A Pilot Study to Evaluate the GlucoWatch Biographer in the Management of Type 1 Diabetes in Children

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DirecNet Outpatient Pilot Study
Enrollment Form

IDENTIFYING INFORMATION

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

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

A. Demographic Information

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

2. Gender: ☐Male ☐Female

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

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

B. 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 3 mos ☐Yes ☐No
(*Must be YES for eligibility)*

C. 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

D. 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)**

E. Physical Exam

1. Weight: _____ _____ ._____ kg **2. Height:** _____ _____ _____ . _____ cm

3. Abnormalities on physical exam? ☐ Yes ☐ No

3.a. If yes, list_____

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

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

F. 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

G. Miscellaneous

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

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

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

   3b. How is it recorded? ☐Paper Diary ☐Computer Diary ☐Computer Download ☐Other_____

4. **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 3 months.**

   d. **No expectation that subject will be moving out of the area of the clinical center during the next 3 months.**

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

H. Study Devices *(Please record the serial numbers for the following devices provided to the subject for the study)*

1. **HGM Serial Number:** _____

2. **Accelerometer Serial Number:** _____

I. Eligibility/Exclusion Checklist

INCLUSION (all must be circled YES)		
Yes	No	1. Age range ≥7 to <18 years. [Age at time of consent]
Yes	No	2. Clinical diagnosis of type 1 diabetes using insulin therapy (either a pump or at least 2 injections per day) for at least one year. Duration of insulin use is > 1 year. The diagnosis of type 1 diabetes is based on the investigator's judgment; C peptide level and antibody determinations are not needed.
Yes	No	3. Insulin regimen stable for the last two months and no plans to switch the modality of insulin administration during the next 3 months (i.e., injection user switching to a pump or switching to Glargine insulin regimen).
Yes	No	4. 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.
Yes	No	5. Subjects ≥11 years old and primary caregiver (i.e., parent or guardian) comprehends written English.
Yes	No	6. For females, subject not intending to become pregnant during the next 3 months.
Yes	No	7. No expectation that subject will be moving out of the area of the clinical center during the next 3 months.
Yes	No	8. Informed Consent Form signed by the parent/guardian.
EXCLUSION (all must be circled NO)		
Yes	No	1. The presence of skin abnormalities or a significant medical disorder that in the judgment of the investigator will affect the wearing of the sensors or the completion of any aspect of the protocol.
Yes	No	2. Prior use of a GWB prescribed for home (non research) use.
Yes	No	3. The presence of any of the following diseases: 1) Asthma if treated with systemic or inhaled corticosteroids in the last 6 months; 2) Cystic fibrosis; 3) Other major illness that in the judgment of the investigator might interfere with the completion of the protocol.
Yes	No	4. Inpatient psychiatric treatment in the past 6 months for either the subject or the subject's primary care giver (i.e., parent or guardian).
Yes	No	5. Current use of oral/inhaled glucocorticoids or other medications, which in the judgment of the investigator would be a contraindication to participation in the study.

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

Coordinator			***Investigator*** ***I certify that this subject has signed the informed consent form and is fully eligible for the study***		
Signature	**DirecNet ID** ___ -___ ___ ___	**Signature Date** ____/____/____	**Signature**	**DirecNet ID** ___ -___ ___ ___	**Signature Date** ____/____/____

J. STEPS TO COMPLETE AT ENROLLMENT

1. Contact Information Form

- Print Contact Information Form
- Write Subject ID and Namecode on the top of the form
- Complete all information and fax to the coordinating center

2. Give following materials to parent/guardian

- Copy of signed Informed Consent Form
- Instructions for study home glucose meter (HGM) use
- HGM and 200 Test Strips
- Instructions for Home Procedures Prior to Baseline Visit
- Instructions for Accelerometer Use
- 8-Point Testing Log
- Accelerometer
- Accelerometer Log
- Home Diary
- Pump Log (pump users only)

3. Schedule baseline visit to be within 14-28 days from enrollment visit: ___ ___ / ___ ___ / ___ ___
mm/dd/yy

DirecNet Outpatient Pilot Study
Baseline Visit Form

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

A. Compliance Assessment

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
3. **Were there any permanent changes in insulin dosing since the enrollment visit?** ☐Yes ☐No

B. HbA1c

1. **HbA1C (from DCA2000): ___ ___ . ___ %**

C. 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**

D. 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)

E. GWB *(Please record the serial number for the GWB provided to the subject for the study)*

1. GWB Serial Number:_____

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

F. Checklist of Items Covered at Baseline Visit

	1. Review downloaded HGM data to assess compliance with the use of the HGM
	2. Collect the Accelerometer and Accelerometer Log
	3. Complete the Insulin Log
	4. Complete Questionnaires: ➢ **The Diabetes Worry Scale (child version and parent version)** ➢ **Diabetes Quality of Life Scale (child version and parent version)** ➢ **Risk Assessment for Severe Hypoglycemia** ➢ **Diabetes Self Management Profile (Treatment Adherence Questionnaire)-By Phone Interview**
	5. Obtain HbA1c with DCA2000
	6. Obtain fingerstick blood sample for HbA1c determination from Central Laboratory
	7. Collect Pump Log and Download Pump data (Pump users only)
	8. Give Instructions on use of home PC and administer computer proficiency test
	9. Record the serial number of the GWB provided to the patient during this visit
	10. Place GWB and instruct subject on use
	11. Provide the subject/primary care give with the following: ➢ **Instructions for Home Procedures after Baseline** ➢ **400 HGM test strips** ➢ **Instructions on GWB use** ➢ **GWB and 2 boxes of autosensors** ➢ **HOME PC Instruction Sheet**
	12. Remind subject/primary care giver to call the clinic if serious adverse events occur
	13. Instruct the subject/primary care giver: ➢ **NOT TO REPEAT CORRECTION DOSE BASED ON GWB READING** ➢ **NOT TO BASE INSULIN DOSAGE SOLELY ON GWB READING AND TO ALWAYS VERIFY (HIGH OR LOW) GWB READING WITH HOME GLUCOSE METER PRIOR TO MAKING ADJUSTMENTS**
	14. Schedule 3-Month Follow-up Visit: ___ ___ / ___ ___ /___ ___ mm/dd/yy
	15. Ship HbA1c blood sample to central laboratory
	16. E-mail HGM data and Pump data (if applicable) to Coordinating Center
	17. Fax 8-point testing log and pump log (if applicable) to the Coordinating Center
	18. Ship Accelerometer and Accelerometer Log to the Coordinating Center

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

DirecNet Outpatient Pilot Study
Insulin Log

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

Completion Time: ☐Baseline ☐3-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

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

DirecNet Outpatient Pilot Study
Phone Contact Form

A. Call Information

1. Call Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy **2. Call window:** Wk1 Wk2 Wk4 Wk8 Wk12

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 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 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

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

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

3. 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

4. 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 your 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 _____

G. Additional Information

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

DirecNet Outpatient Pilot Accuracy Study
Phone Contact Checklist

Protocol Specified Phone Contacts (1, 2, 4, and every 4 weeks after enrollment)

	Is this a convenient time to talk?
	Have you had any problems (colds, injuries, etc.) since the last contact?
	Have you had to seek emergency medical attention (ER visit, paramedics, hospitalization) since the last contact? **[If applicable, please record on Adverse/Serious Event Form**. **See Chapter 12 of Procedure Manual for reporting requirements].**
	Have you made any permanent (long-term) changes in diabetes management since the last contact?
	If yes, what types of permanent changes were made?
	How many episodes of symptomatic hypoglycemia did you have in the last 7 days?
	How many of these episodes did you verify with a fingerstick blood glucose reading?
	How many of these episodes were severe (caused you to faint or have a seizure)?
	When did the severe episode happen? Were you asleep at the time? Did you confirm the low with a fingerstick reading? What treatment did you receive?
	How many times per during the day did you use the GWB in the last 7 days?
	How many times per during the night did you use the GWB in the last 7 days?
	Did you have any problems with the function of the watch?
	If problems occurred, was it due to early shut off, sweating, discomfort, GWB failing to calibrate (reason?), or being knocked off?
	Ask the subject/primary caregiver to look at the photographs of skin and make a comparison in areas where the GWB was worn in the last 7 days.
	Did you record your blood sugars during the last 7 days? If yes, how often and how was it recorded?
	Are you running low on Autosensors for the GWB or test strips for the HGM?
	Have you recharged the batteries for your GWB?

Additional Information for Phone Call Prior to 3-Month Follow Up Visit

	Confirm 3-month appointment date
	Remind subject/parent to bring the GWB with data to the visit to be downloaded
	Remind subject/parent to bring accelerometer and accelerometer log to visit to be downloaded
	Remind subject/parent to bring HGM and 8-point testing log to visit

DirecNet Outpatient Pilot Study
3-Month Visit

Visit Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy ☐ **Visit was missed and will not be made up**

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. GWB Use

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

C. HbA1c

1. **HbA1C (from DCA2000): ___ ___ . ___ %**

D. Medical History and Physical Exam

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 _____

3. Abnormalities on physical exam? ☐ Yes ☐ No

a. If yes, please explain _____

E. Skin Assessment

1. Acute Assessment

Please inspect each extremity and complete a separate assessment for each location where there is an acute skin changes 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 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

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

F. Items to be covered at time of 3-month visit

1. Download HGM data
2. Download GWB with the Bit Load software
3. Download Pump data (if applicable)
4. Collect the Accelerometer and Accelerometer Log
5. Complete Insulin Log
6. Complete Questionnaires: ➢ **The Diabetes Worry Scale (child version and parent version)** ➢ **Diabetes Quality of Life Scale (child version and parent version)** ➢ **Risk Assessment for Severe Hypoglycemia** ➢ **Diabetes Self Management Profile (Treatment Adherence Questionnaire)-By Phone Interview** ➢ **Continuous Glucose Monitor Satisfaction Scale** ➢ **Pilot Study Exit Questionnaire**
7. Obtain HbA1c with DCA2000
8. Obtain fingerstick blood sample for HbA1c determination from Central Laboratory
9. Complete a physical exam including acute and general skin assessments
10. Review data summary with the subject
11. Process payment
12. Email GWB, HGM and Pump data (if applicable) to coordinating center
13. Fax 8-point testing log and pump log (if applicable) to the coordinating center
14. Ship HbA1c blood sample to central laboratory
15. Ship Accelerometer and Accelerometer Log to the Coordinating Center

DirecNet Outpatient Pilot Study
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 skin reaction **[If checked please complete section C]**
☐ 4. Subject experienced hyperglycemia
☐ 5. Subject experienced a hypoglycemic event
☐ 6. Subject encountered a problem or had a question related to his or her Home PC
☐ 7. Reminder for timely completion of Weekly Questionnaire
☐ 8. Other **[If checked please detail in section D]**

C. Skin Assessment

1. 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

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

DirecNet Outpatient Pilot Study
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 skin reaction [If checked please complete section B]
- ☐ 4. 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 ≥ 6 requires completion of Adverse Event Form

C. Comment

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

DirecNet Outpatient Pilot 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.

Since the study involves an FDA-approved device and does not require an IND, adverse event reporting will be limited to (1) events that meet criteria for a serious adverse event (SAE), (2) unanticipated adverse device events, (3) skin reaction from the GWB with a score of 6 or greater (see section 8.3 of the protocol), (4) events that are considered to have a possible (or greater) relationship to the GWB or any study procedure, (5) hyperglycemia resulting in diabetic ketoacidosis or hyperosmolar nonketotic coma, and (6) hypoglycemia resulting in seizures or loss of consciousness. After 7 days following the completion of sensor use and all study procedures, only adverse events with a possible or greater relationship to sensor use or study procedures will be reported.

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: ___ ___ / ___ ___ /___ ___ **mm/dd/yy**

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

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

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

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

7. Effect on sensor: ☐no change ☐discontinued 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: ___ ___ / ___ ___ /___ ___ **mm/dd/yy**
leave blank if not resolved

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 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
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 Pilot Study
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

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

F. 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

G. 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)*

H. 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.)

I. Comments

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

DirecNet Outpatient Pilot Study
Discharge/Subject Withdrawal 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. *(If subject was withdrawn from study, detail reasons in COMMENTS)*

- ☐ Study Completed
- ☐ Subject not compliant prior to Baseline Visit and was withdrawn
- ☐ Subjected requested withdrawal prior to Baseline Visit
- ☐ Subject requested withdrawal after Baseline Visit
- ☐ Loss to Follow-up

B. COMMENTS

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