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Determining IIDP Minimal Donor Criteria V.4

Integrated Islet Distribution Program¹

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ABSTRACT

This SOP defines the pancreas donor profile acceptable for use in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) sponsored research in the Integrated Islet Distribution Program (IIDP). This SOP applies to all IIDP islet distribution centers using funds from the NIDDK to manufacture purified human pancreatic islets for basic research studies for IIDP approved investigators.

Note

Integrated Islet Distribution Program (IIDP) (RRID:SCR_014387)

The IIDP depends on the subcontracted human islet isolation centers to provide research investigators with human islets. It is the responsibility of the human islet centers to obtain research quality pancreata from the Organ Procurement Organizations (OPO). Some criteria are stricter than those used by transplant centers for organ transplant donors. This protocol provides the inclusion and exclusion criteria in order to determine the proper parameters for research donors.


The donor criteria also reflects the required 2020 testing for COVID-19. Positive testing for COVID-19, HIV, Hepatitis C, and Hepatitis B are examples of some exclusion criteria.

References (attached)

- [Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection – U.S. Public Health Service Guideline, 2020](#) (Click on hyperlink pop-up)
-  [optn_policies 3_17_23.pdf](#) Policies - OPTN (hrsa.gov); Policy 2, 5, 11 (Click on hyperlink pop-up or pdf)

GUIDELINES

OPO Organ Acceptance Criteria

- Each organ procurement organization (OPO) must establish criteria for an acceptable deceased donor or deceased donor organ for the transplant programs in its Donation Service Area (DSA). More information is included in the attached [OPTN Policy last updated 3/16/23](#).  [optn_policies 3_17_23.pdf](#)

Center Responsibilities

- This SOP applies to all IIDP islet distribution centers using funds from the NIDDK to manufacture purified human pancreatic islets for basic research studies for IIDP approved investigators.
- It is the responsibility of the IIDP Islet Isolation Center to both follow and ensure adherence to the donor criteria outlined in this SOP prior to acceptance of pancreata.
- It is the responsibility of the IIDP Islet Isolation Center to verify that the donor criteria provided by the Organ Procurement Center (OPO) on the paperwork accompanying the pancreata is accurate before the isolation.

Definitions

- ***Integrated Islet Distribution Program (IIDP) (RRID:SCR_014387)***: The IIDP is a contracted program commissioned and funded by the NIDDK to provide quality human islets to the diabetes research community to advance scientific discoveries and translational medicine. The IIDP consists of the NIDDK, the Project Officer (PO), the External Evaluation Committee (EEC) and the CC at City of Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.
- ***IIDP Coordinating Center (CC)***: Joyce Niland, Ph.D. is the Principal Investigator for the IIDP CC and leads staff from the Department of Research Information Sciences at COH to coordinate the activities of the IIDP and assist the participating centers and investigators in the distribution of human islets.
- ***Organ Procurement Organizations (OPO)***: Organ Procurement Organizations (OPOs) are not-for-profit organizations responsible for recovering organs from deceased donors for transplantation in the U.S. There are 58 OPOs, each mandated by federal law to perform this life-saving mission in their assigned donation service area.

I. IIDP Donor Inclusion Criteria

1 The following are IIDP Inclusion Criteria for Pancreas Donors for Human Islet Isolation:

- 1.1** A multi-organ donor or pancreas-only donor if the donor meets all the criteria for multi-organ donation
- 1.2** Adequate *in situ* hypothermic perfusion using UW or similar organ preservation solution for perfusion and cold storage
- 1.3** Maximum 18-hour cold ischemia
- 1.4** Donor age of 0 years to 75 years (no minimum age)
- 1.5** Duration of life support < 14 days
- 1.6** Warm ischemia / Down time < 60 minutes (including cardiac arrests)
- 1.7** Body Mass Index (BMI) of 10-50 kg/m²

II. General Donor Preclusions / Exclusions

2 The following are frequently encountered disease states or other conditions which constitutes rejection of a potential donor:

2.1 Clinical or active viral Hepatitis (A, B, or C)

2.2 Acquired Immunodeficiency Syndrome (AIDS)

2.3 HIV seropositivity (HIV-I or HIV-II)

2.4 Syphilis

2.5 Active viral encephalitis or encephalitis of unknown origin

2.6 Creutzfeldt–Jacob Disease

2.7 Rabies

- 2.8** Recently treated (last 2 years) or active Tuberculosis
- 2.9** Untreated septicemia
- 2.10** Malignancies except primary brain tumors or non-melanoma of the skin
- 2.11** Serious illness of unknown etiology as the cause of death
- 2.12** EBV IgM positive
- 2.13** CMV IgM positive
- 2.14** Toxoplasma Immunoglobulin G (IgG) positive
- 2.15** COVID 19 (Sars-CoV-2 test) positive active infection at time of donation (*As of May 1, 2020 the IIDP is requiring negative testing for COVID-19 for all IIDP pancreas donors*)
- Evidence of previous positive donor COVID-19 testing >28 days, prior to negative testing at time of donation, is acceptable

3 The following are the revised recommendations:

Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection – U.S. Public Health Service (PHS) Guideline, 2020

Note


Note: Transplant surgeons make decisions to transplant organs based on individual situations with regards to these guidelines.

- 3.1 People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 3 months
- 3.2 Men who have had sex with men (MSM) in the preceding 3 months
- 3.3 A person with unknown medical or social history
- 3.4 People who have had sex in exchange for money or drugs in the preceding 3 months
- 3.5 People who have had sex with a person who had sex in exchange for money or drugs in the preceding 3 months

- 3.6** People who injected drugs for non medical reasons.
- 3.7** People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 3 months
- 3.8** A child born to a mother with HIV, HBV, or HCV infection
- 3.9** A child breastfed by a mother is known to be infected with HIV infection
- 3.10** People who have been incarcerated (confinement in jail, prison, or a juvenile correctional facility) for >72 consecutive hours in the preceding 3 months

IV. Minimum IIDP Donor Criteria List

- 4** Attached is a condensed list of the Donor Criteria.

 Minimal IIDP Donor Criteria Doc rev
10_31_23.pdf

V. Donor Information Forms

- 5** A copy of the Donor Information Form, including Serology Test results, Medical and Social History, Consent Form, and OR Management Sheets should be received, with the pancreas or by fax, before the Center's start processing however this information does not need to be provided to IIDP