The Accuracy of Continuous Glucose Monitors in Children with Type 1 Diabetes
&
A Pilot Study to Assess the Accuracy of Continuous Glucose Monitors in Normal Children

Table of Contents

DirecNet Inpatient Accuracy Study
Screening and Eligibility Form

IDENTIFYING INFORMATION

DirecNet Subject ID # ☐☐☐☐☐☐
complete after enrollment of subject on DirecNet website

Namecode: ☐☐☐☐☐
1st 2 letters of 1st name, middle initial (X if none), 1st 2 letters of last name

Form completion date ☐☐☐ ☐☐ ☐☐☐☐
month *day* *year*

Type of Subject: ☐Diabetic ☐Normal

A. DATA FOR DIABETIC AND NORMAL SUBJECTS

1. Date of birth: ☐☐☐ ☐☐ ☐☐☐☐
month *day* *year*
(age must be 1.0 to < 18.0 yrs for diabetic subjects and 7.0 to <18.0 yrs for normal subjects)

2. Gender: ☐Male ☐Female

3. Ethnicity: ☐Hispanic or Latino ☐Not Hispanic or Latino ☐Unknown/not reported

4. Race: ☐White ☐Black/African-American ☐Asian ☐Native Hawaiian/Other Pacific Islander
☐American Indian/Alaskan Native ☐More than one race_____ ☐Unknown/not reported

5. Weight: ☐☐.☐ kg *(for eligibility, diabetic subjects must be >=12.0 kg for age <7.0 and must be >=16.0 kg for age >=7 and normal subjects must be >=16.0 kg)*

6. Height: ☐☐☐.☐ cm

7. BMI between 5th and 95th (diabetic subjects) or 10th and 90th percentiles (normal subjects) for age and sex: ☐Yes ☐No
(must be YES for eligibility)

8. Skin abnormalities that might affect completion of the protocol: ☐Yes ☐No *(must be NO for eligibility)*

9. Medical disorder that might affect completion of the protocol: ☐Yes ☐No *(must be NO for eligibility)*

10. Hematocrit: ☐Normal ☐Abnormal ☐Pending *(must be normal for eligibility; if pending must be normal prior to 1st gold standard blood draw)*

11. Date informed consent form signed: ☐☐☐ ☐☐ ☐☐☐☐
month *day* *year*

12. Date child assent form signed: ☐☐☐ ☐☐ ☐☐☐☐
month *day* *year*
(if ≥ 7 yrs old)

B. DATA FOR DIABETIC SUBJECTS

1. Diagnosis of type 1 diabetes: ☐Yes ☐No *(must be YES for eligibility)*

2. Duration of insulin use: ☐ yrs ☐ mos *(must be >12 mos for eligibility)*

3. Hx of seizures unrelated to hypoglycemia or fever: ☐Yes ☐No *(must be NO for eligibility)*

4. Current use of oral glucocorticoids: ☐Yes ☐No *(must be NO for eligibility)*

5. Planned CGMS initiation: ☐2 days pre-CRC ☐1 day pre-CRC ☐On CRC admission

C. DATA FOR NORMAL SUBJECTS ONLY

1. Hx of diabetes, (+) islet cell antibodies, or sibling/parent with type 1 or 2 diabetes: ☐Yes ☐No *(must be NO for eligibility)*

2. HbA1c: ☐Normal ☐Abnormal ☐Pending (*must be <6.0 for eligibility; if pending, must be known to be <6.0 prior to first gold standard blood draw)*

3. Use of any medications (Rx or non-Rx) in the 7 days prior to CRC admission: ☐Yes ☐No *(must be NO for eligibility)*

******Signatures and dates must be complete prior to data entry******

Coordinator			**Investigator verification of eligibility:** **I verify that the patient meets all eligibility criteria**		
_____ Signature	__ -__ __ __ DirecNet ID	____/____/____ Signature Date	_____ Signature	__ -__ __ __ DirecNet ID	____/____/____ Signature Date

PERSONAL CENSUS DATA

Name:

☐ **You are not required to complete this form. Check here if you do not wish to provide some or all of the information below.**

ETHNICITY

1. Do you consider your child to be Hispanic or Latino? (See definition below.)

   ☐ YES ☐ NO

   Hispanic or Latino
   A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin," can be used in addition to "Hispanic or Latino."

RACE

2. What race do you consider your child to be? (If more than one race, select all that apply.)

   ☐ **American Indian or Alaska Native**
   A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

   ☐ **Asian**
   A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

   ☐ **Black or African American**
   A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or "African American."

   ☐ **Native Hawaiian or Other Pacific Islander**
   A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

   ☐ **White**
   A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

   ☐ **Uncertain**

DirecNet Inpatient Accuracy Study
Laboratory Data

A. IDENTIFYING INFORMATION

DirecNet Subject ID #: | | | | | | | **Namecode:** | | | | | |
1st 2 letters of 1st name, middle initial (X if none), 1st 2 letters of last name

B. LABORATORY

1a. HbA1c: | | . | | **1b. HbA1c Test Date:** | | | month | | day | | | | year

2a. Hematocrit: | | . | | **2b. Hct Test Date:** | | | month | | day | | | | year

Tests can be done within 2 weeks prior to CRC admission or at the time of admission

Coordinator			Investigator		
_____ Signature	__ -__ __ __ DirecNet ID	____/____/____ Signature Date	_____ Signature	__ -__ __ __ DirecNet ID	____/____/____ Signature Date

DirecNet Inpatient Accuracy Study
History and Physical Examination Form

DirecNet Subject ID #: ☐☐☐☐☐☐ **Namecode:** ☐☐☐☐☐
1st 2 letters of 1st name, middle initial (X if none), 1st 2 letters of last name

A. HISTORY

1. Date history elicited: ☐☐☐ ☐☐ ☐☐☐☐
month day year

Complete only for diabetic subjects

2. Date of onset of diabetes: _____ _____
month year

3. Number of hypoglycemic seizures/loss of consciousness in last year: ☐0 ☐1 ☐2 ☐3 ☐>3 Num

4. Insulin route: ☐pump ☐injections **4a. Total daily insulin:** ☐☐☐ units *(average if not constant)*

4b. For injections, number of shots per day: ☐ *(usual number if not constant)*

5. Current insulin used: ☐NPH ☐Lente ☐Ultralente ☐Glargine ☐Novolog ☐Humalog ☐Regular ☐Other
Check all that apply *(list in COMMENTS)*

6. Prior continuous glucose monitor use? ☐Yes ☐No **6a. If YES:** ☐CGMS ☐GWB ☐Other *(list in COMMENTS)*
Check all that apply

Complete for both diabetic and normal subjects

7. Medications (daily): ☐Yes ☐No **7a. If YES:** ☐ACE Inhibitor ☐Other Hypertensive Drug ☐Other
Check all that apply (list all drugs/dosages in COMMENTS)

8. Allergies to medications? ☐Yes ☐No *(If yes, list in COMMENTS)*

9. Other active/pertinent medical conditions? ☐Yes ☐No *(If yes, list in COMMENTS)*

B. PHYSICAL EXAM

1. Date of physical exam: ☐☐☐ ☐☐ ☐☐☐☐
month day year

2. Abnormalities on physical exam including skin abnormalities? ☐Yes ☐No *(If yes, list in COMMENTS)*

3. Tanner staging: 3a. Pubic hair: ☐1 ☐2 ☐3 ☐4 ☐5 **3b. Breasts (F) or genitalia (M):** ☐1 ☐2 ☐3 ☐4 ☐5

C. COMMENTS

Complete for each question above for which a write-in response is needed. List the question by section and question #. Use more than one line for a question if needed. To record a miscellaneous comment that is not directly related to a question, record '99' for both the section and question (please only record miscellaneous comments that have importance for the database).

Section (A-B)	Question (1...)	Comment/Description

Coordinator			Investigator		
_____	__-__ __ __	____/____/____	_____	__-__ __ __	____/____/____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
Insulin Log

Complete this form at the end of the CRC admission by transcribing information from CRC records.

A. Injections and Pump Boluses

If 2 types of insulin given at same time, record each in a separate row.

	Date/Time	Insulin Type*	Units
1			
2			
3			
4			
5			
6			
7			
8			

	Date/Time	Insulin Type*	Units
9			
10			
11			
12			
13			
14			
15			
16			

*Insulin Types: NPH Lente Ultralente Glargine Novolog Humalog Regular Other

B. Pump Basal Rate

1. Type of Insulin Used ☐ Humalog ☐ Regular ☐ Novolog

Cross out squares prior to hospitalization. Enter basal rate in the time slot at time of admission. Complete whenever basal rate changes.

Date:											
12 am	1 am	2 am	3 am	4 am	5 am	6 am	7 am	8 am	9 am	10 am	11 am
12 pm	1 pm	2 pm	3 pm	4 pm	5 pm	6 pm	7 pm	8 pm	9 pm	10 pm	11 pm
Date:											
12 am	1 am	2 am	3 am	4 am	5 am	6 am	7 am	8 am	9 am	10 am	11 am
12 pm	1 pm	2 pm	3 pm	4 pm	5 pm	6 pm	7 pm	8 pm	9 pm	10 pm	11 pm

Coordinator			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
CGMS #1 Form

REMINDER: If CGMS#1 was inserted prior to CRC admission, download monitor at time of admission to verify that CGMS is functioning.

A. CGMS MONITOR INFORMATION

1. Monitor Serial #	2. Cable Serial #	3. Sensor Lot #	4. HGM synched to CGMS #1	5. ID to enter into CGMS
			☐ completed	**6 001**

B. SENSOR INSERTION AND REMOVAL

Complete row '1' for the initial sensor for this CGMS monitor. Rows '2', '3' and '4' are only completed if the sensor for this monitor is replaced.

	Sensor ID	"Nurse" DirecNet ID	Date/Time of Insertion	Insertion Site* (R/L, area)	Insertion Cream (none, EMLA, ELAMAX)	Blood at Insertion** (A,B,C)	Valid ISIG + VCTR?*** (Y,N,NA)	Date/Time of Removal	Sensor Appearance on Removal**** (A,B,C)	Removal Reason***** (A−D)
1	**1−1**									
2	**1−2**									
3	**1−3**									
4	**1−4**									

***Area:** Abd−UQ Abd−LQ Buttocks Thigh Hip Other
****Blood at insertion:** **A**=None Insertion Site **B**=Through Sensor **C**= Both at Insertion Site and Through Sensor
*****Valid ISIG and VCTR:** enter NA for not applicable if inserted as an outpatient and subject left office prior to this assessment
******Sensor Appearance on removal:** **A**=straight **B**=moderately curled **C**=pig's tail
*******Removal Reason:** **A**=sensor or subject complete **B**="voluntary" removal **C**=sensor failure **D**=other

C. CALIBRATION VALUES ENTERED INTO CGMS

Enter 'date' (month,day) in the first cell and then again if the date changes. Reminder: gold standard blood draw needed at time of each calibration.

	Date/Time	Value	F or V*	GS		Date/Time	Value	F or V*	GS
1				☐	5				☐
2				☐	6				☐
3				☐	7				☐
4				☐	8				☐

***Type of blood used:** **F**=finger stick **V**=Venous

D. REASON FOR EARLY REMOVAL OF SENSOR

Complete below for any sensors removed early (in section B, removal reason = B, C, or D)

	Sensor ID	"Nurse" DirecNet ID	Detail Reason for Early Removal
1			
2			
3			
4			

Coordinator			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
GlucoWatch Biographer #1 Form

Use this form for the GWB #1

A. GWB #1 INFORMATION

1. GWB Serial #	2. Ref #	3. Sensor Lot #	4. System Check	5. Time synched to CGMS #1; batteries inserted	6. Alarm Settings
			☐ pass	☐ completed	**a. High_____ b. Low_____**

B. SENSOR PLACEMENT AND REMOVAL

Complete a row for each new sensor used for this GWB

			Placement Site					
	Sensor ID	**"Nurse" DirecNet ID**	**Date/Time of Placement**	**Location** Code*	**Site Shaved?** 'No' or if yes, date	**Time Calibration Value Accepted**	**Date/Time of Removal**	**Removal Reason** (A−D)**
1	**1−1**							
2	**1−2**							
3	**1−3**							
4	**1−4**							

***Location:** Right(R) or Left(L) **/** Arm(A) or Leg(L) **/** Upper(U) or Lower(L) **/** Inner(I) or Outer(O) Ex: R/A/U/I=right upper arm or inner aspect
****Removal reason:** **A**=sensor or subject complete **B**="voluntary" removal **C**=sensor failure **D**=other

C. CALIBRATION VALUES ENTERED INTO GWB

Enter 'date' (month, day) in the first cell and then again if the date changes. Reminder: gold standard blood draw needed at time of each calibration.

	Date/Time	Value	F or V*	GS		Date/Time	Value	F or V*	GS
1				☐	5				☐
2				☐	6				☐
3				☐	7				☐
4				☐	8				☐

***Type of blood used:** **F**=finger stick **V**=venous

D. REASON FOR EARLY REMOVAL OF SENSOR

Complete below for any sensors removed early (in section B, removal reason = B, C, or D)

	Sensor ID	"Nurse" DirecNet ID	Detail Reason for Early Removal
1			
2			
3			
4			

Coordinator			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirectNet Subject ID #: **Namecode:** **Weight:** kg

DirecNet Inpatient Accuracy Study
Insulin−induced Hypoglycemia Test Form

*****Note: this test is performed only on subjects ≥ 7 years old (and weigh ≥ 23.1 kg for discard sites)*****

PRETEST PREPARATION AND CHECKLIST

Estimated start time for test: _____

☐ 2.5 hours before the scheduled start of the test, verify that subject has a functioning biographer and CGMS

- If not, initiate a new sensor (CGMS or biographer). If necessary, delay start of test until sensor calibration is completed.

☐ 1 hr prior to test, check blood glucose with study HGM: _____

- If between 70 − 80 mg/dl, give 10 grams of carbohydrate orally
- If < 70 mg/dl, give 15 grams or more of carbohydrate as per usual treatment of hypoglycemia.
- If <80 mg/dl, continue glucose monitoring every 15 minutes and repeat treatment as indicated until blood glucose is >80 mg/dl.

☐ Prior to starting the test, check blood glucose with study HGM: _____

- If between 70 − 80 mg/dl, give 10 grams of carbohydrate orally
- If < 70 mg/dl, give 15 grams or more of carbohydrate as per usual treatment of hypoglycemia.
- If <80 mg/dl, continue glucose monitoring every 15 minutes and repeat treatment as indicated until blood glucose is >80 mg/dl.

☐ Verify that physician is present prior to starting test

☐ Verify that IV dextrose is available (dose to be given if needed is 0.5 grams/kg over 3 minutes as either D25 or D50).

☐ Compute initial insulin dose and infusion rate and enter on data recording form

☐ Enter target times for blood draws on Gold Standard Blood Draws for IV Insulin Test Form

NOTES

1. If the testing time overlaps with a meal, withhold the meal until after the test.
2. If the usual timing of an injection of intermediate acting insulin would occur within 2 hours prior to the scheduled start of the test, defer the injection until after the test is completed.
3. For subjects using an insulin infusion pump, continue the basal rate during the test.

INSTRUCTIONS FOR TEST

INSULIN DOSAGE

For the test, regular insulin will be given by IV bolus.

- If the starting blood glucose is 80−100 mg/dl, then 0.05 units/kg of insulin will be given.
- If the starting blood glucose is >100 mg/dl, then 0.1 units/kg of insulin will be given.
- A second bolus can be given, at investigator discretion, 30−60 minutes after the initial bolus if the target glucose level has not been reached

MONITORING

1. During the test, blood glucose levels will be checked every 5 minutes.
   - Use the study HGM while the blood glucose is >80 mg/dl. When the glucose falls below 80 mg/dl, use a YSI, Beckman, or similar instrument for the rest of the test.
   - Venous blood from the gold standard blood draw can be used instead of a fingerstick.
2. IV dextrose can be given at physician discretion (0.5 grams/kg intravenous over 3 minutes as either D25 or D50).
3. Continue blood glucose monitoring every 5 minutes until glucose is >80 mg/dl.
4. Continue blood glucose checks at least once an hour for two hours following the completion of the test (record all HGM glucose values on this form during first two hours after the test)
5. If hypoglycemia recurs, a meal may be needed.

DirectNet Subject ID #: **Namecode:** **Weight:** kg

DirecNet Inpatient Accuracy Study
Insulin−induced Hypoglycemia Test Form

A. TEST INITIATION INFORMATION

1. Starting blood glucose: _____ mg/dl

2. Initial insulin dose: 2a. # of units _____ 2b. Time ___ ___ : ___ ___ ☐ AM ☐ PM

3. Was a 2nd insulin bolus given? ☐ Yes ☐ No

If YES, Insulin dose: 3a. # of units _____ 3b. Time: ___ ___ : ___ ___ ☐ AM ☐ PM

B. BLOOD GLUCOSE MONITORING with HGM (optional/not for data entry)

	Time	Value		Time	Value		Time	Value		Time	Value
1			7			13			19		
2			8			14			20		
3			9			15			21		
4			10			16			22		
5			11			17			23		
6			12			18			24		

C. BLOOD GLUCOSE MONITORING (values < 80 mg/dl)

1. Type of Instrument: ☐ **YSI** ☐ **Beckman** ☐ **IStat** ☐ **Other** _____

Complete this table for monitoring while the blood glucose is below 80 mg/dl.

	Time	Value		Time	Value		Time	Value		Time	Value
1			7			13			19		
2			8			14			20		
3			9			15			21		
4			10			16			22		
5			11			17			23		
6			12			18			24		

D. SYMPTOMS OF HYPOGLYCEMIA AND ANY TREATMENT GIVEN

	Time	Sx of hypoglycemia	Rx for hypoglycemia
1			
2			
3			

E. PHYSICIAN STATEMENT AT CONCLUSION OF TEST

1. Did any of the following clinical signs of hypoglycemia develop during the test?

1a. Pallor, sweating, and/or shakiness ☐ Yes ☐ No

1b. Confusion ☐ Yes ☐ No

1c. Seizures, loss of consciousness ☐ Yes ☐ No **If YES, complete an Adverse Event Form**

2. Was IV dextrose given? ☐ Yes ☐ No **If YES, complete an Adverse Event Form**

F.COMMENTS *Record any additional pertinent comments (if any) for the database*

Coordinator			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
Meal−induced Hyperglycemia Test Form

PRETEST PREPARATION AND CHECKLIST

☐ 2 hours before the scheduled start of the test, verify that subject has a functioning biographer and CGMS

- If not, initiate a new sensor (CGMS or biographer). If necessary, delay start of test until sensor calibration is completed.

☐ 2 hours prior to test, check blood glucose with study HGM: _____ mg/dl

- If the glucose value is greater than 250 mg/dl, the subject will be given a subcutaneous insulin dose (Humalog or Novolog) estimated to decrease the blood glucose to 150 mg/dl.
- Before starting the meal−induced hyperglycemia test, a HGM blood glucose level should again be obtained. If the blood glucose level is greater than 250 mg/dl, then an insulin dose should be given as described above to lower it to be less than 250 mg/dl.
- The start of the meal test should be deferred until the blood glucose level is less than 250 mg/dl.

☐ If an insulin injection or pump bolus would ordinarily be given at the time of the test, it should be withheld until 30 minutes after the carbohydrate meal/drink.

☐ Enter target times for blood draws on Gold Standard Blood Draws for Meal−induced Hyperglycemia Form

A. TEST INFORMATION

Subject's Weight: kg **Carbohydrate content of meal should be:** grams

1. Time meal started: _____ **:** _____ ☐ am ☐ pm **2. Time meal completed:** _____ **:** _____ ☐ am ☐ pm

3. Approximate percentage of meal consumed: ☐ **0%** ☐ **1−24%** ☐ **25−49%** ☐ **50−74%** ☐ **75−99%** ☐ **100%**

B. COMMENTS *Record any pertinent comments (if any) for the database*

Coordinator			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
Skin Assessment Form
CRC Discharge
Observer #1

For CGMS, fill in 'Insertion Site' and for GWB fill in 'Location Code' prior to completing this form. The insertion site/location code entries must match the CGMS and GWB data forms.

A. Examiner

1. DirecNet ID of Individual Making Skin Assessment ____ − ____ ____ ____

2. Date ☐☐☐ ☐☐ ☐☐☐☐
month *day* *year*

B. CGMS

Complete a separate assessment for each location where a CGMS was inserted. Insertion site(s) must match CGMS Form(s).

	Sensor ID	**Insertion Site** (R/L, area)	**Induration** (mm)	**Erythema** (mm)	**Comment**
1	**1−1**				
2	**1−2**				
3	**1−3**				
4	**1−4**				
5	**2−1**				
6	**2−2**				
7	**2−3**				
8	**2−4**				

Area: Abd−UQ Abd−LQ Buttocks Thigh Hip Other

C. GlucoWatch Biographer

Complete a separate assessment for each location where a GWB was worn. Location codes must match GWB Form(s).

			Outer Adhesive Area					**Inner Circle (gel pad−extraction site)**				
	Sensor ID	**Location Code***	**Erythema** (0−4)	**Edema** (0−4)	**Total****	**Blister (Y/N)**		**Erythema** (0−4)	**Edema** (0−4)	**Total****	**Blister (Y/N)**	**Comment**
1	**1−1**											
2	**1−2**											
3	**1−3**											
4	**1−4**											
5	**2−1**											
6	**2−2**											
7	**2−3**											
8	**2−4**											

* Right(R)−Left(L)/Arm(A)−Leg(L)/Upper(U)−Lower(L)/Inner(I)−Outer(O) ex: R/A/U/I=right upper arm on inner aspect
****Total=erythema score + edema score. If any total score is >=6, complete an Adverse Event Form.**

Individual Completing Form			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
CRC Discharge/Subject Withdrawal Form

This form is completed for every subject enrolled into the study and is used to record (1) the dates of the hospital stay and CGMS initiation for subjects who were admitted to the CRC and (2) the reason for withdrawal from the study for subjects who did not complete the study.

A. DISPOSITION OF SUBJECT

Select one of the following to indicate the disposition of the subject. *(If subject was withdrawn from study, detail reasons in COMMENTS)*

☐ Inpatient stay completed

☐ 12 or more hours of use of each sensor completed, but withdrawn prior to end of inpatient stay

☐ Admitted to CRC, but withdrawn from study prior to successfully completing at least 12 hrs of use of either the CGMS or the GWB

☐ CGMS initiated as outpatient but subject never admitted to CRC

☐ Withdrawn from study prior to using either sensor

B. DATES OF CRC STAY AND INITIATION OF CGMS

1. CGMS #1 initiation: 1a. Date ☐☐☐ ☐☐ ☐☐☐☐ *Month Day Year* **1b. Time:** ___ ___ : ___ ___ ☐ AM ☐ PM

2. CRC admission ☐☐☐ ☐☐ ☐☐☐☐ *Month Day Year*

3. CRC discharge ☐☐☐ ☐☐ ☐☐☐☐ *Month Day Year*

C. CRC PROCEDURES AND EVENTS

1. Procedures: ***Check all that were done*** *(If all age−weight specified procedures not fully completed, detail reasons in COMMENTS)*

☐ Hourly blood draws ☐ 1/2−hour overnight blood draws ☐ Insulin−induced hypoglycemia ☐ Meal−induced hyperglycemia

2. Did subject use the optional 2nd simultaneous CGMS (CGMS#2)? ☐ Yes ☐ No

3. Skin assessment completed? ☐ Yes ☐ No

4. Did any reportable adverse events occur in the CRC? ☐ Yes ☐ No *(If YES, an Adverse Event Form must be completed.)*

5. Ancillary studies *(diabetic subjects only)*: 5a. Physical activity ☐ Yes ☐ No **5b. GWB alarm** ☐ Yes ☐ No

6a. Ultra serial number _____ **6b. PtID entered in CGMS #1** _____ **6c. PtID entered in CGMS #2** _____

6d. GWB #1 serial number _____ **6e. GWB #2 serial number** _____

*****For diabetic subjects remember to complete the Insulin Log*****

D. COMMENTS

Coordinator			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
Skin Assessment Form
Post−CRC Outpt Visit
Observer #1

For CMGS, fill in 'Insertion Site' and for GWB fill in 'Location Code' prior to completing this form. The insertion site/location code entries must match the CGMS and GWB data forms.

A. Examiner

1. DirecNet ID of Individual Making Skin Assessment ____ − ___ ___ ___

2. Date ☐☐☐ ☐☐ ☐☐☐☐ *month* *day* *year*

B. CGMS

Complete a separate assessment for each location where a CGMS was inserted. Insertion site(s) must match CGMS Form(s).

	Sensor ID	**Insertion Site** (R/L, area)	**Induration** (mm)	**Erythema** (mm)	**Comment**
1	**1−1**				
2	**1−2**				
3	**1−3**				
4	**1−4**				
5	**2−1**				
6	**2−2**				
7	**2−3**				
8	**2−4**				

Area: Abd−UQ Abd−LQ Buttocks Thigh Hip Other

C. GlucoWatch Biographer

Complete a separate assessment for each location where a GWB was worn. Location codes must match GWB Form(s).

			Outer Adhesive Area					**Inner Circle (gel pad−extraction site)**				
	Sensor ID	**Location Code***	**Erythema** (0−4)	**Edema** (0−4)	**Total****	**Blister (Y/N)**		**Erythema** (0−4)	**Edema** (0−4)	**Total****	**Blister (Y/N)**	**Comment**
1	**1−1**											
2	**1−2**											
3	**1−3**											
4	**1−4**											
5	**2−1**											
6	**2−2**											
7	**2−3**											
8	**2−4**											

* Right(R)−Left(L)/Arm(A)−Leg(L)/Upper(U)−Lower(L)/Inner(I)−Outer(O) ex: R/A/U/I=right upper arm on inner aspect

****Total=erythema score + edema score. If any total score is >=6, complete an Adverse Event Form.**

Individual Completing Form			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
Post−CRC Outpatient Visit Form

A. VISIT INFORMATION

1a. Visit Date: ☐☐☐ ☐☐ ☐☐☐☐ *Month* *Day* *Year* ☐ **1b. visit missed (and will not be completed)**

2. Skin assessment form completed? ☐ Yes ☐ No

3. Did any reportable adverse events occur since the subject was discharged? ☐ Yes ☐ No

(if YES, complete an Adverse Event Form)

4. Is any further follow up for skin reaction needed? ☐ Yes ☐ No

B. COMMENTS *If the visit was missed, indicate whether a phone call assessment of the skin was completed.*

Coordinator			**Investigator**		
_____	___−___ ___ ___	_____/_____/_____	_____	___−___ ___ ___	_____/_____/_____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

DirecNet Inpatient Accuracy Study
Adverse Event Form

This form is used to record adverse events. One form is to be completed for each adverse event experienced by a subject. Definitions for completion of this form appear in the protocol and on a separate page.

DirecNet Subject ID #: _____ **Namecode:** _____

1st 2 letters of 1st name, middle initial (X if none), 1st 2 letters of last name

A. ADVERSE EVENT INFORMATION

1. Adverse Event (Describe):

2. Date of Onset: ☐☐☐ ☐☐ ☐☐☐☐ *month day year*

3. Did this condition exist prior to enrollment? ☐Yes ☐No

4. Intensity (severity): ☐mild ☐moderate ☐severe

5. Related to sensor(s): ☐not related ☐possible ☐probable ☐definite

6. Related to study procedures other than sensor use: ☐not related ☐possible ☐probable ☐definite

7. Effect on sensor(s): ☐no change ☐discontinued CGMS ☐discontinued GWB ☐discontinued CGMS and GWB
check one

8. Treatment required: ☐Yes ☐No (*If YES, detail in COMMENTS)*

9. Criteria met for Serious Adverse Event? ☐Yes ☐No

9a. If YES, which criteria met? ***check all that apply*** ☐death ☐life-threatening ☐required or prolonged hospitalization ☐permanent disability ☐required intervention to prevent permanent impairment/damage

10. Outcome: ☐Recovered, no residual effects ☐Recovered with sequelae ☐Persistent active condition ☐Death
check one

11. Date of Resolution: ☐☐☐ ☐☐ ☐☐☐☐
leave blank if not resolved *month day year*

B. ADDITIONAL COMMENTS

******Signatures and dates must be complete prior to data entry******

Coordinator			**Investigator**		
_____	___-___ ___ ___	____/____/____	_____	___-___ ___ ___	____/____/____
Signature	DirecNet ID	Signature Date	Signature	DirecNet ID	Signature Date

Definitions:

Adverse event- Any untoward medical occurrence in a research subject treated with a medical device during a clinical trial or post-study follow-up period, regardless of causality assessment. This includes adverse clinical or laboratory findings, intercurrent illness, or an exacerbation or progression of a disease/condition present at baseline.

Unanticipated Adverse Device Event- An adverse event caused by, or associated with, a device, if that effect or problem was not previously identified in nature, severity, or degree of incidence.

Serious Adverse Event (SAE)- An adverse event that meets one or more of the following criteria: (1) death, (2) life-threatening, (3) required or prolonged hospitalization, (4) permanent disability, or (5) required intervention to prevent permanent impairment/damage.

Life-threatening adverse event- Any adverse event in which the patient was at immediate risk of death from the event as it occurred. It does not include an event that might have caused death had it occurred in a more serious form. For example, drug-induced hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening even though drug-induced hepatitis can be fatal.

Requires inpatient hospitalization- Hospital admission required for treatment of the adverse event.

Intensity of adverse event – Graded on three point scale
1=Mild – Symptom(s) barely noticeable to subject or does not make subject uncomfortable; does not influence performance or functioning; prescription drug not ordinarily needed for relief of symptom(s).

2=Moderate – Symptom(s) of sufficient severity to make subject uncomfortable; performance of daily activity is influenced; subject is able to continue in study; treatment for symptom(s) may be needed.

3=Severe – Symptom(s) cause severe discomfort; severity may cause cessation of use of study device; treatment for symptom(s) may be given and/or subject hospitalized.

Relationship of Adverse Event to Study Device
1=Not related- Any reaction that does not follow a reasonable temporal sequence from administration of study device AND that is likely to have been produced by the subject's clinical state or other modes of therapy administered to the subject.

2=Possible – Any reaction that does not follow a reasonable temporal sequence from administration of study device OR that is likely to have been produced by the subject's clinical state or other modes of therapy administered to the subject.

3=Probable – A reaction that follows a reasonable temporal sequence from administration of study device AND that could not be reasonably explained by the known characteristics of the subject's clinical state or other modes of therapy administered to the subject.

4=Definite – A reaction that follows a reasonable temporal sequence from administration of study device AND that follows a known response pattern to the suspected device AND that recurs with re-administration, and/or is improved by stopping the use of the device.

Reporting Requirements
Skin Irritation
A skin assessment resulting in a biographer irritation score of 6 is considered an Adverse Event and will be recorded on an Adverse Event Form in addition to being recorded on the skin assessment case report form.

Hyperglycemia and Hypoglycemia
For the diabetic subjects, high and low blood glucose levels are expected and will not per se constitute adverse events. Hyperglycemia is only recorded as an adverse event if diabetic ketoacidosis or hyperosmolar nonketotic coma develops. Hypoglycemia is only recorded as an adverse event if seizures or loss of consciousness occurs and/or the episode requires treatment other than oral ingestion of carbohydrate. This also pertains to the insulin-induced hypoglycemia test--complete an Adverse Event Form if IV dextrose is given (even if seizures or loss of consciousness do not occur).

Serious and/or Unexpected Adverse Events
Any serious or unexpected adverse event occurring during or after completion of the study, irrespective of the treatment received by the patient, will be reported to the Coordinating Center within one working day of occurrence. A written report on such an event will be sent to the Coordinating Center within five days of occurrence, stating a description of the reaction, any required intervention, and the outcome. Each principal investigator is responsible for informing his/her IRB of serious study-related adverse events and abiding by any other reporting requirements specific to their IRB.

Contact Information for the Jaeb Center:
M-F 8:00 am – 5:00 pm Eastern time
Phone: 1-813-975-8690
Fax: 1-813-903-8227
Email: direcnet@jaeb.org