NIP DIABETES PILOT TRIAL
TYPE 1 DIABETES ONSET FORM

Form NPP24
15Nov2007(v.1.1)

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[1] of diabetes plus casual[2] plasma glucose concentration ≥ 200 mg/dL (11.1 mmol/L).
2) Fasting[3] 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. The test should be performed as described by WHO, using a glucose load containing the equivalent of 1.75g/kg body weight to a maximum of 75 g anhydrous glucose dissolved in water.
4) Unequivocal hyperglycemia with acute metabolic decompensation (e.g. ketoacidosis)

*Serum is also acceptable
[1]The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.
[2]Casual is defined as any time of day without regard to time since last meal.
[3]Fasting 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	☐ 15	15 Months Old	☐ 36	36 Months Old
☐ 1	Infant Screening	☐ 95	Entry A 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).*

Site: __ __ __ __ Screening ID: __ __ __ __ __ - __ Letters: __ __ __ Visit Date: __ __/__ __ __/__ __ __ __

C. SIGNS AND SYMPTOMS OF DIABETES

Did the participant experience:

	Yes/No		a. Month/Year of Onset
1. Polyuria	Y N	*If Yes,*	__ __ __ / __ __ __ __ MONTH YEAR
2. Polydipsia	Y N	*If Yes,*	__ __ __ / __ __ __ __ MONTH YEAR
3. Polyphagia	Y N	*If Yes,*	__ __ __ / __ __ __ __ MONTH YEAR
4. Fatigue	Y N	*If Yes,*	__ __ __ / __ __ __ __ MONTH YEAR
5. Unexplained weight loss	Y N	*If Yes,*	__ __ __ / __ __ __ __ 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:

	1) Result[1]	2) Units[2]	Reference Range (if available) 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

[1]Results should be reported based on initial visit

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

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).*

Site: __ __ __ __ Screening ID: __ __ __ __ __ - __ Letters: __ __ __ Visit Date: __ __/__ __ __/__ __ __ __

D. GLUCOSE LEVELS

	a. Glucose Result [1]	b. Units (*check one*)	Reference Range (*if available*) c. Low	d. High	e. Glucose Date	f. Glucose Type	g. Measured By
1	__ __ __ . __	☐1 mg/dl ☐2 mmol/L	___._	___._	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR	☐1 Random ☐2 Fasting ☐3 2-hr OGTT	☐1 TrialNet ☐2 Other Lab ☐3 Meter
2	__ __ __ . __	☐1 mg/dl ☐2 mmol/L	___._	___._	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR	☐1 Random ☐2 Fasting ☐3 2-hr OGTT	☐1 TrialNet ☐2 Other Lab ☐3 Meter
3	__ __ __ . __	☐1 mg/dl ☐2 mmol/L	___._	___._	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR	☐1 Random ☐2 Fasting ☐3 2-hr OGTT	☐1 TrialNet ☐2 Other Lab ☐3 Meter
4	__ __ __ . __	☐1 mg/dl ☐2 mmol/L	___._	___._	__ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR	☐1 Random ☐2 Fasting ☐3 2-hr OGTT	☐1 TrialNet ☐2 Other Lab ☐3 Meter

[1] Glucose levels must be based on plasma or serum

E. OTHER LABORATORY VALUES

Laboratory Values	a. Result	Reference Range (*if available*) b. Low	c. High	d. Date
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)