Policy & General Indications for Transplant

Policy
To be considered for a transplant, a patient must be evaluated using the OSOTC patient selection criteria by the appropriate multidisciplinary treatment team at one of the following member hospitals:

- Cincinnati Children’s Hospital Medical Center
- Nationwide Children’s Hospital
- The Cleveland Clinic Foundation
- The Ohio State University Medical Center
- University Hospitals Case Medical Center
- University of Cincinnati Hospital

The patient will then be presented to the hospital-based Patient Selection Committee to determine the medical suitability of the candidate. The exact composition of the interdisciplinary committee is determined by each hospital.

General Indications for Transplant by Organ
It has been agreed by all member hospitals that patients will be evaluated for transplantation solely based on their medical suitability. The general indications are as follows:

<table>
<thead>
<tr>
<th>Organ</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>Children and adults suffering from irremediable terminal cardiac disease with severely compromised survival despite application of other available medical and surgical therapies. Survival estimates are based on standard heart failure risk assessments</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>Irremediable terminal disease which a heart or lung transplant alone would not treat, and with an expected survival of not more than 12-24 months - functionally limited but not totally disabled</td>
</tr>
<tr>
<td>Single/Double Lung</td>
<td>End-stage fibrotic lung disease which is unresponsive to known alternative therapy End-stage pulmonary disease with increased compliance (emphysema, eosinophilic granuloma, etc.) or chronic pulmonary infection (cystic fibrosis, bronchiectasis)</td>
</tr>
<tr>
<td>Liver</td>
<td>Children and adults suffering from irreversible liver dysfunction or the effects of liver dysfunction after alternative medical and surgical treatments have been utilized and where the benefits of transplantation out weigh the risk of alternative modalities.</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Insulin dependent diabetes mellitus Type I (JODM), with secondary complications that may include renal transplant, or insulin dependent Type II diabetes</td>
</tr>
<tr>
<td>Pancreas Islet Cell</td>
<td>Insulin-dependent diabetes mellitus Type I with absent C-peptide</td>
</tr>
<tr>
<td>Small Bowel/Small Bowel &amp; Liver</td>
<td>Short bowel syndrome and short bowel syndrome complicated by irreversible liver failure resulting from long-term total parenteral nutrition, or liver failure due to diseases that are Consortium-approved specific indications for liver transplantation alone or in combination with short bowel syndrome after all alternative medical and surgical treatments have been exhausted and the patients are approaching the terminal phase of their illness</td>
</tr>
</tbody>
</table>
Candidate Reviews

Potential transplant candidates must be reviewed by the respective organ-specific Patient Selection Committee. Each Patient Selection Committee consists of one representative from each appropriate member hospital, a representative from the Ohio Department of Health, and ethicist or bioethicist, and a lay representative who may be an attorney. Upon hospital approval for transplantation, a representative of the hospital’s organ-specific pre-transplantation department will submit the clinical summary to the Consortium by uploading the clinical summary to the OSOTC secure online review system at https://review.osotc.org.

The clinical summary must be typed, accurate, and submitted on the approved form as a MS Word document (the approved forms can be found under the Forms section on www.osotc.org.) If a summary is deemed unacceptable due to inadequate information, the Consortium office shall notify the presenting center of the problem, remove the inadequate submission from system, and wait for the clinical summary to be resubmitted by the presenting institution. The clinical summary is used to verify that the patient meets the statewide patient criteria and must include:

- Adequate medical history
- Complete lab data as designated on the form
- A thorough psychosocial evaluation including the patient's support system, any psychosocial issues, attitude toward and understanding of transplant, and informed consent as well as a chemical dependency history, if appropriate.
- Liver programs: if the patient has a BMI >40, the summary will contain a more detailed physical description, including an estimate of the ascites, location of masses and if either hypertension or renal insufficiency is a problem.
- Lung programs: if the patient has a BMI >30 but <35, the summary will contain a more detailed physical description.

When a center submits a clinical summary to the online review system it is considered a pending candidate and can only be viewed by the Consortium and the presenting center. After the clinical summary is submitted as a pending candidate the Consortium will process the document, which consists of entering all pertinent information into the Consortium database, remove identifying information, converting the de-identified patient summary from a Word document to a non-modifiable PDF document, and finally, registering the new PDF document onto the review system where it can be viewed by the voting representatives.

Reviewers have the option of unconditionally approving, conditionally approving, or rejecting a patient. With all three options the reviewer may also post a question to the referring program, open for all reviewers to see. The referring program will answer the question, again posting for all reviewers to view. Once all members of the committee have voted and there are no outstanding discussion items, the OSOTC office will certify that the review has been completed and post the OSOTC determination letter. The referring program will be notified via email that a determination has been made regarding their candidate. The presenting center can then logon to the online review system to retrieve the OSOTC determination letter. A majority approval is required for the patient to be accepted as a transplant candidate for listing with UNOS.

Each committee representative will receive a daily “reminder to vote” email for all pending candidates for whom they have not yet voted. It is requested that the committee representatives review the clinical summary within 48 business hours following registration. The Consortium office will contact committee members, requesting their decision if they have not responded after 72 business hours of registration.

Should the primary reviewer not be available, the email notification should be forwarded by the primary reviewer’s office to his/her alternate reviewer, requesting him/her to review the patient’s medical information. The primary reviewer’s office should notify the OSOTC office of the absence as soon as possible so that voting rights can be granted to the alternate reviewer during the primary reviewer’s absence.
Second Reviews
Second reviews for a second transplant are not necessary if the patient is being listed within one year of the first transplant unless the transplanted organ is lost to either recurrent disease or non-compliance. However, the Consortium office must be notified at the time the patient is relisted. Information will be requested regarding the reason for relisting and current patient demographics. All patients requiring listing for a second transplant more than one year following the first transplant will require a second review.

Second Reviews for Non-listed Candidates
Candidates who have been previously reviewed by the OSOTC but were never listed, or who were previously listed but removed from the waiting list due to reasons other than having been transplanted, a second (or subsequent) review will be required if more than six months has elapsed since their previous review.

Reviews for Third or Subsequent Transplants
Prospective reviews will be conducted for any patient being listed for a third or subsequent transplant regardless of when the last review or transplant took place. The summary must contain detailed information regarding why the previous transplants failed and an explanation of why the program feels a subsequent transplant will be successful and what measures will be taken to improve the chance for success. In addition to the review, a conference call may be held for the committee to discuss the case.

Urgent Patient Listings Prior to OSOTC Review
All patients who are not deemed urgent shall not be listed with UNOS until the review is completed by the OSOTC. Urgent patients are defined as follows:

- **Heart**: status 1A or an occasional unstable 1B as deemed appropriate by the Medical Director
- **Liver**: status 1 or a MELD/PELD score of equal to or greater than 22
- **Lung**: calculated LAS score of equal to or greater than 50. A lung candidate with a calculated LAS score of less than 50 may be reviewed as medically urgent, on a case-by-case basis, and should include a statement of medical urgency within the medical summary submitted for review.

The OSOTC online review system is accessible 24/7; urgent patients should be submitted to the OSOTC online review system simultaneous with UNOS listing. The patient summary must note that the patient is being urgently listed and specify reasons for urgent listing. A patient who is listed and transplanted without having been submitted to the OSOTC will not undergo review and may risk loss of reimbursement. A patient who is listed and delisted (for any reason) without having been submitted to the OSOTC will not undergo review, however, the completed patient summary shall be sent to the OSOTC office to keep on file.

The Exceptional Patient
The unusual patient who does not completely fulfill the selection criteria may be considered for a transplant. The summary will be prepared as described previously noting the special condition(s) when the patient does not comply with selection standards. The referring program must explain why this patient should be considered as an exception. If the organ specific committee's questions are not satisfied, a conference call will be scheduled and the patient's eligibility determined by a majority vote. Should the exception patient be the first of a new group of patients now considered to be eligible for transplant, either based on data or the natural extension of the current technology, the committee may elect to recommend to the Board of Trustees that the selection criteria be amended to include that group of transplant candidates.
Candidate Approval
It is requested that all reviews be completed within 48 business hours of registration. A majority approval is required for the patient to be accepted as a transplant candidate for listing with UNOS. Once all members of the committee have voted and there are no outstanding discussion items, the OSOTC office will certify that the review has been completed and upload the OSOTC determination letter to the online review system. The OSOTC determination letter will also document any comments or suggestions raised during the course of review. The presenting center will then be notified via email that a determination has been made regarding their candidate and can then logon to the online review system to retrieve the OSOTC determination letter. Additionally, the Consortium office will fax a determination letter to Ohio Medicaid, Division of Prior Authorization, for patients who are Ohio Medicaid recipients or Ohio Medicaid pending.

Appeals Process
When a decision is not acceptable to the referring physician, a conference call with all the members of that particular Patient Selection committee shall be scheduled. If the conference call does not adequately resolve all concerns, the referring physician may appeal the decision to the Executive Committee of the Consortium's Board. No individual shall review a patient as both a member of the Patient Selection Committee and as a member of the Executive Committee. The Executive Committee's decision is binding.

Online Review System Security
The system housing the secure online review system https://review.osotc.org has 128-bit SSL security encryption and complies with all HIPAA requirements. The system runs on three USA based geographically dispersed, mirrored data centers with built-in replication, disaster recovery, a redundant network backbone, and no single point of failure. The system performs two remote backups per day.

No identifying information is sent through the e-mail system to the reviewers with the exception of the patient’s review number, which is automatically generated by the system, and the link to the patient’s information is inaccessible without entering the online review system with a correct password.

OSOTC Office Security
Electronic records will be maintained on a networked PC in the OSOTC office. Each PC will have a network password as well as a screen saver password to ensure the confidentiality of patient records. No patient records shall be removed from the OSOTC office. The OSOTC office will be locked unless at least one person is on the premises. Visitors to the OSOTC office will not be left unattended so as to restrict access to patient records. Paper records shall be scanned and retained indefinitely by the OSOTC office. After scanning, paper records shall be disposed of by secure document shredding.
**Patient Waiting List**

**Process**
The Extra-renal Recipient Waiting List (the “patient waiting list”) is intended for the use of the transplant teams and is not to be duplicated or given to anyone who is not a member of the team. On a weekly basis, the OSOTC office prepares a statewide list of all patients in Ohio waiting for an extra-renal transplant. The statewide information is collated with the UNOS list. The password protected waitlist file is then emailed to designated representatives of the member programs.

**Candidate Updates**
Each program notifies the OSOTC on a weekly basis of if a patient has been added to the list, or if a patient has been removed from the list, along with the reason for removal.

**Transfer of Waiting Time**
If a patient transfers his/her waiting time from one center to another, a copy of the signed UNOS Wait Time Adjustment Form must be sent to the Consortium office. A second review is not necessary if the patient has already been reviewed and approved for another Ohio program.

**Joint Listing**
If a patient wishes to be jointly listed, the OSOTC office will be notified and the first transplant center will remain the primary center with the original "on waiting list" date. If a patient wishes to change his/her transplant center, the original "on waiting list" date is only transferable if the patient moves his/her residence to the new transplant center. Otherwise, patients wishing to have a double listing, but not physically relocating their residence will have an "on waiting list" date at the second center as of the time of the second listing.

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Approved:
- Board of Trustees, July, 1984
- Board of Trustees, April 15, 1988
- Board of Trustees, November 18, 1988
- Board of Trustees, April 21, 1989
- Board of Trustees, November 18, 1988
- Board of Trustees, April 21, 1989
- Board of Trustees, April 21, 1989
- Board of Trustees, July 7, 1989
- Board of Trustees, August 3, 1989
- Board of Trustees, July 13, 1992
- Board of Trustees, May 7, 1990
- Board of Trustees, April 23, 1993
- Board of Trustees, April 23, 1993
- Board of Trustees, October 24, 1997
- Board of Trustees, July 30, 1999
- Liver Committee, September 9, 1999
- Board of Trustees, May 5, 2000
- Liver Committee, February 21, 2002
- Board of Trustees, August 22, 2003
- Lung Committee, April 20, 2005
- Board of Trustees, November 20, 2009

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HEART PATIENT SELECTION CRITERIA

Indications
1. Children and adults with irremediable terminal cardiac disease with severely compromised survival despite application of other available medical and surgical therapies. Survival estimates are based on standard heart failure risk assessments.
2. Any patient who is continually on the waiting list for more than two years will require verification from the transplant team that he/she is still a candidate for transplantation and continues to meet the patient selection criteria as described below.
3. Age 70 years or younger (older patients will be considered on a case-by-case basis).

Contraindications
1. Absolute:
   a. Significant active infection (unless related to an LVAD) or uncontrolled malignancy.
   b. Diabetes with end organ damage other than non proliferative retinopathy or poor glycemic control despite optimal effort.
   c. Pulmonary artery hypertension and elevated PVR when PVR is > 5 Woods units or the PVR index is >6 or the TPG exceeds 16 to 20 mm Hg.
   d. Clinically severe symptomatic cerebrovascular disease which is not amendable to revascularization.
   e. Chemical dependency, including illegal narcotic usage (i.e. marijuana), not consistent with screening criteria in Substance Dependence Addendum.
   f. Absence of adequate external psychosocial support (Irreversible hepatic or renal dysfunction unless patient is being considered for multiple organ transplant).
   g. Non-compliance.
2. Smoking or tobacco use not consistent with screening criteria in the Addendum B Heart and Lung Patients Presenting with History of Tobacco Use Relative:
   a. BMI >35 kg/m² (or) % BMI of >140%.

Relative Contraindications for Pediatric Candidates (to be reviewed on a case by case basis)
1. Prematurity (less than 36 weeks gestation).
2. Small size (less than 2 – 2.5 kg).
3. Cardiac anatomic abnormalities
   a. Significant pulmonary artery hypoplasia.
   b. Uncorrectable pulmonary venous abnormalities.
   c. Ectopia cordis.
4. Cardiac physiologic abnormalities
   a. Elevated pulmonary vascular resistance which is irreversible with pulmonary vasodilator testing ( > 6 Wood units per meter squared).
5. Impaired and/or irreversible dysfunction or abnormality of other organ system, eg: acute renal failure, acute hepatic failure, multisystem organ failure, severe dysmorphology or genetic abnormality, profound metabolic or neuromuscular/neurologic/CNS disorder.
6. Severe or significant systemic illness, for example: active infection (pneumonitis, septicemia, fever of unknown origin), HIV infection, hepatitis B and possibly C infection, active malignancy.
7. Psychosocial pathology including alcohol or substance abuse in parents or patients, child abuse or neglect, psychiatric illness in patient (parents?), strong, and irremediable history of non compliance.
8. Parental non-compliance with physician recommendations for pediatric candidates to have all age appropriate immunizations.
9. Other life limiting illnesses.
HEART-LUNG PATIENT SELECTION CRITERIA

General Indications
In the past, it has been shown that pulmonary transplant as a desperate attempt for deathbed rescue has been doomed to failure. Only with rigid selection criteria has clinical success been realized.

All patients considered for heart-lung transplantation shall be:
1. less than 60 years of age
2. free from other major organ failure
3. expected to have a survival time of not more than 12 to 24 months without a transplant

Specific Indications
Patients with the following disease processes are considered as candidates for transplantation. They should be functionally limited, but not totally disabled. There is a "transplant window" during which the patient has a gradual decline from the natural history of his/her disease, but has not deteriorated so much that he/she is no longer a viable transplant candidate.

Patients to be considered include, but are not limited to, those with the following diagnoses:
1. Eisenmenger's syndrome
2. Primary pulmonary hypertension
3. Cardiomyopathy with pulmonary hypertension
4. Emphysema
5. Alpha-1 antitrypsin deficiency
6. Pulmonary fibrosis
7. Cystic fibrosis
8. Bronchiectasis
9. Bronchopulmonary dysplasia
10. Post-transplant obliterative bronchiolitis
11. Pulmonary disease in young infant for technical surgical issues (typically due to the airway size)
12. Ischemic heart disease

Contraindications
1. Absolute:
   a. Significant systemic or multi-system disease
   b. Active or systemic infection limiting survival
   c. In general, a five year malignancy -free interval is prudent, This time frame may be modified in the setting of low grade malignancies with little to no risk of recurrence on a case-by-case basis.
   d. Major psychiatric illness
   e. Non-compliance
2. Relative:
   a. Previous cardiac or thoracic surgery
   b. Diabetes Mellitus
   c. Peptic ulcer disease
   d. Cachexia (<17 BMI) or obesity (>30 BMI: Patient medical summary shall provide details regarding the patient’s body composition)
   e. Corticosteroid therapy (>20 mg/day)
   f. Psychosocial issues
   g. Chemical dependency, including illegal narcotic usage, not consistent with screening criteria in Substance Dependence Addendum
   h. Smoking or tobacco use not consistent with screening criteria in the Addendum B Heart and Lung Patients Presenting with History of Tobacco Use
Approved: Board of Trustees, May 7, 1990
Amended: Board of Trustees, May 8, 1995
Revised General Indication of survival time to include “without a transplant”: Board of Trustees, November 3, 2000
Added Contraindication “non-compliance”: Board of Trustees, November 2, 2001
Amended Cachexia to use BMI: Board of Trustees, August 22, 2003
Deleted “free of steroid medications or on less than 20 mg of prednisone/day”: Board of Trustees: November 14, 2003
Revised Absolute Contraindication Corticosteroid therapy (>20 mg/day) to Potential Contraindication: Board of Trustees, November 14, 2003
Added Pulmonary disease in young infant for technical surgical issue Board of Trustees, November 10, 2006
Revised General Indications Board of Trustees, November 10, 2006
Added “Pulmonary disease in young infant...” to Specific Indications Board of Trustees, November 10, 2006
Revised Absolute and Relative Contraindications Board of Trustees, August 10, 2012
SINGLE/DUPLICATE LUNG PATIENT SELECTION CRITERIA

General Indications
All patients considered for pulmonary transplantation shall be suffering from end-stage pulmonary disease and be:
1) less than 65 years of age, patients older than 65 will be reviewed on a case-by-case basis
2) free from other major organ failure
3) free from major psychosocial problems
4) capable of participating in pre- and post-operative rehabilitation programs and follow-up
5) expected to have a survival time of less than 18 months without a transplant

Specific Indications
Patients with the following disease processes will be considered for lung transplantation:
1) Eisenmenger's physiology, COPD, emphysema, Alpha-1 antitrypsin deficiency
2) Primary pulmonary hypertension
3) Pulmonary fibrosis (primary or secondary)
4) Cystic fibrosis
5) Bronchiectasis
6) Other--including, but not limited to, sarcoidosis, systemic lupus, pulmonary hemosiderosis, bronchiolitis obliterans, broncho alveolar carcinoma, etc.
7) Advanced pediatric lung disease

Contraindications
1) Absolute:
a. Significant systemic or multi-system disease
b. Active or systemic infection limiting survival
c. In general, a five year malignancy-free interval is prudent, This time frame may be modified in the setting of low grade malignancies with little to no risk of recurrence on a case-by-case basis.
d. Major psychiatric illness
e. Non-compliance

2) Relative:
a. Previous cardiac or thoracic surgery
b. Diabetes Mellitus
c. Peptic ulcer disease
d. Cachexia (<17 BMI) or obesity (>30 BMI: Patient medical summary shall provide details regarding the patient's body composition)
e. Corticosteroid therapy (>20 mg/day)
f. Psychosocial issues
g. Chemical dependency, including illegal narcotic usage, not consistent with screening criteria in Substance Dependence Addendum
h. Smoking or tobacco use not consistent with screening criteria in the Addendum B Heart and Lung Patients Presenting with History of Tobacco Use
Approved: Board of Trustees, November 18, 1988

Expanded Indications:

Board of Trustees, July 9, 1990

Expanded Indications:

Board of Trustees, February 18, 1991

Expanded Indications:

Board of Trustees, August 5, 1991

Expanded Indications:

Board of Trustees, May 8, 1992

Removed Right Ventricular Failure (General Indication h):

Board of Trustees, November 1, 1993

Amended Indications & Contraindications:

Board of Trustees, May 8, 1995

Revised General Indication on age to include “physiological”:

Board of Trustees, November 3, 2000

Revised General Indication on survival to include “without a transplant”:

Board of Trustees, November 3, 2003

Added Potential Contraindication “Uncontrolled esophageal reflux”:

Board of Trustees, March 3, 2000

Added Potential Contraindication “Symptomatic osteoporosis”:

Board of Trustees, November 3, 2000

Added Potential Contraindication “Non-compliance”:

Board of Trustees, February 22, 2003

Amended Cachexia to use BMI:

Board of Trustees, November 14, 2003

Deleted “free of steroid medications or on less than 20 mg of prednisone/day”:

Board of Trustees, November 14, 2003

Revised Absolute Contraindication “Active fungus infection” to include “invasive”:

Board of Trustees, November 14, 2003

Revised Potential Contraindication Corticosteroid therapy (>20 mg/day):

Board of Trustees, November 14, 2003

Added Potential Contraindication “Inability to participate in exercise program”:

Board of Trustees, November 14, 2003

Added Advanced pediatric lung disease to Specific Indications

Board of Trustees, November 10, 2006

Revised General Indication, Specific Indications, & Contraindications

Board of Trustees, November 10, 2006

Revised Contraindications: BMI>35, BMI>30 a patient’s body composition shall be included in the patient medical summary

Board of Trustees, February 1, 2008

Revised Specific Indications: Other, Revised Contraindications: Absolute and Relative

Board of Trustees, November 20, 2009

Revised Absolute and Relative Contraindications

Board of Trustees, August 10, 2012
HEPATIC PATIENT SELECTION CRITERIA

Indications
In general, liver transplantation is indicated in children and adults suffering from irreversible liver dysfunction or the effects of liver dysfunction after alternative medical and surgical treatments have been utilized and where the benefits of transplantation outweigh the risk of alternative modalities.

Specific Indications
1) Acute hepatic fulminant failure
2) Extrahepatic biliary atresia or hypoplasia
3) Inborn errors of metabolism:
   a. Alpha-I antitrypsin deficiency
   b. Crigler-Najjar disease, Type I
   c. Byler's disease
   d. Glycogen storage disease (O and IV)
   e. Wilson's disease
   f. Hemochromatosis
   g. Tyrosinemia
   h. Wolman's disease
   i. Familial amyloidotic polyneuropathy (FAP)
   j. Primary hyperoxaluria type I
   k. Other
4) Sclerosing cholangitis
5) Hepatic vein thrombosis (Budd-Chiari)
6) Hepatocellular Carcinoma (HCC), Stage I or II, or: single lesion \( \leq 6.5 \text{ cm} \), or multiple lesions \( \leq 3 \) with the largest \( \leq 4.5 \text{ cm} \) with total maximum tumor diameter \( \leq 8 \text{ cm} \) (UCSF criteria)
7) Cirrhosis:
   a. Alcohol cirrhosis (see Alcohol or Substance Dependence Addendum)
   b. Biliary cirrhosis (primary or secondary): Caroli, choledochal cyst, congenital cholestasis (PFIC), iatrogenic biliary tree injury/damage, trauma
   c. Chronic active hepatitis (A, B, C, non A, non B, autoimmune)
   d. Congenital biliary cirrhosis
   e. Cryptogenic cirrhosis
   f. Cystic fibrosis
   g. Hemochromatosis
   h. Alpha I Antitrypsin Deficiency
   i. NASH
   j. Viral cirrhosis
   k. Other
8) Congenital hepatic fibrosis
9) Controlled biliary sepsis resulting from acute (or chronic) hepatic artery thrombosis (ischemic coagulopathy)
10) Hepato-pulmonary syndrome, with cirrhosis
11) Polycystic liver disease with symptoms such as: portal hypertension, Budd-Chiari-like symptoms, refractory and unmanageable ascites following cyst fenestration
12) Porto-pulmonary hypertension in the presence of cirrhosis and mean pulmonary artery pressures of \( < 35 \text{ mm Hg} \)
Indications for Retransplantation

1) Primary non-function
2) Irreversible vascular compromise of either the hepatic artery, portal vein, or hepatic vein
3) Recurrent primary disease
4) Intractable, acute, or chronic rejection
5) Biliary disease not correctable by any mechanism other than transplantation
6) Small for size syndrome
7) Poor early graft function (PEGF)

Indications Special Cases (To be reviewed on a case-by-case basis)

1) Stage III tumors outside UCSF
2) Slow-growing metastatic leiomyosarcoma, neuroendocrine tumors including metastatic carcinoid syndrome and hemangioendotheliomas
3) Cholangiocarcinoma transplanted under approved institutional protocol
4) Hepatitis C (retransplant within 1 year for recurrent disease)

Contraindications

1) Chemical dependency (see Alcohol or Substance Dependency Addendum)
2) Active infection outside hepatobiliary system limiting survival
3) Significant cardiac, pulmonary, or nervous system failure (this does not apply for patients being considered for heart and/or lung transplant)
4) Unstable current psychotic disease (pre-liver failure)
5) Uncontrolled malignancy
6) AIDS
7) Persistent pattern of non-compliance considered likely to interfere with following a disciplined medical regime

Approved:

Revised Hepatitis B: Board of Trustees, January 17, 1986
Revised State-of-Art: Board of Trustees, April 25, 1986
Revised Abstinence/Tumors: Board of Trustees, April 21, 1989
Revised Hepatocellular Carcinoma: Board of Trustees, May 24, 1989
Revised Abstinence: Board of Trustees, July 7, 1990
Addendum Approved: (Screening Guidelines for Liver Patients with Significant Histories of Substance Abuse):
Addendums: Board of Trustees, May 6, 1991
Revised Cystic Fibrosis: Board of Trustees, August 5, 1991
Revised Criteria for tumor: Board of Trustees, October 30, 1992
Revised Criteria for tumor: Board of Trustees, April 23, 1993
Revised Abstinence Criteria: Board of Trustees, November 14, 1995
Deleted “imminent” from “other imminent life-limiting illness”:
Deleted “cholangiocarcinomas” from Relative Indications and added “Histologically documented cholangiocarcinoma” to contradictions:
Revised Specific Indication “acute hepatic fulminant failure”:
Added Relative Indication “Cholangiocarcinoma under approved protocol”:
Removed Contraindication “Histologically documented cholangiocarcinoma”:
Added Contraindication “non-compliance”:
Added Specific Indication HCC. Added Relative Indications:
Added Specific Indication “Controlled biliary sepsis resulting from acute or chronic hepatic artery thrombosis”:
Added Specific Indication “Recurrent Hepatitis C infection (greater than one year following transplant)”:
Added Specific Indication “Special case with detailed explanation and 100% committee approval”:
Revised Contraindication Alcoholism to include “current illicit narcotic usage (marijuana)”:
Revised Indications, Specific Indications, Indications for Retransplantation, Indications: Special Cases, and Contraindications
**Indications**

1) **Group I**: Insulin-dependent Diabetes Mellitus Type I (JODM) with secondary complications but no renal or early renal involvement. Early pancreatic transplantation may be indicated for those who cannot be adequately controlled with insulin and/or with chronic complications of diabetes likely to be impacted by a pancreas transplant.

2) **Group II**: Insulin-dependent Diabetes Mellitus Type I with secondary complications and renal involvement in the absence of morbid obesity. Synchronous pancreatic and renal transplantation may be indicated.

3) **Group III**: Type I or Type II insulin-dependent diabetes mellitus with secondary complications, end-stage renal disease and previous renal transplant. Asynchronous pancreatic transplantation may be indicated.

**Contraindications**

1) **Absolute:**
   a. Chemical dependency, including illegal narcotic usage, not consistent with screening criteria in Substance Abuse Addendum
   b. Active sepsis
   c. End-stage organ dysfunction:
      i. Pulmonary
      ii. Cardiac
      iii. Cerebrovascular
      iv. Hematological
   d. Inability to understand the transplant procedure and care for self after receiving a new organ
   e. Uncontrolled malignancy

2) **Relative:**
   a. BMI >35
   b. Non-compliance

Approved: Board of Trustees, July 1984
Revised Consistent with Renal: Board of Trustees, January 30, 1987
Deleted Policy for Islet Cells: Board of Trustees, July 19, 1996
Revised Indication Group III to include Type I and Type II: Board of Trustees, November 3, 2000
Revised Contraindication concerning Chemical Dependency: Board of Trustees, November 3, 2000
Added Contraindication “Non-compliance”: Board of Trustees, November 2, 2001
Deleted “Type I (JODM)” from Group II: Board of Trustees, November 14, 2003
Added “in the absence of morbid obesity” to Group II: Board of Trustees, November 14, 2003
Revised Contraindication “Active infection” to “Active sepsis”: Board of Trustees, November 14, 2003
Deleted Contraindication “Active ulcer disease”: Board of Trustees, November 14, 2003
Added Relative Contraindication BMI>35: Board of Trustees, November 14, 2003
Added “chronic complications of diabetes likely to be impacted by a pancreas transplant” to Indications: Board of Trustees, November 10, 2006
Revised Contraindications: Absolute & Relative: Board of Trustees, November 20, 2009
PANCREAS ISLET PATIENT SELECTION CRITERIA

**Indications**
1) All recipients must have Type I insulin-dependent Diabetes Mellitus with absent C-peptide
2) Previous kidney transplant (or kidney-pancreas transplant with failed pancreas with satisfactory kidney graft function)
3) GFR >50 based on calculated GFR, or based on a 24 hour urine study, or base on iothalamate clearance as appropriate (This is to only apply to patients who have not previously received a kidney transplant and are potential kidney recipients)
4) Kidney transplant candidates with Type I insulin-dependent Diabetes Mellitus

**Contraindications**
1) History of malignancy (except adequately treated localized basal cell carcinoma of skin without evidence of recurrence, or other cancers considered cured by therapy)
2) Patients with current episodes of acute renal allograft rejection
3) Patients with panel reactive antibody (PRA) level > 50%
4) Chemical dependency, including illegal narcotic usage (i.e. marijuana), not consistent with screening criteria in Substance Dependence Addendum
5) Active infection
6) Non-compliance
SMALL INTESTINAL PATIENT SELECTION CRITERIA

Background
Small intestinal transplantation, combined liver/intestinal transplantation, and multivisceral transplantation are operations that are reserved for life-threatening conditions, but no longer considered investigational. Worldwide, from the early 1980s until mid 2003, 61 centers had performed 989 transplants upon 923 patients. (433 isolated small intestinal, 386 liver/intestinal, and 170 multivisceral). Sixty one percent of all transplants have been performed upon children. In this era, one-year survival has remained between 65 and 70% and five-year survival is between 40 and 50%. When reserved for patients with no possibility of long-term survival without transplantation, the procedure should be strongly considered.

Factors governing success of the procedure will include the general health of the recipient before transplant, the size of the center, the experience of the physicians within that center with small bowel or liver transplantation and/or related procedures, and recent advances in surgical technique, graft monitoring techniques, immunosuppressive regimens, and antiviral therapies. The average length of stay varies from 55 days for small intestinal transplantation to 72 days for multivisceral transplantation. Success can be monitored by outcome-measures that include cost of the procedure and the morbidity and mortality of the patients undergoing the procedure.

Indications
Isolated small intestinal transplantation is an operation reserved for patients with irreversible short bowel syndrome (or intestinal failure despite intact intestinal length) associated with life-threatening complications due to either parenteral nutrition or the underlying disorders themselves. When prospects for weaning from parenteral nutrition are nil, or patients have experienced multiple serious episodes of septicemia, progressive loss of vascular access, are at risk for serious morbidity and mortality from disease itself, or are at risk for progressive cholestasis associated with parenteral nutrition, isolated small intestinal transplantation may be considered.

When candidates have suffered irreversible liver damage (usually associated with prolonged parenteral nutrition) in addition to irreversible intestinal failure, liver/small intestinal transplantation should be considered. If the candidate’s disease process is one which renders gastroduodenal function unacceptable, or when localized tumors or other causes of vascular occlusion seriously compromise the arterial blood supply to stomach, liver, small bowel, and pancreas, multivisceral transplantation may be performed.

Specific Indications
1) Surgical short bowel syndrome due to:
   a. Volvulus
   b. Gastrochisis
   c. Necrotizing enterocolitis
   d. Hirschsprung’s Disease
   e. Congenital atresias
   f. Crohn’s Disease
   g. Trauma
   h. Mesenteric vascular insufficiency
   i. Localized intra-abdominal tumors (such as desmoid tumors or inflammatory pseudotumor)
   j. Other causes of surgical short bowel syndrome
2) Secretory diarrhea associated with uncorrectable malabsorption
   a. Microvillus inclusion disease
   b. Tufting enteropathy
   c. Intestinal pseudo-obstruction
   d. Other life-threatening diarrheal disorders uncorrectable by medical or surgical means short of transplantation
3) Liver failure in association with intestinal failure
   a. TPN-associated liver failure
   b. Other causes of liver failure (such as primary sclerosing cholangitis or biliary atresia) in association with intestinal failure
4) Other Consortium-approved indications for transplantation

Contraindications
1) Active chemical dependency, including illegal narcotic usage (i.e. marijuana), not consistent with screening criteria in Substance Dependence Addendum
2) Active infection outside the hepatobiliary system limiting survival
3) Disseminated, non-resectable malignancy
4) Insufficient venous patency to guarantee central venous access
5) Severe dysfunction of other organ systems (cardiac, pulmonary, vascular, renal, neurologic), rendering transplantation risk unacceptable
6) Other life-threatening, uncorrectable illnesses not referable to the gastrointestinal system
7) Unstable, uncontrollable psychiatric illness
8) Proven non-compliance

Reference
“Intestinal Transplant Registry” David Grant MD. URL--http://www.intestinaltransplant.org/

Approved: Board of Trustees, February 12, 2001
Added Contraindication “Non-compliance”: Board of Trustees, November 2, 2001
Added Surgical Indication “Intestinal pseudo-obstruction”: Board of Trustees, November 14, 2003
Added Surgical Indication “Other causes of liver failure in association with intestinal failure”: Board of Trustees, November 14, 2003
Revisions to Background, Indications, Specific Indication, and Contraindications Board of Trustees, November 10, 2006
ADDENDUM A TO PATIENT SELECTION CRITERIA
Screening Criteria for Patients Presenting with Significant Histories of Substance Dependence

Evaluation Process
Individuals presenting with histories suggestive of alcohol or substance abuse or dependency shall be evaluated by an interdisciplinary team including at least the following: a chemical dependency specialist (may be a social worker, psychologist, psychiatrist, or addictionologist), an internist, and a surgeon. The evaluating committee will determine the patient’s suitability for transplantation and will make recommendations regarding rehabilitation or counseling prior to listing or as a condition of listing.

Standard Criteria
For patients with a diagnosis of alcohol or substance dependence as defined by DSM-IVTR at the time of evaluation, the patient must sign a contract pledging not to use alcohol or any illicit or addictive substances (unless under a doctor’s order) in the future and agreeing to unlimited, random drug and/or alcohol screening both while awaiting as well as following transplantation. All patients must satisfy the following requirements prior to listing:

1) Patients must demonstrate complete abstinence from all addictive substances (unless under a doctor’s order) throughout the pre-transplant period and must meet one of the three determining factors:
   a. Abstinence for more than two years prior to listing and confirmed by collateral information;
   b. At least three months abstinence prior to listing and three months current participation in an active recovery program (structured treatment program; and/or documented 12-Step meeting attendance with sponsor selection/contact) AND random toxicology screens prior to listing and confirmed by collateral information; or
   c. Meets criteria as a medically urgent patient (see following section on: Criteria for Medically Urgent Patients Unable to Meet Condition 1a or 1b).

2) Patients must also have demonstrated to the transplant treatment team:
   a. Insight into their past substance dependency;
   b. A good understanding of how substance dependency has had an impact on their current health; and
   c. Adequate coping skills for dealing with stressors; or
   d. Meets criteria as a medically urgent patient (see following section on: Criteria for Medically Urgent Patients Unable to Meet Condition 1a or 1b).

Current and consistent participation in an active recovery program, corroborated by the transplant team could satisfy these requirements. (Patients are expected to continue active participation in a recovery program after listing.)

3) Additionally, other prognostic factors for abstinence will be taken into consideration, such as:
   a. The presence of a sober, stable social network which will be available both pre- and post-transplant to offer ongoing support;
   b. A stable work history; and
   c. The presence of a family unit which acknowledges the issues posed by substance dependency and will support the patient’s commitment to abstinence.

Even if the patient satisfies all the above standard criteria, the transplant center does not necessarily have to accept the patient as a transplant candidate. The rationale for why the patient should not be a transplant candidate shall be included in the patient’s medical summary or medical record.
Medically Urgent Patients Unable to Meet Conditions 1a or 1b of the Standard Criteria
Any transplant candidate with a diagnosis of alcohol or substance dependency who has not been abstinent at least 2 years and though committed to maintaining sobriety is too ill (as defined below) to actively work a recovery program for 3 months, may qualify for listing through one of the following mechanisms:

<table>
<thead>
<tr>
<th>Organ</th>
<th>For those with a <strong>MELD score ≥ 22</strong> (calculated or eligible for exception) the following will apply:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver</td>
<td>For those who are status 1a the following will apply:</td>
</tr>
<tr>
<td></td>
<td>▪ For those who are status 1b and are hospitalized, on inotropes, and unable to have VAD placement, the following will apply:</td>
</tr>
<tr>
<td>Heart</td>
<td>For those with a calculated <strong>LAS ≥ 50</strong> (candidates with a calculated LAS &lt; 50 will be reviewed on a case-by-case basis) the following will apply:</td>
</tr>
<tr>
<td>Lung</td>
<td>For those who are status 1 the following will apply:</td>
</tr>
<tr>
<td>Intestine</td>
<td>For those who are status 1 the following will apply:</td>
</tr>
</tbody>
</table>

Low Risk
Patients who are low-risk for recidivism as defined below and confirmed by the treatment team are eligible for statewide review and listing with at least 1 month confirmed abstinence, a signed contract and commitment to begin a rehabilitation program pre-transplant if patient’s health will permit, and continue to actively working the recovery program post transplant.

a) No previous failure with substance rehabilitation;  
b) Never been told that substance was affecting health; and  
c) Good social support

Medium Risk
Patients who are at medium risk for recidivism as defined below and confirmed by the treatment team are eligible for statewide review with at least 3 months confirmed abstinence, a signed contract and commitment to begin a rehabilitation program pre-transplant if the patient’s health permits, and to continue actively working the recovery program post transplant.

a) One or more failures with rehabilitation; and  
b) Minimal support system

High Risk
Patients who are at high risk for recidivism as defined below and confirmed by the treatment team are eligible for listing based on the recommendation of the treatment team and only if they meet the criteria as specified in section 1b of the standard criteria.

a) Two or more failures to remain abstinent despite medical complication;  
b) Refusal to sign contract; and  
c) Minimal to poor social support

For all patients who do not actively work a recovery program for 3 months pre-transplant, each transplant program agrees to closely monitor post-transplant compliance with ongoing active participation in a recovery program. Failure to follow treatment recommendations will be reported to the OSOTC for future use in modifying the CD criteria.
Even if the patient satisfies all of the above medically urgent criteria, the transplant center does not necessarily have to accept the patient as a transplant candidate. The rationale for why the patient should not be a transplant candidate shall be included in the patient’s medically summary or medical record.

**Chemical Dependency Committee Evaluation**

The CD representatives from the Consortium programs shall review the patient’s medical history and forward their advisory recommendations to the organ specific Patient Selection Committee. This review process will be conducted before or simultaneously with the medical review. The organ specific Patient Selection Committee will take the recommendations of the CD Committee under consideration as they determine whether the patient is appropriate to list for transplantation.

In so far as it reasonably practical, based on first person and/or collateral resources, medically urgent criteria patients will be evaluated regarding:

a) Insight into their past substance dependency;
b) A good understanding of how substance dependency has had an impact on their current health; and
c) Adequate coping skills for dealing with stressors

Additionally, other prognostic factors for abstinence will be taken into consideration, such as:

a) The presence of a sober, stable social network which will be available both pre and post-transplant to offer ongoing support;
b) A stable work history; and
c) The presence of a family unit which acknowledges the issues posed by substance dependency and will support the patient’s commitment to abstinence.

**Medically Urgent Chemical Dependency Patient Listing Prior to Review**

Should it be necessary to list a medically urgent CD candidate (MELD≥22 and too ill to actively work a recovery program for 3 months and meets criteria for low, medium or high risk) with UNOS prior the review by the CD Committee or the organs specific Patient Selection Committee, the transplant center must notify the OSOTC immediately by phone and/or email and submit the patient’s clinical summary with chemical dependency history to the OSOTC office the next business day.
**Exception**
If a patient is unable to actively participate in a recovery program as determined by the medical team and does not fulfill the definition of medical urgency but the referring team determines that the patient should be an acceptable candidate for transplantation, a conference call with the Chemical Dependency (CD) Committee to facilitate a full and complete assessment of the patient’s situation will be required. The CD representatives from the Consortium programs along with the medical specialists shall review the patient’s medical history and forward their advisory recommendations to the organ specific Patient Selection Committee. This review process will be conducted before or simultaneously with the medical review. The organ specific Patient Selection Committee will take the recommendations of the CD Committee under consideration as they determine whether the patient is appropriate to list for transplantation. *(The previous mechanism for exceptions will no longer be used.)*

**Patient Non-Compliance**
If evidence arises that the patient has failed to maintain complete abstinence during the evaluation process or after listing, the patient is immediately made inactive or removed from the list. The evaluating team will reconsider the patient and recommend appropriate chemical dependency treatment. The evaluating team will have the discretion to reevaluate the patient or refer the patient on to another center for reevaluation. To be listed at a program in Ohio the patient must requalify for listing by 3 months active participation in a recovery program and 3-6 months confirmed abstinence. Confirmation of the patient’s participation in an ongoing recovery program must be presented to the Consortium and will require a conference call with the CD Committee prior to re-listing or reactivating the patient on the waiting list.

Patients who have a second relapse while awaiting a transplant will not be eligible for relisting. Failure to submit to random blood or urine screening is considered to be evidence of a relapse.

Patients who are non-compliant with following treatment recommendations will not be eligible for transplant.

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Addendum Approved:
- Board of Trustees, May 6, 1991
- Board of Trustees, January 20, 1995
- Board of Trustees, November 14, 1995
- Board of Trustees, November 14, 1995
- Board of Trustees, November 14, 1995
- Board of Trustees, October 29, 1999
- Board of Trustees, January 1, 2000
- Board of Trustees, February 1, 2002
- Board of Trustees, May 2, 2003
- Board of Trustees, May 13, 2005
- Board of Trustees, August 11, 2006
- Board of Trustees, November 20, 2008
- Board of Trustees, September 3, 2010
ADDENDUM B TO PATIENT SELECTION CRITERIA
Screening Criteria for Heart and Lung Patients Presenting with History of Tobacco Use

Heart and lung transplant candidates must be free of nicotine and tobacco use, including chewing tobacco, for six months prior to an initial listing.

1) This six month time period may be reduced for heart transplant candidates if:
   a. The patient has not previously been made inactive on the waiting list or de-listed from the waiting list because of a positive cotinine urine test; and
   b. The patient is medically urgent and unlikely to survive the required six month period prior to listing, as determined by either one of the following:
      i. The patient meets UNOS medical definition of Status 1A; or
      ii. The patient meets the UNOS medical definition of Status 1B and is unstable as indicated by being hospitalized on inotropes and unable to have a ventricular assist device placement.
   c. Patients with less than six months of being free of nicotine and tobacco use under the medically urgent exception noted above will be reviewed by the Heart Patient Selection Committee comprised of, at a minimum, the Director of Health, one experience transplant physician from each organ transplant program who actively participates in transplant services, an ethicist or bioethicist, and a lay representative who may be an attorney. The candidate shall sign a contract pledging not to use nicotine or tobacco in the future, must attend smoking cessation classes as prescribed by each transplant center and agree to unlimited, random cotinine urine tests both while awaiting, as well as after transplantation. The Heart Patient Selection Committee shall determine whether the patient is appropriate to list for transplantation.

2) This six month time period may be reduced for lung transplant candidates on a case-by-case basis.
   a. Patients with less than six months of being free of nicotine and tobacco use under the medically urgent exception noted above will be reviewed by the Lung Patient Selection Committee comprised of, at a minimum, the Director of Health, one experience transplant physician from each organ transplant program who actively participates in transplant services, an ethicist or bioethicist, and a lay representative who may be an attorney. The candidate shall sign a contract pledging not to use nicotine or tobacco in the future, must attend smoking cessation classes as prescribed by each transplant center and agree to unlimited, random cotinine urine tests both while awaiting, as well as after transplantation. The Lung Patient Selection Committee shall determine whether the patient is appropriate to list for transplantation.

3) While on the waiting list, unannounced nicotine screens by cotinine urine test will be performed at least every four to six weeks.

4) If the patient has a positive cotinine urine test during the time he or she is awaiting transplant, the transplant center will either make the patient inactive on the waiting list or de-list the patient from the waiting list. Before being re-activated or re-listed, the patient:
   a. Must re-establish a six month period of abstinence; and
   b. Attend smoking cessation classes as prescribed by each transplant center’s treatment team.
Patient Selection Criteria will be reviewed at least once a year.

Each criterion under "indications" and "contraindications" shall be reviewed as to its appropriateness by the physicians of that organ specific committee. The decision to change criteria must be justified by either experimental or theoretical knowledge. Experimental data shall be generated through a review of the literature, recent proceedings, and direct communications with other transplant centers or the Ohio Solid Organ Transplantation Consortium patient registry. When changes are made, it is recommended that such changes will be based on the experience of at least two other centers with a combined experience of 10 patients, reporting a combined survival rate of 50% or 20 patients at one center with a 50% survival rate.

These changes, with the supporting rationale and documentation, shall be written and presented to the Board of Trustees for ratification.

There may be times when it is desirable to change criteria even when there is little experience. In these cases, a representative of the Patient Selection Committee shall present the theoretical argument directly to the Board of Trustees for review and ratification.
OHIO EXTRA-RENAL ORGAN SHARING AGREEMENT

On the thirteenth of February 1995, the transplant center members of the Ohio Solid Organ Transplantation Consortium and the respective Ohio Organ Procurement Organizations agreed to a system for organ allocation in the state of Ohio. In January 1998, the allocation system was revised to accommodate a UNOS Region 10 (including Indiana and Michigan) sharing arrangement for status 1 livers. The sharing agreement was once again modified in February 2002 to reflect UNOS’s adoption of the MELD (Model for End-Stage Liver Disease)/PELD (Pediatric End-Stage Liver Disease) system.

Liver
The distribution of livers will be as follows:

- Region 10 Status 1 patients
- Local list of patients (local OPO list) with MELD/PELD scores of 35 or more
- Statewide list of patients with MELD/PELD scores of 35 or more
- Local list of patients with MELD/PELD score of 20-34
- Statewide list of patients with MELD/PELD score of 20-24
- Local list of patients with a MELD/PELD score of 15-19
- Statewide list of patients with a MELD/PELD score of 15-19

Thoracic Organs (Sharing Agreement was dissolved in July 2006)
In 1999 UNOS modified its definition of urgent heart patients by dividing status 1 into two categories: 1A and 1B. The Ohio sharing agreement was modified to reflect the change in the national system. Hearts, heart-lungs and lungs will be allocated as follows:

- Local Status 1A, State Status 1A patients
- Local Heart/Lung patients
- Local Status 1B, State Status 1B
- State Heart/Lung patients
- Local Status 2 patients
- State Status 2 patients
- Regional/National: Zone A Status 1 patients
- Zone A Heart/Lung patients
- Zone B Status 1 patients
- Zone B-C Heart/Lung patients
- Zone A Status 2 patients
- Zone B Status 2 patients
- Zone C Status 1 patients
- Zone C Status 2 patients

Thoracic organs from Ohio Valley Life Center and Life Connection of Ohio will be allocated to patients on this list which will zig-zag with the other state centers on the above allocation system. Thoracic organs from the two remaining OPOs, Lifeline of Ohio Procurement in Columbus and LifeBanc in Cleveland, will be allocated to their respective local center lists and zig-zag with the remainder of the state on the allocation system.

This system will comply with the following UNOS objectives:
1) A single waiting list for each organ within each local unit.
2) A local unit review. The OPO or OPOs involved shall collect and review data on organ procurement, organ distribution, organ quality and organ function for the local unit.
3) Equitable organ distribution. Equitable organ distribution should attempt to balance justice and medical utility.
4) Monitorable organ distribution. Data collection and review are necessary to be certain that the distribution system is being followed and that it is achieving its goals.
5) No organ distribution predicated on the procuring transplant center or individual.
6) Effective organ procurement throughout the local unit. Enhancement of the organ supply should be a primary goal of any organ distribution system.

This agreement is the Consortium’s response to the UNOS request to modify the 50-mile radius organ sharing system in the state of Ohio. The members of the Ohio Solid Organ Transplantation Consortium and the State of Ohio Procurement Organizations believe that the above agreement will best meet the objectives of the Ohio Department of Health in allowing fair and equal distribution of organs to Ohio residents awaiting organ transplantation, and will allow the respective transplant centers to continue to cooperate and assure quality, cost-effective organ transplantation on an equal basis to Ohio residents. This system is reviewed annually to assure that the objectives of fair organ distribution are being met.

**Pancreas/Islet Cell**

The distribution of Pancreas/Islet Cells will be as follows:

- High PRA Locals
  - O ABDR Mismatch Local OPO
  - O ABDR Mismatch Regional
  - O ABDR Mismatch National
- Local OPO Pancreas List
- Regional Pancreas List
- Local OPO Islets Status 1
- Local OPO Islets Status 2
- National Pancreas List
- Regional Islets Status 1
- Regional Islets Status 2
- National Islets Status 1
- National Islets Status 2

Approved: UNOS, February 1995
Revised: UNOS, January 1998
Revised: UNOS, February 2002
**REPORTING CHANGES IN KEY PERSONNEL**

The OSOTC's Executive Director and the Ohio Department of Health shall be notified in advance of the departure of a key person (such as the Program Director, the transplant surgeon, or the primary transplant physician) and given the name and curriculum vitae of the replacement person. If the program is unable to fill the position prior to the departure of the key person, the program shall be made "inactive" until the institution is able to recruit new staff. This status may be maintained for up to 24 months and extended for an additional twelve months upon approval by the Board. At the time the program is prepared to reactivate its service, the institution will so notify the Consortium and submit the curriculum vitae of any new team member to confirm that his/her (their) credentials meet the Consortium standards. The institution will also be asked to verify that all other team members are still present and a site visit may be requested.

Should a program be inactive for more than 36 months, it may reapply for membership by submitting a full application demonstrating that it complies with institutional requirements as specified in the Ohio Department of Health Quality Rule 3701-84-16 through 3701-84-21.
Facility Standards for Institutions Requesting Entry Into and Maintaining Membership in the Ohio Solid Organ Transplantation Consortium

Determination of entry into the Consortium shall be based upon standards described in the ODH Quality Rule 3701-84-16 through 3701-84-21 and demonstration that the proposed program has satisfied UNOS membership standards.

Thereafter, ongoing membership standards are defined by 1) continued compliance with the ODH Quality Rule, 2) maintenance of membership in UNOS, and 3) compliance with organ specific program criteria.

At the end of two years in the Consortium, the program must be performing the organ-specific minimum volume to maintain full, active membership.

Approved: Board of Trustee, July 1984
Added Reference to CON: Board of Trustees, June 28, 1991
Amended Volume Requirements: Board of Trustees, July 23, 1993
Amended Volume Requirements: Board of Trustees, April 12, 1996
Amended New Program Requirements: Board of Trustees, April 12, 1996
Amended Volume Requirements: Board of Trustees, May 5, 1997
Approved ODH Reference Change: Board of Trustees, April 24, 1998
Removed reference to an active kidney program: Board of Trustees, August 22, 2003
Amended survival rate to 80%: Board of Trustees, November 16, 2007
MEMBERSHIP CRITERIA

Members in Good Standing
Organ specific programs within member institutions of the Ohio Solid Organ Transplantation Consortium (OSOTC) shall be considered as “Members in Good Standing” when in compliance with the following criteria:

1) Participation in all OSOTC committees and other activities as deemed appropriate by the Board of Trustees;
2) Annual submission of data as indicated in the Cooperative Agreement or as specifically requested by the Program Peer Review Committee or organ specific committee;
3) Implementation of measures for program improvement when recommended by the Program Peer Review Committee;
4) Member institution payment of annual dues and other fees as directed by the OSOTC Board of Trustees.

Notification of membership status, including program status, will be confirmed in writing annually to each member and to the Director of the Ohio Department of Health.

New and Reactivated Programs
1) At the end of two years of membership in the Consortium, the program must perform the minimum volume as specified by each organ.
2) A new program must list a patient by the end of the first year and must have performed a transplant by the end of the second year from the start of their program.
3) The Peer Program Review Committee has the prerogative to extend the start up period to three years in order for a new program to meeting volume requirements.

Application Process for New Transplant Programs
1) Complete the Program Application Form indicating Personnel/Credentials
   a. Attach CV’s for new individuals
2) Complete the Administrative Review Form
   a. Include the facility floor plan
   b. Include documentation on nurse training and education
3) For the Surgical Director:
   a. Number of transplants as primary
   b. Number of transplants, assisting
   c. Role in developing policies and procedures
   d. Attach job description
4) A copy of the UNOS Approval Letter
5) The application will be reviewed by the organ-specific committee and the Program Review Committee with a recommendation for approval or disapproval forward to the Board of Trustees and the applying center will be notified of the decision.
Standards developed by the organ-specific Committee for quality and volume requirements.

**Heart Transplantation Programs**

1) The personnel standards and facility requirements shall meet the ODH Quality Rules 3701-84-17, 3701-84-18 and UNOS.

2) All patients undergoing heart transplantation shall be reviewed and approved by the Consortium's Heart Patient Selection Committee.

3) The minimum volume shall be 10 heart transplants per year. Any program that has a volume of less than 15 transplants during the reporting period and does not meet survival thresholds will be reviewed based on the last 20 transplants ending the last day of the current review period.

4) The 30 day patient and graft actual survival rate for the reporting period shall be a minimum of 88%.

5) The 90 day patient and graft actual survival rate for the reporting period shall be a minimum of 85%.

6) The 1 year patient and graft actual survival rate for the reporting period shall be a minimum of 82%.

7) The 3 year patient and graft actual survival rate for the reporting period shall be a minimum of 72%.

8) In addition to the actual patient and graft survival rates for 30 days, 90 days, 1 year and 3 years, the one-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

9) In addition to the actual patient and graft survival rates for 30 days, 90 days, 1 year and 3 years, the three-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

10) All pediatric heart transplant cases shall be reviewed on a case-by-case basis in lieu of using the aforementioned volume criteria and survival rates. The pediatricians will follow both short-term and long-term outcomes.

11) If the program does not meet the above standards, there shall be a review of that program’s experience by the Program Director to determine what factors produced the substandard results. A report including case by case reviews of all requested deaths and graft losses shall be submitted to the organ specific committee which will in turn report its recommendations to the Program Peer Review Committee.

12) The Program Peer Review Committee will present their evaluation and recommendations back to the Program Director and also to the Board of Trustees. The Program Peer Review Committee or the Organ Specific Committee may recommend an independent review by either an outside consultant or from an OSOTC member program as outline in the Program Review Protocol Policy.
Lung Transplantation Programs

1) The personnel standards and facility requirements shall meet the ODH Quality Rules 3701-84-17, 3701-84-18 and UNOS.

2) All patients undergoing lung transplantation shall be reviewed and approved by the Consortium's Lung Patient Selection Committee.

3) The minimum volume requirement for lung transplant programs shall be 10 per year. If a program performs fewer than 10 lung transplants per year, it will participate in a case-by-case review of all transplants. Any program that has a volume of less than 15 transplants during the reporting period and does not meet survival thresholds will be reviewed based on the last 20 transplants ending the last day of the current review period.

4) The 30 day combined single and double lung patient/graft actual survival rate for the reporting period shall be a minimum of 90%.

5) The 90 day combined single and double lung patient/graft actual survival rate for the reporting period shall be a minimum of 80%.

6) In addition to the actual patient and graft survival rates for 30 days and 90 days, the one-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

7) In addition to the actual patient and graft survival rates for 30 days and 90 days, the three-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

8) Pediatric lung and pediatric heart-lung transplant deaths shall be reviewed on a case-by-case basis in lieu of using the aforementioned volume criteria and survival rates.

9) A new lung transplant program has three years to meet the volume criteria. During that time, all deaths will be reviewed on a case-by-case basis. After the first two years the minimum one-year patient actual survival rate will be a minimum of 70%.

10) If the program does not meet the above standards, there shall be a review of that program’s experience by the Program Director to determine what factors produced the substandard results. A report including case by case reviews of all requested deaths and graft losses shall be submitted to the organ specific committee which will in turn report its recommendations to the Program Peer Review Committee.

11) The Program Peer Review Committee will present their evaluation and recommendations back to the Program Director and also to the Board of Trustees. The Program Peer Review Committee or the Organ Specific Committee may recommend an independent review by either an outside consultant or from an OSOTC member program as outline in the Program Review Protocol Policy.
Liver Transplantation Programs

1) The personnel standards and facility requirements shall meet the ODH Quality Rule 3701-84-17, 3701-84-18 and UNOS.

2) All patients undergoing liver transplantation shall be reviewed and approved by the Consortium's Liver Patient Selection Committee.

3) The minimum volume requirement for livers shall be 10 per year.

4) The 30 day patient/graft actual survival rate for the reporting period shall be a minimum of 92%/88% respectively.

5) In addition to the actual patient and graft survival rates for 30 days, the one-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

6) In addition to the actual patient and graft survival rates for 30 days, the three-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

7) If the program does not meet the above standards, there shall be a review of that program’s experience by the Program Director to determine what factors produced the substandard results. A report including case by case reviews of all requested deaths and graft losses shall be submitted to the organ specific committee which will in turn report its recommendations to the Program Peer Review Committee.

8) The Program Peer Review Committee will present their evaluation and recommendations back to the Program Director and also to the Board of Trustees. The Program Peer Review Committee or the Organ Specific Committee may recommend an independent review by either an outside consultant or from an OSOTC member program as outline in the Program Review Protocol Policy.
Pancreas Transplantation Programs

1) The personnel standards and facility requirements shall meet the ODH Quality Rule 3701-84-17, 3701-84-18 and UNOS.

2) All patients undergoing pancreas transplantation shall be reviewed and approved by the Consortium's Pancreas Patient Selection Committee.

3) No minimum volume is required for pancreas. (Pancreas/kidney combinations and pancreas after kidney transplant patients will be reviewed together as well as pancreas/kidney combination separately.)

4) The 30 day patient survival rate shall be a minimum of 90% and the 30 day graft survival rate shall be a minimum of 80% for the reporting period.

5) The 90 day patient survival rate shall be a minimum of 90% and the 90 day graft survival rate shall be a minimum of 80% for the reporting period.

6) In addition to the actual patient and graft survival rates for 30 days and 90 days, the one-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

7) In addition to the actual patient and graft survival rates for 30 days and 90 days, the three-year patient and graft risk adjusted [observed (O) vs. expected (E)] survival rates from the most recently published Scientific Registry of Transplant Recipients (SRTR) will also be considered as part of the quality review. A program may not meet quality standards and require further review when O/E>1.5, O-E>3 and p<0.05.

8) If the program does not meet the above standards, there shall be a review of that program’s experience by the Program Director to determine what factors produced the substandard results. A report including case by case reviews of all requested deaths and graft losses shall be submitted to the organ specific committee which will in turn report its recommendations to the Program Peer Review Committee.

9) The Program Peer Review Committee will present their evaluation and recommendations back to the Program Director and also to the Board of Trustees. The Program Peer Review Committee or the Organ Specific Committee may recommend an independent review by either an outside consultant or from an OSOTC member program as outline in the Program Review Protocol Policy.
**Program Peer Review**

The Program Peer Review Committee will perform reviews which will be organ specific and address the four following areas:

1) Institutional resources as defined in the Consortium membership standards and described in ODH Quality Rule 3701-84-17 and 3701-84-18.
2) Personnel requirements as defined in the Consortium membership standards and described in ODH Quality Rule 3701-84-17 and 3701-84-18.
3) Maintaining a quality program as defined by meeting or exceeding the threshold for outcome survival as specified in the Organ Specific Quality and Volume Requirements
4) Maintaining the recommended organ-specific patient volume as specified in the Organ Specific Quality and Volume Requirements. (New programs will have two years to meet the minimum volume requirement.)

**Criteria**

Each program shall be reviewed annually. The criteria to be used in review shall be:

1) The Consortium membership standards as they pertain to institutional resources and personnel requirements.
2) Standards as developed by the organ specific Patient Selection Committees for the quality and volume requirements.

**Review Process**

1) Each program in each member hospital shall submit in writing, on the form provided by the OSOTC, a document summarizing their patient activity during the previous year, a list of the transplant team members and their credentials along with other documents demonstrating compliance with the four areas of review to the Program Peer Review Committee noting that the information within is confidential and protected by law (ORD 2305.25, 2305.251) and will comply with all HIPAA standards (45 C.F.R. Part 160 and Part 164).

2) The committee via conference call or face to face meeting will review each program’s report. If the committee determines a program does not meet the volume and/or quality standards, as specified in the ODH Quality Rules 3701-84-16 to 3701-84-21 and/or the OSOTC Policy: Quality and Volume Requirements, the program will be assigned the status of “Active: Under Quality Improvement Plan.”

   a. “Active: Under Quality Improvement Plan”: A program assigned to “Active: Under Quality Improvement Plan” will develop its Quality Improvement Plan under the direction of the Program Peer Review Committee and its organ specific committee.

      i. During the first year of “Active: Under Quality Improvement Plan” the program may continue to perform transplants and shall submit case-by-case reviews of all deaths or graft losses as requested by Program Peer Review Committee at the time of the annual program review as well as semi-annual reports to the organ specific committee documenting implemented improvement measures.

      ii. If a program fails to meet the specified patient or graft survival thresholds for two consecutive years, the Program Peer Review Committee shall direct the program to submit a formal program improvement plan which may include a site visit from either an outside consultant or from an OSOTC member program. The program will have three months to submit said program improvement plan from the date of the Program Peer Review Committee request.

   b. A program will remain under the “Active: Under Quality Improvement Plan” until such time as the volume and/or quality measures are met. The Program Peer Review Committee with provide the Board of Trustees and ODH representatives of the status of the Improvement Plan. The ODH may require additional independent review according to ODH quality rules.
3) The OSOTC Board at its April Meeting will review the Program Peer Review Committee’s recommendations on which programs have satisfactorily met standards as well as how programs with deficiencies should be addressed. The Board will then confirm which programs are in compliance with the OSOTC standards and direct the Board of Trustees Chairman to notify programs of their “Member in Good Standing,” including program status, annually.

4) The Board will ultimately rule on whether a program remains “Active,” is assigned "Active: Under Quality Improvement Plan" or made "Inactive," as specified in the **Code of Regulations**, (ii Program Status).

5) Appeals will be made to an ad hoc Appeals Board which will consist of three members:
   a. The Chairman of the Consortium's Board of Trustees
   b. An expert named by the appellant
   c. An expert named by the Consortium's Board of Trustees in consultation with the Program Peer Review Committee

6) All decisions made by the ad hoc Appeals Board shall be binding.

**Temporary Program Suspension**

If a program temporarily suspends services, that program must:

1) Inform the Consortium of the hiatus
2) Advise the Program Peer Review Committee chairman of the hiatus
3) Submit documentation to the Consortium that its patients have been advised of the hiatus and arrangements for urgent patients have made, i.e., listing them with another center
4) Advise the Program Peer Review Committee in writing when they wish to restart services

As part of the ongoing quality assurance standards, this committee will do a yearly review of the Consortium's data in aggregate. Factors to be reviewed will include survival rates, average length of stay, days in an ICU and/or step down unit, etc. This committee will issue a report summarizing the Consortium's experience and it will be included in the Consortium's Annual Report.
NEW TECHNOLOGY EVALUATION CRITERIA

1) The scientific evidence available and reported upon during the review must be sufficient to permit conclusions about the benefit of the technology on health outcomes:
   a. The evidence should consist of well designed, scientific investigations published in peer-reviewed journals. The quality of studies and the consistency of their results are integral parts in appraising and assessing the evidence.
   b. There shall be evidence or a convincing argument, based on established medical facts that the technology can: (1) alter the physiological changes related to a disease, injury or illness and (2) such alteration affects the health outcome.
   c. Opinions and evaluations by national medical associations, consensus panels or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

2) The technology must improve the net health outcome: The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

3) The technology must be as beneficial as any established alternatives: The technology should improve the net health outcome as much as or more than established alternatives.
CUSHION FUND GRANTS

Patient Assistance Grants
Grants from the Cushion Fund will be awarded to assist extra-renal transplant recipients with non-reimbursable medical expenses such as anti-rejection medications. Medication grants are limited to $1,500.00 per patient, per year.

The total amount of money awarded in patient assistance grants in any one year will not exceed the interest accrued on the previous year plus 5% of the principle.

Eligibility
Patients eligible to apply must have received their transplant at a Consortium hospital and must have a functioning extra-renal transplanted organ.

Process
Social Worker and patient complete the standardized form and forward to the Consortium office. The statewide Cushion Fund Committee that reviews the requests consists of the Executive Committee and the Director of the Ohio Department of Health or his/her designee.

Upon Approval
If the grant request is approved, a check is sent to the institution’s social worker who then forwards it to the pharmacy that will be dispensing the medications. A check is never made payable directly to the patient. The approval process generally takes one month. Upon receipt of the check, the institution will respond in writing that the check was received and the purpose for which the funds are to be used. The acknowledgment is necessary for the OSOTC financial audit.

Unused Grant Monies
If insurance coverage is received for any part of the grant item or if a patient dies before the total grant amount is used, the unused portion shall be returned to the Consortium office for deposit back into the Cushion Fund.

Discretionary Fund
The Board of Trustees shall set aside 5% of the money available annually to be used for other emergency situations according to the discretion of the Cushion Fund Committee. Individual grants for emergency care shall not exceed $500.

Non-Patient Specific Grants
Monies from the Cushion Fund may also be designated to support non-patient specific endeavors as chosen by a majority vote of the Board of Trustees that, in general, benefit Ohio transplant patient well-being, transplant awareness and education, or promote organ donation.

Collaborative Research Grants

Purpose
This research initiative is intended to identify and establish new or novel projects that focus on supporting multi-institution collaborative research projects focusing on heart, lung, heart-lung, liver, pancreas, pancreas/kidney or small bowel transplantation in Ohio with the ultimate goal of improving public health.

Eligibility Requirements
Applications will only be accepted from OSOTC member hospital organizations. The Principal Investigator (PI) shall be a current transplant professional at an OSOTC member hospital. OSOTC organ-specific committees are also encouraged to apply.

Mechanisms of Support
The OSOTC Cushion Fund may provide up to $25,000 per year to fund research grants as determined by the Board of Directors. Multiple grants of varying amounts may be awarded for a total amount of $25,000 annually. The use of OSOTC funding for personnel costs is strongly discouraged. Grant awards may be renewable after the first year based on the project progress.

**Deadline for Applications**
To be determined annually by the Board of Directors

**Research Objectives**
The OSOTC is interested in receiving applications to conduct multi-disciplinary collaborative research in clinical, translational, psychosocial or other areas closely related to transplantation. For this application, collaborative research is defined as the joint application of at least two OSOTC centers with a strong preference for three or more centers involved. OSOTC organ-specific committees are also encouraged to apply.

a) Translational projects: the application of discoveries from basic biomedical, behavioral research towards the treatment or prevention of transplant related disease with a goal of improving the health of transplant patients

b) Clinical research: patient oriented research conducted with human subjects or human materials for which an investigator directly interacts with human subjects or epidemiologic and behavioral studies, outcomes research and health services research

c) Psychosocial projects: patient oriented research focusing on psychological, social and ethical issues in transplant to create an improved quality of life for transplant patients

**Application Procedures**
Applications will not be formally reviewed until the OSOTC receives a complete application, consisting of three documents: (1) A research plan that addresses each of the elements listed on the “Application to OSOTC for Research Funding” form; (2) The curriculum vitae of the primary investigator (PI) designated on the Application; and (3) the IRB letter of approval, if applicable. If IRB approval is not in place, please send IRB letter after grant approval, if applicable. IRB status has no bearing on grant review.

The original application and one copy must be mailed to:
Ohio Solid Organ Transplantation Consortium
Attn: Collaborative Research Grants
9200 Memorial Drive
Plain City, OH 43064

**Review Considerations**
Applications will be reviewed by the organ-specific committee deemed appropriate by the OSOTC Executive Committee or an external review may be more appropriate. In the event that external review is necessary the PI will be asked to name two external reviewers with expertise in the field with contact information. The review criteria are the traditional considerations underlyiing scientific merit. Applications will be reviewed for scientific and technical merit. Applications compete on the basis of scientific merit. Applications will be approved as is, preliminarily approved pending requested changes, held for further information, or denied by majority vote of the OSOTC Executive Committee. The OSOTC Board of Trustees will provide final determination at their quarterly Board meetings.

**Award Criteria**
Applications will compete for available funds with all other approved applications to the OSOTC. The following will be considered in making funding decisions:

a) Quality of the proposed project as determined by peer review
b) Availability of funds
c) Program balance among research areas of the announcement
Review Criteria
Applications will be reviewed using the following categories and point assignment for a total of 100 points possible:

Executive Summary: 5 points
- Is the summary concise, constructive and clearly addresses all of the review criteria?

Significance/Problem and Needs Assessment: 15 points
- Does the study address an important problem broadly related to transplantation?
- If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
- What will be the effect of these studies on the concepts, methods, and technologies that drive this field?

Well Defined Target Population: 5 points
- Is the target population well justified?
- Does the project target potential transplant candidates, potential recipients, or patients with end stage organ specific diseases?
- Does the project target heart, lung, heart-lung, liver, pancreas or pancreas/kidney transplant related issues?

Project Goals/Objectives: 20 points
- Are the goals and objectives clearly defined and measurable?
- Does the project have statewide or national potential impact – is project replicable?
- Is the project consistent with the OSOTC mission (clarify specific purpose(s))?

Approach/Methodology: 25 points
- Are the conceptual framework, design, methods and analyses adequately developed, well integrated, well reasoned, feasible (as determined by preliminary data) and appropriate to the aims of the project?
- Is the timeline is realistic and appropriate?
- Are the projected budget and other resources (e.g. personnel and facilities etc) appropriate and adequate and tie closely to the project objectives?
- Does the application specify in-kind support?

Innovation and Collaboration: 20 points
- Is the project original and innovative?
- Does the project challenge existing paradigms and address an innovative hypothesis or critical barrier to progress in the field?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- Does the project demonstrate collaboration of at least two OSOTC transplant programs?
- Does the project demonstrate collaboration of three or more OSOTC transplant programs?

Investigator: 5 points
- Is the investigator appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to the experience level of the principal investigator and other researchers?
- Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Evaluation: 5 points
- Is the potential impact of the project well defined?
- Does the evaluation plan appropriately correspond with project objectives and methodologies?
• Does the project include an evaluation timeline?

Deliverables
The PI must agree to provide the OSOTC with a copy of each substantive presentation or article based on the data set prior to its public release. PI must also agree to present research outcomes at the OSOTC Research Collaborative Meeting or alternately, an OSOTC Board meeting.

INQUIRIES
Jennifer Dorrell
Executive Director
Ohio Solid Organ Transplantation Consortium
9200 Memorial Drive
Plain City, OH 43064
E-mail: Jennifer@osotc.org
Phone: (614) 504-5705
Fax: (614) 504-5707
STATEMENT OF UNDERSTANDING OF POLICY CONCERNING PUBLICATIONS AND PRESENTATIONS

Individuals or institutions wishing to conduct a study or review of data held by the OSOTC must submit a brief written proposal specifying the hypothesis and requesting specific data points. Upon approval by the Organ Specific Committee of the research proposal or manuscript outline, the OSOTC office will provide the investigator with the minimum necessary data in a limited data set, without patient names, social security numbers, birth date, transplant date, institutional name or any other identifier. Investigators are encouraged to collaborate with a statistician in the analysis of the data and preparation of the manuscript. Results are to be presented in aggregate unless prior approval to present institution-specific results is obtained. When institution-specific results are presented, institutions are to be identified by letter (A, B, C, etc.) rather than name and may be reported in percentages instead of actual numbers. Under no circumstances will individual patients be identified or will their identities be included in any report. Abstracts and manuscripts must be reviewed by all participating transplant programs before submission for publication or consideration for an oral or written presentation. To insure adequate review time, abstracts must be delivered to reviewers at least two days before submission deadlines. Investigators should allow at least 7 days for manuscript reviews.

All publications must acknowledge the OSOTC and its participating institutions with each program identifying its representatives as a co-author. Manuscripts initiated by the Executive Committee will also list the members of the OSOTC Executive Board.

Clinical Trials
When a program plans to institute a clinical trial, it shall present to the appropriate Patient Selection Committee its proposal for approval in advance of commencing the series. Upon approval by the Committee, the proposal shall be considered by the Board at its next scheduled meeting. However, the clinical study may begin prior to the Board's approval.
POLICY ON DATA COLLECTION FOR STATEWIDE PATIENT DATABASE

The following information is collected to build a statewide extra-renal database for the Consortium. Types of data and due dates are included for your convenience.

Clinical Data
The INITIAL DISCHARGE FOR ALL TRANSPLANT RECIPIENTS FORM (Initial Form) is to be completed at the time of the patient's discharge or death (when death date is discharge date) following transplant. If you are reporting a patient's second or third transplant, use the same form and label it TX#2, TX#3, etc.

The ANNUAL FOLLOW-UP FORM FOR ALL TRANSPLANT RECIPIENTS (Annual Form) is to be completed on, or shortly after, the patient's transplant anniversary date for the first two years and/or at the time of death.

If a copy of the UNOS form is submitted, the patient's marital status needs to be included. The Consortium office will make periodic checks to ensure that forms are received on a timely basis. If forms are missing, a reminder will be issued.