Metabolic Control RCT
Adverse Event Form
tblPAdvEvent

PtID	**Patient ID:** _____
Namecode	**Namecode:**_____

InvID	**Investigator**: _____

Description of Event

ParentAdvEventListID **AdvEvent**	**1. Adverse Event:** _____
AdvEventDs	**2. Provide detailed description of the event:** _____ _____ _____ _____
AEOnsetDt	**3. Date of Onset:** ___ ___ ___ /___ ___ / ___ ___ ___ ___ *MMM/dd/yyyy*
AEPrEnroll	**4. Did this condition exist prior to enrollment?** ☐ Yes ☐ No
AEIntensity	**5. Intensity (Severity)** ☐ Mild ☐ Moderate ☐ Severe
AERelSensB	**6. Is there a reasonable possibility that the event was caused by the CGM?** ☐ Yes ☐No
AERelProcB	**7. Is there a reasonable possibility that the event was caused by a study procedure other than CGM use:** ☐ Yes ☐ No
AEEffSensor	**8. Effect on CGM:** ☐no change ☐discontinued temporarily ☐discontinued permanently
AESerious	**9. Does the event meet criteria for a serious adverse event?** ☐ Yes ☐ No

Treatment of Adverse Event

AETrt	**1. Did subject receive treatment for the Adverse Event?** ☐Yes ☐ No
	If *Yes*, complete the following:
AESurg	**1a. Surgery:** ☐ Yes ☐ No
AESurgDs	**If *Yes*, complete the following: Type of surgery** _____
AESurgDt	**Date of surgery:** ___ ___ ___ /___ ___ / ___ ___ ___ ___ *MMM/dd/yyyy*
AEMeds	**1b. Medication:** ☐Yes ☐ No
	1c. If yes, list medications here and add details on Concomitant Medication Form:
AEMedsCmts	_____
	_____
	Other: ☐ Yes ☐ No
AEOthTrt	
	If yes, detail:
AEOthTrtCmts	_____
	_____

Outcome

	1. Outcome: ☐ Recovered with sequelae ☐ Complete Recovery
AEOutcome	☐ Ongoing (further improvement or worsening possible)
	☐ Ongoing, medically stable (further change not expected)
	☐ Fatal
	1a. Date of Recovery (with or without sequelae):
AEResDt	__ __ __ /__ __ / __ __ __ __ *MMM/dd/yyyy*
	If *Fatal*, complete the following:
	1b. Cause of Death:
AEDeathCause	_____
	1c. Date of Death:
AEDeathDt	__ __ __ /__ __ / __ __ __ __ *MMM/dd/yyyy*

Additional Information for Hypoglycemia Events

	1. Indicate the approximate time of the event:
AEHypoTime	**☐ 00:01 – 03:00 ☐ 03:01 – 06:00 ☐ 06:01 – 09:00 ☐ 09:01 – 12:00**
	☐12:01 – 15:00 ☐15:01 – 18:00 ☐ 18:01 – 21:00 ☐ 21:01 – 00:00 ☐Unknown
AEHGM	**2. Was the glucose level checked on a home glucose meter?** ☐ Yes ☐ No
AEHGMMgdl	**2a. If yes, what was the result?** _____ **mg/dl** ☐ Unknown
AEHGMUnknown	
	3. Please select all of the following that apply for this event
AESiezure	**☐ Seizure ☐ Loss of consciousness ☐ Required assistance**
AEConscious	**☐ ER Visit ☐ Ambulance Called ☐ EMT Assistance**

AEAssist **AEERVisit** **AEAmbulance** **AEEMTAsst** **AEHospital**	☐ **Hospitalization**
AESensorUsed	**4. Was the subject wearing an unblinded sensor at the time of the event?** ☐ Yes ☐No
AESensorMgdl **AESensorUnknown**	**4a. If yes, what was the glucose reading at the time the event was identified?** _____ **mg/dL** ☐Unknown
AEHypoTx	**5. What was the treatment given for the event?** _____
AEHypoResp	**6. What was the subject's response to the treatment?** _____

Additional Information for Serious Adverse Event (Complete this section only if event meets at least one of the criteria in # below.)

AEDeath **AEConAnomaly** **AELifeThreat** **AEHosp** **AEDisability** **AEOther**	**1. Outcomes Attributed to the Serious Adverse Event:** *(check all that apply)* ☐ Death ☐ Congenital Anomaly ☐ Life Threatening ☐ Hospitalization -- initial or prolonged ☐ Disability/Incapacity ☐ Other _____
AERelLabData **AERelLabDataDs**	**2. Relevant Tests/Laboratory Data (including dates)?** ☐ Yes ☐ No **If 'Yes', list:** _____
AEOthRelHx **AEOthRelHxDs**	**3. Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)? ☐ Yes ☐ No **If 'Yes', detail:** _____
AEMedProd **AEMedProdDs**	**4. Concomitant medical products and therapy dates (exclude treatment of event)?** ☐ Yes ☐ No **If 'Yes', please explain:** _____

Comments **FormCmts**
