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🌐 Donor Eligibility Criteria and Pancreas Recovery for HuBMAP TMC-PNNL-UF V.2

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Human BioMolecular Atlas Program (HuBMAP) Method Development Community

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This document outlines inclusion and exclusion criteria for pancreas donors for the Human BioMolecular Atlas Program (HuBMAP) by the Tissue Mapping Center (TMC) at the University of Florida and pancreas recovery procedures to be conducted by the Organ Procurement Organization Recovery Team.

A member of the HuBMAP TMC-PNNL-UF team will accept pancreas offers using standardized inclusion and exclusion criteria for equal numbers of female and male donor with consideration for transportation issues that could delay receipt at the University of Florida.

Redacted documents pertinent to donor and hospitalization course will be obtained and data entered into HuBMAP HIVE portal.

Donor and Tissue Eligibility, HuBMAP, pancreas donor

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Negative testing for COVID-19, HIV, hepatitis, and other transmissible diseases.

Testing of donors and recovery and organ shipping will meet standards of 42 CFR § 486.346 - Condition: Organ preparation and transport.

Consent for research donation of pancreas is obtained from donor or authorized next of kin.

1 Acceptance Criteria

1.1 Inclusions
- Age range: 18-40 years
- Equal number of female and male donors will be accepted
- All race and ethnicity are eligible
- BMI <28
- Cause of death due to brain death (excludes donor after cardiac death (DCD))
- ICU time <6 days
- Reason pancreas was declined for transplantation may factor into acceptance.
- Negative for sepsis (bacterial infection, meningitis) or MRSA+ culture
- Serologies
  - Required 2020 testing for COVID-19
  - Negative for COVID-19, HIV, Hepatitis B or C virus, CMV or EBV.
- Ischemia times
  Warm ischemia time (WIT) < 60 minutes
  Cold ischemia time (CIT) < 18 hours

1.2 Exclusions
- Diabetes, pancreatitis, Cystic Fibrosis, or other diseases of the pancreas

- Chronic moderate to severe cardiac, pulmonary, hepatic or renal disease
- High risk behaviors related to sexual activities, drug or heavy alcohol use
- Jail time during preceding 3 months
- Abdominal CT scans show pancreatic lesions or calcifications

2   Pancreas recovery

2.1   Visual inspection in the operating room shows no pancreas abnormalities such as bruising (hematoma) or calcification.

Pancreas can be recovered without transection or pieces removed for recovery of vessels for liver transplantation

Sample includes
- Attached proximal duodenum with both ends closed by staple or suture
- Attached portion of spleen
- Attached peripancreatic fat and vessels

2.2   Pancreas recovered < 4 hours of cross-clamp time.

2.3   Organ Procurement Organization Recovery Team obtains pancreas and attached organs and places in chilled shipping media (UW, HTK or similar) in screw-top plastic container. Securely closed container is placed on ample ice to ensure chilling during transportation. Organ is triple-bagged and shipped in properly labeled shipment box by standard courier.

Recovery Team package and ship according to standard organ requirements.

3   Documentation

3.1   Redacted copies of documents will be sent in organ transport box or electronically by email to HPAP-Pancreas TMA team member.

Donor forms, including serology test results, toxicology screen, emergency room and hospitalization notes, OR management sheets, and medical and social history forms.

Donation for Research Consent Form.

3.2

Abdominal CT scan access will be requested. When provided, research staff will follow HIPAA requirements for access to records with PHI.