DENMARK

Law No. 402 of 13 June 1990 on the examination of cadavers, autopsies, and transplantation, etc. (*Lovtidende*, 1990, 14 June 1990, No. 63, pp 1331-1334).

Chapters 1 and 4 read as follows:

Chapter 1

Determination of death

1. The death of a person shall be determined to have occurred:
    1) in the event of irreversible cessation of respiration and cardiac activity;
    2) in the event of irreversible cessation of all brain functions.
2. The National Board of Health shall be responsible for laying down provisions concerning the examination to be performed in order to determinate that death has occurred, in accordance with item 2 of Section 1.

(…omissis…)

Chapter 4

Transplantation

Transplantation from living person

13. (1) Tissues and other biological materials may be removed from a person during his lifetime for the purposes of treating disease or restoring a physical injury in another person, provided that the donor has given his consent thereto in writing.

(2) Such consent may be given by any person who is more than 18 years of age. If there are specific reasons, the intervention may be performed on a person under 18 years of age with his consent, provided that such consent has received the approval of the person exercising parental authority.

(3) Before giving his consent, the person concerned properly informed by a physician about the nature of the information, its consequences, and the risks. The physician must ensure that the person concerned has clearly understood the significance of the information that has been communicated to him.

(4) The intervention may only be performed if, taking into account its nature and the state of health of the person giving consent, it may be undertaken without any immediate danger to that person.

Transplantation from the deceased person

14. (1) Tissues and other biological materials may be removed from a person who has died in a hospital or other similar institutions, or who is dead on arrival at such an institution, in accordance with subsections 2 and 4, with a view of the treatment of a disease or the restoration of a physical injury in another person.

(2) The intervention may only be performed if the decease person, after reaching the age of 18, confirmed in writing that this was his decision. The same provision shall apply if the person had expressed orally himself in favor of such an intervention.

(3) Other than in the circumstances referred to in subsection 2, an intervention can only be made if the deceased person has never expressed his opposition to it, and his close relatives had given their consent. In the event that the deceased person leaves no close relatives, the intervention may not be performed.

(4) If the deceased person is less than 18 years old, the intervention may be done only if the person exercising parental authority has consented for it.

15. (1) The removal of tissues, etc. as referred to in sections 13 and 14, may be undertaken only by physicians attached to hospitals or similar institutions that have been approved for the purpose by the National Health Board.

(2) The intervention referred to in section 14 may not be performed by a physician who treated the deceased person during his last disease or who determined the person to be dead.

(3) The intervention referred to in sections 14 may not be performed if the body of the deceased person has to undergo a medicolegal examination or autopsy, except if the intervention may be assumed to have no significance to the result of the autopsy.

Section 16 of Chapter 5 (Other provisions) lays down that all interventions on a cadaver other than referred to in Chapter 3 (Autopsies) and 4, may be performed only if the deceased person, after reaching the age of 18, confirmed in writing that this was indeed his decision, and irreversible cessation of respiration and cardiac activity has been duly ascertained.

Subsection 3 of section 20 of Chapter 6 (Penal provisions, entry into force, etc.) lays down that any person who offers or receives payment or any other valuable consideration in respect of the removal or transfer of tissues or other biological materials for therapeutic purposes, as referred to in sections 12 and 14, is liable to a fine. The same provisions apply to any person who knowingly collaborates in this kind of transaction.

Danish Health Act (N. 546 of 2005) §§ 52-56

Section IV

Transplantation

Chapter 12

Transplantation from living and deceased persons

Transplantation from living persons

§ 52. Tissues and other biological materials may be removed from a person during his lifetime for the purposes of treating disease or restoring a physical injury in another person, provided that the donor has given his consent thereto in writing.

PCS. 2. Such consent may be given by any person who is more than 18 years of age. If there are specific reasons, the intervention may be performed on a person under 18 years of age with his consent, provided that such consent has received the approval of the person exercising parental authority. For a person who is under 15 years of age, the consent may be given by the holder of parental responsibility when the conditions in PCS 3 are met. For a person who lacks the ability to give consent himself, the consent may be given by his guardian when the conditions in PCS. 3 are met. In case where a patient has submitted a *future power of attorney* that includes personal matters, including health matters, the consent of a person who lacks the ability to give consent himself may be given by the *future power of attorney*, in so far as the future power of attorney authorizes the future agent and if the conditions in PCS.3 are met. However, consent may not be given for the removal of non-recoverable tissue from a person under 18 years of age or from a person who lacks the capacity to consent.

PCS. 3. From a person who is under 15 years of age or who lacks the ability to give consent himself, tissue may only be removed if:

1) there is no suitable donor who has the ability to consent;

2) the recipient is a brother, sister, child, parent or, in special cases, a close family member of the donor;

3) the donation creates the opportunity to save the recipient's life;

4) the potential donor in question does not object.

PCS. 4. Interventions on people under 18 years of age and people who cannot give consent must be approved by the National Board for Patient before surgery takes place.

PCS. 5. Before giving his consent, the person concerned properly informed by a physician about the nature of the information, its consequences, and the risks. The physician must ensure that the person concerned has clearly understood the significance of the information that has been communicated to him.

PCS. 6. The intervention may only be performed if, taking into account its nature and the state of health of the person giving consent, it may be undertaken without any immediate danger to that person.

Transplantation from deceased person.

§ 53. Tissues and other biological materials may be removed from a person who has died in a hospital or other similar institutions, or who is dead on arrival at such an institution, in accordance with subsections 2 and 4, with a view of the treatment of a disease or the restoration of a physical injury in another person.

PCS. 2. The intervention may only be performed if the decease person, after reaching the age of 15, confirmed in writing that this was his decision. The same provision shall apply if the person had expressed orally himself in favor of such an intervention. Notwithstanding paragraph 4, the relatives of the deceased cannot oppose the intervention if the deceased has communicated this in writing, unless the deceased has agreed that the decision is subject to the agreement of the relatives.

PCS. 3. Other than in the circumstances referred to in subsection 2, an intervention can only be made if the deceased person has never expressed his opposition to it, and his close relatives had given their consent. In the event that the deceased person leaves no close relatives, the intervention may not be performed.

PCS. 4. If the deceased is under the age of 18, the intervention can only be carried out if the holder of parental responsibility has consented to the intervention.

Instructions etc.

Consent for transplantation from deceased persons and for transplantation-related research (Patient Safety Guide no. 10099 of 5/12 2019).

Legislative changes

1/7 2019 by Act no. 1732 of 27/12 2018 (Amendment of the age limit for taking a position on organ donation and transplant-related research on brain deaths and autopsies of people who die suddenly and unexpectedly) §1 [LF 710 2018-79].

§ 54. The removal of tissues, etc. as referred to in § 52 and § 53, may be undertaken only by physicians attached to hospitals or similar institutions that have been approved for the purpose by the Danish Agency for Patient Safety.

PCS. 2. The approval given under subsection. 1 may be amended, suspended or revoked by the Danish Agency for Patient Safety if the conditions for approval are no longer present.

PCS. 3. Interventions pursuant to §§ 53 and 54 may not be performed by a physician who treated the deceased person during his last disease or who determined the person to be dead.

PCS. 4. Intervention pursuant to section 53 may not be performed if the body of the deceased person has to undergo a medicolegal examination or autopsy, except if the intervention may be assumed to have no significance to the result of the autopsy.

Legislative changes

1/1 2020 by Act no. 1436 of 17/12 2019 (Strengthening citizens' security and trust in health research as well as improved frameworks for health research) § 2 [LF 35 2019-20]

§ 54 a. Research on a deceased person as part of the removal of his organ pursuant to Section 53 may only be carried out in accordance with the rules in paragraphs 2 to 4 if the health-scientific research project is intended to improve transplant results.

PCS. 2. Research may only be performed if the decease person, after reaching the age of 15, confirmed in writing that this was his decision. The same provision shall apply if the person had expressed orally himself in favor of it. Notwithstanding paragraph 4, the relatives of the deceased cannot oppose the research if the deceased has communicated this in writing, unless the deceased has agreed that the decision is subject to the agreement of the relatives.

PCS. 3. Other than in the circumstances referred to in subsection 2, research can only be made if the deceased person has never expressed his opposition to it, and his close relatives had given their consent. In the event that the deceased person leaves no close relatives, research may not be performed.

PCS. 4. If the deceased is under the age of 18, the research can only be performed if the holder of parental responsibility has consented to it.

Legislative changes

Inserted 1/7 2019 by Act no. 1732 of 27/12 2018 (Amendment of the age limit for taking a position on organ donation and transplant-related research on brain deaths and autopsies of people who die suddenly and unexpectedly) § 1 [LF 110 2018-19].

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§ 55. Interventions on a deceased person other than those mentioned in this chapter may only be made if the deceased, after reaching the age of 18, confirmed in writing that this was his decision.

PCS. 2. Such interventions can be performed only when irreversible cessation of breathing and cardiac activity has occurred.

§ 56. The provisions of this chapter apply correspondingly to children who are born after the end of the 22nd week of pregnancy without showing signs of life (stillborn children).

PCS. 2. The provisions of this chapter do not apply to the collection of blood, the removal of small areas of skin and other minor procedures, which must be equated with this.

Law No 151 of 28/02/2012

Act on quality and safety requirements for the handling of human organs for transplantation

Chapter 1

Purpose of the law

§ 1. The purpose of the Act is to establish quality and safety requirements for the handling of human organs for transplantation, thereby promoting a high level of health protection and facilitating the exchange of organs with other countries.

§ 2. The Act shall apply to the donation, testing, characterization, procurement, preservation, transport andtransplantation of human organs intended for transplantation.

Paragraph 2. In the case of organs used for research purposes, the provisions of the Act shall apply if the organs in question are also intended for transplantation into the human body.

For the purposes of this Act:

1) Serious adverse reaction: an unintended complication, including a communicable disease, of the livingdonor or recipient of the organ at any stage of the process from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalization or illness.
2) Other disposition: the final disposition of an organ when it is not used for transplantation.
3) Serious adverse event: any undesirable event at any stage of the process from donation to transplantation that may result in the transmission of communicable diseases, death, life-threatening or disabling conditions or incapacity of the donor or organ recipients, or that triggers or prolongs hospitalization or disease.
4) Donation: giving organs for transplantation.
5) Donor characterization: the collection of relevant information on the characteristics of the donor necessary to assess his/her suitability as a donor, in order to carry out a thorough risk assessment andminimize the risks for the recipient of the organ and ensure an optimal allocation of organs.
6) Organ characterization: the collection of relevant information about the donor's characteristics necessary to assess his or her suitability as a donor in order to conduct a thorough risk assessment and minimize hazards to the organ recipient and ensure optimal organ allocation.
7) Organ: a differentiated part of the human body, composed of different tissues that maintain its structure, vascularization and capacity to develop physiological functions with a high degree of autonomy. A part of an organ is also considered an organ if it is intended to be used for the same purpose as the wholeorgan of the human body and its structure and vascularization are maintained.
8) Preservation: the use of chemical substances, environmental changes or other means to prevent or delaythe biological or physical deterioration of organs from the time of removal to transplantation.
9) Recipient: a person who receives an organ by transplantation.
10) Traceability: the ability to locate and identify the organ at any stage in the process from donation to transplantation or other disposition, including the ability to:
    a. identify the donor and the place of collection,
    b. identify the recipient(s) and the transplantation center(s);

c. locate and identify all relevant non-personal information on products and materials coming into contact with the body concerned.

11) Transplantation: trying to restore some human body function by transferring an organ from a donor to a recipient.

12) Transplantation center: a health care facility, hospital team, hospital unit, or organization involved in human organ transplantation and licensed for that purpose in accordance with applicable regulations.

13) Procurement: a process by which the donated organs are obtained.

14) Procurement organization: a health care institution, hospital team, hospital unit, person, or organization that participates in or coordinates organ procurement and is authorized to do so in accordance with applicable regulations.

Chapter 2

Quality and safety of organs

§ 4. The National Board of Health shall lay down rules on quality and safety covering all stages of the process from donation to transplantation or other disposition. In particular, the National Board of Health shall lay down rules on:

1) requirements for risk assessment and organ donor selection, including requirements for donor and organ characterization, testing and evaluation,

2) requirements for the procedures of organ procurement organizations, including for obtaining donor consent and identification,

3) living donor donation requirements,

4) requirements for transplantation centers on pre-transplantation procedures, including proper donor and organ characterization, etc.,

5) requirements for the professional qualifications of health professionals,

6) requirements for anonymization of all information collected under regulations issued pursuant to this Act to which third parties may have access,

7) requirements for the transport of organs for transplantation, including packaging and labelling;

8) requirements for salvage materials and equipment, including whether they are managed in accordance with relevant EU, international, and national legislation, and medical device sterilization standards and guidelines.

In exceptional cases, the doctor in charge may authorize the use of an organ for transplantation despite the failure to comply with the provisions of Article 4(1). This is subject to the condition that the expected benefits to the recipient, according to an analysis of the risks and benefits in the specific case, including life-threatening emergencies, outweigh the risks associated with incomplete information.

Chapter 3

Exchange of organs

§ 6. The Danish Health Authority concludes agreements on the exchange of organs between Denmark and the other EU and EEA Member States and with third countries.

Paragraph 2. The National Board of Health shall lay down rules on the communication and transmission of information in connection with organ exchange.

Chapter 4

Traceability

Transplantation centers and procurement organizations shall use a donor identification system so that all organs procured, allocated and transplanted can be traced from donor to recipient and vice versa. The National Board of Health shall lay down rules to this effect.

Paragraph 2. Transplantation centers and procurement organizations shall keep all information necessary to ensure traceability at all stages from donation to transplantation or other disposition and information on organ and donor characterization in accordance with the provisions laid down pursuant to Article 4.

Paragraph 3. Information necessary for full traceability shall be kept for at least 30 years after donation.

Chapter 5

Incident and adverse reaction reporting

Transplantation centers and procurement organizations shall report to the Danish Health Authority serious adverse events that may affect the quality and safety of organs and that may be attributed to the testing, characterization, procurement, preservation and transport of organs, and serious adverse reactions during or after transplantation that may be related to the above activities. In addition, measures to manage serious adverse events and reactions shall be reported to the Agency.

Paragraph 2. Transplantation centers and procurement organizations shall report to the National Board of Health information on serious adverse reactions in living donors that are attributable to the donation.

Paragraph 3. The National Board of Health shall keep a register of information reported pursuant to paragraphs 1 and 2.

Paragraph 4. The Minister for Health and Prevention shall lay down rules on the processing by the National Board of Health of information reported pursuant to paragraphs 1 and 2.

Paragraph 5. The National Board of Health shall forward reports received pursuant to paragraph 1 to the National Board of Medicines' reporting system for human tissues and cells for transplantation.

Paragraph 6. The Danish Health Authority shall lay down rules on the reporting and handling of serious adverse events and reactions by procurement organizations and transplantation centers.

Chapter 6

Control company

§ 9. The National Board of Health shall monitor compliance with the provisions of this Act and the rules laid down pursuant to the Act on the donation, testing, characterization, procurement, preservation, transport and transplantation of organs and on the registration, processing and reporting of information on serious adverse events and reactions.

Paragraph 2. The National Board of Health shall monitor compliance with the provisions of this Act and the rules laid down pursuant thereto in respect of organs exchanged with other countries.

Paragraph 3. Representatives of the Public Health Agency shall have access, on production of appropriate identification and without a warrant, to all premises where the activities referred to in paragraph 1 are carried out. The Public Health Board may require any information necessary for the inspection.

Chapter 7

Record keeping and disclosure of information

Transplantation centers and procurement organizations shall report to the National Board of Health information on the total numbers of living and dead donors and on which and how many organs have been procured and transplanted or otherwise disposed of.

Paragraph 2. The National Board of Health shall prepare and publish an annual report on the activities of transplantation centers and procurement organizations on the basis of the reports referred to in paragraph 1.

Paragraph 3. The National Board of Health shall lay down detailed rules on reporting by transplantation centers and procurement sites.

The National Board of Health shall establish and maintain an updated register of approved transplantation centers and procurement organizations, including information on the activities they may perform and any conditions attached thereto.

Paragraph 2. The National Board of Health shall make the register referred to in paragraph 1 available to the public.

Paragraph 3. The National Board of Health shall, at the request of the European Commission or an EU Member State, provide information on the rules for granting authorization for the procurement of organs and the transplantation of organs respectively.

§ 12. The Danish Health Authority may disclose to the European Commission and competent authorities of other countries concerned information on serious adverse events and reactions reported in accordance with § 8, paragraphs 1 and 2, and control activities carried out, as referred to in § 9, paragraph 1.

Paragraph 2. The Minister for Health and Prevention may lay down rules on the disclosure referred to in paragraph 1.

Paragraph 3. The Danish Health Authority shall report every three years to the European Commission on the implementation of this Directive, for the first time on 27 August 2013.

Chapter 8

Administration

The National Board of Health shall perform all duties relating to administration and control pursuant to the provisions of this Act and the regulations issued pursuant thereto.

Paragraph 2. The National Board of Health may entrust the administration of tasks pursuant to section 6(1), section 9(2) and section 10(1) and (2) to a private organization and in connection therewith lay down detailed rules for the organization’s activities in connection with the administration of the tasks.

Paragraph 3. The National Board of Health may, with the prior approval of the Minister for Health and Prevention, delegate tasks and control functions which the National Board of Health performs pursuant to paragraph 1 to other institutions, etc.

Chapter 9

Prohibition of advertising by bodies

It is prohibited to advertise or offer organs for donation with a view to making or receiving payment or any other financial benefit.

Chapter 10

Penalties, entry into force, etc.

Unless a higher penalty is prescribed by other legislation, a fine shall be imposed on anyone who infringes Section 7, Section 8(1) and (2), Section 10(1) and Section 14.

Paragraph 2. Rules issued pursuant to the Act may provide for a penalty of a fine for infringement of the provisions of the rules.

Paragraph 3. Criminal liability may be imposed on companies or firms (legal persons) in accordance with the rules laid down in Chapter 5 of the Criminal Code.

The Act shall enter into force on 15 August 2012.

Paragraph 17(1) shall also apply to approvals granted before 15 August 2012.

Section 17 of the Health Care Act, cf. Legislative Decree No 913 of 13 July 2010, as last amended by Act No 1388 of 28 December 2011, is amended as follows:

In Article 54, a new paragraph is inserted after paragraph 1:

"Paragraph 2. Approval granted under paragraph 1 may be amended, suspended or revoked by the Danish Health Authority if the conditions for approval are no longer met."

Paragraphs 2 and 3 become paragraphs 3 and 4.

The Act shall not apply to Greenland and the Faroe Islands. However, Section 17 may be brought into force for the Faroe Islands by Royal Decree, with such amendments as the Faroese circumstances may require.

VEJ nr. 10099 of 5 December 2019

Guidance on consent for transplantation and transplantation -research on deceased persons

(For the hospitals in the country)

1. Introduction

1.1. Context

In winter 2013, the then Minister of Health and Prevention established a working group to develop an action plan for organ donation. Based on the recommendations of the working group, the Ministry of Health and Prevention published the 'National Action Plan for Organ Donation' in July 2014. The aim of the action plan was to strengthen the field of transplantation so that as many people as possible in need of a new organ would have the opportunity to receive a transplant. The action plan states that there is a need to increase the number of organ donors in Denmark, as there are more people on the waiting list for a new organ than the organs available. One reason is that there are few cases of brain death in Denmark. It should be ensured that the possibility of organ donation is explored in all appropriate cases, but it is important to emphasize that there should never be any doubt that the focus should be on treating the patient as long as treatment is an option.

With the adoption of Law No. 1732 of 27 December 2018, the age limit for taking a position on organ donation was changed and access to transplant-related research on brain dead was established. According to the law, brain death research must be carried out in connection with organ removal and the research project must be aimed at improving transplantation results. This means that the research project must be able to improve the health of the recipient or the transplant outcome of future transplant patients. This will be a general consensus for research related to organ donation and not for a specific research project.

1.2. Purpose

The aim of the guide is to inform doctors and other health professionals involved about the content and meaning of the regulations, including the obligations of doctors in relation to the need for consent for organ donation and consent for transplant-related brain death research.

1.3. Legal basis

The Health Care Act, Statutory Order No. 1286 of 2 November 2018, as amended by Act No. 1732 of 27 December 2018, contains in section 53 rules for consent to transplantation and in section 54a rules for consent to transplant-related brain death research.

Section 53 reads as follows:

“From a person who has died or who has been taken to a hospital or similar institution, tissue and other biological material may be removed for the treatment of a disease or bodily injury in another human being in accordance with the rules laid down in paragraphs 2 to 4.

Paragraph 2. The operation may be performed if the deceased, after reaching the age of 15, has made a written decision to this effect. The same applies if the person has declared orally in favor of such an intervention. Notwithstanding paragraph 4, the relatives of the deceased may not object to the intervention if the deceased has so decided in writing, unless the deceased has stipulated that the decision is subject to the agreement of the relatives.

Paragraph 3. Except in the cases referred to in paragraph 2, the operation may be carried out only if the deceased has expressed no objection to the operation and the next of kin consent to it. If the deceased leaves no next of kin, the operation may not be carried out.

Paragraph. 4. If the deceased is under 18 years of age, the intervention may only be carried out if the holder of parental responsibility has consented to the intervention".

Section 54a. reads as follows:

"Research on a deceased person in connection with the removal of his organ pursuant to Article 53 may be carried out in accordance with the rules in paragraphs 2 to 4 only if the health research project is intended to improve the results of the transplantation.

Paragraph 2. The search may be carried out if the deceased has made written arrangements to this effect after reaching the age of 15. The same applies if the person has declared this orally. Notwithstanding paragraph 4, the relatives of the deceased may not oppose the search on the deceased if the deceased has so decided in writing, unless the deceased has stipulated that the decision is subject to the agreement of the relatives.

Paragraph 3. Outside the cases referred to in paragraph 2, a search may be carried out only if there is no indication from the deceased against the search and if the next of kin of the deceased consent to it. If the deceased leaves no next of kin, no search may be conducted on the deceased.

Paragraph 4. If the deceased is under 18 years of age, the search may only be carried out if the holder of parental responsibility has consented to the search".

2. Responsibility

Responsibility for ensuring that the conditions set out in Articles 53 and 54a of the Health Care Act are met lies with the doctor responsible for carrying out the transplantation procedure, cf. Article 54(1) of the Health Care Act, according to which the procedures set out in Article 53 of the Act may only be carried out by doctors employed by hospitals or similar institutions and authorized for that purpose by the National Council for Patient Safety. The doctor in charge of the transplantation operation and, if applicable, the research operation shall not be the same doctor who treated the donor during his last illness or certified the person's death.

3. Examination of opinions on organ donation before discontinuing treatment

If the treatment is deemed inappropriate, the doctor must, before stopping the treatment, examine the possible indications of the patient and/or relatives regarding organ donation to ensure that organ donation can take place if the necessary conditions for consent are met.

3.1. Position statement on organ donation and transplantation research.

People aged 15 and over can express their opinion on organ donation and transplantation research. There are no immediate formal requirements for the form of expression, but the following three equal ways are the most common:

- registering on the organ donor register, which can be done via www.sundhed.dk;
- by filling in and carrying a donor card,
- expressing their opinion to their closest relatives.

People who have taken a position on organ donation and transplant-related research can always, regardless of the form of expression, change or withdraw their position at a later stage.

The Danish health authority has produced a booklet entitled 'Organdonation - Take a stand' to help people make a choice about organ donation.

The National Health Council has also produced a booklet "For relatives - on brain death and organ donation", which is aimed at relatives of a brain-dead person and explains what brain death and organ donation are.

3.2. Opportunities to express one's views

Regardless of whether the deceased has expressed his or her position on organ donation by joining the Organ Donor Registry, filling out a donor card, expressing it to relatives or in any other way, there are the same opportunities to express the extent of donation and position on transplant-related research in all cases.

A citizen has the following options to indicate the size of his/her donation:

A1. Full authorization. → Permission is granted for the use of all organs for transplantation, as well as for donation-related research aimed at improving transplantation results.

A2. Full permission. → Permission is only granted for the use of all organs for transplantation, but not for research related to donation.

A3. Full authorization (A1 or A2) with agreement of relatives.

B1. Limited authorization. → Authorization is granted for the use of one or more specific organs for transplantation and for transplant-related research aimed at improving transplantation results.

B2. Limited authorization. → Authorization is only granted for the use of one or more specific organs for transplantation, but not for research related to donation.

B3. Limited authorization (B1 or B2) subject to agreement of relatives.

C. No choice. → It is up to the relatives to decide whether the person's organs can be used for transplantation and whether, in this context, research can be carried out in connection with the donation with the aim of improving the results of the transplantation.

D. Prohibition. → Under no circumstances may organs be removed for transplantation.

4. Procedure for obtaining consent

The following describes the procedure to be followed by the physician to check whether there is consent from the patient concerned for organ donation and, in this context, possibly also for transplant-related research. The procedure should be followed when death has been confirmed or is imminent and it has been assessed that organ donation for transplantation may be appropriate.

4.1. Acknowledgement by the deceased

The removal of organs for transplantation and transplant-related research may be carried out if the deceased, after reaching the age of 15, has consented in writing to organ donation alone or simultaneously

to transplant-related research, or has orally expressed his support for such intervention, and the expression of the deceased may not otherwise be regarded as revoked or invalid.

If the deceased's consent is conditional on the relatives' acceptance, it is an additional condition that the relatives' consent to organ donation and, if indicated by the deceased, to donation-related research. However, if the deceased has prohibited transplant-related research in the event of brain death, the relatives cannot reverse this and give their consent. The same applies when the deceased has made a prohibition, see 3.2(D).

For young people who die between the ages of 15 and 18, the holder of parental responsibility must always consent, whether the young person has given consent with the consent of their relatives or not.

4.1.1 Organ donor register

In all cases where transplantation may be considered, the doctor must first check whether an indication has been entered in the organ donor register. This is done by contacting the transplant centers.

4.1.2 Donor card

If there is no declaration registered in the organ donor register, it should be checked whether the deceased has a donor card. In this context, it is sufficient to examine the personal effects of the potential donor.

The donor card is part of the brochure "Organdonation - Take a Stand" and is a small card designed to be carried with you. The donor card is pre-printed with the various options for making a donation, and a tick in one of the options indicates that the donor has made a donation. Two crosses will appear if full or limited consent is required from relatives.

Where several options are ticked, the least intrusive option should be respected.

4.1.3 Other written declaration

If the deceased did not express his or her position on organ donation in connection with transplantation by entering himself or herself in the organ donor register or by filling out a donor card, it must be verified whether the deceased consented to or prohibited organ donation and/or research by other written means after the age of 15.

It is not supposed to be a big investigation, but if the deceased has a mobile phone, there may be an indication of organ donation in the 'emergency information' on the phone, which in some cases can be accessed without a password. The emergency information on the phone can in some cases be found in the "Sundhed" app. The deceased may also have a handwritten statement in his or her wallet, which is why the deceased's person and personal effects should be examined if there is a possibility of organ donation for transplantation and research in connection with donation.

4.1.4 Previous donor cards

Since it cannot be ruled out that some citizens still registered their declaration in the organ donor register before 2001 without renewing it, or that they still carry the old donor cards that did not allow organ donation to be authorised with the consent of his/her relatives, the declarations before 2001 must be interpreted as meaning that the next of kin must have the possibility of opposing the operation. New donor cards have also been issued in connection with the entry into force of the law in July 2019. Therefore, there may also be cases where citizens have not renewed their consent after this change and therefore have not taken a position on consent for transplant-related research. In these cases, consent should be interpreted to mean that only transplantation of donated organs can be carried out, but not transplant-related research on the brain decedent at the same time, unless consent is obtained from the closest relative of the decedent. If

the brain-deceased has expressed his or her opposition to transplant related research orally, in writing or in any other way, valid consent cannot be obtained from the next of kin.

4.1.5 Other declarations by the deceased

If there is no written statement from the deceased, it must be examined whether the deceased expressed his opinion orally on the matter. It will normally be the deceased's next of kin who will provide information on such an expression.

4.1.6 Other declarations

If the deceased has registered his intention to donate and to carry out research in connection with donation in the organ donor register and at the same time carries a completed donor card, and there are divergent intentions between the two, the less intrusive intention should be respected.

If both declarations are clearly dated, the most recent declaration must be respected. This means that if, for example, the entry in the organ donor register is dated 7 January 2019 and the completed donor card is dated 13 April 2019, the declaration of 13 April 2019 must be complied with.

4.2 non-declaration of the deceased

If there is no written or oral indication from the deceased or if there is any doubt about the deceased's wishes, organs can only be removed for transplantation and research in connection with donation if the close relatives of the deceased have given their express consent to the operation. In the case of transplant-related research aimed at improving transplant results, the relatives cannot give their consent if the deceased has prohibited organ donation.

4.2.1 The next of kin

The close relatives of the deceased are mainly the spouse or cohabiting partner of the deceased, direct relatives, including adopted children, and, depending on the circumstances, siblings. Foster children will also normally be included. In some circumstances, particularly where the deceased did not leave a spouse, partner or children, relatives with whom the deceased was closely associated or closely related will be considered to be the deceased's next of kin.

4.2.2 Explicit consent

The consent of the close relatives to organ donation from a deceased person and to transplant related research must be given as an explicit (direct) expression of consent to the procedure. This means that consent to organ donation does not imply consent to transplant-related research. There must be a specific consent for transplant-related research.

Consent for organ donation for transplantation and donation-related research aimed at improving transplantation results is not given if only one of the deceased's close relatives has expressed opposition to the procedure or has withdrawn consent before the procedure is performed. This means that if one of the close relatives opposes the procedure, even if the others consent, it cannot be performed.

4.2.2.1 Informed consent

The consent of the deceased’s close relatives to organ donation must be based on verbal information from a doctor:

(a) death has occurred or is imminent;

(b) the possibility of organ donation and related research aimed at improving transplantation outcomes;

(c) it is possible to give consent only to organ donation and to waive research relating to donation;

(d) tissues and other biological material (organs) to be removed for transplantation;

(e) that the research is intended to improve the results of the transplantation and may consist of studies on the organs to be transplanted and on the donor, and that the research may only be carried out on processes that the donor normally undergoes as part of the transplantation;

(f) the next of kin shall have the opportunity to express their opposition to the operation or their wish not to take a position, with the result that the operation may not be carried out;

(g) in the case of imminent death, the expression of the opinion of the next of kin does not influence the treatment of the patient;

(h) the next of kin may withdraw consent until the organs are removed.

Information should include time and opportunity for dialogue with relatives about the organ donation process. Relatives should have the opportunity to ask questions, for example about the planned operation, the possibility of saying goodbye to the deceased or similar.

4.2.2 Informed consent for transplantation research

With regard to organ donation-related research aimed at improving transplantation outcomes, specific consent is required for the research, which means that consent for organ donation alone is not sufficient. Family members should be informed that the consent is for transplant-related research and not for a specific research project, but that the research project has been approved by the National Scientific Ethics Committee. In this context, they should be informed that transplant-related research aims to improve transplant outcomes and that the research should not expose brain dead people to extensive interventions that would not normally be performed in the context of a transplant situation, including their preparation. This means that only processes that brain dead people would normally undergo in the context of organ donation could be studied. It must also be made clear that the research project should not impede the recipient's ability to make optimal use of the donated organ. Relatives should also be informed that a brain-dead research project will be conducted in the same hospital where the brain-dead person is admitted, whereas organ examination may take place in transplant centers.

Relatives have the opportunity to ask further questions after the research information.

4.3. No indication

In the absence of a declaration by the deceased and if the deceased leaves no next of kin, organ donation and research relating to transplantation operations cannot be carried out.

5. Deceased under 18 years of age

With the change in the 2018 law, people between the ages of 15 and 17 have the option to consent to organ donation and transplant research. However, it is stipulated that regardless of whether the young

person aged between 15 and 17 has given consent to organ donation and transplant research while alive, the holder of parental responsibility must always be consulted and given the opportunity to override the child's decision. This applies irrespective of whether the young person aged between 15 and 17 has given his or her consent, subject to the consent of his or her parents.

In the absence of written consent from a young person aged between 15 and 17, transplantation and transplant-related research can only be carried out with the express consent of the holder of parental responsibility.

6. Record keeping

If consent has been given for organ donation and transplant-related research, the patient's file must indicate whether the consent was given by registration in the organ donor register, by indication on a donor card, or in another form. The name of the doctor who examined the deceased's consent must appear in the patient's file. If the deceased has given consent to organ donation and transplant-related research with the agreement of the next of kin, the name of the next of kin who gave consent and the relationship of the next of kin to the deceased must also appear in the patient's medical record. If there is no written or verbal consent from the deceased, the medical record must indicate what information was given to the next of kin, what consent was given, the name of the next of kin who gave consent, the relationship of the next of kin to the deceased and the name of the doctor who informed and obtained consent from the next of kin.

7. Cancellation

The guidance is effective from 1 January 2020. Guideline no. 101 of 8 December 2006 on consent to transplantation from deceased persons is therefore revoked.