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L.N. 222 of 2014

HUMAN BLOOD AND TRANSPLANTS ACT (CAP. 483)

Human Tissues and Cells (Quality and Safety) (Amendment) Regulations, 2014

IN exercise of the powers conferred by article 16 of the Human Blood and Transplants Act, the Minister for Energy and Health, after consultation with the Licensing Authority, has made the following regulations:-

Citation.

S.L. 483.01

1. The title of these regulations is the Human Tissues and Cells (Quality and Safety) (Amendment) Regulations, 2014, and these regulations shall be read and construed as one with the Human Tissues and Cells (Quality and Safety) Regulations, hereinafter referred to as "the principal regulations".

Amends regulation 1 of the principal regulations.

2. Immediately after sub-regulation (2) of regulation 1 of the principal regulations, there shall be added the following new sub-regulation:

"(3) The scope of these regulations is also to transpose Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells.".

Amends regulation 2 of the principal regulations.

3. In regulation 2 of the principal regulations, for the definition "Directive 2006/17/EC", there shall be substituted the following new definition:

" "Directive 2006/17/EC" means the Directive of the European Parliament and of the Council of the 8th February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells as amended by Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells;".

Amends regulation 3 of the principal regulations.

4. Paragraph (c) of sub-regulation (1) of regulation 3 of the principal regulations shall be substituted by the following:

"(c) ensuring that appropriate control measures are in place within the tissue establishment and implementing the requirements of regulations 4, 5, 7, 8, 11, 12, 13, 14, 15 within

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the tissue establishment;".

5. Regulation 4 of the principal regulations shall be amended as follows:

Amends regulation 4 of the principal regulations.

(a) for paragraphs (b), (c) and (d) thereof there shall be substituted the following:

"(b) ensure that all donations of human tissues and cells are subjected to tests in accordance with the requirements referred to in these regulations and any schedules and any amendments thereto and that the selection and acceptance of tissues and cells comply with the requirements referred to in these regulations and any schedules and any amendments thereto;

(c) ensure that human tissue and cells and associated documentation comply with the requirements referred to in these regulations and any schedules and any amendments thereto;

(d) verify and record the fact that the packaging of human tissue and cells received complies with the requirements referred to in these regulations and any schedules and any amendments thereto;";

(b) for paragraph (k) thereof there shall be substituted the following:

"(k) ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements referred to in these regulations and any schedules and any amendments thereto;";

(c) for paragraph (n) thereof there shall be substituted the following:

"(n) ensure that all procedures associated with the storage of tissues and cells are documented in the standard operating procedures and that the storage conditions comply with the requirements referred to in these regulations and any schedules and any amendments thereto;";

(d) for paragraph (q) thereof there shall be substituted the following:

"(q) not to distribute processed tissues and cells until all the requirements laid down in these regulations and any schedules and any amendments thereto have been met;"; and

(e) for paragraphs (s) and (t) thereof there shall be substituted the following:

"(s) ensure that labelling and documentation and packaging conform to the requirements set by these regulations and any schedules and any amendments thereto; and

(t) ensure that the quality of tissues and cells during distribution and that the distribution conditions comply with the requirements set by these regulations and any schedules and any amendments thereto.".

Amends regulation 5 of the principal regulations.

6. Paragraph (b) of sub-regulation (1) of regulation 5 of the principal regulations shall be substituted by the following:

"(b) evaluate and select third parties on the basis of their ability to meet the standards laid down in these regulations and any schedules and any amendments thereto;".

Amends regulation 6 of the principal regulations.

7. Paragraph (c) of regulation 6 of the principal regulations shall be substituted by the following:

"(c) all tissues and cells are identified with a label that contains the information or references allowing a link to the information referred to in the schedules to these regulations and any amendments thereto; and".

Amends regulation 7 of the principal regulations.

8. Sub-regulation (1) of regulation 7 of the principal regulations shall be substituted by the following:

"(1) Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and, or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in these regulations and any schedules and any amendments thereto.".

Amends regulation 9 of the principal regulations.

9. Regulation 9 of the principal regulations shall be amended as follows:

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(a) for paragraph (c) thereof, there shall be substituted the following:

"(c) put and keep in place procedures for the evaluation of donors in accordance with the requirements set by these regulations and schedules and any amendments thereto;"; and

(b) for paragraph (h) thereof, there shall be substituted the following:

"(h) the tissues and cells are procured, packaged and transported in accordance with the requirements set by these regulations and any schedules and any amendments thereto.".

Amends regulation 10 of the principal regulations.

10. In sub-regulation (4) of regulation 10 of the principal regulations, for the words "the Annex to Directive 2004/23/EC" there shall be substituted the words "Schedule I".

Amends regulation 12 of the principal regulations.

11. Regulation 12 of the principal regulations shall be amended as follows:

(a) in sub-regulation (2) thereof, for the words "Annex I of Directive 2006/17/EC" there shall be substituted the words "Schedule II";

(b) in sub-regulation (6) thereof, for the words "Annex IV, section 1.3 of Directive 2006/17/EC" there shall be substituted the words "section 1.3 of Schedule V"; and

(c) in sub-regulation (11) thereof, for the words "section 1.4 of Annex IV of Directive 2006/17/EC" there shall be substituted the words "section 1.4 of Schedule V".

Substitutes regulation 13 of the principal regulations.

12. Regulation 13 of the principal regulations shall be substituted by the following:

"13. Tissue and cells establishments shall in respect of donors adopt the selection criteria set out in these regulations namely:

(a) Schedule II for donors of tissues and cells, except donors of reproductive cells;

(b) Schedule IV for donors of reproductive cells.".

Substitutes regulation 14 of the principal regulations.

13. Regulation 14 of the principal regulations shall be substituted by the following:

"14. It shall be the duty of the establishment to ensure that:

(a) donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Schedule III;

(b) such tests are carried out in compliance with the general requirements set out in point 2 of Schedule III;

(c) donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Schedule IV;

(d) such tests are carried out in compliance with the general requirements set out in point 4 of Schedule IV.".

Amends regulation 15 of the principal regulations.

14. In regulation 15 of the principal regulations, for the words "Annex IV of Directive 2006/17/EC" there shall be substituted the words "Schedule IV".

Adds new schedules to the principal regulations.

15. Immediately after regulation 16 of the principal regulations, there shall be added the following new schedules:

"SCHEDULE 1

Information to be provided on the Donation of Cells and/or Tissues

A. Living donors

1. The person in charge of the donation process shall ensure that the donor has been properly informed of at least those aspects relating to the donation and procurement process outlined in paragraph 3. Information must be given prior to the procurement.

2. The information must be given by a trained person able to transmit it in an appropriate and clear manner, using terms that are easily understood by the donor.

3. The information must cover: the purpose and nature of the procurement, its consequences and risks; analytical tests, if they are performed; recording and protection of donor data, medical confidentiality; therapeutic purpose and potential benefits and information on the applicable safeguards intended to protect the donor.

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4. The donor must be informed that he/she has the right to receive the confirmed results of the analytical tests, clearly explained.

5. Information must be given on the necessity for requiring the applicable mandatory consent, certification and authorisation in order that the tissue and/or cell procurement can be carried out.

B. Deceased donors

1. All information must be given and all necessary consents and authorisations must be obtained in accordance with the National legislation in force.

2. The confirmed results of the donor's evaluation must be communicated and clearly explained to the relevant persons in accordance with the relevant national legislation.

SCHEDULE II

Selection Criteria for Donors of Tissues and/or Cells
(except Donors of Reproductive Cells)
as referred to in paragraph (a) of regulation 13.

Selection criteria for donors are based on an analysis of the risks related to the application of the specific cells/tissues.

Indicators of these risks must be identified by physical examination, review of the medical and behavioural history, biological testing, post-mortem examination (for deceased donors) and any other appropriate investigation. Unless justified on the basis of a documented risk assessment approved by the responsible person as defined in regulation 3, donors must be excluded from donation if any of the following criteria applies:

1. Deceased Donors

1.1. General criteria for exclusion

1.1.1. Cause of death unknown, unless autopsy provides information on the cause of death after procurement and none of the general criteria for exclusion set out in the present section applies.

1.1.2. History of a disease of unknown aetiology.

1.1.3. Presence, or previous history, of malignant disease, except for primary basal cell carcinoma, carcinoma in situ of the

uterine cervix, and some primary tumours of the central nervous system that have to be evaluated according to scientific evidence. Donors with malignant diseases can be evaluated and considered for cornea donation, except for those with retinoblastoma, haematological neoplasm, and malignant tumours of the anterior segment of the eye.

1.1.4. Risk of transmission of diseases caused by prions. This risk applies, for example, to:

(a) people diagnosed with Creutzfeldt-Jakob disease, or variant Creutzfeldt-Jacob disease, or having a family history of non-iatrogenic Creutzfeldt-Jakob disease;

(b) people with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin;

(c) recipients of hormones derived from the human pituitary gland (such as growth hormones) and recipients of grafts of cornea, sclera and dura mater, and persons that have undergone undocumented neurosurgery (where dura mater may have been used).

For variant Creutzfeldt-Jakob disease, further precautionary measures may be recommended.

1.1.5. Systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissues and cells to be donated. Donors with bacterial septicaemia may be evaluated and considered for eye donation but only where the corneas are to be stored by organ culture to allow detection of any bacterial contamination of the tissue.

1.1.6. History, clinical evidence, or laboratory evidence of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections.

1.1.7. History of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the tissue to be retrieved.

1.1.8. Indications that test results of donor blood samples will be invalid due to:

(a) the occurrence of haemodilution, according to the

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specifications in Schedule III, section 2, where a pre-transfusion sample is not available; or

(b) treatment with immunosuppressive agents.

1.1.9. Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor travel and exposure history and local infectious disease prevalence.

1.1.10. Presence on the donor's body of physical signs implying a risk of transmissible disease(s) as described in Schedule V, point 1.2.3.

1.1.11. Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.

1.1.12. Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist.

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 meet any of the exclusion criteria described in section 1.1 must be excluded as donors until the risk of transmission of infection can be definitely ruled out.

(a) Children aged less than 18 months born from mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have been breastfed by their mothers during the previous 12 months, cannot be considered as donors regardless of the results of the analytical tests.

(b) Children of mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have not been breastfed by their mothers during the previous 12 months and for whom analytical tests, physical examinations, and reviews of medical records do not provide evidence of HIV, hepatitis B, hepatitis C or HTLV infection, can be accepted as donors.

2. Living donors

2.1. Autologous living donor

2.1.1. If the removed tissues and cells are to be stored or cultured, the same minimum set of biological testing requirements must apply as for an allogeneic living donor. Positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and reimplanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts and/or no risk of contamination with adventitious agents and/or mix-ups.

2.2. Allogeneic living donor

2.2.1. Allogeneic living donors must be selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained healthcare professional with the donor, in compliance with point 2.2.2. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves. For any donation, the collection process must not interfere with or compromise the health or care of the donor. In the case of cord blood or amniotic membrane donation, this applies to both mother and baby.

2.2.2. Selection criteria for allogeneic living donors must be established and documented by the tissue establishment (and the transplanting clinician in the case of direct distribution to the recipient), based on the specific tissue or cells to be donated, together with the donor's physical status and medical and behavioural history and the results of clinical investigations and laboratory tests establishing the donor's state of health.

2.2.3. The same exclusion criteria must be applied as for deceased donors with the exception of point 1.1.1. Depending on the tissue or cell to be donated, other specific exclusion criteria may need to be added, such as:

(a) pregnancy (except for donors of umbilical cord blood cells and amniotic membrane and sibling donors of haematopoietic progenitors);

(b) breastfeeding;

(c) in the case of haematopoietic progenitor cells, the potential for transmission of inherited conditions.

SCHEDULE III

Laboratory Tests required for Donors (except Donors of Reproductive Cells) as referred to in paragraph (a) of regulation 13.

1. Biological tests required for donors

1.1. The following biological tests must be performed for all donors as a minimum requirement:

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HBsAg Anti HBc
Hepatitis C	Anti-HCV-Ab
Syphilis	See 1.4 (below)

1.2. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

1.3. When anti-HBc is positive and HBsAg is negative, further investigations are necessary with a risk assessment to determine eligibility for clinical use.

1.4. A validated testing algorithm must be applied to exclude the presence of active infection with Treponema pallidum. A non-reactive test, specific or non-specific, can allow tissues and cells to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. A donor whose specimen tests reactive on a Treponema-specific test will require a thorough risk assessment to determine eligibility for clinical use.

1.5. In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi).

1.6. For autologous donors, Schedule II, 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, authorised as a testing centre by the Licensing Authority, using EC-marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific

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knowledge.

2.2. The biological tests will be carried out on the donor's serum or plasma; they must not be performed on other fluids or secretions such as the aqueous or vitreous humour unless specifically justified clinically using a validated test for such a fluid.

2.3. When potential donors have lost blood and have recently received donated blood, blood components, colloids or crystalloids, blood testing may not be valid due to haemodilution of the sample. An algorithm must be applied to assess the degree of haemodilution in the following circumstances:

(a) ante-mortem blood sampling: if blood, blood components and/or colloids were infused in the 48 hours preceding blood sampling or if crystalloids were infused in the hour preceding blood sampling;

(b) post-mortem blood sampling: if blood, blood components and/or colloids were infused in the 48 hours preceding death or if crystalloids were infused in the hour preceding death.

Tissue establishments may accept tissues and cells from donors with plasma dilution of more than 50 % only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available.

2.4. In the case of a deceased donor, blood samples must have been obtained just prior to death or, if not possible, the time of sampling must be as soon as possible after death and in any case within 24 hours after death.

2.5. (a) In the case of living donors (except allogeneic bone marrow stem-cell and peripheral blood stem-cell donors, for practical reasons), blood samples must be obtained at the time of donation or, if not possible, within seven days post donation (this is the 'donation sample').

(b) Where tissues and cells of allogeneic living donors can be stored for long periods, repeat sampling and testing is required after an interval of 180 days. In these circumstances of repeat testing, the donation sample can be taken up to 30 days prior to and 7 days post donation.

(c) Where tissues and cells of allogeneic living donors cannot be stored for long periods and repeat sampling is therefore not

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possible, point 2(5)(a) above applies.

2.6. If in a living donor (except bone marrow stem-cell and peripheral blood stem-cell donors) the 'donation sample', as defined in point 2(5)(a) above, is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

2.7. In the case of bone marrow and peripheral blood stem-cell collection, blood samples must be taken for testing within 30 days prior to donation.

2.8. In the case of neonatal donors, the biological tests may be carried out on the donor's mother to avoid medically unnecessary procedures upon the infant.

SCHEDULE IV

Selection Criteria and Laboratory Tests required for Donors of Reproductive Cells as referred to in regulation 13(b) and regulation 14(c)

1. Partner donation for direct use

Donor selection criteria and laboratory testing do not need to be applied in the case of partner donation of reproductive cells for direct use.

2. Partner donation (not direct use)

Reproductive cells that are processed and/or stored and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria:

2.1. the clinician responsible for the donor must determine and document, based on the patient's medical history and therapeutic indications, the justification for the donation and its safety for the recipient and any child(ren) that might result;

2.2. the following biological tests must be carried out to assess the risk of cross-contamination:

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HBsAg Anti-HBc
Hepatitis C	Anti-HCV-Ab

In case of sperm processed for intrauterine insemination and not to be stored, if the tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required;

2.3. where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the donor is known to be a source of infection risk, a system of separate storage must be devised;

2.4. HTLV-I antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

2.5. in certain circumstances, additional testing may be required depending on the donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. Rh D, malaria, CMV, T. cruzi);

2.6. positive results will not necessarily prevent partner donation in accordance with national rules.

3. Donations other than by partners

The use of reproductive cells other than for partner donation must meet the following criteria:

3.1. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or health risks to themselves (e.g. superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor);

3.2. the donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested in accordance with Schedule III, point 1.1, and sperm donors must additionally be

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negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT);

3.3. HTLV-I antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

3.4. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, T. cruzi).

3.5. for autologous donors, SCHEDULE II, point 2.1.1 applies;

3.6. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the requirements in force in Member States. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

4. General requirements to be met for determining biological markers

4.1. The tests must be carried out in accordance with Schedule III, points 2.1 and 2.2.

4.2. (a) For donations other than by partners, blood samples must be obtained at the time of each donation.

(b) For donation by partners (not for direct use), blood samples must be obtained within three months before the first donation. For further partner donations by the same donor, further blood samples must be obtained according to these regulations, but no later than 24 months from the previous sampling.

4.3. Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

SCHEDULE V

Cell and/or Tissue Donation and Procurement Procedures and Reception at the Tissue Establishment as referred to in regulation 15

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 regulation 9(a) and (b); 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;

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(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

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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 Licensing 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

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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 Schedule 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

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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.".

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