

# SOP-NOD-0001 Study Enrollment

DRAFT

T1D Pre-Clinical Consortium SOPs

Protocol 1: Combined anti-CD20 / Oral Insulin

## STANDARD OPERATING PROCEDURE

Pre-clinical Consortium on Combination Therapies for Type I Diabetes

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Applicable to: ITN Project 1

Category:

**Title: Subject Identification, Inclusion/Exclusion Criteria, and Study Enrollment**

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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 methods by which study participants will be identified, evaluated and entered into the 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.

### PROCEDURES

1. Beginning at 10 weeks of age, the blood glucose of female NOD mice will be monitored three times a week in the morning (Monday, Wednesday, and Friday).
2. The blood glucose of mice registering an initial blood glucose reading of  $\geq$  250 mg/dl (14 mmol/L) will be measured again the day after the first reading.
3. Mice exhibiting blood glucose readings of  $\geq$  250 mg/dl (14 mmol/L) on two consecutive days will then be evaluated to determine whether they meet the inclusion and exclusion criteria for the study.
4. Inclusion criteria:
  - Sex: female

- Age: Between 10 and 26 weeks of age
- Blood glucose: Blood glucose readings of  $\geq 250$  mg/dl (14 mmol/L) on two consecutive days
- Overall health status: Good as defined by normal activity, well-groomed appearance, normal temperament

5. Exclusion criteria:

- Sex: male
- Age:  $< 10$  weeks or  $> 26$  weeks
- Blood glucose: Blood glucose readings of  $< 250$  mg/dl (14 mmol/L)
- Overall health status: unthrifty, skin lesions, eye infections

6. Subjects meeting the inclusion criteria and failing to meet the exclusion criteria will then be entered into the study.

**DOCUMENTATION TO BE MAINTAINED**

The following information should be recorded for all study enrollees: Animal ID, sex, date of birth, overall health status, blood glucose measurements, weight, source of mice, length of time in colony.

**REFERENCES TO OTHER APPLICABLE SOPS**

**REFERENCES**

None

**FORMS/ATTACHMENTS**

**REVISION HISTORY**

Effective Date	Revision	Author	Description of Changes
August 5, 2011	.01	T Kupfer	Corrected problems with symbols that did not import properly into the program, added documentation to be maintained.