

Domain Summary

# BASELINE ETHICAL PRINCIPLES

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PREPARED BY



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**TRANSPLANT  
QUÉBEC**

*Organ donation,  
together for life  
for **50 years***

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# INTRODUCTION

Transplant Québec and the Canadian Donation and Transplantation Research Program (CDTRP) collaborated to co-host The International Donation and Transplantation Legislative and Policy Forum (the Forum). The Forum assembled 61 national and international experts in donation and transplantation, including patient, family, and donor partners, to provide consensus guidelines on the structure of an ideal organ and tissue donation and transplantation (OTDT) system.

**Baseline Ethical Principles**, one of seven domains developed through the International Donation and Transplantation Legislative and Policy Forum, proposes an ethical framework to assist stakeholders and decision-makers in incorporating ethical principles into OTDT practice and policy to maintain public trust and integrity.

The ethical principles working group acknowledged the importance of international standards of baseline ethical principles within OTDT regulations, policies, and legislation, as outlined in the World Health Organization (WHO) Guiding Principles, the Declaration of Istanbul, and the Barcelona Principles. What is less well established is how to evaluate newly proposed practices or programs according to these principles.

The proposed framework represents a practical tool to assist those responsible for making and approving ethical policy decisions consistent with the established international agreements, declarations, and resolutions on the ethical underpinnings of an OTDT system. The publication can be [accessed here](#).

# THE BUILDING BLOCKS OF ETHICAL POLICY & PRACTICE IN OTDT SYSTEMS

We recognize that policy approval processes differ across jurisdictions and are subject to local factors, including, but not limited to, the structure of the overall health care system, legal frameworks, cultural influences, power differentials, and conflicts of interest. Yet, the merit of the proposed framework is its applicability to diverse jurisdictions, including those building or reforming their OTDT system.

There is an associated and explicit ethical requirement for decision-makers to involve those affected by any policy decision. This should include respect for cultural sensitivity, diversity, and harder-to-engage population groups. This report suggests the following principles when considering a new question:

- There is a duty to consult;
- Stakeholders are encouraged to include lay and patient representation in decision-making bodies;
- The more granular the decision, the higher the need for specific lay and patient representation and involvement;
- Decision-makers should act transparently and be able to mitigate against any perceived or actual conflict of interest.



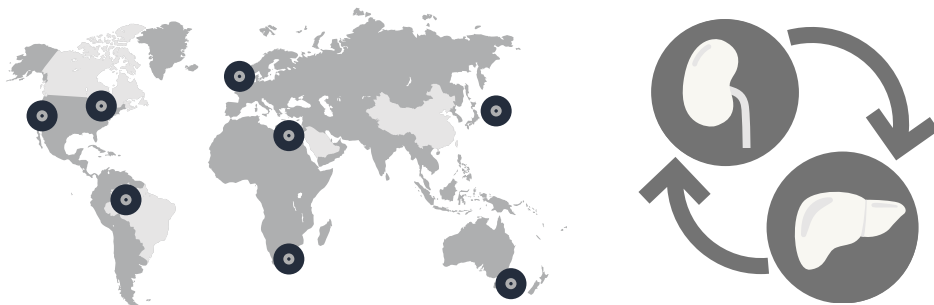
# UNDERSTANDING ETHICAL CHALLENGES IN OTDT SYSTEMS

The willingness of donors and recipients to give and receive organs relies upon widespread public trust in the OTDT system. This can only occur if the system is considered safe. Safety can be on a technical level (i.e., the science of transplantation), but safety is also strongly dependent on the ethical robustness of the system. Without a robust ethical foundation, there is a possibility of abuse, discrimination, and loss of public trust.

Challenges in global OTDT systems include the commercialization of transplantation, [1,2] exploitation and coercion of donors, [3] lack of consent, [4] allocation scandals [5] and the execution of prisoners for donation. [6,7] The global shortage of transplantable organs has led to a globalized exchange of both legitimately and illegitimately sourced organs. This includes travel across national boundaries, so there is an urgent need for a shared global understanding of ethical values.

## INTERNATIONAL RESPONSES TO THE UNETHICAL EXCHANGES OF ORGANS

The globalized nature of donation and transplantation has resulted in international cooperation and widely recognized guiding principles. These principles help maintain and build public trust and confidence when incorporated into law, regulation, and practice.



The World Health Organization (WHO) first endorsed its Guiding Principles on Human Organ Transplantation in 1991, [8] most recently revised it in 2010. [9] The WHO justifies the Guiding Principles as a way of committing member states to the following:

- Principles of human dignity and solidarity which condemn the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations, and the human trafficking that results from such practices;
- Prevention of harm caused by the seeking of financial gain or comparable advantage in transactions involving human body parts, including organ trafficking and transplant tourism;
- Voluntary, non-remunerated donation of organs, cells, and tissues from deceased and living donors to ensure a vital community resource;
- International exchange of data to optimize the safety and efficacy of transplantation.

In 2007 it was estimated that up to 10% of transplants worldwide involved organ trafficking, trafficking in persons for organ removal, or recipients who travelled abroad to purchase organs from poor and vulnerable people. [10] To address the urgent and growing problems posed by these activities, the Declaration of Istanbul was produced by leaders in donation and transplantation.

As a way of aligning the WHO Guiding Principles with the Declaration of Istanbul, the Third Global Consultation on Organ Donation and Transplantation resulted in the Madrid resolution in 2011. [11] This Resolution called for a paradigm shift toward self-sufficiency, where “every country, in light of its own level of economic and health system development, should progress toward the global goal of meeting patients’ needs based on the resources obtained within the country, for that country’s population, and through regulated and ethical regional or international cooperation when needed.”

Inspired by the Declaration of Istanbul and in accordance with the WHO Guiding Principles, the Global Alliance of Eye Bank Associations published The Barcelona Principles: An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies in 2018. [12] Like the Madrid resolution, it called for the development of self-sufficient services in corneal transplantation and provided a global bioethical framework for the eye bank and ophthalmic communities.

The resulting 30 statements from these documents have been supported by work and similar statements from the World Medical Association. [13,14] The International Donation and Transplantation Legislative and Policy Forum recommends that these ethical principles should govern any country or jurisdiction’s OTDT system.

# A FRAMEWORK FOR ETHICAL POLICY DECISION-MAKING

We categorized the 30 baseline ethical principles identified in the above documents into four themes and incorporated them into a spiral model. This model helps assess and make ethical policy decisions in OTDT systems.

As discussed in detail below, the four underlying themes in developing the ethical policy framework were:

- **Self-sufficiency** – does the policy promote self-sufficiency?
- **Margin of Appreciation** – does the policy fall within an acceptable margin of appreciation?
- **Efficacy** – will the policy be effective?
- **Protection** – what protections are required?



From a policy and decision-making perspective, the model starts by asking overarching questions. As decision-makers move toward policy approval, there is a requirement for greater granularity and detail.

By encouraging these types of reflections and considerations in developing OTDT policies, the framework can help decision-makers implement policies that promote self-sufficiency and efficacy, protect autonomy and the vulnerable, and accommodate reasonable disagreement.

At a national level, it is critical that legislation, regulation, and policy decisions be open to public consultation, that there be efforts to reach harder to engage populations or those most affected by or culturally sensitive to any proposal, and that lay and patient representation be included within decision-making bodies.

# SELF-SUFFICIENCY



Does the policy promote self-sufficiency? The goal of self-sufficiency in transplantation is based on a societal responsibility to prevent and, where necessary, provide and find treatments for organ failure. Decision-makers should ask if the policy is intended to:

- 1.Reduce organ failure and the need for transplantation and/or
- 2.Increase the number and quality of organs that are transplanted?

Any system that relies on importing organs or tissues for transplant (or a nation's residents going elsewhere for transplantation) risks worsening health inequities and exploitation of residents from resource poor areas by those with more resources. Until jurisdictions with OTDT systems are self-sufficient, trafficking in human organs and trafficking in persons for organ removal will continue. Carefully constructed ethical systems for regional cooperation, however, can support and improve self-sufficiency and should be explored wherever possible.

Other benefits of self-sufficient systems include more accurately monitoring the health and safety of both donors and recipients, emphasizing that it is not just the quantity of organs but also the quality of organs that must be improved (this is discussed further as part of the efficacy section). Finally, from Spain, there is some evidence that making self-sufficiency an explicit goal can promote a culture of donation that will not only increase rates of transplantation but become a part of the national identity. [15]

# MARGIN OF APPRECIATION



Even within the 30 baseline ethical principles, OTDT stakeholders differ in opinion of how to interpret and implement them. These differences lead to different policy decisions between jurisdictions. Regardless, individual jurisdictions need to be respectful of policies that are different but acceptable in another context while simultaneously being able to judge what policies and practices are universally unacceptable. In utilizing this framework, it is usually evident when policies are universally acceptable (i.e., transplant surgeons should be competent to perform the surgery) or unacceptable (i.e., taking organs against the donor's wishes). However, margin of appreciation can be applied to the ethically controversial questions arising out of the development and implementation of OTDT policy in different jurisdictions, but where reasonable debate is needed (i.e., opt-out consent model).



Therefore, the term 'margin of appreciation' is intended to reflect the reality of reasonable disagreement about policies and practices. Decision-makers should decide if a policy is acceptable within a margin of appreciation. To accomplish this, we suggest asking two questions:

1. Would this policy be accepted by all reasonable decision-makers with the appropriate expertise and background knowledge to decide if the policy should be accepted or refused? If so, the policy is non-controversial and should be accepted or refused;
2. If the answer to the first question is No, we then ask: Is this a policy reasonable decision-makers can reasonably disagree with?

The central function of the margin of appreciation in this framework is to provide a way to acknowledge that reasonable decision-makers may allocate different weights to conflicting principles. It also recognizes that the balance between conflicting principles may reasonably differ across or within various jurisdictions.

## EFFICACY



A high-functioning OTDT system requires implementing and supporting effective donation and transplantation practices and policies. Determining if a policy will be effective requires examining its proposal and deciding if it warrants further exploration, including analyzing options that may work best within its jurisdiction.

In discussing efficacy, our framework encourages decision-makers to consider the benefits and burdens of any given policy proposal, allowing competing proposals or differing formulations to be compared and prioritized.

When assessing efficacy, decision-makers should ask:

1. What is the evidence base for the benefit(s) of the policy?
2. What burdens or safety concerns does the policy have, and to whom?
3. How does this policy proposal compare?
4. What further areas of research and evaluation are required?

The WHO Guiding Principle 10 calls for "high-quality, safe, and efficacious procedures... for donors and recipients alike." Efficacious refers to the likelihood of achieving the desired result. Although a policy intends to promote self-sufficiency and fall within the acceptable margin of appreciation, it may not be a feasible policy option. For example, there may be insufficient evidence of benefit (scientific evidence), burdens and safety concerns (risks too high), or, compared to other policy proposals, may be of lower priority.

# PROTECTION



Given that OTDT systems rely upon the willingness of donors and recipients to give and receive organs, protection is the final step in the framework. Any ethical donation and transplantation policy must ensure that relevant protections have been identified and implemented. This is important for demonstrating and establishing the baseline ethical principles, which help to foster and maintain public trust.

Decision-makers must address what protections are required to ensure:

1. Respect for people? (i.e., the patient is the first concern, vulnerable populations)
2. Respect for autonomy? (i.e., donor and recipient choice)
3. Fairness, equity, and justice? (i.e., allocation, prioritization)
4. Privacy and transparency? (i.e., confidentiality, data, policies)
5. Professional probity? (i.e., behaviour, institutional trustworthiness)

Decision-makers' role is to identify, communicate, and implement the necessary protections before approving any policy or practice. Other focuses include: Who needs to be protected? This can consist of donors, donor families, recipients, clinicians and health care teams, the overall donation and transplantation system itself and, where relevant, communities and groups within society. Who are the individuals most involved with and affected by organ and tissue donation and transplantation?

## CONCLUSION

The proposed ethical policy framework is intended to guide policymakers, government, clinical leaders, decision-makers, and other stakeholders make ethical policy decisions. It is guided by internationally accepted ethical principles incorporated into a model that prioritizes care for patients, families, and donors and maintains trust in their OTDT system.

If a proposed policy were to be favorably evaluated along all the steps of the proposed spiral, we suggest that it likely would be acceptable for implementation from an ethical standpoint. Of course, multiple other factors – legal, financial, political – might prevent such a policy from being realized. Still, decision-makers could likely be confident that it would be ethically acceptable in the international OTDT community, and the people would be most impacted.

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