



NIP DIABETES PILOT TRIAL
TYPE 1 DIABETES ONSET FORM

Form NPP24
15Nov2007(v.1.1)
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Site Number: Screening ID: Participant Letters:

The Study Coordinator should complete this form when a participant (infant) is diagnosed with Type 1 Diabetes.

Criteria for Type 1 Diabetes Diagnosis:

- 1) Symptoms of diabetes plus casual plasma glucose concentration >= 200 mg/dL (11.1 mmol/L).
2) Fasting Plasma* Glucose (FPG) >= 126 mg/dL (7.0 mmol/L).
3) 2-hour Plasma* Glucose (PG) >= 200 mg/dL (11.1 mmol/L) during an OGTT.
4) Unequivocal hyperglycemia with acute metabolic decompensation (e.g. ketoacidosis)

*Serum is also acceptable

1The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

2Casual is defined as any time of day without regard to time since last meal.

3Fasting is defined as no caloric intake for at least 8 hours.

A. REPORT INFORMATION

1. Date of Diagnosis (e.g. 05/Sep/2006):

DAY / MONTH / YEAR

2. Current visit or last scheduled visit preceding diagnosis of diabetes:

- 92 Delivery, 94 Infant Enrollment/ 6 Month Visit Entry A, 15 15 Months Old, 36 36 Months Old, 1 Infant Screening, 95 Screening/ Infant Enrollment, 18 18 Months Old, 42 42 Months Old, 2 Infant Enrollment, 6 6 Months Old, 21 21 Months Old, 48 48 Months Old, 3 3 Months Old, 9 9 Months Old, 24 24 Months Old, 99 Other, 93 Infant Enrollment combined with 3 Month Visit, 12 12 Months Old, 30 30 Months Old

3. Diagnosis made by (check one): 1 TrialNet Laboratory 2 Other Facility

a. If Other Facility,

4. Date Insulin Treatment Started:

DAY / MONTH / YEAR

B. HOSPITALIZATION INFORMATION

1. Was the participant hospitalized at the time of diagnosis?

Y N

If YES,

a. Admission Date:

DAY / MONTH / YEAR

b. Discharge Date:

DAY / MONTH / YEAR

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).



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C. SIGNS AND SYMPTOMS OF DIABETES

Did the participant experience:

	Yes/No			a. Month/Year of Onset
1. Polyuria	Y	N	<i>If Yes,</i>	____/____ MONTH YEAR
2. Polydipsia	Y	N	<i>If Yes,</i>	____/____ MONTH YEAR
3. Polyphagia	Y	N	<i>If Yes,</i>	____/____ MONTH YEAR
4. Fatigue	Y	N	<i>If Yes,</i>	____/____ MONTH YEAR
5. Unexplained weight loss	Y	N	<i>If Yes,</i>	____/____ MONTH YEAR
b. If YES, amount of weight lost	____ . ____ lb		OR	____ . ____ kg
6. Ketoacidosis	Y	N		

If YES, report as many of the following as available:

	Reference Range (if available)				
	1) Result ¹	2) Units ²	3) Low	4) High	5) Date
a. Plasma ¹ Glucose (serum also acceptable)	____ . ____	____	____ . ____	____ . ____	____/____/____ DAY MONTH YEAR
b. pH (Serum)	____ . ____	____	____ . ____	____ . ____	____/____/____ DAY MONTH YEAR
c. Serum Ketones (acetoacetate)	____	____	____	____	____/____/____ DAY MONTH YEAR
d. Anion Gap	____	____	____	____	____/____/____ DAY MONTH YEAR
e. Bicarbonate (Serum)	____	____	____	____	____/____/____ DAY MONTH YEAR
f. Urine Ketones	____	____	____	____	____/____/____ DAY MONTH YEAR

¹Results should be reported based on initial visit

²Units: 1=mg/dl 2=mmol/L 3=ug/ml 4=meq/L 5=no units

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D. GLUCOSE LEVELS

	a. Glucose Result ¹	b. Units (check one)	Reference Range (if available)		e. Glucose Date	f. Glucose Type	g. Measured By
			c. Low	d. High			
1	_____ . _____	<input type="checkbox"/> 1 mg/dl <input type="checkbox"/> 2 mmol/L	_____ . _____	_____ . _____	____/____/____ DAY MONTH YEAR	<input type="checkbox"/> 1 Random <input type="checkbox"/> 2 Fasting <input type="checkbox"/> 3 2-hr OGTT	<input type="checkbox"/> 1 TrialNet <input type="checkbox"/> 2 Other Lab <input type="checkbox"/> 3 Meter
2	_____ . _____	<input type="checkbox"/> 1 mg/dl <input type="checkbox"/> 2 mmol/L	_____ . _____	_____ . _____	____/____/____ DAY MONTH YEAR	<input type="checkbox"/> 1 Random <input type="checkbox"/> 2 Fasting <input type="checkbox"/> 3 2-hr OGTT	<input type="checkbox"/> 1 TrialNet <input type="checkbox"/> 2 Other Lab <input type="checkbox"/> 3 Meter
3	_____ . _____	<input type="checkbox"/> 1 mg/dl <input type="checkbox"/> 2 mmol/L	_____ . _____	_____ . _____	____/____/____ DAY MONTH YEAR	<input type="checkbox"/> 1 Random <input type="checkbox"/> 2 Fasting <input type="checkbox"/> 3 2-hr OGTT	<input type="checkbox"/> 1 TrialNet <input type="checkbox"/> 2 Other Lab <input type="checkbox"/> 3 Meter
4	_____ . _____	<input type="checkbox"/> 1 mg/dl <input type="checkbox"/> 2 mmol/L	_____ . _____	_____ . _____	____/____/____ DAY MONTH YEAR	<input type="checkbox"/> 1 Random <input type="checkbox"/> 2 Fasting <input type="checkbox"/> 3 2-hr OGTT	<input type="checkbox"/> 1 TrialNet <input type="checkbox"/> 2 Other Lab <input type="checkbox"/> 3 Meter

¹ Glucose levels must be based on plasma or serum

E. OTHER LABORATORY VALUES

Laboratory Values	a. Result	Reference Range (if available)		d. Date
		b. Low	c. High	
1. HbA1c (only if obtained outside of TrialNet)	_____ . _____ %	_____ . _____ %	_____ . _____ %	____/____/____ DAY MONTH YEAR

Signature of physician reviewing this form: _____

Initials (first, middle, last) of person completing this form: _____

F M L

Date form completed: _____

____/____/____
DAY MONTH YEAR

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White Copy – Send to TrialNet Coordinating Center

Yellow Copy – Retain at site