



## **Inclusion and Exclusion Criteria for Autoantibody Screening (for donors who DO NOT have type 1 diabetes)**

### 1.0 Purpose

The purpose of this document is to define the parameters for autoantibody screening of organ donors who have not been diagnosed with type I diabetes; individuals whom while not formally diagnosed, may be in an early/pre-symptomatic stage of the disease.

### 2.0 Application/Scope

This procedure shall be applied to all autoantibody screening undertaken by both the NDRI as well as OPOs in partnership with screening labs participating in the nPOD project.

### 3.0 Definitions

**Autoantibodies:** Serum autoantibodies can be detected during the preclinical period of type I diabetes. The most significant of these autoantibodies include insulin autoantibodies (IAA), glutamic acid decarboxylase antibodies (GADA), Zn Transporter 8 autoantibodies (ZnT8A), and Insulinoma-Associated Protein 2 (IA-2A) antibodies. For the purposes of nPOD, organ donors will be screened for two of these: GADA and IA-2A.

### 4.0 References

- 4.1 McColloch, D.K. & Pietropaolo, M. (2008). *Prediction of type I diabetes mellitus*. Retrieved from [www.uptodate.com](http://www.uptodate.com) on July 14, 2008.

### 5.0 Associated SOPs

- 5.1 New Case Protocol
- 5.2 IA-2A
- 5.3 GADA

### 6.0 Screening Parameters

Criteria	Parameters
Age	0 to 45 years
Sex	All
Cause of death	All
Race	All

Criteria	
Other autoimmune disease(s)	Included
Hemodilution	Included
HBV Surface Antibody	Included
Type II Diabetes	Excluded
HIV Positive	Excluded
HBC Positive	Excluded
HBV Core, NAT, or Antigen Positive	Excluded

JDRF nPOD Standard Operating Procedures	
SOP #nPOD2	Title: Inclusion/Exclusion Criteria
Original Effective Date: 8/1/2008	
Current Version Effective Date: 7/15/2009	Page 2