Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

Complete this form at Baseline and for all regularly scheduled follow-up visits.

A. VISIT INFORMATION

1. Visit Date: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

2. For which visit is this form being completed? *(check one)*

☐ 0	Baseline	☐ 8	Visit 8	☐ 16	Visit 16	☐ 24	Visit 24
☐ 1	Visit 1	☐ 9	Visit 9	☐ 17	Visit 17	☐ 25	Visit 25
☐ 2	Visit 2	☐ 10	Visit 10	☐ 18	Visit 18	☐ 26	Visit 26
☐ 3	Visit 3	☐ 11	Visit 11	☐ 19	Visit 19	☐ 27	Visit 27
☐ 4	Visit 4	☐ 12	Visit 12	☐ 20	Visit 20	☐ 28	Visit 28
☐ 5	Visit 5	☐ 13	Visit 13	☐ 21	Visit 21	☐ 29	Visit 29
☐ 6	Visit 6	☐ 14	Visit 14	☐ 22	Visit 22	☐ 30	Visit 30
☐ 7	Visit 7	☐ 15	Visit 15	☐ 23	Visit 23	☐ 31	Visit 31

For Sections B, C, and D,
Record information collected from a 3-day period in the last week.

B. GLUCOSE MONITORING

1. Is the person using a Continuous Glucose Monitoring System (CGMS)? Y N

C. COMPLETENESS OF RECORD

1. Are there at least three glucose values available for at least three days? Y N
2. Is the insulin dose information available for at least three days? Y N

D. GLUCOSE

1. Total number of home blood glucose monitorings over three days: __ __ __
2. Number of home blood glucose monitorings over three days that were less than 65 mg/dl: __ __
3. Average of recorded **fasting** glucoses (over three days): a. __ __ __ . __ b. ☐ 1 mg/dl ☐ 2 mmol/L
4. Average of **all** recorded glucoses (over three days): a. __ __ __ . __ b. ☐ 1 mg/dl ☐ 2 mmol/L
5. **Lowest** recorded glucose (over three days): a. __ __ __ . __ b. ☐ 1 mg/dl ☐ 2 mmol/L
6. **Highest** recorded glucose (over three days): a. __ __ __ . __ b. ☐ 1 mg/dl ☐ 2 mmol/L

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: __ __ / __ __ __ / __ __ __ __

E. INSULIN

1. Daily insulin routine *(check one)*:
   - ☐ 1 No insulin
   - ☐ 2 1-2 Injections per day
   - ☐ 3 3 + Injections per day (MDI)
   - ☐ 4 Insulin Pump (CSII)

2. Average units/day of short acting insulin *(average over 3 day period)*:
   (e.g. Regular, LisPro, Novolog, Humalog, bolus doses if on pump) __ __ __ . __ units

3. Average units/day of intermediate/long acting insulin *(average over 3 day period)*:
   (e.g. Lantus, NPH, Lente, Ultralente, basal rate if on pump) __ __ __ . __ units

F. HYPOGLYCEMIA

Record information from any records or history by the participant since the last visit.

1. Have you experienced any severe hypoglycemic events (loss of consciousness, seizure, or assistance required from another person due to an altered state or consciousness) since the last visit? Y N

   If YES,
   a. How many severe hypoglycemic events have occurred since the last visit? __ __

If any **severe** hypoglycemic events have occurred since the last visit, complete Adverse Event Report Form (**CTL13**) for each event.

G. CONTACT WITH DIABETES HEALTH CARE PROVIDER

Record the number of visits, emails, phone calls, or other contact since the last visit with:

1. Study associated: Diabetes Educator: __ __
2. Study associated: Endocrinologist: __ __
3. Study associated: other health care provider: __ __
4. Non-study associated: Diabetes Educator: __ __
5. Non-study associated: Endocrinologist: __ __
6. Non-study associated: other health care provider: __ __

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __ / __ __ __ / __ __ __ __ (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).*