I. Purpose

To describe the process of education and obtaining informed consent, ensuring medical, psychosocial, and financial appropriateness of potential kidney, kidney-pancreas, and pancreas transplant candidates in accordance with the center's established selection criteria.

II. Policy Statement

All potential kidney, kidney-pancreas and pancreas transplant candidates shall undergo a multidisciplinary evaluation to ascertain their psychological and physiological status. This includes, but not limited to, a medical, psychosocial, and financial evaluation prior to selection and subsequent registration on the transplant waiting list. The UCI Health Ethics Committee shall be consulted when there are conflicts with treatment and personal values.

All patients will be treated with consideration, dignity, and respect. In accordance with UCI Health Medical Center policy, the Division of Transplantation shall provide fair and non-discriminatory process for determining suitability for transplantation and organ acceptance, and provide impartial access to treatment regardless of race, religion, sex, ethnicity, or handicap. Potential transplant candidates may be ruled out at any time during the evaluation process for any medical or psychosocial contraindications that may be identified. Candidates must be approved in accordance with the center's established selection criteria. A copy of the selection criteria will be provided upon the patient's or dialysis center's request.

III. Roles and Responsibilities of the Pre-Transplant Team

1. **Administrative Assistant**
   - Completes the intake process for all patients referred for transplant evaluation
   - Assists the Transplant Nurse Coordinators in the coordination of the evaluation process
   - Schedules the prospective candidate for transplant education class and initial clinic visit as indicated
   - Schedules the candidate for the complete transplant evaluation, clinic visits, and consultations as indicated
2. **Transplant Nurse Coordinator**
   - Directs, coordinates, and facilitates the evaluation process
   - Provides education regarding the evaluation process, the risks and benefits of transplantation, alternative treatment options, the surgical procedure, post-surgery care and patient rights.
   - Obtains clinical information from the dialysis center, referring physician, or other medical professionals
   - Reviews results of all laboratory and diagnostic testing and consultation referral notes
   - Compiles and presents all results, reports, and recommendations to the Selection Committee
3. **Transplant Surgeon**
   - Directs and coordinates the evaluation process in collaboration with the Transplant Nurse Coordinator
   - Interviews the candidate to assess motivation and medical suitability
   - Reviews results of all laboratory and diagnostic testing to assess the need for

further evaluation and medical suitability
- Provides education regarding the transplant surgery, risks and benefits of surgery as well as pre- and post-surgery care instructions
- Refers the candidate for specialty consultations as needed

4. **Transplant Nephrologist**
   - Advises on the evaluation process in collaboration with the Transplant Nurse Coordinator and Transplant Surgeon
   - Interviews the candidate to assess motivation and medical suitability
   - Reviews results of all laboratory and diagnostic testing to assess the need for further evaluation and medical suitability
   - Provides education regarding kidney health, risks and benefits of transplantation, and alternative treatment options
   - Refers the candidate for specialty consultations as needed
5. **Nurse Practitioner/Physician Assistant**
   - Advises on the evaluation process in collaboration with the Transplant Nurse Coordinator, Transplant Surgeon and Transplant Nephrologist
   - Reviews results of all laboratory and diagnostic testing to assess the need for further evaluation and medical suitability
   - Provides education regarding kidney health, risks and benefits of transplantation, and alternative treatment options
   - Refers the candidate for specialty consultations as needed
6. **Social Worker**
   - Completes a comprehensive psychosocial evaluation of the candidate
   - The Clinical Social Worker will provide referrals to appropriate resources for patients and families, as necessary
   - Refers the candidate for specialty consultations as needed
7. **Dietitian**
   - Assesses candidate's level of nutritional health, special diet, if any, and nutritional issues.
   - Assures that the nutritional needs of candidates are assessed and addressed prior to, during, and after transplantation
   - If appropriate, dietitian will refer the patient to the dialysis dietitian and/or referring physician for further nutritional needs
8. **Pharmacist**
   - Provides comprehensive pharmaceutical assessment of transplant candidate.
9. **Financial Coordinator**
   - Obtains pre-authorization for the initial consult and transplant evaluation
     i. Financial eligibility must be confirmed prior to scheduling of tests or procedure
   - Obtains pre-authorization for transplant services for candidates approved to be registered on the waiting list, as needed.
   - Educates candidates on the general costs related to the evaluation, transplant surgery and post-transplant care.
   - Provides resources for candidates to determine the estimated costs related to the evaluation, transplant surgery and post-transplant care, for any services that are the responsibility of the candidate's insurance and require authorization from the insurer before they occur.
     i. It is the patient's responsibility to maintain adequate insurance to cover and/or mitigate the costs of the evaluation, transplant surgery and post-

transplant care including medications needed after transplantation.

IV. Patient Confidentiality

Strict privacy and confidentiality shall be given to each potential candidate during the evaluation, waiting time, surgery and post-op process.

V. Education and Informed consent of Potential Transplant Candidates

Potential transplant candidates and their families are provided education through a variety of media to meet their learning needs, abilities, and preferences. These include but are not limited to written material, digital media, pictorial handouts; interpreters, to aid in communication over language barriers; recognized website material (OPTN/UNOS); and class instruction. Education content will include but is not limited to:

- The evaluation and candidate selection process
- Benefits and risks of transplantation
- Alternative treatment options
- Option to list at multiple transplant centers

The transplant multidisciplinary team shall provide ongoing opportunities for discussion and education at all stages of the transplant evaluation.
The Pre-Transplant team must obtain documentation of informed consent to proceed with evaluation.

VI. Indication for Transplantation

The goal of the transplant program at UCI Health is to provide transplantation to the individuals who will obtain the maximum benefit from the procedure. Specific indications for transplant include but are not limited to the following:

Indications for Kidney Transplantation
Patient has end stage renal disease (ESRD) and is on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD) ***or***
Patient has chronic kidney disease (CKD) evidenced by calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 mL/min/1.73m2 ***or***
Patient has chronic kidney disease (CKD) with a calculated GFR (Cockcroft-Gault or other reliable formula) of less than 30 mL/min/1.73m2 with anticipated progression to kidney failure ***and***
Patient is over 18 years of age.
Indications for Kidney-Pancreas Transplantation
Patient has end stage renal disease (ESRD) and is on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD) ***or***
Patient has chronic kidney disease (CKD) evidenced by calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 mL/min/1.73m2 ***or***
Patient has chronic kidney disease (CKD) with a calculated GFR (Cockcroft-Gault or other reliable formula) of less than 30 mL/min/1.73m2 with anticipated progression to kidney failure ***and***
Pancreatic exocrine insufficiency with renal insufficiency ***and***
Diagnosis of Type 1 diabetes mellitus or type 2 diabetes and is insulin dependent ***and***
Require the transplantation of a pancreas as part of a multi-organ transplant for technical reasons ***and***
Is between 18 and 55-years-of-age

Indications for Pancreas Transplantation
Have been evaluated for suitability of other appropriate medical and surgical therapies that may yield short- and long-term survival comparable to transplantation
Patients referred for pancreas transplant alone must have a history of hypoglycemia unawareness.
Pancreatic exocrine insufficiency
Diagnosis of Type 1 diabetes mellitus or type 2 diabetes and is insulin dependent
Secondary complications such as diabetic neuropathy, retinopathy or vasculopathy
Is between 18 and 55-years-of-age

VII. Evaluation of Potential Transplant Candidates

All potential kidney, kidney-pancreas and pancreas transplant candidates shall undergo a multidisciplinary evaluation to ascertain the psychological and physiological status. This includes, but not limited to, a medical, psychosocial and financial evaluation prior to selection and subsequent registration on the transplant waiting list. The transplant team will notify the dialysis center and referring nephrologist of the patient's transplant status and communicate intermediate updates as necessary to ensure efficient care and management.

1. *Patient Referral and Intake*

Any patient referred to UCI Health for evaluation of kidney, kidney-pancreas and pancreas transplant candidacy will be contacted by the pre-transplant administrative assistants to obtain necessary information (intake) in order to begin the evaluation process. The administrative assistant may also obtain clinical information from the dialysis center, referring physician, or other medical professionals. Once clinical information or medical records are obtained, the initial evaluation period formally begins.

Potential candidates who meet the following criteria can be reviewed by the appropriate transplant team member for screening prior to proceeding with the evaluation:

- Over 70 years old
- History of cancer
- Cardiac history
- BMI > 40
- History of psychosocial issues
- History of mental illness or disorders

Following to intake process, the patient's referral will be forwarded to the financial coordinator to confirm financial eligibility and to request preauthorization for consultation and further evaluation. Once financial eligibility is verified and preauthorization is granted from the potential candidate's insurance, the administrative assistant will schedule the patient for consultation and further evaluation.

2. *Medical Evaluation*

The potential transplant candidate must be evaluated by the following members of the transplant team to determine initial acceptability:

- Transplant Nurse Coordinator

- Transplant Nephrologist *or* Transplant Surgeon
- Social Worker
- Dietitian
- Pharmacist

Additional evaluations may be performed by the following to determine initial acceptability:

- Nurse Practitioner/Physician's Assistant

If the potential transplant candidate meets the initial acceptability criteria the candidate will proceed with the comprehensive testing required or requested by the transplant team.

Results of recently performed tests may be accepted at the discretion of the transplant team. The transplant team may require additional testing or consultations at their discretion.

Endocrinology Assessment will be obtained if initial HbA1c > 8%

At *minimum*, the following tests are required as part of the medical evaluation:

Laboratory Testing

ABO typing (X 2), Candidates with B blood type require Anti-A Isoagglutinin Titer in the event of an identified potential A2 (A, non-A1) or A2B living donor.	Hepatitis panel
HLA A, B, C, DR and DQ typing	HIV
cPRA level	RPR/Syphilis
CMP (including calculated GFR)	Epstein-Barr virus
CBC with differential	CMV IgG and IgM
Magnesium	HSV I/II, IgG and IgM
Phosphorous	Varicella
PT, PTT	Cocci
Lipid panel	Toxoplasmosis
Liver Panel	Chagas
Serum Free Light Chains > 60 years of age	TB Quantiferon Gold
Toxicology screening	Pregnancy test for females 18-55 years of age
Urinalysis, if still urinating	PSA for males > 40 years of age
HgA1c, if diabetic	Kappa Lambda >60
Hypercoagulation panel as indicated	Strongyloides IGG
Parathyroid Hormone Level (PTH)	West Nile IGG &IGM

Diagnostic Testing

Chest X-ray	EKG
Abdominal Ultrasound or CT Scan ABD/Pelvis without contrast	Echo
	Cardiac Stress

Patients being considered for combined kidney-pancreas transplant candidacy must also complete the following tests:

Amylase	C-peptide
Lipase	

The following health maintenance is recommended in accordance with national guidelines by the transplant team but is **not** required prior to candidate selection or registration on the waiting list *unless* specified by the transplant team:

Health Maintenance Testing

Pap smear for women > 18 years of age, who have not undergone a hysterectomy	Bilateral mammogram for women > 45 years of age or family history of breast cancer.

Colonoscopy > 45 years of age	
Prostate screening for men > 40 years of age	

3. Psychosocial Evaluation

The psychosocial evaluation is conducted by a Licensed Clinical Social Worker with experience in transplantation to determine if there are any pre- or post-transplantation emotional concerns or needs, to assess decision making capacity and to screen for any potential mental health issues.

The psychosocial evaluation must include the following components:

- **i.** Review the occupation, employment status, health insurance status, living arrangements, and social support of the potential recipient
- **ii.** Assess history of smoking, alcohol, and drug use/abuse and dependency.
- **iii.** Identify factors that warrant educational or therapeutic intervention prior to final transplantation decision including recommending a psychiatric consult when necessary.
- **iv.** Determine that the potential candidate understands the short and long-term medical and psychosocial risks associated with transplantation.
- **v.** Assess the potential candidate's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes the potential recipient having a realistic plan for surgery and recovery with social, emotional and financial support available as recommended.
- **vi.** Assess for any psychosocial issues that might complicate the candidate's recovery and identify potential risks for poor psychosocial outcome.
- **vii.** Summarize the psychosocial assessment and make recommendations to the transplant team and Selection Committee

Psychosocial evaluations are deemed current in accordance with the center's risk stratification protocol. Additionally, minimum recommended follow up and referral procedures for transplant candidates that require additional consultation or evaluation are outlined in the center's risk stratification protocol.

VIII. Selection Committee

All potential candidates will be presented at the Transplant Selection Committee for review. A candidate may be presented to the Transplant Selection Committee at any time in the process by any member of the interdisciplinary team. Upon presentation, the following members of the interdisciplinary team are expected to provide their individual assessment and recommendations pertaining to a patient's candidacy:

- Transplant Nurse Coordinator
- Transplant Surgeon
- Transplant Nephrologist
- Social Worker

- Dietitian
- Pharmacist

Additional assessments and recommendations may be presented by the following members to determine candidacy:

- Nurse Practitioner/Physician's Assistant

The transplant team may determine that a potential candidate is not a suitable candidate at any time during the evaluation, based on the established selection criteria. Each transplant center has its own set criteria for potential transplant candidates; therefore, even if a potential candidate is deemed unsuitable by the transplant team at UCI, they may qualify for transplant at another center.

The Selection Committee may recommend that additional evaluation, including testing or consultations, be required before final determination on candidacy or for continued candidacy following registration on the waiting list.

Approved candidates are re-evaluated per waitlist management policy to ensure they are still able to tolerate and maintain a successful transplant should an organ become available. Candidates deemed higher risk may be required to return annually.

All Selection Committee decisions will be documented in the patient's medical record. The referring physician and, when applicable, dialysis center and case manager will be notified of the Selection Committee's decision. The candidate will be informed of the Committee's decision, at a minimum, by letter and when deemed appropriate by the committee, by phone or in person as well. Patients deemed appropriate candidates for listing and patients deemed no longer appropriate for listing will receive written correspondence in accordance with the UCI Waitlist Registration, Modification and Removal policy. Patients deemed "not a candidate" will receive written correspondence accompanied by the *OPTN Contractor's Patient Information Letter* within 10 days of the Selection Committee's determination.

Contraindications to Transplantation

Some factors, medical or social, make the possibility of a successful kidney, kidney-pancreas, and pancreas transplant unlikely. The following factors are carefully considered during the transplant evaluation and ***may*** exclude a patient from candidacy:

Relative Contraindications for Kidney, Kidney-Pancreas and Pancreas Transplantation

Active infection	Any active infection
Age	Advanced age patients will be evaluated on a case-by-case basis.
Alcohol and Tobacco use	Will be evaluated on a case-by-case basis by the surgeon; use may be determined an absolute contraindication in patients with multiple risk factors.

Chronic Infection	Examples include: ● Diabetic foot ulcers must be free of infection ● Active Tuberculosis (TB) requires a full course of therapy and, preferably, 1 year of subsequent observation for relapse (prior TB is not a contraindication) ● Active coccidiomycosis (cocci) (Prior Cocci will require long-term fluconazole therapy after transplant) ● Chronic active or persistent hepatitis. History of hepatitis B or C may be transplanted if not active hepatic process. Hepatitis B & C patients need to be informed by their nephrologist regarding the possible increase risk of liver disease
Chronic liver disease (biopsy proven cirrhosis)	Patient must be evaluated by hepatology ● Patients must not have advanced disease beyond mild stage II on liver biopsy

High Risk or Recurrent Renal Disease	High risk or recurrent renal diseases will be evaluated on a case-by-case basis. Examples include: ● Oxalosis ● Fabry's Disease ● Amyloidosis ● FSGS
HIV positive	As per HIV Protocol
Noncompliance to current medical regime	This will be determined by the LCSW during the psychosocial evaluation and discussed by the Selection Committee.
Obesity	● Patients with centralized or abdominal obesity ● BMI > 35kg/m2; a BMI of > 40 may be listed with guidelines for weight loss and, when appropriate, referred to bariatric surgery. ● BMI 35 to 40 kg/m2 can be listed with guidelines for weightless. ● In order to accrue waiting time, BMI may not exceed 32 $kg/m^2$for Kidney-Pancreas or Pancreatic Patients
Peripheral vascular disease	● Claudication and rest ischemia should be evaluated before transplant ● History of significant cerebrovascular disease, such as TIAs and/or CVAs within the past 12 months should result in carotid duplex and treatment as appropriate by current vascular surgery standard.
Recent Malignancy	Past medical history of malignancy will be evaluated on a case-by-case basis. Consultation with hematology/oncology may be required. Generally, a 2-year disease-free interval after the treatment of a malignant tumor is required unless indicated.

Functional Status	Patients with diminished functional capacity have reduced physical reserves to withstand major surgery. This will be determined on a case-by-case basis.

Any situation causing the inability of the patient to achieve adequate post-transplant follow-up care.

Some factors, medical or social, make kidney, kidney-pancreas, and pancreas transplant non-beneficial or even unsafe. The following factors are carefully considered during the transplant evaluation and ***always*** exclude a patient from candidacy:

Absolute Contraindications for Kidney, Kidney-Pancreas and Pancreas Transplantation

Alcohol or Drug Addiction	Active drug abuse
Psychiatric Illnesses	Patients with active or unstable psychosis, dementia and recent suicide attempts are not transplant candidates. Social Work will refer for evaluation and treatment.
Chronic lung disease	● Patients requiring portable or nocturnal oxygen are not candidates.
Complex Cardiac Needs	● Severe or inoperable cardiac disease ● Left ventricular ejection fraction < 30% (patient with non-ischemic cardiomyopathy may still be considered) ● Uncontrolled cardiac arrhythmias
Current malignancy	Past medical history of malignancy will be evaluated on a case-by-case basis.
Persistent coagulation disorder	Examples include: ● Hemolytic Uremic Syndrome ● Disseminated Intravascular Coagulation ● Immune Thrombocytopenic Purpura

If a patient is deemed an appropriate candidate and is cleared from a medical, surgical, psychosocial, and financial perspective, the candidate will be registered on the UNOS waiting list.

Any deviations or exceptions to the acceptability criteria (such as advanced age in conjunction with multiple comorbidities, weight, or clinical condition), indications and contraindications for transplant must be approved by the Selection Committee and documented in the patient's medical record.

REFERENCES:

OPTN Policy 3.5: Patient Notification
CMS, Conditions of Participation, 482.9 "Patient and Living Donor Selection" CMS, Conditions of Participation, 482.102 "Patient and Living Donor Rights" CMS, Conditions of Participation, 482.98 "Human Resources"
OPTN Policy 3, "Candidate Registrations, Modifications and Removal