

# SOP-NOD-0003 Study Endpoints

## STANDARD OPERATING PROCEDURE

### Pre-clinical Consortium on Combination Therapies for Type I Diabetes

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Document #: SOP-NOD-0003.02

Version #: 02

Supersedes: 01

Effective Date: September 1, 2011

Applicable to: ITN Project 1

Category:

**Title: Study Endpoints**

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#### INTRODUCTION/PURPOSE

The goal of this study is to determine the efficacy of anti-CD20 monoclonal antibody therapy (alone), oral insulin (alone), or the combination of anti-CD20 plus oral insulin to reverse hyperglycemia in NOD mice with recent onset autoimmune diabetes.

The purpose of this Standard Operating Procedure is to describe the endpoints of this study.

#### DEFINITIONS

Diabetes: Blood glucose  $\geq$  250 mg/dl (14 mmol/L)

New onset diabetic: Blood glucose readings of  $\geq$  250 mg/dl (14 mmol/L) on two consecutive days.

Therapy failure: For purposes of removing animals from the study for euthanasia. Maximum weight loss as permitted by each site's IACUC (or 20% weight loss if IACUC does not have a weight loss restriction) or 3 consecutive maximum blood glucose measurements as permitted by each site's IACUC (or 3 consecutive blood glucose measurements of  $\geq$  500 mg/dl (28 mmol/L) if IACUC does not have a guideline for blood glucose measurements).

Therapy success: Two consecutive blood glucose measurements of  $<$  250 mg/dl or 14 mmol/L after 120 days post-onset of diabetes.

#### PROCEDURES

Animals will be removed from the study and euthanized according to IACUC protocol once their weight drops below that permitted by each site's IACUC (or 20% weight loss if IACUC does not have a weight loss restriction) or 3 consecutive maximum blood glucose measurements as permitted by each site's IACUC (or 3 consecutive blood glucose measurements of  $\geq$  500 mg/dl (28 mmol/L) if IACUC does not have a guideline for blood glucose measurements).

#### DOCUMENTATION TO BE MAINTAINED

None

#### REFERENCES TO OTHER APPLICABLE SOPS

None

#### REFERENCES

None

**FORMS/ATTACHMENTS**

None

**REVISION HISTORY**

| <b>Effective Date</b> | <b>Revision</b> | <b>Author</b> | <b>Description of Changes</b>  |
|-----------------------|-----------------|---------------|--|
| August 5, 2011        | .01             | T Kupfer      | Corrected characters that did not import properly.   |
| September 1, 2011     | .02             | T Kupfer      | Changed definition of therapy failure for purposes of humane euthanasia to maximum weight loss per IACUC or 20% or 3 consecutive maximum blood glucose measurements per IACUC or $\geq$ 500 mg/dl. |