A Randomized Clinical Trial to Assess the Effectiveness of the GlucoWatch Biographer in the Management of Type 1 Diabetes in Children

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DirecNet Outpatient Randomized Clinical Trial
Enrollment Visit Form

A. Identifying Information

1. Namecode: ____ ____ ____ ____ ____

2. Date of birth: ___ ___ **/** ___ ___ **/**___ ___ **mm/dd/yy** *(Age must* be ≥ *7.0 to < 18.0 yrs)*

3. Informed Consent Form signed by the parent/guardian on ___ ___ **/** ___ ___ **/**___ ___ **mm/dd/yy**

4. Child Assent Form signed by the subject on ___ ___ **/** ___ ___ **/**___ ___ **mm/dd/yy**

5. Study ID of Enrolling Investigator ____**--**____ ____ ____

Enrollment Visit History Form

B. Demographic Information

1. Gender: ☐Male ☐Female

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

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

C. Diabetes History

1. Date of diagnosis of diabetes: ___ ___ / ___ ___ **mm/yy**

2. Dx of Type I diabetes: ☐Yes ☐No *(Must be YES for eligibility)*

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

4. Prior continuous glucose monitor use? ☐Yes ☐No **4a. If Yes,** ☐CGMS ☐GWB ☐Other_____
Check all that apply. Pt is not eligible if prior GWB home use, except in research study

5. Insulin Use

5a. Duration of insulin use > 1 year? ☐Yes ☐No (*Must be YES for eligibility)*

5b. Insulin route: ☐pump ☐injections

5c. Total daily insulin: _____ _____ _____ Units *(Average if not constant)*

5d. For injections, number of shots per day: _____ *(Usual number if not constant)*

5e. Current insulin used: ☐NPH ☐Lente ☐Ultralente ☐Glargine ☐Novolog ☐Humalog ☐Regular ☐Other_____
Check all that apply

5f. Has insulin regimen been stable for ≥2 mos, with no plans to switch modality during next 6 mos ☐Yes ☐No
(*Must be YES for eligibility)*

D. Other Medical History

1. Medications (daily): ☐Yes ☐No **1a. If yes, list drug/dosage** _____

Pt ineligible if current use of oral/inhaled glucocorticoids or other medications, which in judgment of investigator would be a contraindication to study participation.

2. Allergies to medications? ☐Yes ☐No **2.a. If yes, list**_____

3. Other active/pertinent medical conditions? ☐Yes ☐No **3.a. If yes, list** _____

4. Are any of the following present: ☐Yes ☐No (*Must be NO for eligibility)*

- Asthma treated with systemic or inhaled corticosteroids in the last 6 months
- Cystic fibrosis
- Other major illness that in the judgment of the investigator might interfere with the completion of the protocol

E. Socioeconomic Information

1. Please circle the highest level of education completed by the primary caregiver(s):

1a. Mother , Father, Other **<4 4 5 6 7 8 9 10 11 12 AA BS/BA MS/MA Professional Degree (eg MD)**

1b. If Other caregiver: **Grandmother Grandfather Aunt Uncle Older Sibling**
Please Circle One

1c. Mother, Father **<4 4 5 6 7 8 9 10 11 12 AA BS/BA MS/MA Professional Degree (eg MD)**

F. Miscellaneous

1. Subject records blood glucose levels? ☐Yes ☐No **1a. If Yes,** ☐Everyday ☐3-5 days per week ☐<3 days per week

1b. How is it recorded? ☐Paper Diary ☐Computer Diary ☐Computer Download ☐Other_____

2. The following have been verified ☐Yes ☐No *(Must be YES for eligibility)*

a. **Parent/guardian and subject understand the study protocol and agree to comply with it, including the performance of at least 4 fingerstick glucose checks a day with a home glucose monitor.**

b. **Subjects ≥11.0 years old and primary care giver (i.e., parent or guardian) comprehend written English.**

c. **For females, subject not intending to become pregnant during the next 6 months.**

d. **No expectation that subject will be moving out of the area of the clinical center during the next 6 months.**

e. **Neither the subject nor the subject's parent/guardian have had inpatient psychiatric treatment in the past 6 months.**

Enrollment Visit Physical Examination Form

G. Physical Exam

1. Exam Date ___ ___ **/** ___ ___ **/**___ ___ **mm/dd/yy** *(Must be within 14 days of enrollment)*

2. Weight: ____ ____ .____ kg **3. Height:** ____ ____ ____ . ____ cm

4. Abnormalities on physical exam? ☐ Yes ☐ No

4.a. If yes, list_____

5. Are there any skin abnormalities that will affect the wearing of the sensors? ☐Yes ☐No *(Must be NO for eligibility)*

6. Tanner staging: **6a. Pubic hair:** ☐1 ☐2 ☐3 ☐4 ☐5 **6b. Breasts (F) or genitalia (M):** ☐1 ☐2 ☐3 ☐4 ☐5

H. HbA1c

1. Date of Test: __ __ / __ __ / __ __ *(Must be within 14 days of enrollment)*	**2. HbA1C (from DCA2000):** ___ ___ . ___ **%** *(Must be 7.0 to 11.0 inclusive for eligibility)*

I. Skin Assessment

1. Are there any patches, scars, dry skin, pigmentation irregularities, or other visible marks on the subject's skin? ☐Yes ☐No
a. If Yes, describe (indicate the location*):

*Right(R)-Left(L)/Arm(A)-Leg(L)/Upper(U)-Lower(L) ex:R/A/U=right upper arm

Comments

DirecNet Outpatient Randomized Clinical Trial
CGMS Insertion Information

A. Visit Information

Visit: ☐ **Enrollment**	☐**3-Months**	☐**6-Months**
Insertion Type:	☐ **Initial**	☐ **Repeat**
☐ **Patient Refused to have CGMS Inserted** ****only appears on 3 month and 6 month form****		

B.CGMS Information

1. **Monitor Serial Number**_____
2. **Sensor Lot Number:** _____
3. **Date of Insertion:** __ __ / __ __ / __ __
4. **Time of Insertion:** __ __ : __ __ ☐**AM** ☐**PM**
5. **Insertion Side:** ☐**Right** ☐**Left**
6. **Insertion Area:** ☐**Abd-UQ** ☐**Abd-LQ** ☐**Buttocks** ☐**Thigh** ☐**Hip** ☐**Other**
   (circle one)
7. **DirecNet ID of Individual Inserting CGMS:**____**--**_____ _____ _____

C. Comments

DirecNet Outpatient Randomized Clinical Trial
Insulin Log

Date of Completion: ___ ___ / ___ ___ / ___ ___ **(mm/dd/yy)**

Completion Time: ☐Randomization ☐3-Month Visit ☐6-Month Visit ☐9-Month Visit ☐12-Month Visit

Modality of Insulin: ☐Injections ☐Pump

A. Short-Acting Insulin (All Patients)

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

2. Insulin to Carbohydrate Ratios (*Complete units per grams of carbs or check not used)*:

2a. Breakfast Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ___ not used

2b. Lunch Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ___ not used

2c. Dinner Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ___ not used

3. Usual Meal Doses (Record all quick acting doses for injection patients and meal bolus doses for pump patients):

Breakfast: _____ Lunch: _____ Dinner: _____ Snack: _____

4. Average Correction (Sensitivity) Factors: 1 unit per _____ mg/dl above ____ ☐Not Used

5. Record average number of injections/day (Injection patients) or boluses/day (pump patients) over the prior 7days: _____

B. Long-acting average insulin dose (Injection Patients Only)

Complete the table for the subject's average insulin doses over the last 7 days. Do not include any rapid acting insulin here. If more than one type of insulin is given at the same time, complete a separate row for each type.

	Timeframe*	Insulin Type**	Usual Units
1			
2			
3			
4			
5			
6			

*** Timeframe**: Breakfast, Lunch, Dinner, Snack, or Bedtime

****Insulin Types:** NPH Lente Ultralente Glargine (Lantus) Other

C. Pump Basal Rate (Pump Patients Only)

Enter current basal rate

12am	1230	1am	130	2am	230	3am	330	4am	430	5am	530	6am	630	7am	730	8am	830	9am	930	10am	1030	11 am	1130
12 pm	1230	1 pm	130	2 pm	230	3 pm	330	4 pm	430	5 pm	530	6 pm	630	7 pm	730	8 pm	830	9 pm	930	10 pm	1030	11 pm	1130

D. Change in Diabetes Management Recommendations

1. Are there any recommendations for changes in diabetes management: ☐Yes ☐No

2. If Yes, please indicate the types of changes made *(select all that apply)*:

- ☐ Dose Change in pre-meal rapid acting insulin
- ☐ Change in basal/intermediate or long-acting insulin
- ☐ Change in correction algorithm
- ☐ Change in insulin to carb ratio
- ☐ Change in treatment of hypoglycemia
- ☐ Nighttime Change Due to Dawn Phenomenon
- ☐ Modification of Regimen for High Fat Meals
- ☐ Modification of Regimen for High Glycemic Foods
- ☐ Referral for Counseling to Improve Adherence with Diabetes Regimen
- ☐ Alteration in the Approach to Exercise
- ☐ Other _____

Comments

DirecNet Outpatient Randomized Clinical Trial
Randomization Visit History Form

Visit Date: ___ ___ / ___ ___ /___ ___ **mm/dd/yy**

DirecNet ID of Investigator Performing Visits:___--___ ___ ____

A. Compliance Assessment

HGM

1. **Did the subject complete at least 6 fingersticks a day for 2 days?** ☐Yes ☐No (Must be Yes for eligibility)
2. **Did the subject record BG values on log during the days of 8-point testing?** ☐Yes ☐No ☐Didn't bring

CGMS

3. **Did the subject enter 4 calibration values per day in CGMS?** ☐Yes ☐No (Must be Yes for eligibility)
4. **Did the subject complete at least 48 hours of CGMS use?** ☐Yes ☐No (Must be Yes for eligibility)

B. Hypoglycemia Assessment

1. **Did the subject have any symptomatic episodes of hypoglycemia during the last 7 days?** ☐Yes ☐No
   If Yes,
   a. **How many episodes?** _____
   b. **How many were verified with blood glucose?** _____
   c. **How many of these low blood sugars were severe? In other words, how many of them caused the subject to faint or have a seizure?** _____
2. **Complete the following for each severe low blood sugar indicated in 1c above.**

Date	Asleep (Y or N)	Confirmed with Fingerstick? (Y or N)	Treatment*

* Glucagon, ER/EMT, Glucose Gel, Oral (Other than glucose gel rubbed on the gums)

C. HbA1c

1. **Date of Test:** __ __ / __ __ / __ __ **2. HbA1C (from DCA2000):** ___ ___ . ___ **%**

Randomization Visit Computer Experience

D. Computer Experience

1. **Does the subject have prior computer experience?** ☐Yes ☐No
2. **Does the parent (primary care giver) have prior computer experience?** ☐Yes ☐No
3. **Does the family currently have a home computer?** ☐Yes ☐No
4. **Did the subject/primary care giver pass the computer proficiency test?** ☐Yes ☐No (Must be Yes for eligibility)

√ All of the following boxes must be checked for the subject/primary caregiver to have passed the PC proficiency test.

- ☐ **Cables connected (mouse, keyboard, monitor, printer, phone line, HGM, and GWB)**
- ☐ **PC turned on**
- ☐ **HGM time recorded and device downloaded**
- ☐ **GWB time recorded and device downloaded**
- ☐ **Practice weekly questionnaire completed**
- ☐ **Understanding of the applications accessible on the PC during the study demonstrated**

Comments

DirecNet Outpatient Randomized Clinical Trial
Phone Contact Form
<<To be Customized by Group>>

A. Call Information

1. Call Date: ___ ___ / ___ ___ /___ ___ *mm/dd/yy*

Call window: ☐**Wk1** ☐**Wk2** ☐**Wk4** ☐**Wk8** ☐**Wk16** ☐**Wk20**

3a. ☐**Call was missed and will not be completed**

3b. Reason: _____

4. Time of Call Initiation: ___: ___ ☐ **AM** ☐**PM**

5. Time of Call Completion: ___: ___☐ **AM** ☐**PM**

6. Person Spoken To: **Subject** **Other**

7. If Other, Relationship to Subject*: _____

[*Please Choose One: Mother, Father, Grandmother, Grandfather, Aunt, Uncle, Older Sibling]

8. DirecNet ID of Person Completing Call: ___ - ___ ___ ___

B. Change in Diabetes Management Decisions

1. Were there any permanent changes in diabetes management since the last contact: ☐Yes ☐No

2. If Yes, please indicate the types of changes made *(select all that apply and whether or not each change was self-initiated or based on study personnel recommendation during the previous contact)*

- ☐ Dose Change in pre-meal rapid acting insulin ☐ Self-initiated ☐Clinician recommended
- ☐ Change in basal/intermediate or long-acting insulin ☐ Self-initiated ☐ Clinician recommended
- ☐ Change in correction algorithm ☐ Self-initiated ☐ Clinician recommended
- ☐ Change in insulin to carb ratio ☐ Self-initiated ☐ Clinician recommended
- ☐ Change in treatment of hypoglycemia ☐ Self-initiated ☐ Clinician recommended
- ☐ Nighttime Change Due to Dawn Phenomenon ☐ Self-initiated ☐ Clinician recommended
- ☐ Modification of Regimen for High Fat Meals ☐ Self-initiated ☐ Clinician recommended
- ☐ Modification of Regimen for High Glycemic Foods ☐ Self-initiated ☐ Clinician recommended
- ☐ Referral for Counseling to Improve Adherence with Diabetes Regimen ☐ Self-initiated ☐ Clinician recommended
- ☐ Alteration in the Approach to Exercise ☐ Self-initiated ☐ Clinician recommended
- ☐ Other _____ ☐ Self-initiated ☐ Clinician recommended

C. Hypoglycemia Assessment

1. Did the subject have any symptomatic episodes of hypoglycemia during the past 7 days? ☐Yes ☐No

If Yes,

a. How many episodes? _____

b. How many were verified with fingerstick blood glucose? _____

c. How many of these low blood sugars were severe? In other words, how many of them caused the subject to faint or have a seizure? _____

2. Complete the following for each severe low blood sugar indicated in 1c above.

Date	Asleep (Y or N)	Confirmed with Fingerstick? (Y or N)	Treatment*

*** Glucagon, ER/EMT, Glucose Gel, Oral (Other than glucose gel rubbed on the gums)**

D. GWB Use (**FOR GWB GROUP ONLY**)

1. **Are you using the GWB at all?** ☐Yes ☐No
   If No, indicate reason (select any of the following that apply):
   - ☐Skin irritation
   - ☐Alarms too frequently
   - ☐Skips too frequently
   - ☐Does not provide accurate readings
   - ☐Too difficult to operate
   - ☐Other _____

2. **How many times during the day did the subject use the GWB the past 7 days?** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

3. **How many times during the night did the subject use the GWB the past 7 days?** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

4. **Has a prescription spray been used for skin irritation since the last contact?**
   ☐Yes, in last 7 days ☐Yes, more than 7 days ago ☐No

5. **Did the subject have any problems while using the GlucoWatch?** ☐Yes ☐No
   If Yes, did any of the following occur?
   - ☐The GWB would not calibrate and sensor had to be replaced
     Check any reasons why the GWB would not calibrate:
     ☐VOLT Error ☐PRSP Error ☐READ Error ☐HIGH or LOW Error ☐Not Known
   - ☐The GlucoWatch was knocked off the subject's skin
   - ☐The subject was sweating and the GlucoWatch read SKIP repeatedly (>5 times)
   - ☐The GlucoWatch shut off early
   - ☐The subject removed the GlucoWatch due to discomfort
   - ☐Other _____

6. **Please have the subject look at the areas of skin where the watch was worn in the past week and ask them to select any of the following that apply:**
   - ☐Skin looks normal, no areas of dryness of skin discolorations
   - ☐Some dry patches of skin or mild changes to skin tone/color (pigment)
   - ☐Very dry patches of skin or moderate to severe changes to skin tone/color (pigment)

7. **Ask the subject to look at the areas of skin where the watch was worn in the past week and have the subject compare skin to the pictures provided in the subject procedure manual or on the home PC.**
   - ☐Skin looks normal, no marks or irritation
   - ☐Slightly irritated (some redness or swelling similar to picture A)
   - ☐Very irritated (very red or swollen similar to picture B or C)

E. Home Diary Use

1. **Did subject/parent record blood glucose levels in the past 7 days?** ☐Yes ☐No
   If Yes,
   1a. How often was it recorded? ☐Everyday ☐3-5 days ☐<3 days
   1b. How was it recorded? ☐Log book ☐Computer Diary ☐Computer Download ☐Other_____

F. Change in Diabetes Management Recommendations

1. **Are there any recommendations for changes in diabetes management:** ☐Yes ☐No
2. **If Yes, please indicate the types of changes made** *(select all that apply)***:**
   - ☐ Dose Change in pre-meal rapid acting insulin
   - ☐ Change in basal/intermediate or long-acting insulin
   - ☐ Change in correction algorithm
   - ☐ Change in insulin to carb ratio
   - ☐ Change in treatment of hypoglycemia
   - ☐ Nighttime Change Due to Dawn Phenomenon
   - ☐ Modification of Regimen for High Fat Meals
   - ☐ Modification of Regimen for High Glycemic Foods
   - ☐ Referral for Counseling to Improve Adherence with Diabetes Regimen
   - ☐ Alteration in the Approach to Exercise
   - ☐ Other _____

Comments

DirecNet Outpatient Randomized Clinical Trial
Follow-up Visit Form

1. Visit Date: ___ ___ / ___ ___ /___ ___ **mm/dd/yy** **2. Visit Type:** ☐**3 Month** ☐**6 Month** ☐**9 Month** ☐**12 Month**

A. Hypoglycemia Assessment

1. **Did the subject have any symptomatic episodes of hypoglycemia during the last 7 days?** ☐Yes ☐No
   If Yes,
   a. **How many episodes?** _____
   b. **How many were verified with a fingerstick blood glucose?** _____
   c. **How many of these low blood sugars were severe? In other words, how many of them caused the subject to faint or have a seizure?** _____

2. **Complete the following for each severe low blood sugar:**

Date	Asleep (Y or N)	Confirmed with Fingerstick? (Y or N)	Treatment*

* Glucagon, ER/EMT, Glucose Gel, Oral (Other than glucose gel rubbed on the gums)

B. Medical History

1. **Have there been symptoms of new medical problems since enrollment?** ☐Yes ☐No
   a. **If Yes, please explain** _____

2. **If subject had previous condition or pre-existing medical problem, has this condition been affected by the study?** ☐Yes ☐No ☐N/A
   a. **If Yes, please explain** _____

C. Physical Examination

1. **Abnormalities on physical exam?** ☐ Yes ☐ No
   a. **If yes, please explain** _____

D. HbA1c

1. **HbA1C (from DCA2000):** ___ ___ . ___ **%** **Date of Test:** ___ ___ / ___ ___ /___ ___ **mm/dd/yy**

COMMENTS

Follow-up Visit GWB Form

(**For GWB Group Only at 3 and 6 months; For all patients at 9 and 12 months**)

E. GWB Use

1. Are you using the GWB at all? ☐Yes ☐No

a. If No, indicate reason (select any of the following that apply):

☐Skin irritation
☐Alarms too frequently
☐Skips too frequently
☐Does not provide accurate readings
☐Too difficult to operate
☐Too busy to use it
☐Forget to use it
☐Does not provide information that is helpful for diabetes management
☐Other _____

b. If Yes, answer the following question:

Many people do not use the GWB as often as it could be used. Please indicate any reasons why you do not use the GWB more often (select any of the responses that apply):

☐Skin irritation
☐Alarms too frequently
☐Skips too frequently
☐Does not provide accurate readings
☐Too difficult to operate
☐Too busy to use it
☐Forget to use it
☐Does not provide information that is helpful for diabetes management
☐Other _____

2. How many times during the day did the subject use the GWB the last 7 days? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

3. How many times during the night did the subject use the GWB the last 7 days? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

4. Has a prescription spray been used for skin irritation since the last contact?

☐Yes, in last 7 days ☐ Yes, more than 7 days ago ☐No

5. Did the subject have any problems while using the GlucoWatch? ☐Yes ☐No

If Yes, did any of the following occur?

☐The GWB would not calibrate and the sensor had to be replaced

Check any reasons why the GWB would not calibrate:

☐VOLT Error ☐PRSP Error ☐READ Error ☐HIGH or LOW Error

☐ The GlucoWatch was knocked off the subject's skin

☐ The subject was sweating and the GlucoWatch read SKIP repeatedly (>5 times)

☐ The GlucoWatch shut off early

☐ The subject removed the GlucoWatch due to discomfort

☐ Other _____

F. Skin Assessment

1. Acute Assessment

1. Are there any acute changes reflective of GWB use? ☐ Yes ☐ No

a. If yes, please inspect each extremity and complete a separate assessment for each location where there is an abnormality reflective of GWB use.

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

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

2. General Assessment

1. Are there any non-acute (i.e. not edema or erythema) skin changes reflective of GWB use? ☐**Yes** ☐**No**

a. If Yes, place a check mark next to all locations that are affected and complete <u>all</u> information for only those locations:

	Location*	Scabbing Present?	Scabbing # Sites	Dry Skin Present?	Hypo/Hyper pigmentation Area**	Scarring Area**	Comment
☐	**R/A/U**	☐Yes ☐No		☐Yes ☐No			
☐	**R/A/L**	☐Yes ☐No		☐Yes ☐No			
☐	**L/A/U**	☐Yes ☐No		☐Yes ☐No			
☐	**L/A/L**	☐Yes ☐No		☐Yes ☐No			
☐	**R/L/U**	☐Yes ☐No		☐Yes ☐No			
☐	**R/L/L**	☐Yes ☐No		☐Yes ☐No			
☐	**L/L/U**	☐Yes ☐No		☐Yes ☐No			
☐	**L/L/L**	☐Yes ☐No		☐Yes ☐No			

*Right(R)-Left(L)/Arm(A)-Leg(L)/Upper(U)-Lower(L) ex: R/A/U=right upper arm
**Area = width X height in cubic centimeters (ex: scar 3 cm long and 0.5 cm wide, Area = 1.5); add up all areas of skin involvement on one location; enter "0" if no changes

COMMENTS

DirecNet Outpatient Randomized Clinical Trial
Non-Protocol Phone Contact

A. Call Information

1. **Call Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy**
2. **Time of Call Initiation: ___: ___☐ AM ☐PM**
3. **Time of Call Completion: ___: ___☐ AM ☐ PM**
4. **Person Spoken To: Subject Other**
5. **If Other, Relationship to Subject*: _____**
   [*Please Choose One: Mother, Father, Grandmother, Grandfather, Aunt, Uncle, Older Sibling]
6. **DirecNet ID of Person Completing Call: ___ - ___ ___ ___**

B. Reason for Call – Please Check One or More of the Following:

☐ 1. Subject encountered a problem or had a question related to the GWB
☐ 2. Subject encountered a problem or had a question related to the HGM
☐ 3. Subject had a GWB skin reaction **[If checked please complete section C]**
☐ 4. Subject encountered a problem or had a question related to the CGMS
☐ 5. Subject experienced hyperglycemia
☐ 6. Subject experienced a hypoglycemic event
☐ 7. Subject encountered a problem or had a question related to his or her Home PC
☐ 8. Reminder for timely completion of Weekly Questionnaire
☐ 9. Reminder for upcoming scheduled visit
☐ 10. Subject requested additional supplies
☐ 11. Other **[If checked please detail in section D]**

C. Skin Assessment

1. **Ask the subject to please look at the areas of skin where the watch was worn in the past 7 days and select any of the following that apply:**
   ☐Skin looks normal, no areas of dryness of skin discolorations
   ☐Some dry patches of skin or mild changes to skin tone/color (pigment)
   ☐Very dry patches of skin or moderate to severe changes to skin tone/color (pigment)
   ☐Other **[If checked please detail in section D]**
2. **Ask the subject to look at the areas of skin where the watch was worn in the past week and have the subject compare skin to the pictures provided in the subject procedure manual or on their home PC.**
   ☐Skin looks normal, no marks or irritation
   ☐Slightly irritated (some redness or swelling similar to picture A)
   ☐Very irritated (very red or swollen similar to picture B or C)

D. Additional Information

DirecNet Outpatient Randomized Clinical Trial
Non-Protocol Visit

Visit Date: ___ ___ / ___ ___ /___ ___ **mm/dd/yy** **Approximate Duration of Visit:** _____ **Minutes**

A. Reason for Visit –Please Check One or More of the Following:

- ☐ 1. Subject encountered a problem or had a question related to the GWB
- ☐ 2. Subject encountered a problem or had a question related to the HGM
- ☐ 3. Subject had a GWB skin reaction [If checked please complete section B]
- ☐ 4. Subject encountered a problem or had a question related to the CGMS
- ☐ 5. Other [If checked please detail in section C]

B. Skin Assessment – Complete if Question #A.3 Above is Checked:

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

*Right(R)-Left(L)/Arm(A)-Leg(L)/Upper(U)-Lower(L) ex:R/A/U=right upper arm
** Total = Erythema score + Edema score. Score of $\geq$ 6 requires completion of Adverse Event Form

C. Comment

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

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 subjects 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.

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

DirecNet Outpatient Randomized Clinical Trial
Serious Adverse Event Form

Instructions for Completion:
1. FAX this form to Jaeb Center for Health Research at (813) 903-8227 within 24 hours of discovering the event.
2. Call the DCC Coordinator at (813) 975-8690 or email (direcnet@jaeb.org) to insure this notification has been received.
3. Fax this form within 24 hours even if information is incomplete; remaining information can be provided at a later time.

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. DESCRIPTION *(description of AE should match listing on AE form)*

Term *(Clinical dx or description for all symptoms of this event)*	**Onset Date** mm/dd/yy	**Resolution Date** mm/dd/yy	**Severity of Adverse Event** *(See below for code)*
1.			
2.			
3.			
4.			
5.			

Severity of Adverse Event Definitions and Codes:
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) but may be given)
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(s); treatment for symptom(s) may be given and/or subject hospitalized)

C. Tests/ Laboratory Data

Date	Relevant Tests/ Laboratory Data

D. Relevant history, including pre-existing medical conditions

E. GlucoWatch Biographer

1. Application: 1a. Date '__ __ /__ __/ __ __ **mm/dd/yy** **1b . Time :__ __: __ __** ☐AM ☐PM

2. Was GWB worn during 48 hours of onset of serious adverse event? ☐Yes ☐No

3. Time from initiation to onset of first event:_____(hrs)

4. Did the subject discontinue use of the biographer? ☐Yes ☐No

5. Did event abate after use stopped? ☐Yes ☐No

6. Did event reappear after reapplying the biographer? ☐Yes ☐No ☐NA

E. CGMS

1. Insertion: 1a. Date '__ __ /__ __/ __ __ **mm/dd/yy** **1b . Time :__ __: __ __** ☐AM ☐PM

2. Was CGMS worn during 48 hours of onset of serious adverse event? ☐Yes ☐No

3. Time from insertion to onset of first event:_____(hrs)

4. Did the subject discontinue use of the CGMS? ☐Yes ☐No

5. Did event abate after use stopped? ☐Yes ☐No ☐NA

6. Did event reappear after reinserting the CGMS? ☐Yes ☐No ☐NA

G. Concurrent Medications

List only those medications taken by patient within 48 hours prior to the event. Do not list medications used to treat SAE. If additional space is required please use additional page.

Name	Dose	Route	Frequency	Start Date	Stop Date

H. Outcomes attributed to adverse event ***(check all that apply)***

☐1- Death ☐2- Life-threatening ☐3- Disability ☐4- Hospitalization ☐5- Overdose ☐6- Cancer
☐7- Congenital Anomaly ☐8- Intervention Required to Prevent Permanent Impairment / Damage
☐9- Other *(detail in COMMENTS)*

I. Investigator's Assessment of Causal Relationship to Study Device(s):

☐1=Not related ☐2=Possible ☐3=Probable ☐4=Definite
(See protocol or AE Form for definitions. If possible or not related, give alternative explanation in COMMENTS section.)

J. Comments

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

DirecNet Outpatient Randomized Clinical Trial
Patient Final Status Form

This form is completed for every subject enrolled into the study and is used to record 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. *(Detail reasons in COMMENTS)*

Pre-Randomization

☐ Patient not eligible / enrollment visit not completed

☐ Enrollment visit completed, but patient was not randomized

Post-Randomization

☐ Patient requested withdrawal after randomization visit

☐ Loss to Follow-up

B. COMMENTS