



**Nicklaus  
Children's  
Hospital**

MIAMI CHILDREN'S HEALTH SYSTEM 



# Pediatric Heart Transplant Proposal

**BUSINESS PLAN – 6/30/2015**

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# Pediatric Heart Transplantation

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## ***I. Executive Summary***

Over 400 pediatric heart transplants are performed in the United States every year, which represent approximately 12% of the total number of heart transplants that are performed worldwide. A primary reason for pediatric heart transplant is pediatric advanced heart failure. Pediatric advanced heart failure is “a progressive clinical and pathophysiological syndrome caused by cardiovascular and non-cardiovascular abnormalities that results in characteristic signs and symptoms including edema, respiratory distress, growth failure, and exercise intolerance, and accompanied by circulatory, neurohormonal, and molecular derangements”<sup>1</sup>. Pediatric advanced heart failure occurs in approximately 1 in 10,000 live births and 10% of these are considered irreparable. The average wait time for a pediatric heart transplant candidate is approximately 1 year. Once a donor heart is located, the patient has 2 to 4 hours to prepare for transplant surgery. Of these patients, approximately 30% require a mechanical device to bridge them while they are waiting for a donor heart. Most programs report survival rates of over 5 years with a 10 year survival rate for children of over 59%. Hospitalizations related to pediatric advanced heart failure occur in 11,000-14,000 children each year in the United States with an overall mortality rate of 7%.<sup>2</sup> Heart transplant recipients can be on up to 10 to 12 medications simultaneously.<sup>3</sup> Today, Nicklaus Children’s Hospital’s Congenital Heart Institute refers approximately 4-6 patients/year to other centers as candidates for heart transplantation evaluation. While this referral is currently in the child’s best interest, referral to other centers lead to the loss of the patient/family along with the family’s out-of-pocket expenses.

### ***a. Purpose and Opportunity***

Florida has 4 providers of pediatric heart transplant programs, of which 2 are located in Service Area 4 where Nicklaus Children’s Hospital resides. Nicklaus currently refers 100% of patients with advanced heart failure that require transplantation out to other programs that provide this complex service.

In order to serve these patients best, Nicklaus Children’s Hospital proposes the establishment of a pediatric heart transplant program. The program will utilize existing facility space within the new Advanced Care Pavilion’s Cardiac Intensive Care Unit. The organization will develop expertise in partnership with an expert adult partner.

The Congenital Heart Institute continues to be recognized by U.S. News & World Report as a top program within the U.S., however lack of a cardiac transplant program adversely impacts the program’s ranking. The cardiac surgical and cardiology team has demonstrated excellent outcome and dedication to the best quality of care for children undergoing heart surgery. Establishing this program eliminates children leaving their providers and homes when they need cardiac transplantation.

### ***b. Value Proposition***

In order to provide the best care to children who are born with congenital cardiomyopathy that is inoperable, cardiac transplantation may be the child/family’s only lifeline. In alignment with Miami Children’s Health System’s vision of “for health, for life”, this complex service would provide the full continuum of care to the children of South Florida and beyond by not having them leave their dedicated medical team who knows them best. This program will also demonstrate the organization’s expertise and commitment to delivering comprehensive and high quality healthcare for children with congenital heart disease and their families.

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<sup>1</sup> Hsu, et al. Heart Failure In Children: Part 1: History, Etiology, and Pathophysiology. *Circulation. Heart Failure* 2009; 2: 63-70.

<sup>2</sup> Rossano, et.al. *Journal of Cardiac Failure* 2012; 18:459-470.

<sup>3</sup> 33 Uncommon Pediatric Heart Transplant Statistics (March 16, 2015). *HealthResearchFunding.org*. <http://healthresearchfunding.org/33-uncommon-pediatric-heart-transplant-statistics/#>

**II. Proposed Program**

**a. Organizational Overview**

Nicklaus Children’s Hospital was established in 1950 as Variety Children’s Hospital by Variety Clubs International. It is under the umbrella of Miami Children’s Health System, a not-for-profit corporation licensed to operate 289 acute care inpatient beds. The hospital is located in Miami-Dade Florida approximately 12 miles from downtown Miami. It is the only licensed freestanding specialty hospital providing services exclusively for children in South Florida. With over 3,500 employees and 720 physicians on staff, the organization is one of the largest free-standing teaching hospitals in the southeastern United States.



**Awards and Recognitions**

Nicklaus Children’s Hospital has been recognized by U.S. News & World Report by achieving national rankings in seven specialties. These rankings for 2015-16 are as follows: Cardiology & Heart Surgery, #34; Diabetes & Endocrinology, #39; Gastroenterology & GI Surgery, #42; Neonatology, #13; Neurology & Neurosurgery, #7; Orthopedics, #33, and; Pulmonology, #21. The Cardiology & Heart surgery program under the Congenital Heart Institute offers many services to its most vulnerable patients from birth to adulthood, including catheterization and interventional program, electrophysiology and fetal echocardiography, free EKG screening, outpatient cardiology and pediatric cardiovascular surgery. The CICU has received the Beacon Award for Excellence, recognizing excellence in clinical care and patient outcomes. The hospital also received its third ANCC Magnet designation in December of 2013 which is the highest honor an organization can receive for professional nursing excellence in clinical practice and outcomes. In 2014, the Cardiac Intensive Care Unit was one of three Nicklaus Children’s Hospital’s intensive care units honored with the Miami Dade County Health Care Hero award for clinical excellence.



**b. Program Description**

Nicklaus Children’s Hospital will implement a Pediatric Heart Transplant Program that will be integral to the Heart Program’s growth and success and will serve children from South Florida and nationally. Infant heart transplantation has been in existence for over 25 years. Children under the age of 15 years with congenital heart disease requiring complex management such as structural congenital heart defects such as hypoplastic left heart syndrome or end-stage heart failure are candidates for heart transplantation. (Chinnock, 2011)<sup>4</sup> Children waiting for heart transplantation may require a ventricular assist device (VAD) as a bridge to transplant. Survival with heart transplantation in children and infants may exceed 15 years post-surgery according to The Society of Thoracic Surgeons<sup>5</sup>.

Currently, one of the only areas of complexity not performed by the MCH Heart Program is heart transplantation. The Nicklaus Children’s Hospital program will work collaboratively with a partner program to develop patient surgical protocols for pre, interim and post-transplant and develop patient/family educational materials. The program will meet and exceed all standards that will enable Nicklaus Children’s Hospital to apply for UNOS designation. UNOS designation requires a computerized database registry that will be developed for tracking, monitoring and reporting demographics and clinical outcomes of patients. The registry will be used to improve quality and safety as well as to assist with research and education regarding pediatric cardiac transplantation.

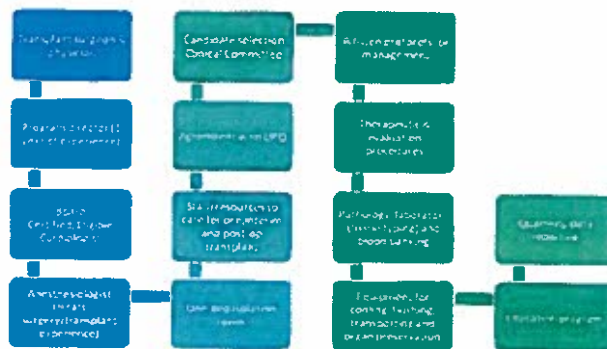
**c. Program Goals: The Pediatric Heart Transplantation Program will:**

- i. Enable children to stay within their continuum of care of existing providers at Nicklaus Children’s Hospital. These children currently are either referred out of the region entirely for care or are transplanted at competitor institutions locally.
- ii. Enable Nicklaus Children’s Hospital to offer a full range of services that currently is not provided by the Heart Program.
- iii. Enhance the organization’s regional and national brand of outstanding quality and outcomes in the care of children with structural and congenital heart problems.

**d. Model**

The Transplant Surgeon, Medical Director and Transplant Coordinator will provide clinical oversight to assure excellence in program quality standards and adherence to regulatory requirements. Figure 1 includes minimal program requirements for initiation of a pediatric heart transplant program.

**Figure 1: Pediatric Heart Transplantation Minimum Requirements  
Florida Agency for Healthcare Administration 59C-1.044**



<sup>4</sup> Chinnock, R.E. & Bailey, L.L. (2011). Heart transplantation for congenital heart disease in the first year of life. *Current Cardiology Review*, 7(2), 72-84.

<sup>5</sup> Long-term survival possible for pediatric heart transplant patients (2014). *The Society of Thoracic Surgeons*.

Implementation of the program requires a trained team comprised of many disciplines such as Nursing, Intensivists, Respiratory Therapists, Child Life Therapists, Nutrition, Pharmacy, Surgical Services, Anesthesiology, Radiology, Laboratory, Blood Bank, Rehabilitative Services (Occupational and Physical Therapy), Infectious Diseases, Dermatology, Ophthalmology, Pulmonary Medicine, Neurology and other pediatric subspecialists (Figure 2). Support for these children and their families requires intense pharmaceutical management and follow up as well as social and psychological services.

**Figure 2: Pediatric Heart Transplant Multi-disciplinary Team**



**e. Facilities/Infrastructure/Location**

Nicklaus Children’s Hospital will be housed in existing space and does not require modification to facilities or infrastructure in order to perform pediatric heart transplantation. The existing heart operating suite will perform all pediatric heart transplants. Patients will be admitted pre-operatively to the existing Cardiac Medical/Surgical Unit or the Cardiac Intensive Care Unit (total of 36 beds) in the new Advanced Care Pavilion while awaiting transplantation. Patients will be seamlessly cared for in the same intensive care setting post-operatively until readied for discharge home.

Patients being seen and evaluated for transplant will receive services from the multi-disciplinary heart team in existing cardiac surgery office/treatment space. Children receiving follow-up care will also be cared for in the same cardiac office space.

**f. Marketing**

The Pediatric Transplant program will require moderate additions onto the Heart Program’s existing website. Promotional marketing materials will be added for transplant surgeon and team as well as search engine optimization adding key words.



**g. Equipment**

Equipment is required in the surgical services area for organ cooling, flushing and transportation. Ventricular Assistive Devices (VAD) are also required as a lifesaving bridge to transplantation if they fail medical therapy. Other equipment would include office space, equipment, furnishings and support for the transplant surgeon and the Transplant Program Director/Coordinator.

**h. MCHS strategic alignment**

Pediatric heart transplant aligns well with MCHS's strategic priority of Growth as well as its mission of "for health, for life". The cardiac service line is one of the organization's premier programs and the addition of transplant services will continue to enhance the program's national brand.

**iii. Market Analysis**

Pediatric heart transplant is performed in large children's hospitals throughout the United States. Table 1 depicts the top ten largest pediatric heart transplant centers in the United States and their respective volumes.

**Table 1: Top 10 Children's Hospital Pediatric Heart Transplant Centers in the United States  
October 1, 2013-September 30, 2014<sup>6</sup>**

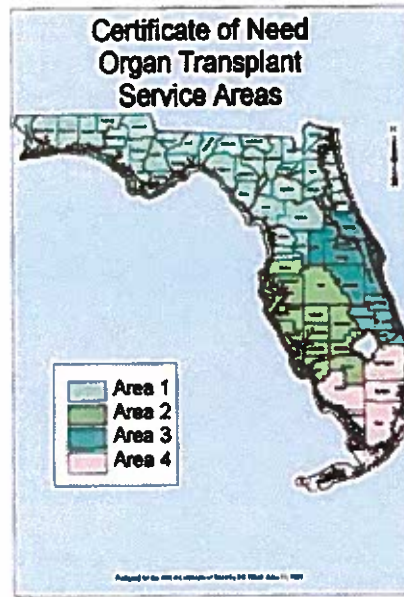
Transplant Center	Location	Volume
Texas Children's Hospital	Houston, TX	43
New York Presbyterian	New York, NY	27
Arkansas Children's Hospital	Little Rock, AK	23
Children's Hospital of Philadelphia	Philadelphia, PA	23
Ludle Packard Children's Hospital	Palo Alto, CA	21
St. Louis Children's Hospital	St Louis, MO	20
Children's Hospital of Pittsburgh	Pittsburgh, PA	19
Ann & Robert Lurie Children's Hospital	Chicago, IL	18
Children's Healthcare of Atlanta	Atlanta, GA	18
Seattle Children's Hospital	Seattle, WA	18
Total		230

Organ transplant in the state of Florida requires a certificate of need application. Nicklaus Children's Hospital is a part of Service Area 4 depicted in Figure 3<sup>7</sup> below which contains 2 pediatric heart transplant programs within its area (Memorial Regional and Jackson Memorial Hospitals).

<sup>6</sup> Pediatric Health Information System (PHIS) from CHA Resource Utilization by APR-DRG 2 Heart &/or Lung Transplant, October 1, 2013-September 30, 2014.

<sup>7</sup> AHCA Certificate of Need, June 11, 1999.

**Figure 3: Certificate of Need Organ Transplant Service Areas**



The following (Table 1) demonstrates current pediatric heart transplant programs according to their rankings in U.S. News & World Report as well as the current volume of pediatric hearts transplanted.

**Table 1: Florida Pediatric Heart Transplant Programs**

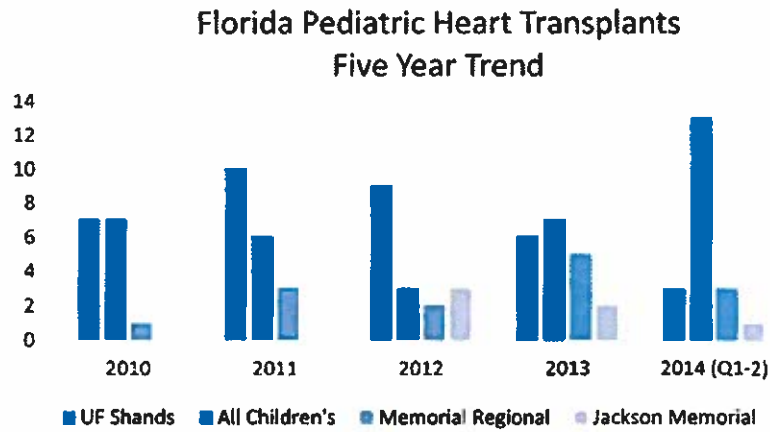
County	Name	U.S. News & World Report ranking	Pediatric Hearts Transplanted 7/2013 to 6/2014
Miami-Dade	Holtz Children's - Jackson Memorial Hospital	40	2
Broward	Joe Dimaggio - Memorial Regional Hospital	50	3
Pinellas	John Hopkins All Children's Hospital	26	13
Alachua	UF Health Shands Hospital	29	4

There are 4 approved pediatric heart transplant programs in Florida and Jackson Memorial will be a direct competitor to Nicklaus Children's in Miami-Dade County.

The critical element for Nicklaus embarking into pediatric heart transplantation is that the Heart Program already serves a substantial population of children who are followed from birth into adulthood. Congenital heart disease/heart failure is a traumatic experience for a family and the organization currently cares for the most critically ill patients. Cardiac transplant patients are the only patients being referred out of the organization and they are often sent to other regions/states to receive care. Table 2 depicts the current 5-year trend for pediatric heart transplantation by Florida facility.

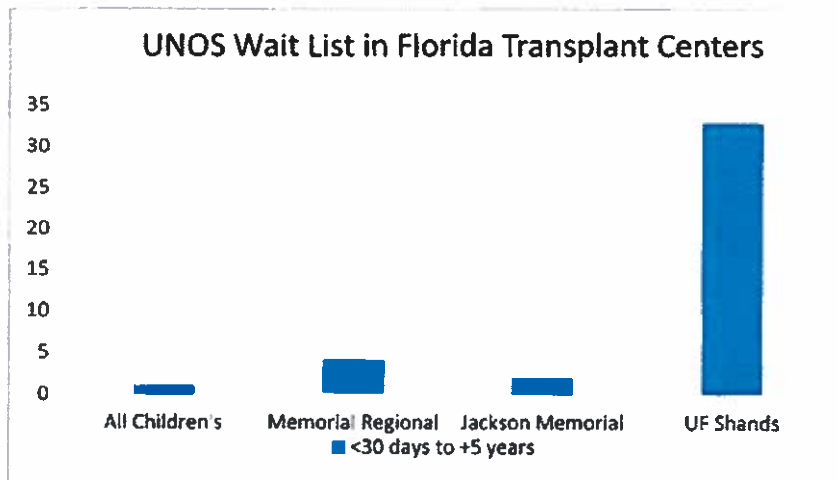


**Table 2: Florida Pediatric Heart Transplants by Facility**



Currently as of February 2015, the UNOS waiting list (Table 3) contains 40 children who are awaiting heart transplantation in the state of Florida<sup>8</sup>.

**Table 3: UNOS Florida Pediatric Heart Transplant Waiting List**



<sup>8</sup> Waitlist: Waiting Time by Transplant Center, Current U.S. Waiting List for Pediatric Heart Transplant, Based on OPTN data as of February 27, 2015 \* 0-17 age range per OPTN on line database.

Table 4 below depicts Florida Pediatric Heart Transplant Program physician and program leadership as well as locations.

**Table 4: Program Leadership in Florida Pediatric Heart Transplant Programs**

Institution	Location	Program Lead
Jackson Memorial <sup>9</sup>	1801 NW 9 <sup>th</sup> Avenue Miami, FL 33136	Anthony Panos, MD Joseph Bauerlein
Memorial Regional <sup>10</sup>	1005 Joe DiMaggio Drive Hollywood, FL 33201	Maryann Chrisant, MD
All Children's <sup>11</sup>	501 6 <sup>th</sup> Avenue South St. Petersburg, FL 33701	Alfred Asante-Korang, MD James Quintessenza, MD Jeffrey Jacobs, MD Tom Karl, MD
UF Shands <sup>12</sup>	1600 SW Archer Road Gainesville, FL 32608	Mark Bleiweis, MD Jay Fricker, MD Gonzalo Wallis, MD

**IV. Operational Plan**

**a. Regulatory Requirements**

Heart transplant requirements are regulated by several programs including: the Agency for Health Care Administration (AHCA); the United Network for Organ Sharing (UNOS) and the Centers for Medicare and Medicaid Services (CMS).

**AHCA<sup>13</sup>**

A certificate of need is required and the Table below demonstrates the batching cycle requirements<sup>14</sup>.

**Table 5: Florida Transplant Batching Cycle Calendar**

	2015					2016	2017	2018
	10/2	10/19	11/18	11/25	12/23	2/19/16	2/20	8/20
Summary Need Projections Published in Florida Administrative Weekly (FAR)	█							
Letter of Intent		█						
Application			█					
Completeness Review				█				
Application Omissions					█			
Agency Initial Decision						█		
Implementation (18 months)							█	█

<sup>9</sup> <http://surgery.med.miami.edu/cardiothoracic/artificial-heart-and-ventricular-assist>

<sup>10</sup> <http://www.jdch.com/html/medical-specialties/cardiac/programs-services/heart-transplant-program.html>

<sup>11</sup> <https://www.allkids.org/Services/Heart-Institute/Heart-Transplant>

<sup>12</sup> <https://ufhealth.org/uf-health-congenital-heart-center/pediatric-heart-transplant-program>

<sup>13</sup> Certificate of Need Competitive Review Cycles. [http://ahca.myflorida.com/MHCQ/CON\\_FA/Batching/index.shtml](http://ahca.myflorida.com/MHCQ/CON_FA/Batching/index.shtml)

<sup>14</sup> CON batching cycles. [https://ahca.myflorida.com/MHCQ/CON\\_FA/Batching/indexz.shtml](https://ahca.myflorida.com/MHCQ/CON_FA/Batching/indexz.shtml)

**UNOS<sup>15</sup>**

All transplant programs must meet general and organs specific requirements for membership. The Organ Procurement and Transplantation (OPTN) bylaws detail requirements for operation as well as the alternative pathways for pediatric programs.

**CMS<sup>16</sup>**

CMS requires a formal letter requesting Medicare approval for new programs. Letter information and corresponding requirements are found on the CMS regulations and guidelines for transplantation. Membership to the OPTN is mandatory prior to seeking Medicare approval. The United Network for Organ Sharing (UNOS) is the contractor servicing OPTN.

The timeline below includes key planning elements in addition to batching cycle requirements from Table 5.

	6/15	10/2	2015					2016	2017	2018
			10/19	10/30	11/18	11/25	12/23	2/19/16	2/20	8/20
Engage Consultant	█									
Data request completion		█								
Data request		█	█	█						
Summary Need Projections Published in Florida Administrative Weekly (FAR)		█								
Letter of intent			█							
Application					█					
Completeness Review						█				
Application Omissions							█			
Agency Initial Decision							█			
Implementation (18 months)								█	█	█

<sup>15</sup> Designated Transplant Program Criteria. [https://www.unos.org/wp-content/uploads/unos/Appendix\\_B\\_Attach1\\_XIII.pdf](https://www.unos.org/wp-content/uploads/unos/Appendix_B_Attach1_XIII.pdf)

<sup>16</sup> National Coverage Determination (NCD) for Heart Transplant. [http://www.cms.gov/medicare-coverage-database/details/ncd\\_details.aspx?NCDId=112&ncdver=3&NCAId=78&lsPopup=y&bc=AAAAAAAAAAAA%3D%3D&](http://www.cms.gov/medicare-coverage-database/details/ncd_details.aspx?NCDId=112&ncdver=3&NCAId=78&lsPopup=y&bc=AAAAAAAAAAAA%3D%3D&)

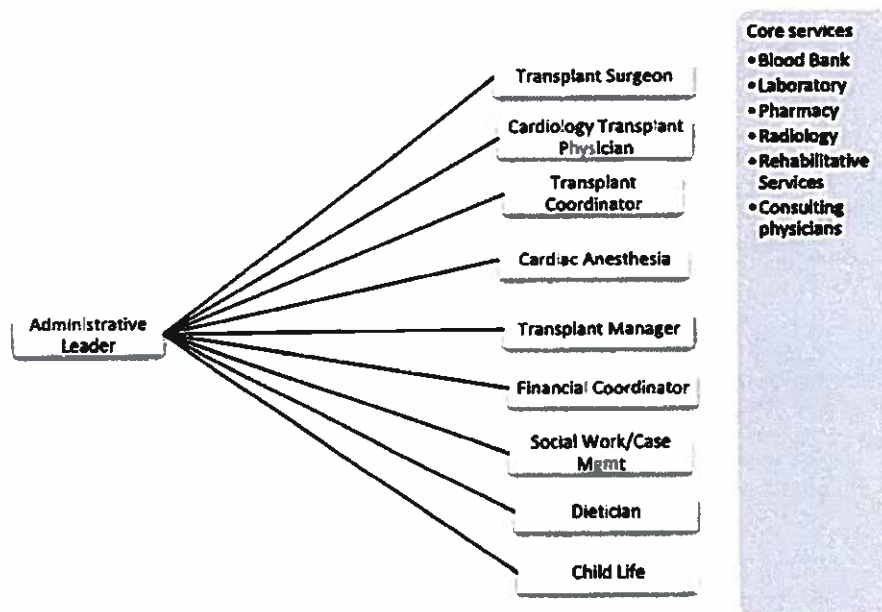
Finally, the SWOT analysis depicts the strengths, weaknesses, opportunities and threats in moving forward with a pediatric heart transplant program as well as risks in not moving forward.

**b. SWOT Analysis**

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• Congenital Heart Program is a flagship service line with excellent clinical outcomes</li> <li>• Supporting services of interventional cardiology and catheterization, electrophysiology, cardiopulmonary support (including only program in the state to provide on transport)</li> <li>• World class physician and provider team</li> <li>• U.S. News ranked program</li> <li>• Dedicated cardiac intensive care unit as well as specialized provider follow-up and after care</li> </ul>	<ul style="list-style-type: none"> <li>• No dedicated pediatric heart transplant specialists on staff</li> <li>• Pediatric transplant surgical expertise will need to be added</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>• All top 10 ten USNWR pediatric heart programs provide heart transplantation services</li> <li>• Alignment with organizational goals to be a top ten USNWR pediatric organization</li> <li>• Keep patients so they remain with their familiar providers, improving quality and outcomes</li> <li>• Enhance revenue stream that we currently lose by referring patients out and additionally pick up new patients referred into program</li> </ul>	<ul style="list-style-type: none"> <li>• Known competitors in our Service Area are quickly surpassing our program in establishing these programs</li> <li>• To do nothing will contribute to volume erosion</li> <li>• Brand reputation for cardiac surgery losing ground to competitor program depth</li> </ul>

**c. Organizational Structure**

The diagram below is a compilation of the collaboration among many disciplines that are necessary in implementing a pediatric heart transplant program.



- V. Financial Plan**
- a. Appendix**