

Site Number: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_ First 3 Letters of First Name: \_\_\_\_\_

**This form should be completed to record the details of any *major* hypoglycemic events that have occurred since the last scheduled clinic visit.**

**A major hypoglycemic event is defined as one that either:**

- **Requires assistance from another individual or**
- **Results in loss of consciousness (coma) or**
- **Results in seizure**

**If more space is required, please attach additional copies of the second page of this form.**

**A. VISIT INFORMATION**

1. For which visit, in the study sequence, is this form being completed? (*check one*)

- |  |  |   |   |
|--|--|---|---|
| <input type="checkbox"/> <sub>2</sub> Baseline | <input type="checkbox"/> <sub>6</sub> Week 4   | <input type="checkbox"/> <sub>14</sub> Month 9  | <input type="checkbox"/> <sub>26</sub> Month 21 |
| <input type="checkbox"/> <sub>3</sub> Week 1   | <input type="checkbox"/> <sub>7</sub> Month 2  | <input type="checkbox"/> <sub>17</sub> Month 12 | <input type="checkbox"/> <sub>29</sub> Month 24 |
| <input type="checkbox"/> <sub>4</sub> Week 2   | <input type="checkbox"/> <sub>8</sub> Month 3  | <input type="checkbox"/> <sub>20</sub> Month 15 |   |
| <input type="checkbox"/> <sub>5</sub> Week 3   | <input type="checkbox"/> <sub>11</sub> Month 6 | <input type="checkbox"/> <sub>23</sub> Month 18 |   |

**B. HYPOGLYCEMIC EVENTS**

An Adverse Event Report Form (**MMF07**) must also be completed to record additional details of any **major** hypoglycemic events that have occurred.

Provide the following information about any *major* hypoglycemic events you have experienced since your last clinic visit. Start with the most recent, assigning it Event Number 1, and then continue down the rows to record all events in reverse chronological order since the last scheduled clinic visit.

Event Number	1. Date of Occurrence	2. Time of Day ( <i>check one</i> )	3. Blood Glucose Level	4. Did you:
1	____/____/_____ MM DD YYYY	<input type="checkbox"/> <sub>1</sub> Morning <input type="checkbox"/> <sub>2</sub> Afternoon <input type="checkbox"/> <sub>3</sub> Evening <input type="checkbox"/> <sub>4</sub> While sleeping	_____ mg/dl	<input type="checkbox"/> <sub>1</sub> Experience Coma <input type="checkbox"/> <sub>2</sub> Have Seizure <input type="checkbox"/> <sub>3</sub> Require Assistance
2	____/____/_____ MM DD YYYY	<input type="checkbox"/> <sub>1</sub> Morning <input type="checkbox"/> <sub>2</sub> Afternoon <input type="checkbox"/> <sub>3</sub> Evening <input type="checkbox"/> <sub>4</sub> While sleeping	_____ mg/dl	<input type="checkbox"/> <sub>1</sub> Experience Coma <input type="checkbox"/> <sub>2</sub> Have Seizure <input type="checkbox"/> <sub>3</sub> Require Assistance
3	____/____/_____ MM DD YYYY	<input type="checkbox"/> <sub>1</sub> Morning <input type="checkbox"/> <sub>2</sub> Afternoon <input type="checkbox"/> <sub>3</sub> Evening <input type="checkbox"/> <sub>4</sub> While sleeping	_____ mg/dl	<input type="checkbox"/> <sub>1</sub> Experience Coma <input type="checkbox"/> <sub>2</sub> Have Seizure <input type="checkbox"/> <sub>3</sub> Require Assistance
4	____/____/_____ MM DD YYYY	<input type="checkbox"/> <sub>1</sub> Morning <input type="checkbox"/> <sub>2</sub> Afternoon <input type="checkbox"/> <sub>3</sub> Evening <input type="checkbox"/> <sub>4</sub> While sleeping	_____ mg/dl	<input type="checkbox"/> <sub>1</sub> Experience Coma <input type="checkbox"/> <sub>2</sub> Have Seizure <input type="checkbox"/> <sub>3</sub> Require Assistance
5	____/____/_____ MM DD YYYY	<input type="checkbox"/> <sub>1</sub> Morning <input type="checkbox"/> <sub>2</sub> Afternoon <input type="checkbox"/> <sub>3</sub> Evening <input type="checkbox"/> <sub>4</sub> While sleeping	_____ mg/dl	<input type="checkbox"/> <sub>1</sub> Experience Coma <input type="checkbox"/> <sub>2</sub> Have Seizure <input type="checkbox"/> <sub>3</sub> Require Assistance

*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 Number: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_ First 3 Letters of First Name: \_\_\_\_\_

**B. HYPOGLYCEMIC EVENTS (cont.)**

Event Number	1. Date of Occurrence	2. Time of Day (check one)	3. Blood Glucose Level	4. Did you:
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance
—	MM / DD / YYYY	<input type="checkbox"/> 1 Morning <input type="checkbox"/> 2 Afternoon <input type="checkbox"/> 3 Evening <input type="checkbox"/> 4 While sleeping	— mg/dl	<input type="checkbox"/> 1 Experience Coma <input type="checkbox"/> 2 Have Seizure <input type="checkbox"/> 3 Require Assistance

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

F M L

**Date form completed:**

MM / DD / YYYY

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