

Appendix

Principle 1: Governments are responsible for assuring the ethical and effective procurement, distribution and use of MPHOs. This responsibility includes the obligation to develop and enforce regulations to assure the maximum level of safety, quality and efficacy within and across national borders.

[Resolution WHA28.72 Utilization and supply of human blood and blood products](#)

Urges Member States to “enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products.”

[World Health Assembly. 2005. WHA 58.13 Blood safety: proposal to establish World Blood Donor Day](#)

Urges Member States to “provide adequate financing for high-quality blood donation services” and “to support the full implementation of well-organized, nationally coordinated and sustainable blood programmes with appropriate regulatory systems.”

[Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation \(VNRBD\)](#)

Calls on national health authorities to “incorporate the goal of achieving self-sufficiency in safe blood and blood products based on VNRDB into the national health policy, and strengthen the national blood system accordingly,” and to “introduce legislation with implementation timelines.”

Principle 2: Equity in donation should be promoted by engaging all members of society in efforts to meet needs for MPHOs.

[Declaration of Istanbul on organ trafficking and transplant tourism](#)

“The act of donation should be regarded as heroic and honored as such by representatives of the government and civil society organizations.”

[The Madrid Resolution on Organ Donation and Transplantation](#)

National authorities need to lead normative change, from a perception of organ donation as a matter of the rights of donor and recipient to one of responsibility across all levels of society, through unambiguous legislation, committed support, and ongoing education and public information campaigns. Meeting needs of patients while avoiding the harms of transplant tourism and commercial donation from living persons is an ethical imperative that relies on the assumption of a collective responsibility for donation after death by all citizens and residents, thereby contributing to the common good of transplantation for all.

Principle 3: MPHOs should be used only when of proven efficacy and in the absence of alternative therapies of comparable or superior efficacy.

[World Health Assembly. 2005. WHA 58.13 Blood safety: proposal to establish World Blood Donor Day](#)

Urges Member States “to ensure the proper use of blood transfusion in clinical practice so as to avoid abuse of blood transfusion, which may result in a shortage of blood and hence stimulate the need for paid blood donation.”

[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](#)

Provides that organs or tissues may be removed from a living person for transplantation persons only where “no other alternative therapeutic method of comparable effectiveness” exists.

[Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, adopted by the Council of Europe in 2002](#)

Provides that organs or tissues may be removed from a living person for transplantation persons only where “no other alternative therapeutic method of comparable effectiveness” exists.

[Declaration of Istanbul on organ trafficking and transplant tourism](#)

Calls on national governments to develop and implement “comprehensive programs for the screening, prevention and treatment of organ failure.”

Principle 4: Donation of components of the human body for use in medical products should be conditional upon informed and voluntary decision-making by donors or their relatives.

[WHO Guiding Principles on Human Cell, Tissue and Organ transplantation](#)

Requires informed consent to organ donation from living donors; provides that “any consent required by law” must be obtained prior to the removal of cells, tissues, and organs from the bodies of deceased persons.

[Amsterdam Forum Consensus Statement on the care of the Live Kidney Donor](#)

Sets forth information to be disclosed to potential live kidney donors.

[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](#)

Requires informed consent to living organ donation.

[Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, adopted by the Council of Europe in 2002](#)

Requires informed consent to living organ donation.

[Declaration of Istanbul on organ trafficking and transplant tourism](#)

“Informed consent should be obtained both for donation and for follow-up processes.”

[Code of Ethics for blood donation and transfusion. Amsterdam, International Society of Blood Transfusion, 2006](#)

“The donor should be advised of the risks connected with the procedure.”

Principle 5: Financial neutrality: In order to guard against the exploitation of vulnerable individuals and promote equity in donation, persons who provide their biological materials for use in MPHOs should not benefit or lose financially as a result of the donation.

[Resolution WHA28.72 Utilization and supply of human blood and blood products](#)

Urges Member States to “promote the development of national blood services based on voluntary nonremunerated donation of blood.”

[World Health Assembly. 2005. WHA 58.13 Blood safety: proposal to establish World Blood Donor Day](#)

Recognizes that “voluntary, non-remunerated blood donation is the cornerstone of a safe and adequate national blood supply that meets the transfusion requirements of all patients.”

[WHO Guiding Principles on Human Cell, Tissue and Organ transplantation](#)

“Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value.”

[Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation \(VNRBD\)](#)

Recognizes the goal of national self-sufficiency in safe blood and blood products based on voluntary non-remunerated blood donation.

[The Melbourne Declaration on 100% voluntary non-remunerated donation of blood and blood components](#)

Calls on governments “to achieve 100% voluntary non-remunerated donations by 2020 as the cornerstone of their blood policies.”

[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](#)

“The human body and its parts shall not, as such, give rise to financial gain.”

[Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, adopted by the Council of Europe in 2002](#)

Affirms that “the human body and its parts shall not, as such, give rise to financial gain or comparable advantage,” but emphasizes that “the aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage.”

[Declaration of Istanbul on organ trafficking and transplant tourism](#)

Comprehensive reimbursement of the actual, documented costs of donating an organ does not constitute a payment for an organ, but is rather part of the legitimate costs of treating the recipient.”

[Code of Ethics for blood donation and transfusion. Amsterdam, International Society of Blood Transfusion, 2006](#)

“Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated.”

Principle 6: Prospective and actual donors of human biological materials for use in medical products should be protected against physical and psychosocial risks to the fullest extent possible.

[Amsterdam Forum Consensus Statement on the care of the Live Kidney Donor](#)

Requires a complete medical and psychosocial evaluation of potential live kidney donors.

[Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, adopted by the Council of Europe in 2002](#)

“Before organ or tissue removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor.”

[Code of Ethics for blood donation and transfusion. Amsterdam, International Society of Blood Transfusion, 2006](#)

“The donor’s health and safety must be protected.”

Principle 7: Information about the relevant product, including its human origin, should be routinely provided when offering MPHOs to prospective recipients.

[Council of Europe \(2002\) Additional Protocol to the Convention on human rights and biomedicine, on transplantation of organs and tissues of human origin](#)

“The recipient and, where appropriate, the person or official body providing authorisation for the implantation must be given appropriate information beforehand as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention.”

Principle 8: Equity in access to the benefits of MPHOs should be promoted by sustained efforts to remove barriers to access, and to establish and implement waiting lists and allocation systems for MPHOs that are based on clinical criteria and ethical norms, not considerations of financial or social status.

[World Health Assembly. 2005. WHA 58.13 Blood safety: proposal to establish World Blood Donor Day](#)

Urges Member States to support “equitable access to blood and blood products.”

[WHO Guiding Principles on Human Cell, Tissue and Organ transplantation](#)

“The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations.”

[Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation \(VNRBD\)](#)

“The right to equal opportunity in access to blood and blood products of uniform and high quality based on patients’ needs is rooted in social justice and the social right to health care.”

[Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, adopted by the Council of Europe in 2002](#)

“Parties shall guarantee that a system exists to provide equitable access to transplantation services for all patients.”

[Declaration of Istanbul on organ trafficking and transplant tourism](#)

“Organs for transplantation should be equitably allocated within countries or jurisdictions to suitable recipients without regard to gender, ethnicity, religion, or social or financial status.”

Principle 9: In order to minimize the risk of harm to donors and recipients and to protect the stability and sustainability of MPHOS services, all steps in the development and use of MPHOS should be fully traceable and subject to rigorous quality management systems and vigilance and surveillance programs.

[World Health Assembly. 2005. WHA 58.13 Blood safety: proposal to establish World Blood Donor Day](#)

Urges Member states to provide “government commitment and support for a national blood programme with quality-management systems.”

[WHO Guiding Principles on Human Cell, Tissue and Organ transplantation](#)

Calls for “implementation of quality systems including traceability and vigilance, with adverse events and reactions reported.”

[Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation \(VNRBD\)](#)

Calls on national health authorities to “introduce strategies and measures to establish appropriate quality systems” and to collect and monitor data on blood product safety and supply.

Principle 10: The organization and delivery of MPHOS-related activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

[WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation](#)

“The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.”

[Declaration of Istanbul on organ trafficking and transplant tourism](#)

Calls for the creation of systems and structures to “ensure standardization, transparency and accountability of support for donation.