



INCLUSION AND EXCLUSION CRITERIA FOR NPOD DONORS

1 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the current nPOD donor groups and provide acceptance inclusion and exclusion criteria for each group.

2 SCOPE

This SOP will be applied to all donor cases referred to the nPOD project by Organ Procurement Organization (OPO) partners.

3 RESPONSIBILITIES

- 3.1 It is the responsibility of both the OPO partner and on-call acceptance team to understand the inclusion and exclusion criteria to aid in case acceptance.

4 EQUIPMENT and MATERIALS

N/A

5 SAFETY

N/A

6 PROCEDURE

6.1 Eligible Donor Groups

- 6.1.1 Type 1 diabetes (T1D), **ANY age, ANY disease duration**
- 6.1.2 Autoantibody positive with no clinical diagnosis of type 1 diabetes for **at least 1 or more** autoantibodies (GADAb, IA-2Ab, or ZnT8), **30 years old or less**
- 6.1.3 Type 2 diabetes (T2D) on Incretin therapy (various therapies listed below)
- 6.1.4 Pancreas or pancreas/kidney transplant recipients with a history of type 1 diabetes (**ANY** disease duration)
- 6.1.5 Diagnosis of rare disease, such as cystic fibrosis-related diabetes, Turner's Syndrome, Prader-Willi.
- 6.1.6 Gestational diabetes or normal pregnancy at time of demise
- 6.1.7 Donors with a history of bariatric (weight-loss) surgery, such as gastric bypass, gastric banding, sleeve gastrectomy, etc.
- 6.1.8 Young donors (age 20 and under) with documented type 2 diabetes (T2D)
- 6.1.9 Young donors (age 20 and under) with a BMI of 33 or greater

See below for detailed criteria information.

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6.2 Inclusion/Exclusion Criteria for **ALL** nPOD Donors (*applies to all eligible groups detailed in 6.1 above*)

Criteria	
Other Autoimmune Disease(s)	Included
Hemodilution	Included
HBV Surface Antibody	Included
HIV Positive	Excluded
HCV Positive	Excluded
HBV Core, NAT, or Antigen Positive	Excluded

Specific Inclusion/Exclusion Criteria by Donor Group

6.3 Type 1 diabetes (T1D), **ANY** age, **ANY** disease duration

Criteria	Parameters
Age	All
Sex	All
Cause of Death	All
Race	All

6.4 Autoantibody positive with no clinical diagnosis of type 1 diabetes for **at least one or more** autoantibodies (GADAb, IA-2Ab, ZnT8), **30 years old or less**.

Criteria	Parameters
Autoantibody	GAD, IA-2, ZnT8
Age	30 years or less
Sex	All
Cause of Death	All
Race	All

6.5 Type 2 diabetes (T2D) on Incretin therapy

Criteria	Parameters
Age	All
Sex	All
Cause of Death	All
Race	All

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Medication Regimen	Incretin therapy (<i>Byetta/Exenatide, Galvus/Vildagliptin, Januvia/Sitagliptin, Onglyza/Saxagliptin, Tradjenta/Linagliptin, or Victoza/Liraglutide</i>) for AT LEAST 12 months
Duration of Type 2 Diabetes	All

6.6 Pancreas or pancreas/kidney transplant recipients with a history of type 1 diabetes (**ANY** disease duration)

Criteria	Parameters
Age	All
Sex	All
Cause of Death	All
Race	All

6.7 Diagnosis of rare disease, such as cystic fibrosis-related diabetes, Turner’s Syndrome, Prader-Willi, gestational diabetes, and normal pregnancy

Criteria	Parameters
Age	All
Sex	All
Cause of Death	All
Race	All

7 REFERENCES

- 7.1 SOP 24 IA-2 Antibody Protocol
- 7.2 SOP 25 GAD Antibody Protocol

8 REVISION HISTORY

Version	Date	Revision
0	10/25/11	Updated age parameter for single and double AAb+ donors at Section 6.4 and added all donors under the age of 12 mos. AW
1	12/01/11	Updated names of various incretin therapies. AW
2	02/24/12	Changed T1D age to 25 years or less and removed duration. Removed BMI criterion for T2D. Changed AAB+ positivity to at least 2 or more (GAD, IA-2, ZnT8) and 30 years old or less. AW
3	06/01/12	Changed T1D age to 30 years or less. SB
4	4/30/13	Changed T1D criteria to any age, any disease duration; Added donors with history of weight-loss surgery; Added T2D donors ≤ 20 years; Added BMI ≥ 33 for donors ≤ 20 years.

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