



## **International Pediatric Transplant Association Outreach Program Guidelines**

**Mission:** To facilitate access for children with end-stage organ failure to safe, ethical, and high quality solid organ transplantation worldwide.

**Summary:** As an association aiming to promote pediatric organ transplantation, IPTA has a responsibility to help establish and support transplant programs worldwide.

The Outreach Program is an official program of IPTA aimed at:

- Engaging with centers wanting to develop new solid organ (kidney, liver, heart) transplant programs.
- Supporting existing programs seeking to expand the scope, or improve the quality of transplant services.

The Outreach Program will address these aims by:

- Assessing applications for programs wishing to develop, expand or improve transplant services to underserved pediatric populations.
- Identifying a transplant program/ institution to partner with the applicant program, called the “sponsoring program”
- Engaging with the center to identify their needs and evaluate their potential, in collaboration with the sponsoring program.
- Based on the specific program needs:
  - Providing training of medical, nursing and allied personnel in collaboration with the sponsoring program.
  - Supporting development of clinical programs, standards, and resources, with the support of the sponsoring program.
  - Advocating for the specific regional needs of children for transplantation and access
- Reviewing the outcome of new/expanded programs and participating in quality improvement, with the support of the sponsoring program.

***The Outreach Program will take place in three phases which are outlined as follows:***

***Phase 1: Identification of Center and Sponsoring program***

***Phase 2: Needs and potential assessment (onsite or virtual)***

***Phase 3: Follow up period / Post-assessment***

### **Phase 1a: Identification of centers**

Centers applying for the program must have at least one active clinician who is an IPTA member in good standing, who will be the primary applicant responsible for the application process and local program development. The applicant will be the applicant program liaison with IPTA and the sponsoring program. If the applicant program does not have an IPTA member in good standing, the applicant must join IPTA for a minimum of two years in order to be considered.

Centers may write to request assistance in establishing a new transplant program or assist with an existing program. Centers interested in applying for participation in the outreach program must provide the following information to IPTA:

- 1) Primary applicant, who is an IPTA member
- 2) Outreach application including the type of help needed (new program, expanding scope, enhanced practice, etc.)
- 3) Letter of support from administrative leadership in institution
- 4) Local government letter of support (where applicable)
- 5) Nomination letter from a potential sponsoring program (if a prior relationship has been established); this does not guarantee approval of that specific program but established relationships will be taken into consideration

**Phase 1b: Identification of sponsor program:**

Although it is anticipated that sponsor and applicant programs may have had a previous relationship (e.g. through fellow training) this is not a requirement. Centers willing to be sponsors may register their interest with the Outreach Committee, and should detail their expertise to be connected to applicant programs. If requested, IPTA may assist in matching a sponsor to an applicant program. A primary sponsoring clinician will be identified, who must be an IPTA member in good standing, and will act as the liaison with IPTA and the applicant program.

Upon receipt of the initial application and confirmation of the sponsoring program by IPTA, a more detailed application proposal will be requested. This will be co-submitted by the sponsor and applicant and should detail the specific needs and supports requested by the applicant program, as well as existing resources that are already in place to support the applicant program. There should be a clear set of objectives to be met by the program, against which success may be measured upon completion. It may include, but should not be limited to discussion about program infrastructure, existing adult transplant program relationships, surgical resources, access to donors, patient recruitment, clinical program resources/protocols, patient survival, training, and funding sources. The proposal should include milestones in the program development and anticipated time frame appropriate to achieve results.

The application proposal should also delineate what supports are available by the sponsoring program to address those needs. This proposal is expected to be 3-4 pages long, in sufficient detail for IPTA to make a preliminary assessment of needs. It may be further revised in collaboration with the IPTA Outreach Committee, if additional information or clarification is requested in order to fully consider the application proposal.

In addition to the program proposal, the sponsor program is expected to provide:

- 1) Written agreement detailing commitment to the applicant program detailing resources (e.g. protocols, training), personnel (e.g. medical/surgical, nursing, allied) and financial support (e.g. travel of personnel) available for the endeavor.
- 2) Information about any previous experience in developing a partner program

The IPTA office will forward all applications to the Outreach Program Committee who will evaluate the application before referring to the IPTA Council for a final decision. Applications may be submitted at any time and will be reviewed on a quarterly basis.

Funding: Allocation and approval of the amount of Outreach program funding based on the information provided in the application will happen at the time of consideration of the proposal by Council.

**Phase 2: Needs and Potential Assessment**

IPTA representatives may visit the proposed site(s) to determine the suitability of the applicant program for the Outreach Program. Not every proposed partnership will need an onsite visit. This will be based upon the information provided in Phase 1, and may include assessment of access to essential infrastructure, resources and clinical services to provide safe transplantation. The composition of the on-site visiting delegation will

be determined on a case by case basis, and may include the Chair of the IPTA Outreach Committee, another member of the Outreach Committee (depending upon the area), one or more representatives from the sponsor program, or a delegate of the IPTA Council. IPTA may bear travel costs of up to two IPTA representatives within the allocated budget from the IPTA Outreach program. Funding for any other IPTA representatives proposed to participate in the onsite needs assessment must be secured from other sources (e.g. sponsor program funds, individual institution funds, other IPTA funding as approved by the EC or Council, etc). The sponsoring program must bear the travel cost for the sponsoring program delegation. Accommodation and meals during the onsite visit should be covered by the applicant program.

The overarching aim of the onsite visit is to:

Evaluate the needs and suitability of the applicant site and feasibility of the objectives to be met by participation in the outreach program. This will include assessment of the challenges and resources required to initiate and sustain the new/expanded scope of services, and/or enhanced practice.

***Program aspects that will be evaluated during the on-site visit include but are not limited to:***

- Existence of a functioning adult transplant program within the same organ
- Qualification and engagement of an existing surgeon to perform the transplant procedure and address potential surgical complications
- Availability of appropriate supportive disciplines including but not limited to nephrology, hepatology, cardiology, anesthesiology, intensive care, dialysis, radiology, drug monitoring lab
- Access to HLA typing and HLA antibody testing and interpretation
- Long term access to immunosuppressive drugs
- Political support from the local institution, the regional and/or national authorities
- A detailed budget to identify local program training and development, implementation, long-term support and quality monitoring.
- Written commitment of financial support with anticipated budget from the local institution, and the regional and/or national authorities who will have to cover the costs of all aspects of the project (infrastructure, personnel, medical costs including immunosuppressive drugs, education and training)
- Existence of a system of social security/health insurance or appropriate resources to guarantee access to transplantation irrespective of income.
- Description of clinical need, catchment area and the projected number of annual transplants
- Existence of a regional/national program of organ procurement and allocation from deceased donors
- Local laws allowing living donation for kidney and liver transplantation.
- Follow up steps and post assessment
- Identify current assets as well as deficiencies and needs for training and education
- Systemic barriers that are associated with priority given to transplantation of children

***A paramount aspect of an onsite visit is to guarantee the ethical aspects of the transplant practice in the country, in accordance with the Declaration of Istanbul [www.declarationofistanbul.org](http://www.declarationofistanbul.org)***

After completion of the initial needs and potential assessment (whether onsite or virtual), a report will be written by the representative member of the Outreach Program Committee; this will comment on:

- Need for new or expanded transplant services, and a legal/ethical framework for transplantation that is permissive for IPTA sponsorship.
- Suitability of existing resources (e.g. team) and feasibility of developing the program.
- Needs requirements for additional support services, material resources, training, and education.
- Hospital and governmental support of the program and commitment to sustainability and addressing program needs and requirements before initiation.
- A timeline, agreed to by the applicant and sponsoring programs toward attainment of the objectives of Outreach Program participation.

After review by the Outreach Program Committee, including any remedial steps that may be required, the report will be forwarded to the IPTA Council with recommendations to approve or not approve the applicant and the sponsoring program partnership and proposal. The report may be updated with recommendations after review by the IPTA Council. With Council approval, the applicant program is now considered a participating center and a copy of the report is provided to the participating center and the sponsoring program.

### **Phase 3: Follow Up Period/Post assessment**

Follow up after the initial assessment will be dependent on program requirements and needs but may include fellowship, allied health or laboratory training, and development of a sustainable transplant program infrastructure. The participating center and the sponsoring institution will develop together and submit to the Outreach Program Committee a program plan for addressing the pre-implementation program requirement needs and for program implementation.

#### **Training:**

It is anticipated that the participating site will need further training of specific personnel in pediatric transplantation. These needs will be identified during the needs assessment (pediatric specialist, transplant surgeon, intensivist, anesthetist, specialty nurses, clinical/organ procurement coordinator). The financial capability to sustain this training by the participant center will have previously been established.

Educational opportunities may be provided to individuals identified from within the participating center. These individuals will ideally receive training at the sponsoring program but may also train at other IPTA pediatric transplant programs given visa and travel restrictions. The Outreach program does not provide any funding or administrative assistance for individuals training in other institutions.

Assistance with management and leadership aspects necessary for a successful transplant program such as infrastructure development and building relationships with transplant specialists at their own institutions (e.g. pathologists, nephrologists, etc.) and through IPTA will be made available. Educational sessions including in-person sessions, hands-on courses and webinars are examples of what may be organized at the participant center by the sponsoring program.

The IPTA member at the sponsoring program where the personnel have trained will function as advisors/consultants during this period of preparation, with the assistance of appropriate members of the IPTA leadership, if needed. They may also travel to assist the newly trained personnel, if and when possible (e.g. if living donor transplants can be scheduled). The sponsoring program must bear the travel cost for the sponsoring program delegation.

In order to ensure continued success, sponsor program representatives should continue to give guidance and support remotely. In addition, the sponsor program may be asked to provide review training for personnel in the participant center on an as needed basis.

***All costs of this phase, including travel and accommodation expenses of representatives of the sponsor program will be covered jointly by the participant center/sponsoring program.*** Details regarding cost commitments should be negotiated in advance.

#### **Follow up visits:**

Under certain circumstances, additional visits by the sponsoring program and the IPTA Outreach Program Committee delegation may be planned, depending on the requirements of the program. The need for these visits should be outlined in the comprehensive program proposal at the outset and, if approved, will be incorporated in the initial funding approval. The IPTA Outreach Program Committee reserves the option to conduct its own follow up evaluations for programs who remain active participants in the Outreach Program.

#### **Annual reporting:**

Both the participating center and the sponsoring program will receive acknowledgement of participation in the IPTA Outreach program both in writing for institutional use, and through IPTA promotional materials (e.g. website, newsletters, social media, etc.), and can use this designation for their own promotional purposes as long as all annual reporting requirements are met (see below). This center acknowledgement will be renewed on an annual basis.

The sponsoring program shares with the Outreach Committee the responsibility of pursuing the evaluation of the progress achieved by the participating program. During the progress of the Outreach Program partnership, the participating program will be asked to submit an annual reporting on progress, including basic program statistics that are relevant to the objectives of the supports requested. This progress will be reported back to the Outreach Program Committee and ultimately the IPTA Council. This requirement will start from the date the outreach application is approved.

Requests for expansion of active Outreach Program Center programs or extension of supports provided by IPTA beyond those approved in the comprehensive program plan must be submitted to the Outreach Program Committee and will require approval by the IPTA Council before being incorporated. This may require additional evaluation and needs assessment to determine feasibility.

The annual report must be submitted each year by the applicant program, and reviewed prior to submission with the sponsoring program. The expectation is that reporting will continue for 5 years after approval in order to remain active under the Outreach Program. Applicant programs that fail to submit reports may have their participation suspended.

## **ETHICAL REQUIREMENTS**

At each phase of the program, IPTA representatives will guarantee that ethical guidelines in the field of organ transplantation, as defined by IPTA and other Transplant Associations and Scientific Societies, are respected.

These ethical requirements include but are not limited to:

- Commitment by the IPTA Outreach Program applicant to avoid involvement of any kind in organ commerce
- Absence of discrimination against patients unable to pay
- Dissuade private practice in the field of organ transplantation since organs to be transplanted, either from living or deceased donors, are “free gifts”
- Writing of a protocol, approved by the local Ethics Committee or the Institution Review board, concerning the selection and management of living donors, particularly regarding full respect of donor’s autonomy, absence of financial compensation, known relationship, either biological or emotional, between donor and recipient and safety for the donor
- Existence of a national transplant law excluding the procurement of organs from prisoners sentenced to death in countries still accepting death penalty

Before local implementation of the new program, a charter listing the above mentioned ethical requirements should be signed by the IPTA Outreach Program participant, local authorities and countersigned by a representative of the sponsor program. The president of IPTA and the chair of the Outreach Program Committee should be provided with a copy.

**Specific questions about these guidelines and/or the application should be directed to Katie Tait, IPTA Section Manager. [Katie.tait@tts.org](mailto:Katie.tait@tts.org)**

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