Type 1 Diabetes TrialNet

MMF-DZB Study
MAJOR HYPOGLYCEMIC EVENTS FORM

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 <u>or</u>**
- **Results in loss of consciousness (coma) <u>or</u>**
- **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)*

☐ 2 Baseline	☐ 6 Week 4	☐ 14 Month 9	☐ 26 Month 21
☐ 3 Week 1	☐ 7 Month 2	☐ 17 Month 12	☐ 29 Month 24
☐ 4 Week 2	☐ 8 Month 3	☐ 20 Month 15	
☐ 5 Week 3	☐ 11 Month 6	☐ 23 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 *(check one)*	3. Blood Glucose Level	4. Did you:
1	__ __ / __ __ / __ __ __ __ MM DD YYYY	☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping	__ __ __ mg/dl	☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
2	__ __ / __ __ / __ __ __ __ MM DD YYYY	☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping	__ __ __ mg/dl	☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
3	__ __ / __ __ / __ __ __ __ MM DD YYYY	☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping	__ __ __ mg/dl	☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
4	__ __ / __ __ / __ __ __ __ MM DD YYYY	☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping	__ __ __ mg/dl	☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
5	__ __ / __ __ / __ __ __ __ MM DD YYYY	☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping	__ __ __ mg/dl	☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 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).*

Type 1
**Diabetes
TrialNet**

MMF-DZB Study
MAJOR HYPOGLYCEMIC EVENTS FORM

Form MMF04
July 06, 2004
Page 2 of 2

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		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance
__		__ __ / __ __ / __ __ __ __ MM DD YYYY		☐ 1 Morning ☐ 2 Afternoon ☐ 3 Evening ☐ 4 While sleeping		__ __ __ mg/dl		☐ 1 Experience Coma ☐ 2 Have Seizure ☐ 3 Require Assistance

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

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

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).*

Top Copy – Send to TrialNet Coordinating Center   **Bottom Copy** – Retain at site