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Version 2

ADI IsletCore Minimal Donor Criteria V.2

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We use this protocol and it's working

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Abstract

This SOP defines the pancreas donor profile acceptable for use by the Alberta Diabetes Institute IsletCore in their human islet isolation program.

ADI IsletCore receives pancreases from multiple Canadian Organ Procurement Organizations (OPO). The OPO reports anonymized donor information and serology results to ADI IsletCore. Informed consent for research use of the pancreas is obtained and held on record by the relevant OPO.

Guidelines

Responsibilities

- This SOP applies to the Alberta Diabetes Institute IsletCore.
- It is the responsibility of ADI IsletCore staff to both follow and ensure adherence to the donor criteria outlined in this SOP prior to acceptance of a pancreas
- It is the responsibility of the ADI IsletCore staff to ensure that information relating to the donor is provided by the Organ Procurement Organization (OPO), and that this is accurately recorded in IsletCore's database, and the accompanying paperwork is filed securely.

Abbreviations

- ADI: Alberta Diabetes Institute
- SOP: Standard Operating Procedures
- NDD: neurological determination of death.
- DCD: Donation after cardiocirculatory death.
- MAID: Medical assistance in dying.
- HbA1c: Hemoglobin A1c.
- CPR: Cardiopulmonary resuscitation.
- HIV: Human immunodeficiency virus
- HTLV: Human T-lymphotropic virus
- HBsAg: Hepatitis B surface antigen
- Anti-HBc: Hepatitis B core antigen
- Anti-HCV: Anti Hepatitis C antibodies
- NAT HIV: Nucleic acid test human immunodeficiency virus



- NAT Hep C: Nucleic acid test hepatitis C
- SARS CoV-2: Virus causing COVID-19

Acknowledgments:

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ADI IsletCore Donor Inclusion Criteria

- 1 **The following are ADI IsletCore inclusion criteria for pancreas donors for human islet isolation:**
 1. A multi-organ donor or pancreas-only donor if the donor meets all the criteria for multi-organ donation
 2. Any type of donation (NDD, DCD, MAID)
 3. DCD warm ischemia time <30 minutes
 4. Adequate in situ hypothermic perfusion using UW or similar organ preservation solution for perfusion and cold storage
 5. Maximum 24 hour cold ischemia
 6. Donor age of 0 years to 100 years (no minimum age)
 7. Any donor body mass index (BMI)
 8. Any donor HbA1c
 9. Any donor diabetes status (no diabetes, Type 1 diabetes, Type 2 diabetes, other types of diabetes)
 10. Peak amylase between 40 to 140 units per litre (no data also acceptable)
 11. Peak lipase between 0 to 160 units per litre
 12. Duration of life support < 14 days
 13. Warm ischemia / Down time < 60 minutes (including CPR)

General Donor Preclusions / Exclusions

- 2 **The following represent disease states or other conditions that are criteria for rejection of a potential donor.**
 1. Recently treated (last 2 years) or active tuberculosis
 2. Serious illness of unknown etiology as the cause of death
 3. Active viral encephalitis or encephalitis of unknown origin
 4. Creutzfeldt–Jacob Disease
 5. Rabies
 6. Positive test result for any of the following:
 - Anti-HIV 1 & 2
 - Anti-HTLV 1 & 2
 - HBsAg
 - Anti-HBc
 - Anti-HCV
 - Syphilis
 - NAT HIV
 - NAT Hep C



- Blood culture
- SARS CoV-2 (evidence of previous positive testing >30 days prior, with negative testing at time of donation, is acceptable)

Additional Criteria

- 3 Additional exclusion criteria may be applied by procurement surgeons and/or IsletCore staff on a case-by-case basis, following review of donor's social and medical history, and physical assessment of the pancreas.

Protocol references

Lyon J et al (2016) Research-focused isolation of human islets from donors with and without diabetes at the Alberta Diabetes Institute IsletCore. **Endocrinology, 157(2): 560-569.**

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