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 person must confirm and record:

(a) that consent for the procurement has been obtained in accordance with Article 13 of Directive 2004/23/EC; and

(b) how and by whom the donor has been reliably identified.

1.1.2. In the case of living donors, the health professional responsible for obtaining the health history must ensure that the donor has:

(a) understood the information provided;

(b) had an opportunity to ask questions and been provided with satisfactory responses;

(c) confirmed that all the information provided is true to the best of his/her knowledge.

1.2. Donor evaluation (this section does not apply to partner donation of reproductive cells or to autologous donors)

1.2.1. An authorised person must collect and record the donor's relevant medical and behavioural information according to the requirements described in section 1.4.

1.2.2. In order to acquire the appropriate information, different relevant sources must be used, including at least an interview with the donor, for living donors, and the following when appropriate:

(a) the medical records of the donor;

(b) an interview with a person who knew the donor well, for deceased donors;

(c) an interview with the treating physician;

(d) an interview with the general practitioner;

(e) the autopsy report.

1.2.3. In addition, in the case of a deceased donor, and in the case of a living donor when justified, a physical examination of the body must be performed to detect any signs that may be sufficient in themselves to exclude the donor or which must be assessed in the light of the donor's medical and personal history.

1.2.4. The complete donor records must be reviewed and assessed for suitability and signed by a qualified health professional.

1.3. Procurement procedures for tissues and cells

1.3.1. The procurement procedures must be appropriate for the type of donor and the type of tissue/cells donated. There must be procedures in place to protect the safety of the living donor.

1.3.2. The procurement procedures must protect those properties of the tissue/cells that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process, particularly when tissues and cells cannot subsequently be sterilised.

1.3.3. For deceased donation, the area of access must be restricted. A local sterile field using sterile drapes must be used. Staff conducting procurement must be clothed appropriately for the type of procurement. Usually, this will extend to being scrubbed, gowned in sterile clothing and wearing sterile gloves, face shields and protective masks.

1.3.4. In the case of a deceased donor, the place of procurement must be recorded and the time interval from death to procurement must be specified so as to ensure that the required biological and/or physical properties of the tissues/cells are retained.

1.3.5. Once the tissues and cells have been retrieved from a deceased donor body, it must be reconstructed so that it is as similar as possible to its original anatomical appearance.

1.3.6. Any adverse event occurring during procurement that has or may have resulted in harm to a living donor and the outcome of any investigation to determine the cause must be recorded and reviewed.

1.3.7. Policies and procedures must be in place to minimise the risk of tissue or cell contamination by staff who might be infected with transmissible diseases.

1.3.8. Sterile instruments and devices must be used for tissue and cell procurement. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.

1.3.9. When reusable instruments must be used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.

1.3.10. Wherever possible, only CE marked medical devices must be used and all concerned staff must have received appropriate training on the use of such devices.

1.4. Donor documentation

1.4.1. For each donor, there must be a record containing:

(a) the donor identification (first name, family name and date of birth — if a mother and child are involved in the donation, both the name and date of birth of the mother and the name, if known, and date of birth of the child);

(b) age, sex, medical and behavioural history (the information collected must be sufficient to allow application of the exclusion criteria, where required);

(c) outcome of body examination, where applicable;

(d) haemodilution formula, where applicable;

(e) the consent/authorisation form, where applicable;

(f) clinical data, laboratory test results, and the results of other tests carried out;

(g) if an autopsy was performed, the results must be included in the record (for tissues and cells that cannot be stored for extended periods, a preliminary verbal report of the autopsy must be recorded);

(h) for haematopoietic progenitor cell donors, the donor's suitability for the chosen recipient must be documented. For unrelated donations, when the organisation responsible for procurement has limited access to recipient data, the transplanting organisation must be provided with donor data relevant for confirming suitability.

1.4.2. The organisation performing the procurement must produce a procurement report, which is passed on to the tissue establishment. This report must contain at least:

(a) the identification, name and address of the tissue establishment to receive the cells/tissues;

(b) donor identification data (including how and by whom the donor was identified);

(c) description and identification of procured tissues and cells (including samples for testing);

(d) identification of the person who is responsible for the procurement session, including signing;

(e) date, time (where relevant, start and end) and location of procurement and procedure (SOP) used, including any incidents that occurred; where relevant, environmental conditions at the procurement facility (description of the physical area where procurement took place);

(f) for deceased donors, conditions under which the cadaver is kept: refrigerated (or not), time of start and end of refrigeration;

(g) ID/batch numbers of reagents and transport solutions used.

The report must also contain the date and time of death where possible.

Where sperm is procured at home, the procurement report must state this and must contain only:

(a) the name and address of the tissue establishment to receive the cells/tissues;

(b) the donor identification.

The date and time of procurement may be included, where possible.

1.4.3. All the records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

1.4.4. Donor records required for full traceability must be kept for a minimum of 30 years after clinical use, or the expiry date, in an appropriate archive acceptable to the competent authority.

1.5. Packaging

1.5.1. Following procurement, all recovered tissues and cells must be packaged in a manner which minimises the risk of contamination and must be stored at temperatures that preserve the required characteristics and biological function of the cells/tissues. The packaging must also prevent contamination of those responsible for packaging and transportation of the tissues and cells.

1.5.2. The packaged cells/tissues must be shipped in a container which is suitable for the transport of biological materials and which maintains the safety and quality of the contained tissue or cells.

1.5.3. Any accompanying tissue or blood samples for testing must be accurately labelled to ensure identification with the donor, and must include a record of the time and place the specimen was taken.

1.6. Labelling of the procured tissues/cells

At the time of procurement, every package containing tissues and cells must be labelled. The primary tissue/cell container must indicate the donation identification or code and the type of tissues and cells. Where the size of the package permits, the following information must also be provided:

(a) date (and time where possible) of donation;

(b) hazard warnings;

(c) nature of any additives (if used);

(d) in the case of autologous donations, the label must state ‘for autologous use only’;

(e) in the case of directed donations, the label must identify the intended recipient.

If any of the information under points (a) to (e) above cannot be included on the primary package label, it must be provided on a separate sheet accompanying the primary package.

1.7. Labelling of the shipping container

When tissues/cells are shipped by an intermediary, every shipping container must be labelled at least with:

(a) TISSUES AND CELLS and HANDLE WITH CARE;

(b) the identification of the establishment from which the package is being transported (address and phone number) and a contact person in the event of problems;

(c) the identification of the tissue establishment of destination (address and phone number) and the person to be contacted to take delivery of the container;

(d) the date and time of the start of transportation;

(e) specifications concerning conditions of transport relevant to the quality and safety of the tissues and cells;

(f) in the case of all cellular products, the following indication: DO NOT IRRADIATE;

(g) when a product is known to be positive for a relevant infectious disease marker, the following indication: BIOLOGICAL HAZARD;

(h) in the case of autologous donors, the following indication: ‘FOR AUTOLOGOUS USE ONLY’;

(i) specifications concerning storage conditions (such as DO NOT FREEZE).

2. Reception of the tissue/cells at the tissue establishment

2.1. When the retrieved tissues/cells arrive at the tissue establishment, there must be documented verification that the consignment, including the transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of this Annex and the specifications of the receiving establishment.

2.2. Each establishment must ensure that the tissue and cells received are quarantined until they, along with the associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant donor/procurement information and thus acceptance of the donation needs to be carried out by specified/ authorised persons.

2.3. Each tissue establishment must have a documented policy and specifications against which each consignment of tissues and cells, including samples, are verified. These must include the technical requirements and other criteria considered by the tissue establishment to be essential for the maintenance of acceptable quality. The tissue establishment must have documented procedures for the management and segregation of non-conforming consignments, or those with incomplete test results, to ensure that there is no risk of contamination of other tissues and cells being processed, preserved or stored.

2.4. The data that must be registered at the tissue establishment (except for donors of reproductive cells intended for partner donation) include:

(a) consent/authorisation; including the purpose(s) for which the tissues and cells may be used (i.e. therapeutic or research, or both therapeutic use and research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;

(b) all required records relating to the procurement and the taking of the donor history, as described in the donor documentation section;

(c) results of physical examination, of laboratory tests and of other tests (such as the autopsy report, if used in accordance with point 1.2.2.);

(d) for allogeneic donors, a properly documented review of the complete donor evaluation against the selection criteria by an authorised and trained person;

(e) in the case of cell cultures intended for autologous use, documentation of the possibility of medicinal allergies (such as to antibiotics) of the recipient.

2.5. In the case of reproductive cells intended for partner donation, the data to be registered at the tissue establishment include:

(a) consent; including the purpose(s) for which the tissues and cells may be used (such as reproductive only and/or for research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;

(b) donor identification and characteristics: type of donor, age, sex, presence of risk factors and, in the case of a deceased donor, the cause of death;

(c) partner identification;

(d) place of procurement;

(e) tissues and cells obtained and relevant characteristics.