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Committee on Bioethics (DH-BIO)

Guide for the implementation of the Principle of Prohibition of Financial Gain with respect to the human body and its parts, as such, from living or deceased donors

As adopted* by the DH-BIO on 4 December 2017 and the by CD-P-TO on 5 January 2018

* The Guide was adopted by written procedure

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 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;

   - respect for the inalienability of the body of the deceased donor.

   It also contributes to:

   - promoting altruistic donation; and

   - the safety and quality of the 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 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 Council of Europe Convention on Human Rights and Biomedicine (CETS No. 164), as well as its Additional Protocol on Transplantation of Organs and Tissues of Human Origin (CETS No. 186), both set out the prohibition of financial gain from the human body or its parts, as such:

    - Article 21 of the Convention on Human Rights and Biomedicine states that, “The human body and its parts shall not, as such, give rise to financial gain”;

    - Article 21 of the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin 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 a basis to establish as a criminal offence the illicit removal of human organs from living or deceased donors.

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 on transplantation of organs and tissues of human origin (CETS No. 186).

11. The Explanatory Report to Article 22 of the Additional Protocol on transplantation of organs and tissues of human origin (CETS No. 186) 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 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 Guides to the Quality and Safety of Tissues and Cells for Human Application, and of Organs for Transplantation.

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

14. In addition several EU directives refer to the notion of “voluntary unpaid donation”. 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 Organisation 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 (CETS No. 164) considers the reimbursement of expenses incurred and compensation for loss of earnings as *acceptable.* This is reiterated in the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (CETS No. 186), 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 sixty-third World Health Assembly in May 2010 (Resolution WHA63.22) stipulate that “the prohibition on sales or purchases 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*, thus *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, 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 the 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, also 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 with the quality of what has been donated, or the outcome for the recipient.

28. The reimbursement and compensation should not lead to inappropriate competition (e.g. financially driven) 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 on transplantation of organs and tissues of human origin (CETS No. 186) 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 "costs of retrieval, transport, preparation, preservation and storage […], which may legitimately give rise to reasonable remuneration".

30. The explanatory report of the Convention on Human Rights and Biomedicine (CETS No. 164) to Article 21 also gives examples of technical acts which can legitimately give rise to reasonable remuneration to cover costs, such as “sampling, testing, pasteurisation, fractionation, purification, storage, culture, and transport of related items”.

31. Article 21 of the Convention on Human Rights and Biomedicine (CETS No. 164), does not prohibit the trade, within the existing legal framework, of 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 with the 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 with the obtaining of consent or authorisation to 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 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, among others.

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 on transplantation of organs and tissues of human origin (CETS No. 186) allows donors to receive compensation for undue damage resulting from the removal, whose occurrence 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 on Transplantation of Organs and Tissues of Human Origin (CETS No. 186) 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. In case the donation requires clinical follow-up measures (e.g. 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 on Transplantation of Organs and Tissues of Human Origin (CETS No. 186) and Article 21 of the Convention against Trafficking in Human Organs (CETS No. 216), 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 taken/involved are "altruistic focused measures", which are compatible with the prohibition of financial gain.

40. Altruistic 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 to 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-altruistic 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

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

- Article 21 of the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (CETS No. 186) http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm

- Council of Europe Convention against Trafficking in Human Organs (CETS No. 216)
https://wcd.coe.int/ViewDoc.jsp?Ref=CM/Del/Dec%282014%291205/10.3&Language=lanEnglish&Ver=app10&Site=COE&BackColorInternet=DBDCF2&BackColorIntranet=FDC864&BackColorLogged=FDC864

- Statement on the prohibition of any form of commercialisation of human organs, adopted by the DH-BIO and the CD-P-TO
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://wcd.coe.int/com.instranet.InstraServlet?Index=no&command=com.instranet.CmdBlobGet&InstranetImage=536836&SecMode=1&DocId=528620&Usage=2

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

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

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

EUROPEAN UNION

- Article 3 of the Charter of Fundamental Rights
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN

- Directive 2002/98/EC on quality and safety for blood and blood components
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2002_98/dir_2002_98_en.pdf

- Directive 2004/23/EC on quality and safety for tissues and cells
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF

- Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation

http://www.hta.gov.uk/_db/_documents/EUODD_Directive_August_2011.pdf

- 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

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

WORLD HEALTH ORGANISATION

- WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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

- Principle 5 of the report by the Secretariat presented to the World Health Assembly in 2017

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

- The Sixty-third World Health Assembly statement on Human Organ and Tissue Transplantation

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

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