donor, the place of...
1.3.5. Once the tissues and cells have been retrieved from a...
1.3.6. Any adverse event occurring during procurement that has or may...
1.3.7. Policies and procedures must be in place to minimise the...
1.3.8. Sterile instruments and devices must be used for tissue and...
1.3.9. When reusable instruments must be used, a validated cleaning and...
1.3.10. Wherever possible, only CE marked medical devices must be used...
1.4. Donor documentation
1.4.1. For each donor, there must be a record containing:
1.4.2. The organisation performing the procurement must produce a procurement report,...
1.4.3. All the records must be clear and readable, protected from...
1.4.4. Donor records required for full traceability must be kept for...
1.5. Packaging
1.5.1. Following procurement, all recovered tissues and cells must be packaged...
1.5.2. The packaged cells/tissues must be shipped in a container which...
1.5.3. Any accompanying tissue or blood samples for testing must be...
1.6. Labelling of the procured tissues/cells
1.7. Labelling of the shipping container

2. Reception of the tissue/cells at the tissue establishment
2.1. When the retrieved tissues/cells arrive at the tissue establishment, there...
2.2. Each establishment must ensure that the tissue and cells received...
2.3. Each tissue establishment must have a documented policy and specifications...
2.4. The data that must be registered at the tissue establishment...
2.5. In the case of reproductive cells intended for partner donation,...

(**1**) OJ L 102, 7.4.2004, p. 48.