

The Barcelona Principles: A Global Bioethical Framework

In 2018, the Global Alliance of Eye Bank Associations (GAEBA), of which EBAA is a founding member, introduced a bioethical agreement regarding the appropriate use of altruistically donated ocular tissue and the responsibility to promote sustainable eye banking operations in countries around the world.

Endorsed by the Cornea Society, the International Agency to Prevent Blindness, the International Council of Ophthalmology and other groups, this agreement came to be known as The Barcelona Principles following their endorsement by the World Health Organization during its meeting in Barcelona. During its governance meetings last month, the American Academy of Ophthalmology endorsed The Barcelona Principles, formalizing its support for the ethical stewardship of donated ocular tissue.

In recognition of AAO's ratification, IJEB is happy to publish The Barcelona Principles.



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The Barcelona Principles

An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies®.

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About GAEBA: The Global Alliance of Eye Bank Associations Inc. is an internationally recognised association of eye bank associations. The Global Alliance supports the WHO's Initiative for Medical Products of Human Origin, and the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (WHA63.22).

As a not-for-profit, non-government-organisation, The Global Alliance functions to provide peer and professional support, knowledge exchange, advocacy, vigilance, surveillance, and research and continual education opportunities to its members, in line with local, national, and international recommended Standards of Practice.

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Preamble

The Barcelona Principles: An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies (Agreement) is a global bioethical framework (GBF), developed by the eye bank and ophthalmic communities, to inform on the management of altruistic and voluntary donations; their subsequent utility within ophthalmology and research; their retention as a public resource for the shared benefit of all; and their accessibility by waiting recipients.

The Agreement is the result of global sector engagement over a 12-month period – led by the Global Alliance of Eye Bank Associations. Its aim is to provide leadership, guidance and recommendations that inform and support sound policy, and sector wide strategic planning and implementation at local, national, regional, and international levels.

Inspired by the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, this Agreement affirms the importance of the missions of the United Nations Sustainable Development Goals (Transforming our World: the 2030 Agenda for Sustainable Development); Universal Declaration of Human Rights; World Medical Association’s Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, and their Statement on Organ and Tissue Donation; The Council for International Organizations of Medical Science’s International Ethical Guidelines for Health-related Research Involving Humans 2016; and accords with the World Health Organization’s 2010 Guiding principles on human cell, tissue, and organ transplantation - WHA63.22.

With millions waiting for a corneal transplant at any given moment¹ – and the majority residing in lower resource locations, a significant component of this Agreement promotes equitable allocation systems for waiting recipients, and the development of self-sufficient services. It recognises important instruments, such as the International Council of Ophthalmology 2017 Position Statement: Donation, Processing, Allocation, Advocacy, and Legislation Supporting Human Corneal Tissue for Ocular Transplant; and World Health Organization’s Universal Eye Health - Global Action Plan 2014-2019, and the mission of the International Agency for the Prevention of Blindness.

Future biological innovations/technologies are also addressed within the Agreement, promoting research and development that seek to improve donation utility, reduce burden, and improve therapeutic options for recipients, without ethical compromise.

The Agreement has been developed by the Global Alliance of Eye Bank Associations in conjunction with the International Council of Ophthalmology, International Agency for the Prevention of Blindness, The Cornea Society, Asian Eye Bank Association, European Eye Bank Association, Eye Bank Association of America, Eye Bank Association of Australia and New Zealand, Eye Bank Association of India, the Pan American Association of Eye Banks, and in countries and regions without eye bank organizations, their ophthalmic societies - such as the Ophthalmological Society of the West Indies, and the Pacific Eye Care Society.

Finally, we endorse the current international consensus that prohibits trafficking and transplant tourism.

Key definitions/abbreviations for the purposes of this document:

- Agreement/Global Bioethical Framework (GBF): Refers to this document
- Cells, Tissues and Organs (CTO): Refers to materials of human origin (cornea, sclera, amnion and other) used within research, product development, and the surgical transplant/treatment of ocular related conditions, diseases or injuries
- Commercialisation: Trade in ocular tissue where a fee is charged for the purposes of making a profit, that may be paid to owners or investors²
- Custodian (also termed Stewards): Includes eye banks, eye bankers, eye care professionals e.g. ophthalmologists and transplant service facilities who care for the tissue from donation until transplant

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- Jurisdiction: Encompasses local, regional, national and/or international. This term applies to geographical regions. The term is used to discuss both laws and regulations, and sector operational activities
- Next-of-Kin (NOK): Represents the donor's designated family member or legal guardian
- Not-for-profit (NFP) exchange or trade: Includes payment for transfer or custody or for access to ocular tissue, but no more than for the purposes of cost recovery. This includes cost of, preparation, processing, testing, storage selection, evaluation and distribution².

Note: This Agreement relates to all donation systems including: opt-in, presumed consent (opt-out) or consent with incentive.

Principles and Strategies: Custodians are encouraged to:

PRINCIPLE 1: Respect the autonomy of the donor and their next-of-kin in the consent process.

Strategy:

- I. Implement consent practices that are respectful of the
 - a. human body and its parts, whether separated or not
 - b. rights, values and expectations of donors or NOK
 - c. terms and conditions under which donations are agreed²
- II. Ensure transparent and informed consent processes and procedures are in place regarding potential utility of the donation prior to decision making. For example, outlining that tissue may be involved in: transplantation (as per equitable allocation systems in Principle 4), research, training, product development, exportation, or transfer to a for-profit affiliated entity, third-party or program - inclusive of the intent to sell (on-sale) or commercialise
- III. Partner with/comply with jurisdictional donation agencies/groups to develop and implement respectful consent processes
- IV. Promote population awareness campaigns/programs that inform on donation options outlined within 1/ii (above).

Commentary: This principle seeks to protect prospective donors (relatives/NOK), including vulnerable individuals and groups from exploitation and violation, such as intellectually or physically disabled, illiterate, and impoverished persons, undocumented immigrants, prisoners, displaced persons and political or economic refugees (WHA63.22, 2010) and those incapable of fulfilling the requirements for voluntary and knowledgeable consent. As altruistic and voluntary donations are a public resource - for the shared benefit of the community, this principle simultaneously encourages transparency in public education programs, to ensure respectful, autonomous and informed decision making prior to the point of consent.

PRINCIPLE 2: Protect the integrity of the altruistic and voluntary donation and its utility as a public resource for the shared benefit of all.

Strategy:

- I. Prevent commercialisation during custodianship
- II. Maintain transparency regarding affiliations and potential conflicts of interest

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- III. Ensure there are no promises or offers of gifts to the donor (relative/NOK), recipients, or any private institution, healthcare professional or public office/officials
- IV. Promote recovery that is based on need – to prevent waste.

Commentary: Preventing commercialisation includes: *Respect for the human person* - their privacy, and their communities when using or commercialising human tissue products; *Justice* - having equitable access to high quality health care; and *Beneficence* - ensuring that consideration for others is not eroded (e.g., by on-selling of donated tissues).²

PRINCIPLE 3: Support sight restoration and ocular health for recipients.

Strategy:

- I. Support the strategies of the ophthalmological and blindness prevention sector
- II. Encourage the development and use of new technologies and methods in conjunction/collaboration with the ophthalmic community, that seek to reduce the burden on donor need, and enhance treatment options for recipients.

PRINCIPLE 4: Promote fair, equitable and transparent allocation mechanisms.

Strategy:

- I. Implement systems, criteria and standard operating procedures that are based on recipient outcome need/urgency
 - a. Promote this system to surgeons/transplant facilities
- II. Adhere to jurisdictional laws and regulations
- III. Promote systems that prevent waste of the altruistic and voluntary donation
- IV. Prevent donation and allocation systems that restrict the equitable access to CTO.

Commentary: Ensure criteria are without regard for the recipients' financial, political, and social status, their income, gender, race, ethnicity, religion, migratory status, minority status, disability, social geographic location, public or private health status, and any other characteristics relevant in the jurisdictional context.^{3,4}

PRINCIPLE 5: Uphold the integrity of the custodian's profession in all jurisdictions.

Strategy:

- I. Collaborate with other Custodians – both governmental and non-governmental
- II. Work harmoniously within the sector, promoting ethical partnerships and good practice
- III. Maintain appropriately trained staff through the provision of qualification programs and continual professional development
- IV. Share knowledge, skills, and resources.

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PRINCIPLE 6: Develop high-quality services that promote ethical CTO management, traceability, and utility.

Strategy:

- I. Ensure partnership, policy and business/operational activities align with the WHO guidelines WHA63.22, 2010, recommended sector standards and this Agreement
- II. Implement reporting, tracking and labelling systems to track CTO movement and utility (e.g., graft registries, recall systems) – ensuring they are consistent with internationally agreed nomenclature (e.g., the ISBT128 system)
- III. Provide de-identified donor and recipient transplant data to available recognised jurisdictional data tracking registries (which contribute to a global tracking) inclusive of import/export data
- IV. Comply with all relevant jurisdictional laws and legislations (e.g., trade laws, or data privacy acts)
- V. Prevent trafficking, tampering, forgery, falsification, and counterfeit activities.

PRINCIPLE 7: Develop local/national self-sufficient services.

Strategy:

- I. Develop local and national self-sufficiency and sustainable services
- II. Prioritise domestic need over exportation
- III. Utilise cross-border collaborations/activities while developing own services (Appendix 1) as needed
 - a. Comply with jurisdictional laws regarding allocation of domestic tissue to citizens, residents and/or foreign nationals.

Commentary: Some countries prohibit local CTO to be used on foreign national residents yet allow importation of CTO to service foreign national need. Therefore, ensure transparent systems are in place to simultaneously manage local CTO use for locals, and imported CTO for non-national residents - within permitted laws.

PRINCIPLE 8: Recognise and address the potential ethical, legal and clinical implications of cross-border activities.

Strategy:

- I. Prioritise domestic need over exportation
- II. Ensure rigorous import and export processes are in place to guarantee the ethical, legal and best use of the CTO
- III. Respect local systems when working in a foreign country/jurisdiction
- IV. Importers and exporters should report issues that arise in the context of cross-border activities to local competent authorities or relevant stakeholders.

Commentary: Cross-border Activities refers to activities in which more than one jurisdiction is involved. Please see Appendix 1 for further recommendations on cross-border activities.

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PRINCIPLE 9: Ensure ethical practice and governance of research (non-therapeutic) requiring CTO.

Strategy:

- I. Ensure consent for research as per Principle 1
- II. Provide tissue to research and technical development projects where all parties demonstrate ethically sound practices and processes
- III. Ensure any intended research for which CTO is requested has been designed, and will be conducted, in accordance with jurisdictional law, and regulations that govern the ethical use of human tissue (inclusive of the Declaration of Helsinki/ International Ethical Guidelines for Health-related Research Involving Humans), and:
 - a. obtain approval from a qualified human research ethics committee
 - b. work with scientific journals and peer associations/societies to promulgate scientific standards that honour the ethical consent of CTO for research
- IV. Researchers should verify that the eye bank providing the tissue has appropriate credentials, policies and practices, and is transparent and open to scrutiny (e.g., demonstrating their ethical consent process for obtaining and allocating CTO for research or further attenuation/commercialisation)
- V. Scientific journals should establish a mechanism to confirm research is conducted on ethically obtained CTO.

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Other References/Recommended Documents

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Agreement Development and participants

The concept of the GBF was first discussed with delegates attending the Second World Eye Bank Symposium in San Diego 2015, and subsequently agreed to by the Global Alliance of Eye Bank Associations (GAEBA) Committee in December 2016 at the Asian Corneal Conference in Seoul, South Korea. Development commenced in May 2017, concluding in February 2018.

The process, designed similarly to that utilised by the Declaration of Istanbul Custodian group, invited at least one representative from every country, to participate in the survey (with default to regional representation should a country representative be uncontactable). GAEBA added to that design, sector advisors and additional representatives from larger multi-location eye bank organisations involved in exportation or sector capacity development programs. Participation was voluntary.

Country representatives were selected by the 6 GAEBA partners. Regions without GAEBA representatives were selected with assistance from regional and national ophthalmological and civil societies. Remaining countries were sought through the sector network. Eye bankers, ophthalmologists (corneal, general and clinician scientists), tissue allocators/brokers and eyecare civil society professionals were approached.

De-identified survey responses from voluntary representatives were utilised by the GBF Stakeholder Group (SHG) to develop the draft. The draft was subsequently provided to the survey respondents for their editorial comment prior to document finalisation by the SHG in January 2018, and ratification by GAEBA in February 2018.

This process involved global and regional stakeholder representation and voluntary participation from 83 countries via 102 sector professionals, across all global regions – many whom are listed in this document.

The Agreement Partners: Global Alliance of Eye Bank Associations (Lead), International Council of Ophthalmology, International Agency for the Prevention of Blindness, The Cornea Society, Asian Eye Bank Association, European Eye Bank Association, Eye Bank Association of America, Eye Bank Association of Australia and New Zealand, Eye Bank Association of India, the Pan American Association of Eye Banks, and in regions without eye bank representation, ophthalmic societies such as the Ophthalmological Society of the West Indies, and the Pacific Eye Care Society.

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Appendix 1: *Cross-border and development activities*

Custodians working in another country/jurisdiction, or with peer Associations (inclusive of humanitarian capacity development projects), are advised to:

- a) Support and respect local/national standards, policies, services, customs and peers - without circumnavigation of existing systems, protocols, or professional bodies
- b) Structure relationships to empower local system ownership and autonomy
- c) Adhere to applicable legal frameworks (e.g., Tissue Act)
- d) Obtain permission/consent from the ministry of health or competent authority
- e) Engage the ophthalmological and eye bank community prior to commencement of activities
- f) Respect and support local self-sufficiency strategies over own agenda/targets
 - i. refer to national or regional eye health plans or organ and tissue plans as available
- g) Confirm partnership goals, timelines and exit strategies, prior to commencement
- h) Ensure funds and services are reinvested in the country/jurisdiction and contribute to self-sufficiency/local capacity development
- i) Collaborate with a wide range of custodians to develop robust capacity and development programs that can be interchanged between custodian groups and service providers
- j) Ensure transparency with agenda, experience/expertise and expectations of the country/jurisdiction
- k) Disclose to each other, all pertinent business/operational and professional affiliations, organisational structures, partnerships, collaborations, and potential conflicts of interest – inclusive of for-profit status – third party or parent company
- l) Ensure expatriate clinicians are licenced and accredited within the country jurisdiction – working within their scope of practice and expertise
- m) Ensure training programs are consistent with jurisdictional training standards and competency frameworks – rather than own internal determinants.

Exportation and Importation:

Both exporter and importer:

- a) Adhere to export nation and import nation applicable legal frameworks (e.g., Tissue Act)
- b) Work nationally (where possible) to manage export and/or import activities
- c) Provide export and import data to relevant competent data collection bodies
- d) Distribute efficiently and without waste (e.g. store and transport appropriately)
- e) Ensure cost recovery systems are fair:
 - i. provide CTO at no-cost (humanitarian aid), or only at levels of cost recovery
 - ii. If price scales are required, do so based on economic national status rather than the grade or expiration of the tissue (examples: Human Development Index <http://hdr.undp.org/en/content/human-development-index-hdi> / Hinari Higher Research Eligibility per Countries <http://www.who.int/hinari/eligibility/en/>)
 - iii. Consider cost (acceptable cost-recovery) to export population and import population (affordability) in determining fair price.

Exporter:

- a) Prioritise local and national need prior to participating in export activities
- b) Provide CTO to entities that put tissue to good use and can provide appropriate post-operative clinical management and reporting
- c) Supply where there are trained ophthalmologists capable of providing long term post-operative management
- d) Supply to locations/nations/partners that uphold the bioethical principles of this Agreement
- e) Utilise appropriate labelling, and provide all requisite support documents for transfer

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- f) Identify recipients (where possible) prior to export or provide details after transplantation to ensure traceability
- g) Allocate based on an equitable and fair distribution
 - i. Use medical standards and organisational processes to prevent the retention of good quality, and the exportation of poor quality CTO
- h) Ensure exports (both humanitarian or at cost) do not undermine the import locations own eye bank service development.

Importing:

- f) Confirm that the exporter/partner upholds the bioethical principals of this Agreement
- g) Import tissues/cells - that meet or exceed local medical standards for safety, quality, and biological risk prevention
- h) Permit importation while local supply does not meet demand
- i) Cease/reduce importation when the local system can provide safe and quality driven self-sufficient service.

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