



INCLUSION/EXCLUSION CRITERIA FOR nPOD DONORS

1 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process for defining the nPOD donor groups and how acceptance criteria is communicated.

2 SCOPE

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

3 RESPONSIBILITIES

It is the responsibility of the nPOD on-call acceptance team to understand the inclusion and exclusion criteria in order to screen and accept optimal donors.

4 EQUIPMENT and MATERIALS N/A

5 SAFETY

N/A

6 PROCEDURE AND DONOR CRITERIA

6.1 The nPOD Scientific Advisory Board (SAB) will determine the categories of donors to be prioritized for inclusion in the nPOD biorepository.

Current 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. Pancreas or pancreas/kidney **transplant recipients** with a history of type 1 diabetes (ANY disease duration)
- 6.1.4 Young donors age 0 to 10 years with no diabetes

When recovery partners have donors that meet the criteria above, please refer to nPOD:

[Direct OPO/tissue banks call 1-866-731-6585](tel:1-866-731-6585)

IIAM referrals call 1-800-486-4426

[NDRI referrals call 1-800-222-6374](tel:1-800-222-6374)

6.2 Organ Procurement and Processing Core (OPPC) will compare the desired categories with current nPOD inventory and prepare a list of cases to accept based on factors such as age, race, gender, BMI, medical or social history.

6.3 The nPOD on-call acceptance team will use the list from SAB/OPPC to screen donor referral calls.

6.4 IIAM, NDRI, and Direct Partners will be notified of any criteria updates by:

JDRF nPOD Standard Operating Procedure	
SOP Number and Version: 13.7 Supersedes: nPOD 2	INCLUSION AND EXCLUSION CRITERIA FOR NPOD DONORS
Original Effective Date: 08/01/08	
Version Effective Date: 09/19/2014	
Page 1 of 3	

- 6.4.1 Email to designated staff contacts
- 6.4.2 Newsletter updates
- 6.4.3 Flyers for printing/posting for staff
- 6.4.4 Webinar sessions
- 6.4.5 Other means as appropriate
- 6.5 All current inclusion/exclusion criteria will be posted on the nPOD website. (www.jdrfnpod.org)
- 6.6 Detailed 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

6.7 Type 1 diabetes (T1D), **any age, any disease duration**

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

6.8 Autoantibody positive with no clinical diagnosis of type 1 diabetes for **at least 1 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

7 REFERENCES

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

Version	Date	Revision
	9/1/2010	Expanded criteria from diabetes duration of 7 years or less to 20 years of disease duration or less.

JDRF nPOD Standard Operating Procedure	
SOP Number and Version: 13.7 Supersedes: nPOD 2	INCLUSION AND EXCLUSION CRITERIA FOR NPOD DONORS
Original Effective Date: 08/01/08	
Version Effective Date: 09/19/2014	

	10/1/2010	Expanded type 1 diabetes criteria to donors under 45 with type 1 diabetes
	11/1/2010	Expanded to type 1 diabetes ANY age ANY disease duration
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
	12/01/11	Changed criteria reported to OPOs but no change in SOP until version 2 below. Changed T1D ae to 25 years or less and removed duration.
	1/1/2012	Changed criteria reported to OPOs but no change in SOP until version 2 below. Narrowed T1D donor age to 20 years old or less.
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 \leq 20 years; Added BMI \geq 33 for donors \leq 20 years.
5	12/01/2013	Temporary restricted criteria: \leq 15 years old w/ any duration or any age \leq 7 years duration; Aab+: \leq 30 years old, \geq 1 Aab+; Any age, any duration of continuous Incretin therapy; Transplant: PA or K/PA with hx T1D; Rare diseases.
6	4/1/14	SOP changed to describe process. Current criteria to be a separate document.
7	9/19/14	Made criteria one document again. Updated criteria to reflect current investigator needs: remove all control categories. Type 1 diabetes criteria changed to any age, any disease duration. Autoantibody positive changed to 1 or more autoantibody. Transplant patients with a history of type 1 diabetes also remained a category.
8	12/1/14	Added young donors age 0 to 10 with no diabetes.

Prepared by	Jayne Moraski		
Approved by	Mark Atkinson		
	Name	Signature	Date 12/10/2014

JDRF nPOD Standard Operating Procedure	
SOP Number and Version: 13.7 Supersedes: nPOD 2	INCLUSION AND EXCLUSION CRITERIA FOR NPOD DONORS
Original Effective Date: 08/01/08	
Version Effective Date: 09/19/2014	Page 3 of 3