

Site Number: _____ Screening ID: _____ - ____

Participant Letters: _____

Complete this form 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)

- | | | | |
|-------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> 2 Baseline | <input type="checkbox"/> 16 Month 6 | <input type="checkbox"/> 27 Month 18 | <input type="checkbox"/> 31 Month 36 |
| <input type="checkbox"/> 4 Week 2 | <input type="checkbox"/> 17 Month 9 | <input type="checkbox"/> 28 Month 21 | <input type="checkbox"/> 32 Month 42 |
| <input type="checkbox"/> 6 Week 5 | <input type="checkbox"/> 18 Month 12 | <input type="checkbox"/> 29 Month 24 | <input type="checkbox"/> 33 Month 48 |
| <input type="checkbox"/> 11 Month 3 | <input type="checkbox"/> 26 Month 15 | <input type="checkbox"/> 30 Month 30 | <input type="checkbox"/> 99 Other |

If OTHER,

a. Specify: _____

**For Sections B, C, and D,
Record information collected from the 3-DAY DIARY RECORD in the last week.**

B. COMPLETENESS OF RECORD

1. Are there at least 3 glucose values available for at least 3 days?

Y N

2. Is the insulin dose available for at least 3 days?

Y N

C. GLUCOSE

1. Total number of home blood glucose monitorings over 3 days:

2. Number of home blood glucose monitorings over 3 days that were less than 65 mg/dl:

3. Average of recorded **fasting** glucoses:

a. _____ . ____ b. 1 mg/dl
 2 mmol/L

4. Average of all recorded glucoses:

a. _____ . ____ b. 1 mg/dl
 2 mmol/L

5. Lowest recorded glucose:

a. _____ . ____ b. 1 mg/dl
 2 mmol/L

6. Highest recorded glucose:

a. _____ . ____ b. 1 mg/dl
 2 mmol/L

D. 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:

(e.g. Regular, LisPro, Novolog, Humalog, bolus doses if on pump)

____ . ____
units

3. Average units/day of intermediate/long acting insulin:

(e.g. Lantus, NPH, Lente, Ultralente, basal rate if on pump)

____ . ____
units

E. HYPOGLYCEMIA

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: ___/___/_____

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) since the last visit? Y N

If YES,

a. How many severe hypoglycemic events have occurred since the last visit? _____

b. What was the recorded glucose during the first severe hypoglycemic event? (if unknown, write “*”) 2) 1 mg/dl
1) _____ . ____ 2 mmol/L

c. What was the recorded glucose during the second severe hypoglycemic event? (if applicable) (if unknown, write “*”) 2) 1 mg/dl
1) _____ . ____ 2 mmol/L

d. What was the recorded glucose during the third severe hypoglycemic event? (if applicable) (if unknown, write “*”) 2) 1 mg/dl
1) _____ . ____ 2 mmol/L

If any **severe** hypoglycemic events have occurred since the last visit, complete Adverse Event Report Form (**RIT13**)

F. 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: Certified Diabetes Educator (CDE): _____
- 2. Study associated: Endocrinologist: _____
- 3. Study associated: other health care provider: _____
- 4. Non-study associated: CDE: _____
- 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).*