

TERMS OF REFERENCE
Preparing a proposal of an Organ Transplantation Bill and Regulations for Guyana
XX March – XX May 2021

1. BACKGROUND

The regulatory framework governing organ transplantation in Guyana is currently absent even though there is an increasing number of people that require transplantation. There is a need to provide a comprehensive solution for two crucial tasks to address the needs of the population that may require organ transplantation, namely: matching available organs to an increasing list of potential recipients, while ensuring key principles are respected and implemented.

During the 57th Directing Council of the Pan American Health Organization (PAHO), held from September 30 to October 4, 2019, PAHO Member States approved the document “Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue and Cell Transplantation 2019-2030” through resolution CD 57/11. The objective is to promote equitable access to transplantation of organ, tissues, and cells, based on voluntary donation. Observing guiding principles on transplantation to help meeting the growing demand for these treatments, save lives and to improve the health conditions of individuals and communities are central in the strategy and action plan.

The Action Plan has 4 strategic lines of action:

1. Strengthen the governance and stewardship of the health authorities for the donation and transplantation of cells, tissues, and organs, in particular their control capacity.
2. Increase the availability of organs, tissues and cells based on voluntary unpaid donation.
3. Improve equitable access to organ, tissue, and cell transplants in health systems.
4. Improve information management and activities for monitoring, surveillance, evaluation and risk management of organ, tissue and cell donation and transplantation.

One of the objectives of the first strategic line is for countries to “Develop, implement, and oversee compliance with legal frameworks and strategies for the organization of donation and transplant services consistent with the Guiding Principles of WHO”. The lack or inappropriate regulation can affect donation and transplantation negatively and therefore people’s access to universal health. In this regard, countries should have legal frameworks in place for all aspects of donation, transplantation, and the fight against transplant trafficking. It is also very important that legislative and regulatory frameworks concede clear rights and legal support to patients requiring transplantation of organs and tissues, during the process of receiving them, and after surgery procedures in a comprehensive environment of a rights-based approach.

In this regard, the Government of Guyana has requested support of PAHO/WHO in the creation of a legal/regulatory framework to define the principles of organ transplantation, the way ethical rules should govern its process, as well as the rights, roles, responsibilities, and limitations of the different actors involved in organ transplantation. It is also needed to define the institutional framework, in special the power and legal capacity of authorities that should be involved in donation, harvesting, preparation and delivery of organs and tissues, including financing rules, the legal framework of hospitals and health facilities catering organ and tissue services including

donation, collection and transplantation. A link to the national health insurance schemes must be also considered in the legislation related to organ and tissue transplantation.

The legal framework should support an efficient and equitable organ transplantation system, defining the governance of the system, stewardship and policy roles, and mechanisms of interaction of the actors involved. Additionally, legal regulations on the gathering, storing and the processing information from potential recipients and donors are also required, as well as a legal framework to a transparent, accountable, and ethical selection of recipients (e.g. waiting lists).

The absence of a regulatory framework makes difficult to address the health needs of the population that are potentially eligible for transplantation in Guyana. The aim of this consultancy is to contribute to the adoption of a legal regulatory framework of an equitable organ transplantation system that is committed to the performance of safe, quality, and efficacious donation and transplantation of human organs for therapeutic purposes.

2. OBJECTIVE

The objective of this assignment is to hire a temporary national consultant. The national consultant will provide the services mentioned below to prepare, using a participatory stakeholder inclusive approach, a proposal of an Organ Transplantation Bill, its accompanying Regulations and support in the development of the draft policy to support the draft.

3. SCOPE OF SERVICES

The main activities are described below:

- a. Inception meeting with stakeholders, including but not limited to the Ministry of Health designated authorities, other local related entities and PAHO/WHO local office, and technical and legal teams from HQ, and the preparation of a work plan.
- b. Implement a collection, review and analysis of Existing Legal and Policy Documents, in special common law and statute legal framework Acts and Regulations that may relate in any form to organ transplantation in Guyana, including the health system legal framework.
- c. Develop a collection, review, and analysis from legal and regulatory frameworks from other two Caribbean Countries and at least one other Latin American country, including the realization of a legal comparative analysis that can show the best practices to follow.
- d. Propose a list of areas of legal regulation and an initial outline of the bill and the correspondent regulations.
- e. Prepare a first draft of the proposed Bill and its regulations for review of the stakeholders.
- f. Organize a stakeholder consultation to discuss the first draft of the proposed Bill and regulations.
- g. Systematize and prepare a report of the contributions gathered throughout the consultation, considering a legal point of view of pertinence according to the draft.
- h. Prepare a final draft of the Bill and Regulations incorporating contributions provided in the stakeholder consultation.
- i. Present the final draft for a second stakeholder consultation, recover, and analyze the second round of contributions with legal opinion to prepare the final draft of Bill.

- j. Deliver the final report including the final draft of the proposed Act and Regulations and present it to the Ministry of Health and other authorities.
- k. All these activities should be developed with close communication with PAHO (GUY and HQ) and with the designated representative of the Ministry of Health for the follow up.

4. TOPICS AND AREAS FOR REGULATION TO CONSIDER

The proposal must address or consider the development of at least the following topics:

- a. Guarantees for human dignity of donors and recipients regulating the fundamental rights and ethical principles including among other pertinent (voluntariness, altruism, confidentiality, absence of profit, gratuity, equity) and rights (life, health protection, confidentiality, protection of personal data).
- b. Legal and ethical aspects to take care in relation with the respect for the life and well-being of donors and recipients, protection of recipients' personal identity, informed consent, and respect for the deceased person, gratuity, non-commercialization, rules for transparent and fair allocation of organs, tissues, and cells.
- c. Consider World Health Organization recommended principles for donor and recipient aspects.
- d. Mechanisms for equitable access to transplants and its inclusion in health interventions.
- e. The guarantee of ethical principles for the use of organs, tissues, and cells of death people, considering legal rules for consideration of death for collection.
- f. Coordination mechanism and regulatory bodies and how and who will define them, with clear and explicit considerations in the legislative ruling.
- g. Mechanisms for development and update of technical aspects of donation and transplantation, with indications on who and how health protocols are adopted and approved.
- h. Mechanisms to prevent organ trade and the regulation of medical tourism and applicable penalties, when needed.
- i. Requirements to authorize organ donation and transplantation centers or how and who will define them.
- j. Cell and tissue legal regulation for use on transplantations, when applicable.
- k. Financing mechanisms for donation and transplantation, including rules for financing (health insurance matters) of interventions and treatments (including long term medications) for both donor and recipient of organs, tissues, and cells.
- l. Creation and ruling for National Registries for donation and transplantation and processes for ethical transparent selection.
- m. Additional legislation that could be needed to develop or review to support donation and transplantation of organs, tissues, and cells.
- n. Every other consideration that comes from the analyses performed by the consultant or suggested by the MoH and PAHO (GUY and HQ).

5. DELIVERABLES

- a. Inception Report inclusive of a work plan.
- b. Draft Final report comprising:
 - (i) Draft copy of the proposed Organ Transplantation Bill.
 - (ii) Draft copy of the proposed Organ Transplantation Regulations.

- c. Final Report comprising:
- (i) Final draft Organ Transplantation Bill.
 - (ii) Final draft Organ Transplantation Regulations.
 - (iii) Report on Activities of consultancy.

6. DURATION

This consultancy is for two (2) months during the period TDB.

7. TOTAL PAYMENT INCLUSIVE OF ALL CONCEPTS

The consultant payment will be within the Band C range, the sum of One million forty-one thousand Guyana dollars (GY\$1,041,000.00) payable in three installments stipulated below.

8. DELIVERABLES & PAYMENT SCHEDULE

Payments will be released based on the recommendation of the Project Manager and approval of the PAHO/WHO Representative Guyana, in accordance with the satisfactory completion of specific deliverables and in tandem with the stages of implementation outlined in these terms of reference.

- 25% on approval of Inception Report;
- 45% on approval of Draft Final Report;
- 30 % on approval of Final Report.

Details as follows:

Payments	Dates	Amount GY\$	Products
1.	TDB	260,250.00	Submission of an Inception Report inclusive of a work plan for review and approval by the Project Manager.
2.	TDB	468,450.00	Submission of Draft Final Report comprising of a: (i) draft copy of the proposed Organ Transplantation Bill and, (ii) draft copy of the proposed Organ Transplantation Regulations for review and approval by the Project Manager.
3.	TDB	312,300.00	Submission of Final Report comprising of a: (i) Final draft Organ Transplantation Bill, (ii) Final draft Organ Transplantation Regulations and, (iii) Report on Activities of consultancy, for review and approval by the Project Manager.
Total GYD		1,041,000.00	

9. ADDITIONAL PROFESSIONALS OR EXPERTS

In the implementation of the assignment the consultant may require additional temporary support from other professionals or experts including regulatory and legal experts. The need to engage additional support from other professionals or experts will be determined in the negotiation of the contract with the national consultant before the beginning of the consultancy, and will be assumed directly from the terms and payments established for the consultancy.

PAHO/WHO Guyana will not have any relationship with additional professionals or experts convened by the national consultant under these TORs. PAHO/WHO Guyana will not be responsible for any payment to the additional temporary support from other professionals or experts convened by the consultant selected under these TORs. Any payment for additional professional or experts will be assumed and done by the national consultant selected under these TORs.

10. CHARACTERISTICS OF THE CONSULTANCY

- Type of consultancy: Individual Consultant.
- Place of work: Individual's choice in Guyana.

11. QUALIFICATIONS AND EXPERIENCE OF SELECTED CANDIDATE

- Law degree with at least 10 years of professional experience.
- At least 10 years' experience working in areas related with legislation for health systems, health services and legal regulation of health affairs in Guyana.
- Excellent written and oral presentation skills and proficient in English Language.

12. PROJECT MANAGER

Mr. Daniel Albrecht, Advisor, Health Systems and Services, PAHO/WHO, Guyana Country Office.

Mr. Ignacio Ibarra, Regional Legal Advisor for Health-Related Law and Mr. Mauricio Beltran, Regional Advisor for Blood and Transplantation Services, both from PAHO/WHO HQ, will also be considered report officials on the duties assigned to the consultant.