



Natural History Study of the Development of T1D DIABETES ONSET FORM

Form NH08

Ver. 1.0

01NOV2004

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Site Number: _____ Participant ID: _____ 1st three letters of First Name: _____

Complete this form when a participant is diagnosed with diabetes.

Criteria for Diagnosis:

- Symptoms of diabetes plus casual plasma* glucose concentration ≥ 200 mg/dL (11.1 mmol/L).
 - Casual is defined as any time of day without regard to time since last meal.
- Fasting Plasma* Glucose (FPG) ≥ 126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 hours.
- 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.
- Unequivocal hyperglycemia with acute metabolic decompensation (e.g. ketoacidosis).

* Note: Serum is also acceptable.

A. REPORT INFORMATION

1. Date of Diagnosis: _____ / _____ / _____
MM DD YYYY

2. Current visit or last scheduled visit preceding diagnosis of diabetes
(Use **P1** for any phase 1 visit; Use **P2** for phase 2 visit; Use **00** for Baseline Phase 3 visit. Use **06, 12, 18**, etc. for phase 3 visits) _____ months

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

a. If Other Facility, specify: _____

B. HOSPITALIZATION INFORMATION

1. Was the participant hospitalized at the time of diagnosis? _____ Y N

If YES,

a. Admission Date: _____ / _____ / _____
MM DD YYYY

b. Discharge Date: _____ / _____ / _____
MM DD YYYY

C. SIGNS AND SYMPTOMS OF DIABETES

Did the participant experience:

	Yes / No		If Yes,	a. Month/Year of Onset
1. Polyuria	Y	N	If Yes,	____ / ____ MM YYYY
2. Polydipsia	Y	N	If Yes,	____ / ____ MM YYYY
3. Polyphagia	Y	N	If Yes,	____ / ____ MM YYYY
4. Fatigue	Y	N	If Yes,	____ / ____ MM YYYY

Did the participant experience:

5. Unexplained weight loss _____ Y N

If YES,

a. Month and Year of onset _____ / _____
MM YYYY

b. Amount of weight lost _____ lb OR _____ kg

Initials of Person Completing this Form: _____ Date: _____



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C. SIGNS AND SYMPTOMS OF DIABETES (cont.)

6. Ketoacidosis

Y N

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

	1. Result ²	2. Units ³	Reference Range (if available)		5. Date
			3. Low	4. High	
a. Plasma ¹ Glucose	_____ . ____		_____ . ____	_____ . ____	___/___/____ MM DD YYYY
b. pH (Serum)	__ . ____		__ . ____	__ . ____	___/___/____ MM DD YYYY
c. Serum Ketones (acetoacetate)	_____		_____	_____	___/___/____ MM DD YYYY
d. Anion Gap	_____		_____	_____	___/___/____ MM DD YYYY
e. Bicarbonate (Serum)	_____		_____	_____	___/___/____ MM DD YYYY
f. Urine Ketones	_____		_____	_____	___/___/____ MM DD YYYY

¹Serum is also acceptable

²Results should be reported based on initial visit

³Units: 1=mg/dL 2=mmol/L 3=ug/mL 4=mEq/L 5=n/a

D. GLUCOSE LEVELS (record information on recently measured 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	_____ . ____	_____ . ____	___/___/____ MM DD YYYY	<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
2	_____ . ____	<input type="checkbox"/> ₁ mg/dl <input type="checkbox"/> ₂ mmol/L	_____ . ____	_____ . ____	___/___/____ MM DD YYYY	<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
3	_____ . ____	<input type="checkbox"/> ₁ mg/dl <input type="checkbox"/> ₂ mmol/L	_____ . ____	_____ . ____	___/___/____ MM DD YYYY	<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

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4	_____	<input type="checkbox"/> ₁ mg/dl	_____	_____	____/____/____ MM DD YYYY	<input type="checkbox"/> ₁ Random	<input type="checkbox"/> ₁ TrialNet
		<input type="checkbox"/> ₂ mmol/L				<input type="checkbox"/> ₂ Fasting	<input type="checkbox"/> ₂ Other Lab
						<input type="checkbox"/> ₃ 2-hr OGTT	<input type="checkbox"/> ₃ Meter ²

¹ Glucose levels must be based on plasma or serum
² Meter readings are NOT ACCEPTABLE diagnostic criteria

E. OTHER LABORATORY VALUES

Laboratory Values	a. Result	Reference Range <i>(if available)</i>		d. Date
		b. Low	c. High	
1. HbA1c <i>(only if obtained outside of TrialNet)</i>	____.____%	____.____%	____.____%	____/____/____ MM DD YYYY

Signature of physician reviewing this form: _____

Signature of Person Completing this Form _____

Date form completed: ____/____/____
MM DD YYYY