



## **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) with **ANY** disease duration
- 6.1.2 Autoantibody (GADAb and/or IA-2Ab) positive with no clinical diagnosis of type 1 diabetes
- 6.1.3 Type 2 diabetes (T2D) on Incretin therapy
- 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, gestational diabetes, and normal pregnancy
- 6.1.6 All donors under the age of 12 months

**See below for detailed criteria information.**

JDRF nPOD Standard Operating Procedure		
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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) with **ANY** disease duration

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

6.4 Autoantibody (GADAb and/or IA-2Ab) positive with no clinical diagnosis of type 1 diabetes

Criteria	Parameters
Autoantibody Positive	0 to 45 years
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
Body Mass Index (BMI)	34+
Medication Regimen	Incretin therapy (Byetta/Exenatide or Januvia/Sitagliptin) for AT LEAST 12 months
Duration of Type 2 Diabetes	All

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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

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