SOP-NOD-0010 Schedule of Assessments

STANDARD OPERATING PROCEDURE
Pre-clinical Consortium on Combination Therapies for Type I Diabetes

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Title: Schedule of Assessments	

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 types and timing of assessments in this study.

DEFINITIONS

None

PROCEDURES

Procedure	**Timepoint for Assessment**
Body weight	Subjects will be weighed weekly
Blood collection	Days 0, 30, 60 and 90 of the study or at study endpoint Collect 25-50 microliters serum. Store at -20 degrees Celsius for future assessment.
Blood glucose monitoring	From 10 weeks of age until onset 3x week From onset to 3 weeks past initiation of therapy 3x week From 3 weeks past initiation of therapy to study endpoint 2x week
In-life observations	Subjects will be observed at same timepoints as blood glucose monitoring for signs of toxicity.
Tissue sample collection	At the end of the study, collect pancreas in formalin for histology, and spleen and bone marrow for flow cytometric analysis for B cells and regulatory T cells. See SOP-NOD-0014 for details.

DOCUMENTATION

REFERENCES TO OTHER APPLICABLE SOPS

SOP-NOD-0003.00: Study Endpoints

SOP-NOD-0005.00: Blood Glucose Monitoring
SOP-NOD-0014.00: Assessment at Study Endpoint

REFERENCES

FORMS/ATTACHMENTS

REVISION HISTORY

Effective Date	Revision	Author	Description of Changes
8/23/11	01	T Kupfer	Added details of blood collection and tissue sample collection at the end of study.