

Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors



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French edition:
*Guide pour la mise en œuvre du principe
d'interdiction du profit relatif au corps
humain et à ses parties provenant
de donneurs vivants ou décédés*

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Foreword

The drafting of this guide was initiated by the Committee on Bioethics (DH-BIO), with a view to clarifying the terms and facilitating the implementation of the principle of prohibition of financial gain laid down in Article 21 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine (ETS No. 164; the Oviedo Convention), as well as in its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (CETS No. 186). According to this principle, “the human body and its parts shall not, as such, give rise to financial gain”.

In February 2016, the DH-BIO set up an ad hoc working group on the prohibition of financial gain as a follow-up to the to the Statement on the prohibition of any form of commercialisation of human organs adopted by the DH-BIO and the European Committee on Organ Transplantation (CD-P-TO) in May 2014, and then taken up in parallel statements by the Parliamentary Assembly of the Council of Europe (PACE) Committee on Social Affairs, Health and Sustainable Development (June 2014) and by the Committee of Ministers (July 2014).

The ad hoc working group was composed of representatives of DH-BIO and experts of other relevant Council of Europe committees, namely the CD-P-TO and the European Committee on Blood Transfusion (CD-P-TS). The World Health Organization (WHO) and the European Commission also participated in the meetings of the ad hoc group. The group was initially chaired by Ms Doris Wolfslehner (Austria), from the DH-BIO Bureau, but following a change in her position at national level and departure from the DH-BIO, Ms Ritva Halila (Finland), also a DH-BIO Bureau member, took over as chair of the ad hoc group.

The preliminary draft of this guide was prepared by the ad hoc group in the course of three meetings held in 2016. The text was then forwarded to the DH-BIO, which conducted an editorial revision on it in 2017, and subsequently adopted it on 4 December 2017. The guide was then sent to the CD-P-TO and the CD-P-TS. The CD-P-TO adopted the guide on 11 January 2018.

Introduction

1. This document gives guidance on how to interpret the principle of the prohibition of financial gain with respect to the human body and its parts from living or deceased donors, as laid down in Article 21 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164; the Oviedo Convention), in order to facilitate its implementation.

2. The principle of the prohibition of financial gain with respect to donation has the purpose of ensuring respect for:

- ▶ the dignity of living donors and recipients and for their human rights;
- ▶ the inalienability of the body of the deceased donor.

It also contributes to:

- ▶ promoting altruistic donation; and
- ▶ the safety and quality of donated human body parts, contributing thereby to maintaining a donation system in which people can trust.

3. Financial gain with respect to the human body and its parts, as such, includes payments or inducements in kind either directly to living donors, to the families of deceased donors or to another third party. It may have the effect of influencing the most vulnerable people in society, and expose them to exploitative actions.

4. The prohibition of financial gain does not prevent:

- ▶ compensation of living donors for loss of earnings and reimbursement of any other justifiable expenses caused by the removal of organs, tissues or cells, or by the related medical examinations;
- ▶ compensation in case of undue damage resulting from the removal of organs, tissues or cells.

The donation should therefore be financially neutral for the donor.

5. Furthermore, the prohibition of financial gain does not hinder payment of a justifiable fee for medical or related technical services rendered in connection with the donation.

6. The principle applies to any donation of the human body or its parts regardless of the purpose of donation.

Legal instruments and professional standards referring to the principle of the prohibition of financial gain

7. The prohibition of financial gain from the human body or its parts, as such, is set out in Article 21 of:

- ▶ the Convention on Human Rights and Biomedicine, which states that, “The human body and its parts shall not, as such, give rise to financial gain”;
- ▶ the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), which states that, “The human body and its parts shall not, as such, give rise to financial gain or comparable advantage”.

8. The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (CETS No. 195) furthermore contains a reference to undue influence, including that of a financial nature, which shall not be exerted on persons to participate in research.

9. The Council of Europe Convention against Trafficking in Human Organs (CETS No. 216) refers to the notion of financial gain or comparable advantage as grounds for qualifying the illicit removal of human organs from living or deceased donors as a criminal offence.

10. The principle of the prohibition of financial gain is intrinsically linked to the prohibition of organ and tissue trafficking, laid down in Article 22 of the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin.

11. The Explanatory Report to the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, with regard to Article 22, gives examples of why trade in organs and tissues, as such, for direct or indirect financial gain must be prohibited, namely the risk of coercion being exercised by traffickers, either in addition to, or as an alternative to, offering inducements. These exploitative practices then lead to the undermining of people’s trust in the donation system.

12. The principle of the prohibition of financial gain has been reiterated by the Committee on Bioethics (DH-BIO) and the European Committee on Organ Transplantation (CD-P-TO) in their joint statement on the prohibition of any form of commercialisation of human organs, which was also adopted by the Committee of Ministers of the Council of Europe. The principle likewise is referred to in Recommendation No. R (95) 14 of the Committee of Ministers to member states on the protection of the health of donors and recipients in the area of blood transfusion, as well as in the CD-P-TO *Guide to the quality and safety of tissues and cells for human application* and the *Guide to the quality and safety of organs for transplantation*.

13. Furthermore, the principle of the prohibition of financial gain is also set out in Article 3(2), sub-paragraph 3, of the Charter of Fundamental Rights of the European Union (EU).

14. In addition, several EU directives refer to the notion of “voluntary unpaid donations”, in particular those concerning human blood and blood components

(Directive 2002/98/EC), human tissues and cells (Directive 2004/23/EC), and human organs intended for transplantation (Directive 2010/53/EU).

15. The prohibition of financial gain is likewise reflected in the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation (Guiding Principle 5).

16. Finally, there are international professional standards which likewise reiterate the principle of the prohibition of financial gain, in particular the Declaration of Istanbul on organ trafficking and transplant tourism.

Reimbursement of justifiable expenses and compensation for loss of earnings for living donors

17. The Convention on Human Rights and Biomedicine states that the reimbursement of expenses incurred and compensation for loss of earnings are acceptable. This is reiterated in the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, which authorises compensation for loss of earnings and reimbursement of justifiable expenses.

18. The WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, endorsed by the 63rd World Health Assembly in May 2010 (Resolution WHA63.22), stipulate that “the prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor”, and thus likewise permit the reimbursement of justifiable expenses.

19. Recommendation No. R (95) 14 of the Committee of Ministers to member states on the protection of the health of donors and recipients in the area of blood transfusion contains the following definition of voluntary non-remunerated donation:

“Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his or her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation”.

20. The above legal instruments therefore call for financial neutrality for the living donor, and thus permit the direct reimbursement and compensation of costs related to a donation. Following the common practice in this field, the term “reimbursement” is used in this guide in relation to expenses (such as travel and other expenses incurred as a result of donation), whereas the term “compensation” is used in relation to the loss of earnings related to the donation.

21. The condition that reimbursement should be justifiable, and therefore acceptable, can easily be met in cases in which only those costs are reimbursed for which the donor can produce receipts, leading to the reimbursement of real costs. This is usually straightforward when reimbursing the cost of travel tickets, or other receipted incidental expenses.

22. Other costs incurred as a result of donation, such as lost earnings, the cost of care for dependents, or the cost of follow-up may be less straightforward to calculate. The overarching principle should be that donors should neither lose nor gain financially as a result of donating. In order to ensure that they are correctly compensated or reimbursed, donors should provide evidence of the losses or expenses actually incurred.

23. Where compensation is provided in the form of a fixed-rate scheme, the conditions of its implementation must be provided for under national law, including the setting of an upper limit for compensation. If the upper limit is not specified by law, it should be established by an independent body set up in accordance with national law.

24. The fixed-rate compensation scheme must be transparent and must not act as an inducement to donate.

25. Measures should be in place to minimise the risk of harm to donors which may result from the donation scheme, such as national registers or traceability systems to limit how frequently a person can donate.

26. Reimbursement and compensation of living donors are directly connected to real expenses incurred and the real loss of earnings to the donor related to the donation procedure, including at the stage of donor screening and follow-up measures, even if the potential donor is not suitable for donation.

27. Reimbursement and compensation must never be connected to the donation as such, as the latter does not have a financial value attributed to it. In practice this means that reimbursement and compensation must not vary according to their final objective, be it for therapeutic or research purposes, nor according to the quality of what has been donated, or the outcome for the recipient.

28. Reimbursement and compensation should not lead to inappropriate competition (e.g. financially-driven competition) between establishments over donor recruitment, in particular in the context of fixed-rate compensation schemes.

Payment for the provision of medical or related technical services

29. The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin explicitly allows for the “payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation”. The explanatory report specifies that this could include “the cost of retrieval, transport, preparation, preservation and storage . . . , which may legitimately give rise to reasonable remuneration”.

30. The explanatory report to the Convention on Human Rights and Biomedicine, with regard to Article 21, also gives examples of technical acts which can legitimately give rise to reasonable remuneration to cover costs, such as the “sampling, testing, pasteurisation, fractionation, purification, storage, culture, transport, etc.” of related items.

31. Article 21 of the Convention on Human Rights and Biomedicine does not prohibit the trade, within the existing legal framework, in medicinal products and medical devices incorporating human tissue which have been subjected to a manufacturing process, as long as the tissue which is used as the starting material is not sold as such.

32. The remuneration and bonus systems within a hospital or donation centre for medical services related to the donation of parts of the human body from living or deceased donors should be comparable to payment for other services provided by the medical team within that hospital or centre or comparable institutions within the member state. Thus, bonus payments linked to obtaining consent or authorisation for donation from the persons concerned are not permissible.

33. The fees related to technical services linked to the donation of the human body and its parts, as such, should not exceed operational costs, and should be comparable to those of similar technical services independent of their legal status within the member state. Fees may include, among other things, the cost of procurement, testing, processing, storage, distribution, personnel and transportation, infrastructure and administration, and the need to invest in state-of-the-art processes and equipment to ensure the long-term sustainability of the services offered.

34. Providers of technical services should be obliged to be transparent in the calculation of their fees for services and in the financial management of their services in order to comply with the prohibition of financial gain, and thus support a donation system which donors and recipients can trust. This obligation of transparency applies also to parts of the human body, as such, used as starting materials for the development and/or preparation of cell-based therapies and medical devices.

Compensation in case of undue damage resulting from the donation

35. The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin allows donors to receive compensation for undue damage resulting from the removal, the occurrence of which is not a normal consequence of the related procedures. The Additional Protocol refers to "fair compensation according to the conditions and procedures prescribed by law".

36. The assessment of undue damage resulting from the donation relies on appropriate clinical follow-up of living donors and the monitoring of adverse reactions. Article 7 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin provides for medical follow-up measures for living donors, and the explanatory report states that "the nature and duration of such follow-up should depend on the nature of the intervention and its potential impact on the individual's health."

37. If the donation requires clinical follow-up measures (for example in case of organ donation or, where allowed, oocyte donation) donors for whom those measures cannot be guaranteed should be excluded from donation.

Acceptable measures for the promotion of donation in the light of the principle of prohibition of financial gain

38. Article 21 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin and Article 21 of the Convention against Trafficking in Human Organs, set out restrictions on promotion activities which make it clear that any attempt to advertise the need for, or availability of, organs or tissues with a view to offering or seeking financial or comparable advantage for any party, is prohibited.

39. However, promotion activities may be acceptable if the measures involved are “altruist-focused” measures, which are compatible with the prohibition of financial gain.

40. Altruist-focused measures include:

- ▶ information about the need for the donation of human body parts for others’ treatment or for medical research, which can include all forms of promotion campaigns, such as the European Day for Organ Donation and Transplantation or the World Blood Donor Day, or information on either governmental websites or websites of donation centres;
- ▶ recognition of, and gratitude for, altruistic donation, through whatever methods are appropriate both for the form of donation and the donor concerned, such as letters of thanks to the donor’s family where permissible and with due regard to privacy, inclusion in public memorials, and certificates for donors;
- ▶ interventions to remove barriers and disincentives to donation experienced by those disposed to donate, such as reimbursement and compensation of real expenses and real loss of income or earnings related to the donation.

41. Non-altruist-focused measures which are not compatible with the prohibition of financial gain include:

- ▶ interventions offering associated benefits in kind to encourage those who would not otherwise have contemplated to consider donating;
- ▶ financial incentives that leave the donor in a better financial position as a result of donating.

Reference texts

Council of Europe

Convention on Human Rights and Biomedicine (CETS No. 164), Article 21
www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164

Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (CETS No. 186), Article 21
www.coe.int/en/web/conventions/full-list/-/conventions/treaty/186

Council of Europe Convention against Trafficking in Human Organs (CETS No. 216)
www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216

Statement on the prohibition of any form of commercialisation of human organs, adopted by the DH-BIO and the CD-P-TO
[www.coe.int/t/dg3/healthbioethic/Activities/05_Organ_transplantation_en/INF\(2014\)10%20e%20declaration.pdf](http://www.coe.int/t/dg3/healthbioethic/Activities/05_Organ_transplantation_en/INF(2014)10%20e%20declaration.pdf)

Statement by the Committee of Ministers on the prohibition of any form of commercialisation of human organs
<https://wcd.coe.int/ViewDoc.jsp?id=2215115&Site=COE&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383>

Recommendation No. R (95) 14 of the Committee of Ministers to member states on the protection of the health of donors and recipients in the area of blood transfusion
<https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016804da051>

Guide of the European Committee on Transplantation of Organs (CD-P-TO) to the quality and safety of tissues and cells for human application
www.edqm.eu/en/publications-transfusion-and-transplantation

Guide to the quality and safety of organs for transplantation, of the European Committee on Transplantation of Organs (CD-P-TO)
www.edqm.eu/en/publications-transfusion-and-transplantation

Guide to the preparation, use and quality assurance of blood components, of the European Committee on Blood Transfusion (CD-P-TS)
www.edqm.eu/en/publications-transfusion-and-transplantation

European Union

Charter of Fundamental Rights, Article 3

www.europarl.europa.eu/charter/pdf/text_en.pdf

Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components

eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0098&from=EN

Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF

Directive 2010/53/UE on standards of quality and safety of human organs intended for transplantation

eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Aasp0008

European Parliament resolution of 19 May 2010 on the Commission Communication: Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between member States

www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0183+0+DOC+XML+V0//EN

World Health Organization

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf

Principles on the donation and management of blood, blood components and other medical products of human origin, Principle 5 (report by the Secretariat presented to the World Health Assembly on 3 April 2017)

http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_19-en.pdf

“Human Organ and Tissue Transplantation”, statement of the 63rd World Health Assembly

http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf

Others

Nuffield Council report on “Human Bodies: Donation for Medicine and Research”

<http://nuffieldbioethics.org/project/donation/>

The Declaration of Istanbul on Organ Trafficking and Transplant Tourism

www.declarationofistanbul.org/about-the-declaration/structure-and-content

The purpose of this guide is to facilitate the implementation of the principle laid down in Article 21 of the Convention on Human Rights and Biomedicine according to which the human body and its parts shall not, as such, give rise to financial gain. It provides clarifications on specific terms relevant to this principle such as compensation and reimbursement. The guide also refers to acceptable measures for the promotion of donation in the light of the principle of prohibition of financial gain.

It is aimed at policy makers, competent authorities, professionals in the health sector as well as donors, recipients, and all those concerned by or involved in the removal and further use of human body materials.

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