1st December 2009

Donation and recovery of organs, tissues, and cells

The National Health and Welfare Council

Statutory Compendium

The Compendium of Statutory Instruments of the National Board of Health and Welfare (SOSFS) publishes regulations and general advice.
- Regulations are binding rules.
- General guidelines contain recommendations on how a regulation can or should be applied and do not exclude other ways of achieving the objectives in the statute.
The National Board of Health and Welfare publishes an annual list of existing regulations and general guidelines.

Regulations of the National Board of Health and Welfare on organ donation and procurement, tissues and cells; adopted on 1 December 2009.

The National Board of Health and Welfare prescribes the following on the basis of sections 2(1), (2), (4) and (5), section 3(1) and sections 4(2), (5) and (7) of the Regulation (1985:796) with certain authorisations for the National Board of Health and Welfare to make regulations etc., Section 4 of the Regulation (2006:358) on genetic integrity etc, Section 5 of the Regulation (2002:746) on biobanks in health care etc, Section 12 of the Infection Control Order (2004:255), Section 12 of the Regulation (2008:414) on Standards of Quality and Safety Handling of Human Tissues and Cells, and Section 4 of the Patient Data Regulations (2008:360).

Chapter 1. Scope and definitions

1 § These Regulations apply to the donation and procurement of organs, tissues and cells of human beings (human biological material) in activities covered by the Health Care Act (1982:763) and the Dental Care Act (1985:125). The Constitution contains additional provisions to the Transplantation Act (1985:831) etc., the Genetic Integrity Act (2006:351) etc. and the Act (2008:286) on Standards of Quality and Safety in the Handling of Human Tissues and Cells.

It aims to ensure that, while respecting the autonomy of the individual, quality and safety of biological material is guaranteed to prevent the transmission of infection or disease when used on humans.

2 § The Regulation applies to the donation and procurement of:
1. organs or parts of organs to be supplied to a health care facility for transplantation purposes,
2. tissues and cells to be supplied to a tissue establishment
For processing in accordance with the Act (2008:286) on standards of quality and safety in the handling of human tissues and cells; and
3. tissues and cells which, without being processed in a tissue establishment are to be supplied to a health care facility for therapeutic purposes.

3 § The Regulation also applies to the donation and preservation of:

1. tissues and cells left over from the diagnosis, care and treatment of a patient and which, with the informed consent of the patient are collected and made available for the treatment referred to in Article 2 (2) and the purposes referred to in Article 2 (3),
2. tissues and cells that, under an agreement between a tissue establishment and the National Council for Forensic Medicine or any other contractor, are available to the tissue establishment for processing referred to in paragraph 2(2), and
3. biological material obtained in the course of a procedure on a living or dead person, deceased donor or aborted foetus for any other medical purpose.
Purposes other than those set out in section 2, e.g., quality assurance, training, development work and research other than clinical research.
4 § does not apply to the donation and procurement of:
1. tissues and cells for autologous use, if collected and used in the same surgical procedure,
2. blood and blood components, when the regulations of the National Board of Health and Welfare (SOSFS 2009:28) regulations on blood activities apply; and
3. breast milk, where the regulations of the National Board of Health and Welfare (SOSFS 1987:8) on the use of breast milk, etc., apply.

5 § of the Act (2002:297) on Biobanks in Health Care etc.
contains provisions on the information and consent requirements that must be met for human biological material, where the material can be traced back to the donor, it can be collected and stored in a biobank for therapeutic purposes, clinical research purposes or other medical purposes. Further provisions on information requirements are contained in the Act 2009:30
Regulations and General Guidelines (SOSFS 2002:11) on Biobanking in Health Care etc. Chapter 1, section 2 of the same regulation contains provisions on when the provisions of the Constitution apply to biological material collected for therapeutic or clinical research purposes and to samples taken from a donor that are stored to ensure the quality of such use.

6 § The following terms shall be used in this Regulation:

allogeneic use	(of biological material:) use on human beings if the donor and recipient are different persons
serious adverse event	event associated with repatriation, control, and distribution of biological material which may lead to transmission of infection or disease or death, or may be life-threatening, incapacitating or resulting in a significant disability of the recipient or which may cause or prolong disease or the need for hospitalisation.
serious side effect	such an unintended reaction in the living donor or recipient in relation to biological material obtained from the donor or used on a recipient, which may lead to death, life-threatening or disabling condition or which may result in or prolong illness or the need for hospital care
assisted conception	measure aimed at medically fertilising egg cells with sperm inside or outside a woman's body
autologous use	(of biological material:) use on human beings if the donor and the recipient are the same person
distribution	(of biological material:) delivery and transport to another activity

direct distribution	(of biological material:) distribution from an establishment where biological material has been procured to a health care facility for the purpose of therapeutic use
donation	procedure resulting in human biological material be obtained
recipient	recipient human being on which biological material is used
therapeutic use	use for the purpose of medical treatment
preservation	(of biological material:) collection of biological material from a donor
medical injury	suffering, discomfort, physical or psychological harm, illness, or death caused by health care and which is not an unavoidable consequence of the patient's condition or an expected effect of the treatment the patient has received because of his or her condition
Tissue establishment	establishment where a natural or legal person undertakes activities that involve testing, processing, storage or distribution of human tissues or cells intended for use in human beings; or for the manufacture of medicinal products intended for use in human beings and which may also include the donation, procurement, import or export of human tissues or cells.

Chapter 2. Responsibility for donation and procurement

Responsibilities of the health professional

Management system

1 § Provisions on management systems for planning, execution, follow-up and development of the quality and safety of health care and dental care are contained in the regulation of the National Board of Health and Welfare (SOSFS 2005:12) on Management Systems for Quality and Patient Safety in Health Care. A healthcare provider carrying out activities involving the donation of biological material is responsible for ensuring that the management system

1. ensures that the quality and safety requirements of these regulations are met in relation to the donation, procurement and other handling of biological materials;
2. includes an information security policy that meets the requirements of the National Board of Health and Welfare's regulations (SOSFS 2008:14) on information management and record keeping in health care.

Provision of biological material 2009:30

2 § The care provider is responsible for

1. the management of health and dental care is organised in a way that promotes the identification of potential donors and otherwise promotes the donation and provision of biological material for medical purposes, the supply of biological materials is based on voluntary, unpaid donation;
2. medical institutions and other entities where biological materials are procured from deceased donors have access to the doctor in charge of donation and the nurse in charge of

donation, referred to in section 13(2) of the Transplantation Act (1995:831) etc., referred to as the contact nurse.

3 § The health care professional shall provide written instructions and ensure that

1. the biological material obtained is handled and stored in such a way that the intended quality and safety is maintained,
2. the organs are delivered only to a health institution in Sweden or another country within or outside the European Economic Area that can meet quality and safety requirements equivalent to the requirements set by Scandiatransplant for that institution.
3. the tissues and cells are only transferred to a tissue establishment which is authorised by the National Board of Health and Welfare to carry out activities in accordance with the Act (2008:286) on standards of quality and safety in the handling of human tissues and cells or to an equivalent establishment in another country of the European Economic Area that has been approved by the competent authority of that country.

If the tissues and cells are to be purchased and supplied on behalf of a tissue establishment operated by another healthcare provider, the commission shall be governed by a written agreement that meets the requirements of the Tissue Establishments in Health and Healthcare Regulations (SOSFS 2009:31). Section 12 of the Act (2008:286) on Quality and Safety Standards in the Handling of Human Tissues and Cells provides that only tissue establishments that have obtained an import licence and can import and export tissues and cells from or to a country outside the European Economic Area (third country).

4 § The health care provider shall provide written instructions and ensure that the tissues and cells to be distributed directly to a health care establishment are only delivered where the conditions set out in Chapter 6, Section 11 are met.

5 § The curator must give written instructions and ensure that the biological material in storage is not
disclosed in violation of the prohibition of commercial manipulation in Chapter 8 Section 6 of the Genetic Integrity Act (2006:351) etc. If financial compensation can be charged for costs attributable to procedures relating to the procurement, control and distribution of biological material, the health care provider must establish the basis for the calculation of the reimbursement. The basis of calculation must ensure that the biological material is not disclosed for profit.

Documentation, archiving and reporting

6 § The health care professional shall provide written instructions and ensure that information on

1. donors and donations of biological material are documented and stored in accordance with these regulations,
2. the procurement of biological material is documented, stored and reported in accordance with these regulations; and
3. serious adverse events and reactions are investigated and reported in accordance with these regulations.

The healthcare professional is responsible for ensuring that the healthcare facility or other units in which biological material is stored has an information system in place to ensure compliance with the requirements set out in points 1 to 3.

Staff

7 § The healthcare professional is responsible for ensuring that healthcare facilities responsible for the donation or procurement of biological material have access to staff with the necessary skills and experience to ensure that:

1. the procedures or any other acts of procurement are carried out only if the conditions set out in the Act (1995:831) on Transplantation, etc. and the Act (2006:351) on genetic integrity, etc., are met,
2. the selection of donors is made considering the safety of the recipient
3. requirements for the safety of living donors are respected,
4. the dignity of deceased donors is respected
5. requirements for laboratory tests and other investigations are met; and
6. a close relative who is contacted in relation to the retrieval of biological material from a deceased person, and a woman who is contacted in relation to the retrieval of tissue from an aborted foetus, are

given the support and information they need.

Where a contractor is responsible for the donation or procurement of tissues and cells, the health care

provider shall enter into a written agreement and ensure that the contractor is able to meet, where applicable, requirements equivalent to those set out in points 1 to 6.

Responsibilities of the head of operations

Management system

8 § The head of the establishment responsible for the donation or procurement of biological material must, in accordance with the management system set out in the following points, establish appropriate

procedures and clearly assign responsibility for

1. the donation procedure
2. procedures or any other action for the procurement of biological material,
3. the management of donor information, donation, and the management of donor, donation and procurement information, which shall be documented and reported in accordance with Chapter 7. Sections 2 to 7; and
4. the investigation of serious adverse events and reactions and their reporting in accordance with Chapter 9 (1) and (2).

If the head of an establishment is responsible for a biobank, the procedures shall also meet the requirements of the National Board of Health and Welfare and General Advice Regulation (SOSFS 2002:11) on Biobanks in Health Care etc. The procedures and division of responsibilities must be documented. The operations manager must continuously monitor the activities and that the procedures and division of responsibilities ensure that the quality and safety requirements of these regulations are met.

Promotion of donation

9 § The head of the institution responsible for the donation of biological material shall ensure that

1. the activities are organised in such a way that potential donors are identified,
2. promotes donation in other ways; and
3. the donation procedure functions satisfactorily.

Staff

10 § The Head of the Institute shall determine:

1. the skills and experience required to perform the tasks within the field of activity and

2. the conditions that must be fulfilled for the competent health personnel to be able to delegate tasks to another official in the field of activity. If biological material is stored in the field of activity the person in charge of operations in accordance with Article 12 of the Transplantation Act (1995:831) etc. shall determine which doctors and dentists may decide on procedures or any other measures for procurement. The requirements in 1 and the conditions in 2 ensure that the risks to donors and recipients are minimised. The requirements and conditions must be documented.

11 § The regulations of the National Board of Health and Welfare (SOSFS 2008:14) on information management and record keeping in the health system contain provisions on the responsibility of the head of operations to ensure that, in accordance with the management system of section 1,

1. the authorisations issued for access to the data to be processed according to Section 8, para 1 (3) and (4) are appropriate and compatible with the tasks of the personnel
2. to monitor the use of information systems through regular checks of records.

Medical responsibility

12 §The Director of Operations may exercise medical responsibility if he or she:

1. is a physician or dentist with expertise in medical matters relevant to the biological material being handled in the establishment,
2. after completing his or her specialist training, has two years' experience of operations referred to in point 1.

If the head of the establishment does not meet these requirements, medical responsibility shall be exercised by a specially appointed responsible person who has specialist knowledge and sufficient experience of operations in a relevant field.

13 § The head of operations or the responsible person, if such a person has been appointed, performs the duties of doctors and dentists pursuant to the Transplantation Act (1995:831) and is responsible for:

1. biological material is not distributed in violation of the directive of the physician in chapter 2, section 3,
2. biological material that is distributed meets the quality and safety requirements in these regulations;
3. information on the donor, donation and procurement is documented, stored and reported in accordance with these regulations.

Doctors and nurses responsible for donations

14 §A doctor and a nurse responsible for donation for one or more health facilities or other units shall

1. ensure the availability of biological material from deceased persons for transplantation and other therapeutic purposes;
2. support and contribute to quality assurance of activities involving the donation of biological material from deceased persons.

The doctor in charge of the donation must have specialist skills and the nurse in charge of the donation
must have relevant specialist medical training. They shall have sufficient working experience in the relevant fields.

15 §The doctor and the nurse responsible for donation shall have overall responsibility for the donation activity and for ensuring the smooth functioning of the activities.
Within a health region, one or more of these doctors or nurses have overall responsibility for co-ordinating the promotion and co-operation within the region and for ensuring that the competence of the activities are maintained. A physician or nurse from a tissue establishment may have corresponding responsibility if the activities of the tissue establishment also include the donation and procurement of tissues and cells.

Responsibilities of healthcare professionals
16 §Healthcare professionals shall be responsible for:

1. donor, donation and procurement information is managed in accordance with the assigned access rights and established security procedures,

2. the responsible physician is informed of patients who may be considered for donation;
3. serious adverse events and reactions are reported to the head of operations or the responsible person, if such a person has been designated. In the National Board of Health and Welfare regulation (SOSFS 2008:14) on information management and record keeping in the health care system the responsibilities of health care professionals and other officials in managing information.

Chapter 3. Premises and equipment

1 § Section 2(e) of the Health Care Act (1982:763) contains general provisions and requirements for the premises and equipment which health care is to be provided there.
In the case of surgery or any other measure for the removal of tissues and cells, the premises and equipment used shall comply with the requirements of these Regulations.

2 §Biological material may be stored in hospitals and other healthcare institutions.
Tissues and cells may also be procured

1. from a tissue establishment authorised by the National Board of Health and Welfare to carry out activities in accordance with the Act (2008:286) on quality and safety requirements in the handling of human tissues and cells,
2. at a forensic department of the National Board of Forensic Medicine that, under contract with a tissue establishment, is responsible for the procurement of tissues and cells,
3. in a sampling unit contracted by a tissue establishment that takes samples on behalf of the tissue establishment,
4. at the donor's home, if the procedure or measurement is carried out by healthcare professionals and physicians from a tissue and cell establishment and if the premises are suitable.

Procurement measures of a simpler nature may also be carried out in a different location from that indicated in points 1 to 4.

3 § Documented procedures are in place to ensure
1. that sterile equipment is used in the procurement process
2. that the equipment is of good quality and is validated or specially certified for medical purposes and that it is regularly maintained;
3. there is a validated procedure for the cleaning and sterilisation of multiple-use instruments.
When using CE-marked medical devices, personnel must receive appropriate training in the use of such devices.

Chapter 4. Donation

Living persons

Examination of conditions for donation

1 §An intervention on a living person for the purpose of obtaining biological material for therapeutic or other medical purposes may be performed if the conditions set forth in Articles 5 to 9 of the Transplantation Act (1995:831) etc. and in these Regulations are met.

The physician or dentist who may decide on the procedure is responsible for ensuring that an investigation is performed to ensure
1. that a procedure is not performed if it may cause serious danger to the life or health of the donor,
2. that the written consent of the donor is obtained if the biological material to be obtained is not reconstituted or if the procedure on biological material that does not regenerate is not subject to the consent of the donor, or if it might otherwise cause significant harm or inconvenience to the donor
3. that a procedure to obtain biological material that does not regenerate is not subject to donor consent is performed only on a donor who is related to the intended recipient or who is otherwise particularly close to the recipient; or if there are special reasons, from any other person,
4. that a procedure to obtain biological material for transplantation purposes from a minor or a person who is incapable of giving consent because of a mental disorder shall be performed only with the approval of the National Board of Health and Welfare in accordance with chapters 5 (1) and (2);
5. that procedures to obtain biological material for any medical purpose other than therapeutic use shall not be performed on persons referred to in subsection (4) and otherwise only with the authorization of the National Board of Health and Welfare when authorization is required under chapter 5, section 3.

2 § An operation to collect sperm for insemination or sperm or ova for fertilization outside the body may be performed if the conditions of chapter 6 (4) and chapter 7 (6) of the Law (2006:351) on Genetic Integrity etc. and in this Regulation are met.

Information for those considering donation
3 § A potential living donor must be informed of
1. the purpose, nature, consequences, and risks of the donation for the donor
2. the infectious agents and diseases that may be transmitted through the donated biological material to the recipient, if the material is to be used for therapeutic purposes or in clinical research trials.
3. laboratory tests and other investigations, if they are to be carried out, and the right to receive the results of such tests,
4. the protection of confidentiality in the health and dental sector for donor information
5. the possibilities for therapeutic treatment and the risks for the recipient, if the material is to be used for therapeutic purposes or in human clinical research trials
6. the safety measures applied to protect the health of the donor,
7. the requirements for consent and, where applicable, approval for the procedure.
Provisions on when the information must also be provided to the donor's guardian, legal representative, or trustee are set out in section 10 of the Act (1995:831) on Transplantation etc.
The information must be provided by a doctor or dentist who may decide on the operation or, if the task has been delegated in accordance with Chapter 2. Section 8, by another authorised health care professional who has been trained and assessed as competent for the task.

4 § In the case of germ cell donation, if the donor is another person other than a spouse, registered

partner or cohabiting partner, the prospective donor shall also be informed of the conditions for donation in accordance with Section 6. 4 § and chapter 7, section 2 of the Act (2006:351) on genetic integrity etc.
The potential donor shall also be informed about the legal, psychological, and social consequences of egg cells or sperm donation.
Information must be provided on:
1. that a child conceived with a donated egg or sperm has the right to be informed of its genetic origin,
2. that the child may contact the donor in the future; and
3. that it may be necessary to contact the donor in the future for blood tests or for any other investigation.

5 § In the case of tissue and cell donation, information must also be provided to the potential donor about
1. which information about the donor and the donation should be communicated to a tissue establishment or, in the case of direct distribution, to a health care establishment in order to ensure traceability; and
2. the processing of personal data that may be carried out pursuant to Article 21 of the Act. (2008:286) on standards of quality and safety in the handling of human tissues and cells.
The information referred to in subsection (2) shall comply with the requirements of the Personal Data Act (1998:204) and the Patient Data Act. If necessary, the information shall be provided orally.

6 § The information to be provided under §§ 3-5 shall ensure that the prospective donor and, where appropriate, his/her guardian, legal representative or fiduciary can take a position on

1. whether biological material can be obtained

2. what material can be stored

3. the purpose(s) for which the material may be used.

The information provided must be sufficient to enable the potential donor and, where appropriate, the
legal guardian or trustee to decide whether the intervention or measure can be carried out, taking into
account the risks involved. The information must be provided in an appropriate and clear manner so that the recipient of the information can easily understand.
The information must ensure that the potential donor themselves or, where appropriate, their guardian,
legal representative or trustee is able to assess when they should refrain from donation. If they have decided not to donate, the reasons are not required.
The potential donor or, where appropriate, the guardian or trustee is not asked to provide information.
The guardian or trustee shall be given the opportunity to ask questions about the donation of biological material and the reasons for non-donation.

Verification of identity and information on the potential donor

7 § The identity of the potential donor shall be verified and information shall be obtained on the potential donor's health status and relevant medical conditions and any risk events and behaviour. If the donation concerns biological material for allogeneic use, the information shall be provided on a specific questionnaire, a health statement and during a personal interview.

The health statement, in addition to questions on the donor's general health status, includes questions on circumstances, events and behaviour that may pose a risk of infection or disease that could be transmitted to the recipient through the donated biological material. Questions should include sexual behaviour, travel habits, geographical origin, length of stay in another country, injection drug use, accidents, vaccination and medication intake, medical and non-medical interventions that may be relevant in light of Annexes 2, 3 and 5.

Additional questions will be asked in a personal interview. The interview shall be conducted with respect for the potential donor's privacy.

If the potential donor is a minor, the interview shall be conducted with both the guardian and the minor. If the potential donor does not have the capacity, due to a mental disorder, to give consent, the interview shall be conducted with a guardian or trustee.

Information about the potential donor must be gathered by the health professional trained and assessed as a competent health professional for the task.

8 § The prospective donor and, if applicable, the legal guardian, custodian or trustee must sign the health declaration and certify that

1. he/she has understood the information on infections and diseases that can be transmitted to the recipient through biological material,

2. he/she has been given the opportunity to ask questions and has received satisfactory answers to those questions

3. the information he has provided in accordance with Section 7 is true.

9 § If it is considered necessary to ensure that the risks of infection or disease that may be transmitted during use are minimised, the relevant information must also be obtained:

1. the medical records of the potential donor, and

2. an interview with the physician(s) responsible for the health care of the potential donor.

If deemed necessary, the potential donor must also undergo a physical examination. The examination must ensure that the issues identified insufficient to exclude a person as a donor, as well as allowing an assessment that takes into account the person's medical history.

The examination shall be carried out by a doctor or dentist who may decide on the procedure or, if the task has been delegated in accordance with Chapter 2. 8, by any other licensed health professional who has been trained and assessed as competent for the task.

Consent to donation

10 §Consent to the donation of biological material for use in human beings shall include consent to

1. blood samples and other relevant samples can be taken from the donor and be stored to ensure quality of use,

2. the necessary laboratory tests and other investigations can be carried out

3. interviews can be conducted in accordance with Article 9(2)

4. the person who is to decide on the intervention or any other procurement measure can consult the relevant information in the donor's medical record

5. information on the donor, donation and procurement may be communicated to a tissue establishment or, in the case of direct distribution, to a health care establishment.

The consent shall be documented in the donor's medical record.

11 §Provisions on consent to the donation of biological material other than germ cells, must in certain cases be in writing is provided for in Articles 6 and 8 of the Transplantation Act (1995:831) and for mentally disturbed persons, the conditions of Chapter 5, Section 1 and 2 §.

The provisions requiring consent to gamete donation to be in written form are contained in chapter 7, section 2 of the Genetic Integrity Act (2006:351).

Deceased people

Examination of conditions for donation

12 §An operation on a deceased person for the purpose of obtaining biological material for therapeutic or other medical purposes may be carried out if the conditions laid down in Articles 3 and 4 of the Transplantation Act (1995:831) etc. and in these Regulations are fulfilled.

An investigation shall be carried out to ascertain whether a potential donor 2009:30 expressed in writing, e.g. by notification to the donor register or with a donation card, or orally, e.g. in a conversation with a close relative, a preference for the use of biological material after his or her death.

If the investigation shows that it is in accordance with the deceased's wishes that the biological material be retained, it is specified that it be further investigated as to the implications of the deceased's position in relation to any restrictions on the biological material that may be retained and the purpose(s) for which the material may be used.

Identification and information of the potential donor

13 §The identity of the potential donor and the information relevant medical conditions must be verified.

14 § The risks of infection or disease that may be transmitted during use in humans must be identified and the relevant information obtained from

1. from the medical records of the deceased

2. from an interview with the doctor(s) responsible for the health care of the deceased,

3. from an interview with someone who knew the deceased well

4. from the autopsy report, if any.

Information about the potential donor must be obtained from a doctor or dentist who can decide on the operation or if the information has been entrusted in accordance with Chapter 2. 8, from another licensed health professional who has been trained and assessed as competent for the task.

15 §The body of a potential donor shall undergo an examination that ensures the detection of elements sufficient in themselves to exclude a person as a donor.

The examination shall be carried out by a medical or dental practitioner who may decide on the procedure or, if the task has been delegated in accordance with Chapter 2. 8, by any other authorised health professional who has received training and has been assessed as competent for that task at a forensic department of the National Council for Forensic Medicine, which under an agreement with a tissue establishment, is responsible for tissues and cells. Tthe examination shall be carried out by a physician who is a decision-maker on procurement.

Information to relatives according to their position

16 § A person who has been close to the deceased must be informed of the planned medical procedure, such as laboratory tests and other examinations to be carried out, including any

investigations that must still be carried out in accordance with Sections 12-14, taking into account the safety of the recipient.
If the donor's intentions are not known, the relatives must be provided with information on
1. the right under the Transplantation Act (1995:831) to prohibit the procedure within a reasonable time and to consult other close relatives,
2. The time limit within which the notification mentioned in point 1 must be made.
The information shall be designed and given taking into account the grief for loss that the close relatives may feel and the support they may need.
The information shall be provided by a medical practitioner who may be asked to determine the suitability of the operation or, if the task has been entrusted in accordance with Chapter 2, Chapter 3. 8, by any other officer who is trained and assessed as competent for the task.
The information may also be given by a medical practitioner or any other person.
The information shall be given by any other person or any other official of a forensic department of the Forensic Medical Service which, under an agreement with the tissue establishment, is responsible for the procurement of tissues and cells.

17 § A decision made by someone who was close in life to the deceased, and which does not prohibit intervention on the deceased, must include a consent for the implementation of the measures corresponding to the measures to be found in section 10.

Aborted foetuses

Investigation of conditions for donation

18 § An action to recover tissue from an aborted foetus for medical purposes can be undertaken if the conditions in section 11 of the Act (1995: 831) on transplantation etc. are fulfilled.
The doctor who may decide on the implementation of such a measure is also responsible for ensuring that tissue from an aborted foetus is only used with the permission of the National Board of Health and Welfare in accordance with chapter 5 of the Swedish Medical Devices Act (ch.5) and that risks of infection or disease that may be transmitted to humans during their use are identified.

Information for the woman

19 § Before deciding whether tissue can be harvested, the woman who has undergone the abortion must be informed about
1. what the measure entails,
2. the medical purpose(s) of the use, and
3. the requirements for consent and authorisation by the National Board of Health and Welfare for the use of the tissue.
The information must be sufficient for the woman to decide whether the measure can be performed taking into account the intended medical use.
It must also be designed and given taking into account the discomfort and pain the woman may experience and the support she may need.
The information is provided by a doctor who has the authority to decide on the intervention.

Consent

20 § The woman's consent to tissue recovery includes:
1. a statement as to which tissue may be obtained

2. the medical purpose(s) for which the tissue may be used; and
3. consent to the adoption of measures corresponding to those in section 10 with respect to the woman.
The consent must be documented in the woman's medical record.

Recipient safety checks
21 § Diagnostic tests used to analyse donor samples must meet the requirements of the Medical Products Agency's regulations (LVFS 2001:7) on medical devices for in vitro diagnostics.

Organs
22 §Prior to the removal of organs or parts of organs, laboratory tests and other examinations must be carried out in accordance with the provisions of Annex 2.

Tissues and cells
23 § Prior to any operation or other measure for the recovery of tissues and cells, other than gametes, laboratory tests and other examinations must be carried out in accordance with Appendices 3 and 4.
When blood is collected from a deceased donor, procedures must be in place to ensure that the sample is collected within the time limit specified in Annex 4 (of Section A, point 4).
Prior to a procedure or any other action to obtain germ cells, laboratory tests and other investigations shall be carried out as specified in Annex 5.

Chapter 5. National Board of Health and Welfare authorisation . Biological material from living donors.
1 § Application for permission of the National Board of Health and Welfare under Section 8 of the Act (1995: 831) on Transplantation, etc. to obtain biological material from living donors in cases where the donor is a minor, or due to a mental disorder is unable to give consent, shall be made on the attached form (Annex 6).
Permission may be granted for transplants and other therapeutic treatments if:
1. the donor is related to the intended recipient,
2. it is not possible to take biological material from another suitable donor;
3. the donor does not object to the procedure;
4. the person who, pursuant to Section 8 of the Transplantation Act etc., is to give consent has been informed in accordance with these regulations and has declared that he or she understands the meaning of the information received,
5. consent to the procedure has been given;
6. There is no fear that the procedure will cause serious danger to the life or health of the donor; and
7. the physician who can decide on the procedure has approved the application.

2 § If the biological material named in section 1 is material that does not regenerate, permission for donation may be granted if:
1. the conditions set out in paragraphs 1 to 4, 6 and 7 are met,
2. written consent has been given, and

3. there are exceptional reasons for the procedure, e.g. there is a very real danger to the life or health of the recipient.

Biological material from living donors for other medical purposes

3 § An application for permission from the National Board of Health and Welfare, pursuant to section 9 of the Transplantation Act (1995:831), to carry out a procedure for the purpose of obtaining biological material from a living donor for any medical purpose other than therapeutic, shall be submitted on the attached form (Annex 7).

Authorisation from the National Board of Health and Welfare is required if the material is not regenerated or if the procedure would otherwise cause substantial harm or any inconvenience to the donor. Authorisation is not required for biological material left over from the diagnosis, care and treatment of a patient and collected and stored for that purpose with the patient's informed consent.

Authorisation may be granted for quality control and assurance, instruction, research, clinical trials, development work, manufacture of medicinal products and other similar purposes, if:

1. the donor is not a minor or does not have the capacity to consent due to a mental disorder,
2. the donor has been informed in accordance with this Regulation and has understood the meaning of the information,
3. the donor has given written consent, and
4. the possibility that the procedure will cause a serious danger to the life or health of the donor is excluded.

Aborted foetal tissue for medical purposes

4 § An application for permission from the National Board of Health and Welfare under Section 11 of the Transplantation Act (1995:831) to obtain tissue from an aborted foetus for medical purposes shall be made on the attached form (Annex 8).

Permission may be granted for an individual therapeutic purpose and a specific research project or for any other general medical purpose if

1. the woman carrying the foetus has given her informed consent,
2. there are exceptional reasons for the removal of tissue, e.g. the therapeutic purpose is of substantial importance for a specific recipient, for the quality of life of a specific recipient or the general medical purpose is relevant and urgent, and
3. a comparable result cannot be achieved by any alternative method.

Chapter 6. Recovery

Conditions for recovery

1 § Section 12 of the Transplantation Act (1995:831) contains provisions on health care professionals who may make a decision on the removal of biological material. The same section states that such a decision may not be taken by the person responsible for the recipient's health care or for the use of the material for any other medical purpose.

If an intervention or any other procurement measure is of a simpler nature and concerns a living donor, the decision may be taken by any other qualified health professional to whom the task has been delegated in accordance with Chapter 2. 8 . The task cannot be transferred without the written consent or authorisation of the National Board of Health and Welfare, as required by the Transplantation Act.

2 § A decision on the procurement of tissues or cells in a forensic medical examination for the purposes mentioned in Chapter 1, Section 2, may be made by a physician from a forensic department of the forensic medicine unit who, under an agreement with the tissue establishment, is in charge of preserving the tissues and cells.

Common conditions

3 § Biological material can be recovered if:

1. the identity of the donor is proven,
2. consent has been given in accordance with chapter 4, sections 10 or 20
3. the procurement is in accordance with the wishes of a deceased donor or the wishes of a close relative in accordance with chapter 4, section 17,
4. the requirements for the safety of the recipient in accordance with chapters 4(22) and (23) and for the safety of the donor in accordance with chapters 6(15) to (17) are fulfilled,
5. the results of laboratory tests on the donor's blood samples are acceptable with the requirement for such tests to be carried out; and
6. the National Board of Health and Welfare has given permission in accordance with Chapter 5, sections 1 to 4, where such permission is required.

Barriers to recovery

4 § A procedure or any other measure for the procurement of biological material to be provided for the handling or purposes referred to in Chapter 1, section 2, shall not be carried out if there is reason to suspect that the results of laboratory tests on the donor's blood samples do not meet the specifications set out in Annex 2 (section C, paragraph 3) and Annex 4 (section A, paragraph 3).

5 § If there are other circumstances that are considered to mean that a procedure or any other measure for the collection of biological material may present an increased risk to a potential living donor or recipient, the responsible physician may decide that the procedure or measure should not be performed.

The risk assessment and the decision must be documented.

6 § A living person may not be accepted as a donor if there is reason to believe that he or she is subject to undue influence or that consent does not guarantee that the quality and safety requirements of these standards can be met.

7 § A living person who does not meet the conditions for donation shall be informed of the reasons. If necessary, the information shall be given to the guardian, legal representative or trustee.

Preservation

8 § A procedure or any other measure for the preservation of biological material may be carried out by a physician or dentist or, if the donation has been transferred in accordance with Chapter 2, by a physician or any other authorised health care professional who is trained and qualified to do so and deemed competent for the task. In the case of sperm, the procedures may be carried out by the donor.

A procedure or any other measure for obtaining tissues and cells may also be carried out by a physician or other official of a forensic department of the National Council of Forensic Medicine who, under an agreement with a tissue establishment, is responsible for the procurement of tissues and cells.

9 § The methods shall ensure that the biological and physical properties necessary for the end use of the recovered material are preserved and that the risk of microbiological contamination is minimised.
Procedures must be in place to minimise the risk that personnel involved in the process of preserving material may be infected with communicable diseases.
10 § When retrieving from a deceased donor, procedures must ensure that unauthorised persons do not have access to the operating area. A local sterile area with sterile drapes must be used. Personnel involved in procurement should normally wear sterile clothing and sterile protective equipment.

Recovery in special cases
§ 11 In the event of serious and imminent danger to the life or health of the recipient, organs, tissues and cells may be recovered for direct distribution, even if the requirements of § 3.3 and 4 are not met or the results of the mandatory laboratory tests are different or do not exist.
Tissues and cells must not be used for direct distribution if it is possible for the tissue establishment to deliver observed tissues and cells for a specific recipient.
A decision on recovery in these cases may be made by the physician or the person responsible for the recovery after consultation with the physician responsible for the recipient's health care. The decision and the risk assessment must be documented.
12 § Biological material from a living donor may be procured from a health care institution other than the one where the donor has been assessed as suitable for donation, if consent has been given in accordance with Chapter 4, Section 10 to the disclosure of the donor's personal data and donation to the other institution.

Continued medical intervention after death is confirmed
13 § Provision is made for the continuation of medical interventions necessary to preserve the biological material of a deceased person and the maximum duration of such interventions pending the performance of a transplantation procedure, as provided for in Section 2a of the Act (1987:269) on criteria for determining human death.
If it is necessary to complete a medical procedure for the purpose of transplantation, and if the procedure means that in a specific case it is possible to save life or if there are other special reasons, the medical procedure may continue for a maximum of several hours beyond the permitted time (24 hours). The action must be started, but does not necessarily have to be finished, before the time limit decided for the specific case has expired. Otherwise, medical interventions referred to in section 2(a) of the Act on Criteria for Determining Human Death may be continued only to save the life of a living foetus in a dead pregnant woman.

14 § The evaluations carried out and the measures taken in relation to the continuation of medical interventions after a confirmed death must be documented in the deceased's medical record.

Safety of living donors
15 § Biological material from a living donor is procured in an environment that minimises risks to the health, safety, and personal integrity of the donor. Procedures must be in place to assess any possible health consequences for the donor, and relevant laboratory tests and other investigations

must be carried out appropriately, taking into account the suitability for donation and the safety of the recipient.

16 § The person responsible for the procurement of biological material may decide on a case-by-case basis that action will be taken even if the test values of a living donor deviate from those specified in Annexes 2 and 4.

17 § If laboratory tests or other examinations justify further investigation into the health status of a potential living donor, the donor must be informed of this and offered the opportunity to undergo such an investigation. If necessary, the donor shall be offered a referral for the necessary care, be it a legal guardian or representative.

Measures in the event of infection

18 § If an infectious disease due to an infectious agent that can be transmitted through biological material is suspected or has been established in a living donor or potential living donor, the physician or dentist responsible for procurement must promptly ensure that

1. the person carrying or suspected of carrying the infection is offered referral to specialist care; and
2. if necessary, action is taken in accordance with the Infection Control Act (2004:168).

Suspected infected biological material to be destroyed shall be handled in accordance with the regulations of the National Board of Health and Welfare and the general advice (SOSFS 2005:26) on the management of infectious cases in the healthcare system. The same applies to products and materials that have come into contact with such recovered biological material.

For biological material that is not to be destroyed, there must be a system to ensure that the material is stored and handled in such a way that there is no risk of contamination.

Measures in the event of damage to health

19 §If a living donor has suffered or is at risk of suffering health damage as a result of a procedure or any other operation involving the use of biological material, the National Board of Health and Welfare must be informed in accordance with chapter 9, section 3.

Dignity of deceased donors

20 § In the case of the collection of biological material from a deceased person, the procedure or measure of collection must be carried out with respect for the dignity of the deceased. At the end of a procedure, the body of the deceased must, as far as possible, be restored to its original state.

Chapter 7. Documentation, archiving and reporting

Documentation

1 § The decision on an intervention or any other measure for procurement of biological material from a donor must always be documented.

The decision and information on the donor shall be documented in the donor's medical record or, in the case of procurement in connection with a forensic examination, in a procurement report. In the case of aborted foetuses, the information must be documented in the medical record of the woman who carried the foetus.

The donor and the donation

2 § The documentation on the donor and the donation must contain information on

1. the name and personal identity number of the donor and, in the case of an aborted foetus, the name and personal identity number of the woman who carried the foetus or, if there is no identity number, other identifying information to ensure complete traceability for at least 30 years,
2. who verified the identity of the donor and how it was established,
3. the information provided to a living donor and, where applicable, to the guardian, legal representative or trustee prior to the donation
4. how the information was provided to the living donor and, where appropriate, the guardian or legal representative prior to collection and who provided the information.
How information was obtained on the conditions for performing a procedure or any other procurement measure on one of the donors and, if a close relative was notified, what information was given to the relative and within what timeframe.
5. What information was provided to a woman who carried an aborted foetus and who provided it,
6. consent under Chapter 4, sections 10 and 20, who obtained the consent and how it was obtained,
7. The notification under Chapter 4, section 17,
8. The consent of the National Board of Health and Welfare, if applicable,
9. The health data collected on the donor and, in the case of an aborted foetus, on the woman who carried the foetus,
10. laboratory tests and other examinations carried out and their results, if available,
11. haemodilution, if applicable,
12. if the biological material is to be used in an operation on a human body, the relationship of the living donor or any other relationship to the recipient
13. the assessment of whether a living donor has been subjected to undue influence and whether the donor's ability to give consent is not impaired due to illness or accident or any other reason.
The written consent of a donor in accordance with Section 6 of the Transplantation Act and Chapter 7, Section 2 of the Genetic Integrity Act (2006:351) shall be included in the medical record. Similarly, an application under Chapter 5, Sections 1-4, for permission from the National Board of Health and Welfare to perform a procedure or any other procurement measure and the decision on the matter shall also be entered in the medical record.
In the case of haematopoietic stem cell donation, the donor's suitability for the intended recipient shall be documented.

Reception - Organs
3 § In the case of organ procurement, the documentation must, where necessary, meet requirements equivalent to those for tissues and cells set out in Section 4.

Procurement - Tissues and cells
4 § The procurement documentation must contain
1. Information on the tissue establishment or health care establishment that procured the tissues and cells
2. The identity of the donor in accordance with section 2(1),
3. Who verified the identity of the donor and how it was confirmed,
4. the consent referred to in Article 2(6),
5. the notification referred to in Article 2(7)
6. the consent referred to in Article 2(8), where applicable
7. the health data referred to in Article 2(9),

8. the results of the laboratory and other tests referred to in Article 2(10) and (11), where they have been carried out
9. the health institution or other unit responsible for storage,
10. the person who decided and is responsible for storage,
11. the date (year, month and day), the time, where appropriate the start and end time, and the place of storing
12. the methods used for storage,
13. the tissues and cells retrieved (including blood samples and other samples for laboratory analysis)
14. the purpose(s) for which the tissues and cells may be used
15. the identification code or batch number of the reagent, fusion liquid and carrier solution used in the procurement,
16. products and materials that have come into contact with the biological material that has been stored, if quality and safety can be affected
17. the refrigeration conditions for the preservation of the body of a deceased donor and the times at which refrigeration was commenced and completed,
18. the suitability of the donor for the recipient in accordance with the third paragraph of Article 2,
19. any serious adverse events and reactions.

In the case of a deceased donor, the documentation must, if possible, include the date and time of death. If additional medical efforts have been made to preserve the donated biological material pending the performance of a transplantation procedure or any other measure for the purpose of medical treatment, the documentation must comply with the requirements of Chapter 6, Section 14.
If a deceased donor is to undergo an autopsy after procurement, the donor's medical record must contain information on observations made during procurement, if these may be relevant to the autopsy.
If procurement has not been completed, this must be recorded in the donor's medical record, which must contain all information on the measures taken until the procedure was terminated.

Reporting of procurement data

5 § In the case of organ distribution, the reporting of information on the donor, donation and procurement to the receiving health care institution shall comply with requirements equivalent to those laid down for tissues and cells in Sections 6 and 7. The information referred to in Article 4(2) shall be provided on an anonymous basis, but still aiming to ensure traceability for at least 30 years of the donor's identity.

Tissues and cells

6 § The information on the donor, donation and procurement in § 4 for the first and second paragraph must be documented in a procurement report.
In the case of the distribution of tissues and cells, the procurement report shall be sent to the recipient tissue establishment. The report must ensure compliance with the traceability requirements of section 21 of the Act (2008:286) on Quality and Safety Standards in the Handling of Human Tissues and Cells.
In the case of direct distribution, the report shall be sent to the recipient health care institution and the tissue establishment, which, according to the donor's decision in Chapter 3, shall contain the

information specified in Section 4, paragraph 2, shall be indicated with an anonymous identifier that guarantees traceability for at least 30 years to the identity of the donor.
A copy of the report must be kept in the donor's medical record.
7 § The authorised healthcare professional who performed the intervention or measure is responsible for the correction of the custody report.
The person responsible for the custody report must sign and certify that the tissues and cells delivered, the mode of transport, packaging, labelling, accompanying documents and attached samples comply with the requirements of this regulation and the specifications of the tissue establishment or health care establishment receiving the tissues and cells.
Where tissues and cells are to be distributed to a tissue establishment or equivalent establishment in a country within or outside the European Economic Area, the report of receipt, the labelling of the packaging and transport container and the accompanying documents must be translated into English or another language.

Archiving
8 § The information referred to in sections 2 to 4 must be stored in accordance with the Patient Data Act (2008:355).

Security of information
9 § The information system used for documenting and reporting donor and donation data and their retrieval must ensure that
1. the information is not destroyed by fire, vandalism or any other means,
2. unauthorised persons do not have access to the data,
3. data cannot be added, deleted or altered by unauthorised persons,
4. information is not disclosed without a legal or regulatory basis,
5. procedures are in place for the correction of data discrepancies; and
6. the identity of the donor is not disclosed to the recipient or the recipient's next of kin, guardian, legal representative or trustee.
In the case of correction under 5, the original data remain read-only.

Chapter 8. Packaging, transport and labelling
Organs
1 § Packaging containing organs shall comply mutatis mutandis with requirements equivalent to those for tissues and cells set out in sections 2 to 4.

Tissues and cells
2 § Tissues and cells purchased must be packaged in such a way as to minimise the risk of contamination. They must be stored at a temperature that ensures that the necessary properties and biological functions of the tissues and cells are maintained. The procedure must ensure that those responsible for packaging and transport are not at risk of contamination.
3 § The packaging of the retrieved tissues or cells (primary packaging) is labelled with information on
1. the identity of the recipient
2. the type of tissue or cells
3. the date (year, month and day) and, if possible, the time of procurement

4. warnings,
5. the type of additives, if used; and
6. the name and personal identity number of the recipient or, in the absence of a personal identity number, other information to ensure full traceability for at least 30 years, if the tissues or cells are intended for a specific recipient.
Packaging containing tissues or cells for autologous use shall be labelled with the name and identity number of the donor or, in the absence of an identity number, other identifying information that ensures full traceability for at least 30 years. The packaging must also be labelled with the words "FOR OTOLOGICAL USE ONLY". The same applies to gametes and fertilised ova (embryos) for assisted reproduction within a couple.
If the size of the package means that any of the information in 3-6 cannot be indicated on the package, it must then be indicated on a special sheet attached to the package.
4 § If blood or other samples for laboratory analysis are included in the package, they must be labelled in such a way as to ensure identification of the donor. The date (year, month and day), time and place of sampling must be indicated.

Transport and marking of transport containers
Organs
5 § The transport and labelling of a transport container containing organs shall comply, mutatis mutandis, with requirements equivalent to those for tissues and cells set out in sections 6 and 7.
Tissues and cells
6 § A package of tissues or cells must be transported in a container that guarantees their quality and safety.
A container used for the transport of tissues and cells contains cells that must be labelled with the warnings "WATER AND CELL MATERIAL" and "HANDLE WITH CARE" and with information about
1. The address and telephone number of the medical establishment or other unit where the tissues and cells were retrieved and the name of a contact person,
2. the address and telephone number of the recipient tissue establishment or, in the case of direct distribution, the recipient health care establishment and the name of the person responsible for reception,
3. the date (year, month and day) and time of commencement of transport,
4. transport conditions relevant to the quality and safety of the tissues and cells; and
5. specifications for storage temperature and other storage conditions.
7 § The transport container must also be marked with the following warnings
1. "DO NOT SPILL", when the transport concerns cells,
2. "BIOLOGICAL RISK", when the tissues and cells are known to be positive for the relevant infectious disease marker,
3. 'FOR OTOLOGICAL USE ONLY', when the tissues and cells are intended for autologous use; and
4. 'DO NOT FREEZE' or any other indication, when special storage conditions apply.
Chapter 9. Notification of abnormal events
Serious adverse events and reactions
Organs
1 § Adverse events in organ procurement shall be handled in accordance with the written instructions of the healthcare provider in chapter 4. 6 of the National Board of Health and Welfare regulation (SOSFS 2005:12) on management systems for quality and patient safety in health care.

Tissues and cells

2 § The director of a health care establishment or other establishment responsible for the procurement of tissues and cells, or the person in charge if such a person has been appointed, shall be responsible, in accordance with section 20a of the Act (2008:286) on standards of quality and safety in the handling of human tissues and cells, for ensuring that the receiving tissue establishment or, in the case of direct distribution, the receiving health care establishment is informed without delay of any suspected or confirmed misuse of tissues and cells regarding:

1. serious adverse events during or after procurement, testing or distribution that may affect the tissues and cells
2. serious adverse reactions in living donors that may affect the quality and safety of tissues and cells.

Medical injury

3 § If a living donor has suffered or is at risk of suffering a medical injury as a result of a procedure or any other action for the collection of biological material, a notification shall be made in accordance with the regulations and general guidelines of the Social Services Agency (SOSFS 2005:28) on mandatory notification under lex Maria.

Events involving medical devices

4 § The regulations of the National Board of Health and Welfare (SOSFS 2008:1) on the use of medical devices in health and medical care contain provisions on the obligation to notify the manufacturer, the Medical Products Agency and the National Board of Health and Welfare of incidents involving medical devices.

Infectious diseases

5 § If an infectious disease covered by the Infectious Diseases Act (2004:168) has been identified or is suspected in a donor or potential donor, the head of operations is responsible for ensuring that a notification and investigation is carried out in accordance with the same Act.

Chapter 10. Other provisions

1 § The National Board of Health and Welfare may grant exemptions from the provisions of this Regulation.

1. This Ordinance shall come into force on 1st April 2010.
2. The Ordinance repeals

- The regulations and general advice of the National Board of Health and Welfare (SOSFS 1994:4) on measures against the transmission of infection in organ or tissue transplantation
- Regulations and general guidance of the National Board of Health and Welfare (SOSFS 1997:4) on the collection of organs and tissues for transplantation or other medical purposes
- The regulations of the National Board of Health and Welfare (SOSFS 2005:11) on continuous medical care after death and the person responsible for donation and (SOSFS 2008:22) on the donation and procurement of tissues and cells.

The National Council for Health and Welfare

LARS-ERIK HOLM

Ingmar Hammer
(Department of Supervision)

(SOSFS 2009:30)
Consent of the donor to the use of sperm or ovum for fertilisation outside the body according to chapter 7, section 2 of the Genetic Integrity Act (2006:351), etc.

Donor details:

Surname and first name .....
Personal number .....
Delivery address and postal code .....

I am aware:
that a donor of sperm or egg cells may withdraw his consent until fertilisation, a paternity or maternity action may never be brought against a donor who has participated in fertilisation carried out in accordance with the Genetic Integrity Act (2006:351) etc,
it may be necessary later in life to participate in blood tests or other investigations, and children born after my donation of sperm or egg cells shall be entitled to receive at maturity information about me recorded in a special register pursuant to Chapter 7 of this Act. 7 of the Act (2006:351) on Genetic Integrity etc.

I have read the above information and understand its meaning.
I agree that my donated sperm can be used for fertilisation.
Date .....
Signature .....

I have read the above information and understand its meaning.
I agree that my donated egg cells can be used for fertilisation.
Date .....
Signature .....

Doctor's signature .....
I have noted the above consent .....
Date .....
Signature and name clarification .....
Place of work .....
Telephone (incl. area code) .....

Withdrawal of consent .....
I withdraw my consent given above .....
Date .....
Signature .....
Doctor's signature on withdrawal .....

I have been informed of the withdrawal of consent in writing or orally (date) .....
Date .....
Signature and name clarification .....
Place of work .....
Telephone (including area code) .....

ATTACHMENT 2

Requirements for donor suitability and mandatory laboratory testing of samples of donors of organs and organ parts

SELECTION CRITERIA FOR DONORS OF ORGANS AND ORGAN PARTS

The selection criteria for donors (deceased and living donors of organs for allogeneic use) are based on an analysis of the risks associated with the use of the organs or parts of organs in question. Indicators of these risks are identified through clinical examination, review of medical and behavioural history, biological tests, post-mortem examination or any other necessary investigation. examination or any other necessary investigation. A person cannot be accepted as a donor if one of the following conditions (A-B) applies. However, a waiver may be granted on the basis of a documented risk assessment approved by the head of the establishment or the responsible person, if this person has been appointed in accordance with Chapter 2, Section 11 A.

General exclusion criteria

A person shall not be accepted as a donor if any of the following exclusion criteria apply.

1. Current or past occurrence of a disease of unknown cause that may clearly impair the quality of an organ

2. Risk of transmission of diseases caused by prions, including in the following cases

(a) A potential donor who has been diagnosed with Creutzfeldt-Jakob disease or variant Creutzfeldt-Jakob disease or who has non-iatrogenic Creutzfeldt-Jakob disease in the family.

b) A potential donor who has rapidly progressive dementia or a degenerative neurological disease of known or unknown origin.

c) A potential donor who has received hormones from a male pituitary gland, such as growth hormones, corneal, scleral or dura mater grafts, or has undergone undocumented neurosurgical procedures in which the dura mater may have been used.

3. systemic infection not under control at the time of donation, such as bacterial diseases, systemic viral, fungal or parasitic infections, or severe local infections of the organs to be donated

4. previous presence or clinical or laboratory findings demonstrating infection with human immunodeficiency virus type 1 or 2 (HIV 1 or HIV 2), acute or chronic infection with hepatitis B virus (except for persons with a documented immune status indicating eradicated infection), infection with hepatitis C virus or infection with human T-cell lymphotropic virus type I or II (HTLV I or HTLV II) or risk of transmission of or evidence of risk factors for these infections.

5. Evidence of other communicable disease risk factors identifiable on the basis of a risk assessment taking into account donor origin, travel habits, and risk exposure, such as sexual risk exposure, injection drug use, or residence in an area with a local geographic prevalence of infectious communicable diseases in transplantation.

6. Recently vaccinated with a live attenuated virus where there is thought to be a risk of transmission.
7. Presence of a systemic autoimmune disease that may adversely affect the quality of the organs to be harvested.
8. Indications that test results of donor blood samples may be unreliable due to
(a) haemodilution, as described in Annex 4 (to Section A, point 3), where no sample is taken prior to transfusion; or
(b) treatment with immunosuppressive agents.
9. exposure to or ingestion of a substance, such as cyanide, lead, copper or gold, which may be transmitted to the recipient to an extent which could endanger his or her health.
10. recent exposure to xenotransplantation.
B. Specific eligibility criteria for child donors In addition to the general exclusion criteria set out in section A, child donors are subject to the following.
1. A child born to an HIV 1 or HIV 2 infected woman or a child of a woman who meets one of the general exclusion criteria in section A cannot be accepted as a donor until the risk of transmission of the infection has been definitively excluded.
2. A child aged less than 18 months born to a woman infected or at risk of infection with HIV 1 or HIV 2, hepatitis B virus, hepatitis C virus or HTLV I or HTLV II and who has been breastfed by its mother during the previous 12 months shall not be accepted as a donor regardless of the results of the laboratory tests.

ATTACHMENT 2

Requirements for donor suitability and mandatory laboratory testing of samples by organ and organ parts' donors

SELECTION CRITERIA FOR ORGAN AND ORGAN PARTS DONORS
The selection criteria for donors (deceased and living donors of organs for allogeneic use) are based on an analysis of the risks associated with the use of the organs or parts of organs in question. Indicators of these risks are identified through a clinical examination, a review of medical history and behavioral patterns, biological tests, post-mortem examination, or any other appropriate investigation.
A person cannot be accepted as a donor if one of the following conditions (A-B) applies. However, exceptions may be granted based on a documented risk assessment approved by the head of operations or by a responsible person, if that person has been appointed in accordance with Chapter 2, Section 11.

A. General exclusion criteria
A person will not be accepted as a donor if one of the following exclusion criteria applies.

1. Current or past manifestation of a disease of unknown cause that may impair the quality of an organ.
2. Current or past presence of a malignant disease
3. The transmission of prion-caused diseases, including in the following cases:
    (a) a potential donor who has been diagnosed with Creutzfeldt-Jakob disease or variant creutzfeldt-Jakob disease or who has a family history of non-iatrogenic Creutzfeldt-Jakob disease.

(b) a potential donor who has rapidly progressive dementia or a degenerative neurological disease of known or unknown origin.

(c) a potential donor who has received hormones from a human pituitary gland, such as growth hormones, corneal, scleral or dura mater grafts, or has undergone documented neurosurgical procedures in which the dura mater may have been used.

4. Systemic infection not under control at the time of donation, such as bacterial, systemic viral, fungal diseases or parasitic infections or serious local infections of the organs to be donated.

5. Previous presence of clinical or laboratory results demonstrating infection with human immunodeficiency virus type 1 or 2 (HIV 1 or HIV 2), acute or chronic infection with hepatitis B virus (except for persons with a documented immune status indicating an eradicated infection), infection with hepatitis C virus or infection with human T cell lymphotropic virus type I or II (HTLV I or HTLV II) or clear risk of transmission of risk factors for these infections.

6. Prove of other risk factors for communicable diseases based on a risk assessment considering the origin of the donor, travel habits and exposure to risk, such as exposure to sexual risk, use of injectable drugs or residence in an area with a local geographical incidence of transplant-transmissible infectious diseases.

7. Recently vaccinated with a live attenuated virus in which a risk of transmission is considered.

8. Presence of a systemic autoimmune disease that can affect in a harmful way the quality of the organs to be procured.

9. Indications that the results of the analysis of donor blood samples may be unreliable due to

(a) hemodilution, as set out in Annex 4 (Section A, point 3), in cases where no sample is taken before transfusion; or

(b) treatment with immunosuppressive agents.

10. The exposure or ingestion of a substance, such as cyanide, lead, copper, or gold, which may be transmitted to the recipient to an extent that could pose a risk to his or her health.

11. The subjecting to xenotransplantation.

B. Specific selection criteria for underage donors

For underage donors, in addition to the general exclusion criteria set out in Section A, the following also apply.

1. A minor born to a woman infected with HIV 1 or HIV 2 or a child of a woman who meets one of the general exclusion criteria in Section A will not be accepted as a donor until the risk of transmission of the infection can be definitively excluded.

2. A minor younger than 18 months old born to a woman who is infected or at risk of HIV 1 or HIV 2 infection, hepatitis B virus, hepatitis C virus or HTLV I or HTLV II and has been breastfed by the mother in the previous 12 months will not be accepted as a donor regardless of the results of laboratory tests.

3. A child born to a woman who is infected with or is at risk of HIV 1 or HIV 2 infection, hepatitis B virus, hepatitis C virus or HTLV I or HTLV II, may be accepted as a donor if the baby has not been breastfed by the mother in the previous 12 months and if infection with these infectious agents cannot be demonstrated in laboratory tests, medical examinations, or review of medical records.

Requirements for mandatory laboratory tests for blood samples of organ donors

C. General requirements for the determination of biological markers

1. The tests shall be carried out by an accredited laboratory and using CE marked medical devices, if any. The tests used must be validated for the purpose in accordance with current scientific knowledge.
2. Biological tests shall be performed on the donor's serum or plasma, but not on other body fluids or secretions such as aqueous humor or vitreous humor, unless there are specific medical reasons, and when performed with a validated test for analysis of the body fluid in question.
3. If a potential donor has lost blood and has recently received blood, blood components, colloids or crystalloids, the blood sample may be unreliable due to hemodilution, which must be considered during sampling.

D. Compulsory laboratory tests

1. The following biological tests shall be performed on all donors to check for markers for the infectious agents listed below:

Infectious agent	**Markers**
HIV 1 and HIV 2	anti-HIV 1 and anti-HIV 2
Hepatitis B	HBsAg, anti-HBc
Hepatitis C	anti-HCV
Treponema pallidum (Syphilis)	see below 3

2. If the HBc test is positive and the HBsAg test is negative, further investigations, including a risk assessment, shall be carried out to determine whether the donor donations are suitable for therapeutic use.
3. A validated control algorithm shall be applied to rule out the presence of an active Treponema pallidum infection. After a non-reactive, specific, or non-specific test, the organs can be approved for use. If a non-specific test is used, a reactive result does not preclude its sampling or authorization for use, provided that a specific confirmatory test of Treponema is not reactive. A potential donor who tests positive for Treponema requires a thorough risk assessment to determine whether he or she can be accepted as an organ donor for transplantation.
4. A potential donor living in or coming from a high-risk area or whose sexual partners or parents come from such areas shall also be tested for the presence of antibodies against HTLV I and HTLV II.
5. In some circumstances, if necessary, additional tests are carried out, considering the background of a potential donor, such as RhD, HLA, malaria, tuberculosis, CMV, toxoplasmosis, EBV, Trypanosoma cruzi, Chikungunya, West Nile Virus and Leishmaniasis.

ATTACHMENT 3

Donor eligibility requirements for tissue and cell donation (except germ cells)

SELECTION CRITERIA FOR TISSUE AND CELL DONORS

The selection criteria for donors (live allogeneic donors and deceased donors) are based on an analysis of the risks associated with the use of the tissues and cells concerned. The tellers of these

risks are identified by clinical examination, review of medical and behavioral history, biological tests, post-mortem examination (for deceased donors) or any other appropriate investigation.

A person cannot be accepted as a donor if one of the following conditions (A-D) applies. However, an exemption may be granted based on a documented risk assessment approved by the head of operations or by a responsible person, if that person has been appointed in accordance with Chapter 2, Section 11.

A. General exclusion criteria for allogeneic donors

A person, living or deceased, cannot be accepted as a donor if one of the following exclusion criteria applies.

1. The presence or past presence of a disease of unknown cause that can compromise the quality of tissues and cells

2. Current or past presence of malignant disease

3. The risk of transmission of prion-caused diseases, including in the following cases:

(a) a potential donor who has been diagnosed with Creutzfeldt-Jakob disease or the variant of Creutzfeldt-Jakob disease or who has a family history of non-iatrogenic Creutzfeldt-Jakob disease.

(b) a potential donor who has rapidly progressive dementia or a degenerative neurological disease of known or unknown origin.

(c) a potential donor who has received hormones from a human pituitary gland, such as growth hormones, corneal, scleral or dura mater grafts, or has undergone documented neurosurgical procedures in which the dura mater may have been used.

4. Systemic infection that is not under control at the time of donation, such as bacterial, systemic viral, fungal, or parasitic diseases or severe local infections of tissues or cells to be donated.

5. History or clinical results or laboratory tests demonstrating human immunodeficiency virus type 1 or 2 infection (HIV 1 or HIV 2), acute or chronic hepatitis B virus infection (except for people with documented immune status indicating a cured infection), infection with hepatitis C or lymphotropic T human virus of type I or II (HTLV I or HTLV II) and the risk of transmission or evidence of risk factors for these infections.

6. Signs of other risk factors for transmissible diseases based on a risk assessment considering the donor's origin, travel habits and risk exposure, such as exposure to sexual risk, use of drugs by parenteral way, permanence in areas with local geographical incidence of infectious diseases that may be transmitted during transplantation.

7. Recently vaccinated with live and attenuated virus where it is believed that there is a risk of transmission.

8. Observations made during a donor study indicating a risk of transmissible diseases in accordance with Chapter 4. Sections 7 and 12.

9. Previous appearance of a chronic and systemic autoimmune disease that can adversely affect the quality of tissues and cells to be collected.

10. Indications that the results of blood tests may be unreliable due to

(a) hemodilution, as described in Attachment 4 (Section A, point 3), in cases where no sample has been taken before transfusion; or

(b) treatment with immunosuppressive agents.

11. Exposure or ingestion of a substance, such as cyanide, lead, copper, or gold, which may be transmitted to the receiver to such an extent that it poses a risk to their health.

12. Xenotransplantation completed.

Exceptions to point 2

Primarybasal cell carcinoma, locally limited cervical cancer, and certain types of primary tumors of the central nervous system, which must be evaluated according to the available scientific knowledge. Donors with malignant diseases can be evaluated and considered for corneal donation, except for donors with retinoblastoma, hematological neoplasm, or malignant tumors in the front of the eyeball.

Exceptions to point 4

A potential donor with bacterial septicaemia may be evaluated and possibly considered for corneal donation provided that the cornea is stored in an adapted environment or to trace any contamination of the tissue's needs.

B. Specific selection criteria for underage donors

For minor donors, other than the general exclusion criteria set out in Section A, the following criteria shall also apply:

1. A minor born to a woman infected with HIV 1 HIV 2 or a child of a woman who meets any of the general exclusion criteria set out in Section A may not be accepted as a donor until the risk of transmission of the infection can be definitively excluded.

2. A minor under the age of 18 months born to a woman infected with or at risk of infection with HIV 1 or HIV 2, hepatitis B virus, hepatitis C virus or HTLV I or HTLV II who has been breastfed by the mother in the last 12 months shall not be approved as a donor regardless of the results of laboratory tests.

3. A minor born to a woman infected with or at risk of infection with HIV 1 or HIV 2, hepatitis B virus, hepatitis C virus or HTLV I or HTLV II may be approved either as a donor and if the minor has not been breastfed by the mother in the last 12 months and, if infection with these agents cannot be detected by laboratory tests, medical examinations, or review of the patient's medical records.

C. Specific selection criteria for deceased donors

In addition to the general exclusion criteria set out in Section A and the specific criteria for minor donors, the following criteria shall also apply to deceased donors.

A deceased person cannot be approved as a donor if the cause of death is unknown, unless the autopsy determines the cause of death after collection, or the donor meets any of the exclusion criteria in sections A and B.

D. Specific criteria for living donors

Autologous use

In the case of donation of tissues and cells for autologous use, the minimum requirements for mandatory laboratory tests set out in Attachment 4 shall be met.

If the tissues and cells taken are to be stored or cultured, the same minimum requirements must be met for biological testing as for potential donors of tissues and cells for allogeneic use. Positive test results shall not prohibit the storage, processing and replanting of tissues and cells or derived products, if storage facilities are available to ensure that there is no risk of cross-contamination with other grafts, contamination with foreign agents or mixtures.

Allogeneic use

In addition to the exclusion criteria in Sections A and B, when donating tissues and cells for allogeneic use, the following also applies.

1. A living person may be approved as a donor following an assessment, in accordance with points 3 and 4, of the information on their health and medical history collected and through a questionnaire (health statement) and an interview conducted by a health professional or qualified person who has been trained or evaluated as competent for this task.

2. The assessment referred to in point 1 shall include relevant factors which may contribute to the identification and exclusion of persons whose tissues and cells may pose a risk to the health of others, for example through the possible transmission of diseases, or whose health may be threatened by the donation of tissues or cells. Regardless of the type of donation, the supply must not affect or endanger the health or care of the donor. In case of donation of umbilical cord blood or blood from the amniotic membrane, this applies to both the mother and the child.

3. The selection criteria for living donors shall be established in accordance with Sections A, B and D and shall be documented by the institute of tissues, in the case of direct distribution, by the doctor responsible for the transplant. The criteria are based on the tissues and cells to be donated, the physical status of the donor, the medical history, and the risky behaviors, as well as the results of clinical examinations and laboratory tests for the potential donor.

4. In addition, depending on the type of tissues or cells to be donated and, other specific exclusion criteria shall be used, such as:

(a) pregnancy, except in the case of donation of umbilical cord blood cells, amniotic membrane, and donation of fetal hematopoietic progenitor cells;

(b) breastfeeding;

(c) risk of transmission of hereditary diseases in the case of hematopoietic progenitor cell donation.

ATTACHMENT 4
Requirements for mandatory laboratory tests on blood samples from tissue and cell donors (except germ cells)

A. General requirements for the determination of biological markers

1. Tests shall be carried out by an accredited laboratory and using CE marked medical devices, where possible. The tests used must be validated for the purpose in accordance with current scientific knowledge.

2. The biological tests referred to in point B shall be performed on the serum or plasma of the potential donor, but not on other body fluids or secretions such as aqueous humor or vitreous humor, unless there are specific medical reasons, and if performed with a validated test for the test of the body fluid in question.

3. If a potential donor has lost blood and has recently received blood, blood components, colloids or crystalloids, the blood test may be unreliable due to hemodilution. An assessment of the degree of hemodilution must be carried out

(a) If blood, its components, or colloids of a potential living donor were donated during the 48 hours prior to sampling or if the crystalloids were donated in the last hour prior to sampling;

(b) If blood, its components, or the colloids of a potential deceased donor were donated in the last 48 hours before death, or the crystalloids were given in the last hour before death.

Tissues institutes may receive tissues and cells from a potential donor with plasma dilution greater than 50%, only if the institute of tissues uses validated test methods for such plasma, or if there is a sample taken before transfusion.

Deceased donors

In the case of a deceased donor, blood samples must have been taken shortly before death or, where this is not possible, promptly and at the latest within 24 hours after death.

Living donors

1. For the collection of blood from a potential living donor, the following shall apply:

(a) Blood samples, except for potential donors of stem cells from bone marrow or peripheral blood for allogeneic use, must be taken at the time of procurement or, where this is not possible, within seven days of supply (the so-called "donation sample").

b) If the tissues and cells taken are to be stored long-term, the blood withdrawal should be repeated after 180 days. If it is necessary to repeat the sampling, the blood sample can be taken up to 30 days before and seven days after the supply.

(c) If the tissues and cells of a living donor are not to be stored for the long term and repeated sampling is therefore not possible, point 5(a) shall apply.

2. If the blood sample referred to in point 5 (a) is also tested for human immunodeficiency viruses of type 1 and 2 (HIV 1 and HIV 2), hepatitis B virus and hepatitis C virus by nucleic acid amplification (NAT), no repeated sampling shall be required after 180 days.

Re-sampling is not required even when the treatment includes an inactivation phase that has been validated for the virus in question. If the sample and blood referred to in point 5(a) is analyzed for the presence of HTLV I and HTLV II antibodies in accordance with point B 4, a new sample shall be taken and the test repeated.

Fetus

1. In case of collection of stem cells from bone marrow or peripheral fetal blood, blood samples for analysis shall be taken within 30 days before the supply.

2. In the case of a potential newborn donor, biological tests relating to the donor may be carried out on the mother so that the child is not exposed to medically unnecessary procedures.

B. Mandatory laboratory tests

1. The following biological tests shall be performed on potential donors to check for markers for the following infectious agents:

Infectious agent	***Marker***
HIV 1 and HIV 2	anti-HIV 1 and anti-HIV 2
Hepatitis B	HBsAg, anti-HBc
Hepatitis C	anti-HCV
Treponema pallidum (Syphilis)	see point 3 below

2. If the anti-HBc test is positive and HBsAg is negative, further investigations, including a risk assessment, shall be carried out to determine whether the potential donor donations are suitable for human use.

3. A validated control algorithm shall be applied to rule out the presence of an active *Treponema pallidum* infection. After a non-reactive, specific or non-specific test, the tissues and cells can be approved for use. If a non-specific test is used, a reactive result shall not constitute an obstacle to supply or to the authorization for use, provided that a specific or confirmatory test of treponem is not reactive. A potential donor who tests positive for a specific test for treponem will require a thorough risk assessment to determine whether it can be accepted as a donor of tissues and cells intended for human use.

4. A potential donor who lives in or comes from high-risk areas or whose sexual partners or parents come from such areas must be tested for the presence of antibodies to the human type lymphotropic virus I and II T-cell (HTLV I and HTLV II).

5. Under certain circumstances, if necessary, additional tests shall be carried out considering the medical history of a potential donor, e.g. RhD, HLA, malaria, tuberculosis, CMV, toxoplasmosis, EBV, Trypanosoma cruzi, Chikungunya, West Nile virus and Leishmaniasis.

6. If tissues and cells intended for autologous use are to be stored or cultured, the same minimum requirements for biological testing as for potential donors of tissues and cells intended for allogeneic use shall be met. Positive test results shall not imply a prohibition on the storage, processing or reimplantation of tissues, cells or derived products, provided that separate storage facilities are available to ensure that there is no risk of cross-contamination with other grafts, contamination with foreign agents or confusion

ATTACHMENT 5

Requirements for donor eligibility and requirements for mandatory laboratory testing of samples from germ cell donors

SELECTION CRITERIA FOR GERM CELL DONORS

In addition to the provisions of the Regulations of the National Council of Health and Welfare (SOSFS 2009:32) on the use of tissues and cells in health care and clinical research, etc., the following requirements also apply to the suitability of a donor considering the safety of the receiver and any children who may be born, as well as the requirements for mandatory laboratory tests.

A. General requirements for the determination of biological markers

1. The tests shall be run by an accredited laboratory and using CE marked medical devices, where possible. The tests used must be validated for the purpose in accordance with current scientific knowledge.

2. Biological tests shall be carried out on the donor's serum or plasma, but not on other body fluids or secretions, except as provided for in point 2 of section C, or for specific medical reasons, and if they are performed with a validated test for the body fluid in question.

3. Blood samples shall be taken before or at the time of collection.

B. Assisted reproduction in cases where the donor and the receiver are married or cohabitant

1. The doctor responsible for the donation shall clarify and document, considering the medical history and therapeutic indications of the donor and recipient, the reasons for the donation and whether it is safe for the receiver and for the children who may be born.

2. The following biological tests for the presence of markers for the following infectious agents shall be performed on potential donors:

Infectious agent	***Marker***
HIV 1 and HIV 2	anti-HIV 1 and anti-HIV 2
Hepatitis B	HBsAg, anti-HBc
Hepatitis C	anti-HCV
HTLV I and HTLV II	anti-HTLV I and anti-HTLV II
Treponema pallidum (Syphilis)	see point 4 below

Biological tests on the receiver shall be run in accordance with the Regulation of the National Council of Health and Welfare (SOSFS 2009:32) on the use of tissues and cells in health care, in clinical research, etc.

3. If the anti-HBc test is positive and HBsAg is negative, further investigations, including a risk assessment, shall be carried out to determine whether the donations of the other spouse or partner are suitable for use in humans.

4. A validated control algorithm is applied to rule out the presence of an active *Treponema pallidum* infection. After a non-reactive test, specific or non-specific, the semen may be authorized for use. If a non-specific test is used, a reactive result shall not constitute an obstacle to supply or to the authorization for use, provided that a specific test confirming the treponema is not reactive. If the samples of the other spouse or partner are positive in a specific treponema test, a thorough risk assessment will be carried out to determine whether they can be approved as a germ cell donor intended for assisted reproduction.

5. If the test results for HIV 1 and HIV 2, hepatitis B or hepatitis C are positive, if there has not yet been received a response to the tests or if it's sure that the other spouse or partner may pose a risk of infection, there shall be a separate storage system.

6. In certain circumstances, if necessary, further tests shall be carried out, considering the context, travel habits and risk exposure of the other spouse or partner, as well as the characteristics of the donated semen.

7. Positive test results do not prevent donation. However, assisted fertilization can only be carried out if it is considered unlikely that infectious agents or diseases, which may endanger the life of the woman or child, are transmitted to the woman or child through fertilization.

C. Assisted reproduction in cases where the donor is different from the spouse, registered partner, or cohabitant

Germ cells donated for assisted reproduction must comply with the following rules.

1.A person may be approved as a semen or egg donor after an assessment of data on their age, health and medical history collected through a questionnaire (health statement) and an interview conducted by a healthcare professional trained and assessed as competent for the task. The assessment shall include relevant factors that may help identify and exclude persons whose germ cells may pose a risk to the health of others, for example through the possible transmission of infections and diseases, such as sexually transmitted diseases, or whose health may be threatened using donated germ cells, such as superovulation, anaesthesia or other risks associated with retrieval of eggs, or psychological consequences for the donor.

2. The intended donor shall show negative test results on serum or plasma samples for HIV 1 and HIV 2, hepatitis B, hepatitis C, HTLV I and HTLV II and syphilis, tested in accordance with section B, paragraphs 2, 3 and 4. In addition, urine samples from semen donors should be tested by nucleic acid amplification (NAT) and tested negative for chlamydia and gonorrhea infection. Alternatively, gonorrhea can be ruled out by a negative urine test for gonococci.

3. Under certain circumstances, additional testing may be necessary depending on the potential donor's background, travel habits and risk exposure, as well as the characteristics of their germ cells.

4. The donated semen shall be kept separate from other tissues and cells for at least 180 days and the donor shall then be re-tested for markers for HIV 1 and HIV 2, hepatitis B, hepatitis C and HTLV I and HTLV II in accordance with section B, paragraphs 2 and 3.

If donor donation samples are also tested for HIV 1 and HIV 2, hepatitis B and hepatitis C with nucleic acid expansion (NAT), the test should only be repeated for HTLV I and HTLV II. Where deemed relevant, the tests carried out in accordance with paragraph 3 shall also be repeated.

5. For a donor belonging to an ethnic group whose autosomal recessive genes are common according to international scientific evidence or belonging to a family in which hereditary diseases at risk of transmission are known, the need for genetic screening shall be considered. Under the Genetic Integrity Act (2006:351), such genetic screening can only be done with the donor's consent. The receiver must receive personalized information on the risk of transmission of hereditary diseases to the child and on the measures taken to reduce these risks.

D. Storage of eggs for autologous use

If egg cells recovered for autologous use are to be stored or cultured, biological tests shall be carried out in accordance with point B.2 and the evaluation of the results shall be carried out in the same way as for other germ cell donors. Positive test results do not prohibit the replanting of an egg cells. However, the replanting of a fertilized egg cells can be carried out only if it is considered unlikely that infectious agents or diseases detected, which can endanger the life of a child, will be transmitted to the child through fertilization.

ATTACHMENT 6

Sent to
National Council for Health
and Welfare
106 30 Stockholm

APPLICATION FOR AUTHORISATION
under Section 8 of the Transplantation Act (1995:831) to obtain biological material from a living donor for transplantation in cases where the donor is a minor or suffers from a mental disorder

Date
.....

The question concerns

Name and surname of the donor		Personal number
Name and surname of guardian 1/legal representative*/custodian*		Personal number
Telephone (including prefix)	Email	
Address		
House number	Postal position	
Name and surname of guardian 2/legal representative*/custodian*		Personal number
Telephone (including prefix)	Email	
Address		
House number	Postal location	
Name and surname of the receiver of the biological material		Personal number

Relationship of the recipient with the donor

Consent

The donor shall be informed, as far as possible, of the operation and the risks involved The donor does not object to the procedure I/we, as guardian, legal representative, or custodian, have been informed of the nature of the procedure and the risks involved. I have/we have given my/our consent to the procedure

Any additional information

Signatures

Place and date	Guardian 1/ caretaker/custodian
Place and date	Guardian 2/caretaker/custodian

*The application can be made for a minor, by a guardian, legal representative, or a custodian.
In the case of a person suffering from mental disorder, the question can be made by a guardian, legal representative, or custodian.
A power of attorney must be attached.

MEDICAL DECLARATION
the application for authorisation under Article 8 of the Transplantation Act (1995:831), etc.

Actions refer to

Name and surname of the donor	Personal number
Name and surname of the recipient of the biological material	Personal number
Diagnosis of the disease	
Biological material to be supplied and transplanted	

Relevant context and alternative treatment methods
If the donor is a relative of the receiver, indicate why it is not possible to obtain biological material from another suitable donor
If the donation is of biological material that cannot be reconstituted, indicate the exceptional reasons for the operation
Any additional information

Healthcare facility

Name and surname of the responsible doctor*		Title
Healthcare facility		Health Care Unit
Delivery address		
House number	Postal position	
Telephone (including prefix)	Email	FAX (including prefix)
Healthcare facility where the procedure will be performed (if different from the one above)		

Responsible doctor's approval

The guardians/legal representative/custodian and the donor received personalised information about the operation and the risks associated with the procedure. The guardian/legal representative/custodian has given his consent to the procedure The donor does not object to the procedure

Date and place	Signature

***** According to section 12(1) of the Transplantation Act (1995:831), the decision on an intervention to obtain biological material for transplantation purposes cannot be made by a doctor who is responsible for caring for the recipient's health.

ATTACHMENT 7

Sent to
National Council for Health and Welfare
106 30 Stockholm

APPLICATION FOR AUTHORISATION

Under Section 9 of the Transplantation Act Etc. (1995:831), to obtain biological material from a living donor for medical purposes other than transplantation

Date
.....

The question concerns

Name and surname of the donor	Personal number
Telephone (including prefix)	Email
Biological material to be recovered	
Purpose of storage	
☐ The biological material does not regenerate ☐ The procedure can cause significant harm or inconvenience to the donor	
Risks associated with the procedure	
Any additional information	

Healthcare facility

Name and surname of the responsible doctor*		Title
Healthcare facility		Health Care Unit
Delivery address		
House number	Postal position	
Telephone (including prefix)	Email	FAX (including prefix)

Donor consent

☐ I have been informedabout the intervention, the purpose and the risks associated with the procedure

☐ I agree to this intervention	
Date and place	Signature

Signature of the responsible doctor

Date and place	Signature

Decisions on interventions for the purpose of obtaining biological material for other medical purposes, under Section 12 of the Transplantation Act (1995:831), shall not be taken by the physician who is to use the material for the medical purpose.

ATTACHMENT 8

Sent to
National Council for Health and Welfare
106 30 Stockholm

APPLICATION FOR AUTHORISATION

Under section 11 of the Transplantation Act (1995:831), to obtain tissues from an aborted fetus

Date
.....

The question concerns the procurement of tissues for individual therapeutic purposes

Name and surname of the pregnant woman	Personal number
Date of abortion	Week of pregnancy in which the abortion is performed

The question concerns the procurement of tissues for general medical purposes

☐ Purpose of the research, attached project plan ☐ Other medical purpose	
Number of fetuses supplied	Supply period

Medical purpose

Tissue to be recovered
Purpose of supply
Specify exceptional reasons for obtaining the tissue for its intended purpose
Any additional information

Healthcare facility (if tissues are to be taken from different healthcare facilities, attach a list of addresses)

Name and surname of the responsible doctor*		Title
Healthcare facility		Health Care Unit
Delivery address		
House number	Postal position	
Telephone (including prefix)	Email	FAX (including prefix)

Consent

☐ I have been informed about the intervention and its intended use ☐ I agree to this intervention	
Date and place	Signature

Signature of the responsible doctor

Date and place	Signature

*Decisions on the use of fetal tissue for medical purposes, in accordance with Section 12 (1) of the Transplantation Act (1995:831), shall not be made by the doctor responsible for the abortion or who determines the time and method of the abortion.