A Pilot Study to Evaluate the Navigator Continuous Glucose Sensor in the Management of Type 1 Diabetes in Children

Table of Contents

DirecNet Navigator Pilot Study
Enrollment Visit Form

A. Identifying Information

1. Namecode: ____ ____ ____ ____ ____ **2. Patient Initials:** ___ ___ ___ *(Enter "X" if no middle initial)*

3. Date of birth: ___ ___ / ___ ___ /___ ___ **mm/dd/yy** *(Age must be ≥3.0 and <18.0 yrs for eligibility)*

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

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

6. Study ID of Enrolling Investigator ____--____ ____ ____

Enrollment Visit History Form

1. Enrollment Visit Date: ___ ___ / ___ ___ /___ ___ **mm/dd/yy**

2. Study ID of Investigator ____--____ ____ ____

B. Eligibility

All of the following are eligibility criteria. Verify by checking each box that subject meets criteria.

☐ **Subject has been diagnosed with type 1 diabetes and has been using insulin therapy for at least 1 year.**

☐ **Subject uses an insulin pump that can be downloaded and plans to continue using it during the next 3 months.**

☐ **Subject has a home computer with internet access.**

☐ **Parent/guardian and subject understand the study protocol and agree to comply with it.**

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

☐ **For females, subject not intending to become pregnant during the next 3 months.**

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

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

☐ **Subject does not have a significant medical disorder that will affect sensor use or completion of any aspect of the protocol.**

☐ **Subject does not have any of the following:**
- **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**

☐ **Subject does not use oral/inhaled glucocorticoids or other medications that would be a contraindication to study participation.**

☐ **Subject has a home computer compatible with Navigator hardware/software/download requirements.**

C. 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

D. Diabetes and Other Medical History

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

2. Insulin Pump Use

2a. Length of insulin pump use: ☐6 mon -<1 yr ☐1-<2 yrs ☐2-<5 yrs ☐≥5 yrs

2b. Type of insulin pump currently being used: ☐Smart Pump ☐Regular Pump

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

3a. Breakfast Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ Not Used

3b. Lunch Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ Not Used

3c. Dinner Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ Not Used

3d. Bedtime Snack Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ Not Used

4. Usual Meal Bolus Doses: Breakfast: _____ Lunch: _____ Dinner: _____ Snack: _____ Bedtime Snack: _____

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

6. Number of hypoglycemic seizures/loss of consciousness in last 6 months: ☐0 ☐1 ☐2 ☐3 ☐>3

7. Prior continuous glucose monitor use? ☐Yes ☐No 7**a. If Yes:** ☐CGMS ☐GWB ☐Other _____
(Check all that apply)

8. Prior participation in a DirecNet study? ☐Yes ☐No **8a. If Yes:** ☐Inpt Accuracy 1 ☐GWB Pilot ☐GWB RCT ☐Inpt Exercise
(Check all that apply)

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)**

Enrollment Visit Physical Examination Form

F. Physical Exam

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

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

G. HbA1c

1. Date of Test: __ __ **/** __ __ **/** __ __
(Must be within 14 days of enrollment visit date)

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

Comments

DirecNet Navigator Pilot Study
CRC Admission Form

1. Admission Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy

2. Study ID of Investigator ____--____ ____ ____

A. Pre-admission Information

1. How many episodes of symptomatic hypoglycemia did the subject experience in the last 7 days? _____

1a. How many symptomatic episodes were confirmed with an HGM test? _____

2. When was the subject's last symptomatic hypoglycemic episode? ☐Last 7 days ☐2-4 wks ☐>1 mon ☐Never

3. When was the subject's last severe hypoglycemic episode (hypoglycemia resulting in seizure or loss of consciousness)?
☐<2 wks ☐2-4 wks ☐1 - <6 mon ☐6 - <12 mon ☐≥1 yr ☐Never

B. Skin Assessment *(Inspect any areas where a Navigator sensor has been inserted and removed prior to admission.)*

1. Acute Assessment

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

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

		Adhesive Area			Sensor Insertion Area				
	Insertion Area (R/L, Location*)	Erythema (0-4)	Edema (0-4)	Total***	Erythema (0-4)	Induration (0-4)**	Total***	# Days Since Removal	Comment
1									
2									
3									
4									

*Location: Abd-UQ Abd-LQ Arm Buttock/Hip
**Induration: 0= No induration, 1= <2mm, 2= 3 to 5mm, 3= 6 to 10mm, 4= >10mm
***Total=erythema score + edema/induration 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 Navigator use? ☐Yes ☐No

a. If Yes, record the locations that are affected and complete all information for only those locations:

	Location*	Scabbing Present?	Scabbing # Sites	Dry Skin Present?	Hypo/Hyper pigmentation Area**	Scarring Area**	Comment
1		☐Yes ☐No		☐Yes ☐No			
2		☐Yes ☐No		☐Yes ☐No			
3		☐Yes ☐No		☐Yes ☐No			
4		☐Yes ☐No		☐Yes ☐No			

*Location: Abd-UQ Abd-LQ Arm Buttock/Hip
**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

C. Navigator Information

1. Sensor #1 – "Blinded" (Sensor inserted at home)

1a. Serial number of blinded Navigator receiver: _____

1b. Serial number of Navigator transmitter: _____

1c. Serial number of sensor to be used during admission: _____

1d. Insertion Side: ☐**Right** ☐**Left**

1e. Insertion Area *(select one)*: ☐**Abd-UQ** ☐**Abd-LQ** ☐**Arm** ☐**Upper buttock/Hip**

1f. Time of Insertion: __ __ : __ __ ☐**AM** ☐**PM** ☐**Unknown (if subject/parent is unsure)**

2. Sensor #2 – "Unblinded"

2a. Serial number of unblinded Navigator receiver: _____

2b. Serial number of Navigator transmitter: _____

2c. Serial number of sensor to be used during admission: _____

2d. Insertion Side: ☐**Right** ☐**Left**

2e. Insertion Area *(select one)*: ☐**Abd-UQ** ☐**Abd-LQ** ☐**Arm** ☐**Upper buttock/Hip**

2f. Time of Insertion: __ __ : __ __ ☐**AM** ☐**PM**

D. Time Synchronization

The unblinded Navigator, room clock, insulin pump, BD Logic, subject's HGM, & HR monitor must be synchronized with the blinded Navigator.

1. Blinded Navigator: __ __ : __ __ ☐**AM** ☐**PM**

2. Unblinded Navigator, room clock, the subject's insulin pump, BD Logic, subject's HGM, and HR Monitor (for exercise session if applicable) are synchronized with the Blinded Navigator: ☐**Yes** ☐**No**

COMMENTS

DirecNet Navigator Pilot Study
Exercise Session Form

A. Eligibility Assessment

1. Does the subject have more than small urine ketones present or blood ketones >1.0? ☐Yes ☐No
(If YES, the exercise session should not be completed.)

B. EXERCISE DATA

Cycle 1

1. Start Time: __ __ : __ __ PM

2. Record the time the subject's heart rate reaches 140 BPM: __ __ : __ __ PM

3. Did the subject complete all 15 minutes of this cycle? ☐**Yes** ☐**No**

a. If No, how many minutes of the protocol specified 15 minutes were completed? _____ minutes

b. If No, indicate the reason all 15 minutes were not completed: ☐**Exhaustion** ☐ **BG <60** ☐**Other** _____

Cycle 2

1. Was Cycle 2 initiated? ☐**Yes** ☐**No**

a. If No, indicate the reason Cycle 2 was not initiated: ☐**Exhaustion** ☐ **BG <60** ☐**Other** _____

2. Start Time: __ __ : __ __ PM

3. Record the time the subject's heart rate reaches 140 BPM: __ __ : __ __ PM

4. Did the subject complete all 15 minutes of this cycle? ☐**Yes** ☐**No**

a. If No, how many minutes of the protocol specified 15 minutes were completed? _____ minutes

b. If No, indicate the reason all 15 minutes were not completed: ☐**Exhaustion** ☐ **BG <60** ☐**Other** _____

Cycle 3

1. Was Cycle 3 initiated? ☐**Yes** ☐**No**

a. If No, indicate the reason Cycle 3 was not initiated: ☐**Exhaustion** ☐ **BG <60** ☐**Other** _____

2. Start Time: __ __ : __ __ PM

3. Record the time the subject's heart rate reaches 140 BPM: __ __ : __ __ PM

4. Did the subject complete all 15 minutes of this cycle? ☐**Yes** ☐**No**

a. If No, how many minutes of the protocol specified 15 minutes were completed? _____ minutes

b. If No, indicate the reason all 15 minutes were not completed: ☐**Exhaustion** ☐ **BG <60** ☐**Other**_____

Cycle 4

1. Was Cycle 4 initiated? ☐**Yes** ☐**No**

a. If No, indicate the reason Cycle 4 was not initiated: ☐**Exhaustion** ☐ **BG <60** ☐**Other** _____

2. Start Time: __ __ : __ __ PM

3. Record the time the subject's heart rate reaches 140 BPM: __ __ : __ __ PM

4. Did the subject complete all 15 minutes of this cycle? ☐**Yes** ☐**No**

a. If No, how many minutes of the protocol specified 15 minutes were completed? _____ minutes

b. If No, indicate the reason all 15 minutes were not completed: ☐**Exhaustion** ☐ **BG <60** ☐**Other** _____

C. TERMINATION OF EXERCISE

1. End Time: __ __ : __ __ PM
2. Reason for Termination:
☐**Exercise Completed** ☐**Exhaustion** ☐**BG <60 mg/dL** ☐**Other** _____

Comments

DirecNet Navigator Pilot Study
CRC Discharge Form

1. Discharge Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy

2. Study ID of Investigator ____--____ ____ ____

A. DISPOSITION OF SUBJECT

1. Did the subject complete the 24-hour admission? ☐ Yes ☐ No

1a. If No, detail reason: _____

B. CRC PROCEDURES AND EVENTS

1. Procedures: Indicate whether or not the protocol-specified procedures were performed
(If all age-weight specified procedures not fully completed, detail reasons in COMMENTS)

1a. ½-hr blood draws: ☐ Yes ☐ No

1b. Exercise session: ☐ Yes ☐ No

1c. Post-breakfast hyperglycemia test: ☐ Yes ☐ No

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

C. MEAL TIMES

1. Lunch Start date/time: __ __ / __ __ / __ __ __ __ : __ __ ☐ AM ☐ PM

2a. Was an afternoon snack given? ☐ Yes ☐ No

If Yes,

2b. Afternoon Snack Start date/time: __ __ / __ __ / __ __ __ __ : __ __ PM

3. Dinner Start date/time: __ __ / __ __ / __ __ __ __ : __ __ PM

4a. Was a bedtime snack given? ☐ Yes ☐ No

If Yes,

4b. Bedtime Snack Start date/time: __ __ / __ __ / __ __ __ __ : __ __ PM

5a. Breakfast Start date/time: __ __ / __ __ / __ __ __ __ : __ __ AM

5b. Breakfast End time: __ __ : __ __ AM

5c. Approximate amount consumed: ____ g Carbohydrates

D. TARGETS AND CORRECTIONS FOR INSULIN DOSE RESPONSE GUIDELINES

Record the targets provided for the patient as part of the Insulin Dose Adjustment Guidelines and the correction factors to be used.

1. Target glucose levels and bolus correction targets:

1a. _____ mg/dL during the day	**☐ Not Used**	**1b. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	**☐ Not Used**
1c. _____ mg/dL overnight	**☐ Not Used**	**1d. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	**☐ Not Used**
1e. _____ mg/dL at bedtime	**☐ Not Used**	**1f. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	**☐ Not Used**
1g. _____ mg/dL pre-exercise	**☐ Not Used**	**1h. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	**☐ Not Used**
1i. _____ mg/dL bedtime after exercise	**☐ Not Used**	**1j. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	**☐ Not Used**

E. 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)***:**
   - ☐ Change in basal/intermediate 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 Navigator Pilot Study
Phone Contact Form

A. Call Information

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

2. Call Window: ☐**3 days** ☐**2 weeks** ☐**4 weeks** ☐**8 weeks** ☐**10 weeks**

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. Current Insulin to Carb Ratios and Bolus Insulin Doses

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

1a. Breakfast Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

1b. Lunch Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

1c. Dinner Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

1d. Bedtime Snack Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

2. Usual Meal Bolus Doses: Breakfast: _____ Lunch: _____ Dinner: _____ Snack: _____ Bedtime Snack: _____

C. 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)*
   - ☐ Change in basal/intermediate 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

D. Hypoglycemia Assessment

1. Did the subject have any symptomatic episodes of hypoglycemia in the last 7 days? ☐Yes ☐No
If Yes,
a. How many episodes? _____

b. How many were verified with a blood glucose test? _____

2. How many severe (i.e. caused the subject to faint or have a seizure) episodes of hypoglycemia did the subject have since the last scheduled contact? _____

2a. 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)

E. Meal / Stressful Event / Menstrual Data

1. What was the subject's last meal prior to the phone call (Remind subject to enter meal markers in the Navigator for each meal/snack**)?** ☐Breakfast ☐Lunch ☐Dinner

1a. What is the subject's estimate of the carbohydrate content of the meal? _____ **g**

1b. Content of the meal: _____

2. Has the subject had any illnesses or stressful events today? ☐Yes ☐No

2a. If yes, describe: _____

3. Is the subject currently menstruating? ☐Yes ☐No ☐N/A (subject is not female or has not started menstruating)

F. Navigator Use

4. How many days per week are you using the Navigator? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
a. If <7, indicate reason (select any of the following that apply):

- ☐Skin irritation
- ☐Alarms 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 _____

5. Did the subject have any problems while using the Navigator since the last contact? ☐Yes ☐No
If Yes, did any of the following occur?

- ☐ Problem connecting transmitter to receiver
- ☐ Inserter not intact upon opening packet
- ☐ Inserter attachment to support mount not straight and secure
- ☐ Problem placing support mount on skin
- ☐ Inserter fired improperly
- ☐ Problem removing inserter from support mount
- ☐ Sensor did not insert properly
- ☐ Too much bleeding at the area of sensor insertion (more than 1 drop)
- ☐ Problem attaching transmitter to support mount
- ☐ The sensor was pulled out accidentally
- ☐ The subject removed the sensor due to discomfort
- ☐ The sensor stopped working early
- ☐ Other _____

G. Targets and Corrections for Insulin Dose Response Guidelines

1. Target glucose levels and bolus correction targets:

1a. _____ mg/dL during the day		**1b. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1c. _____ mg/dL overnight		**1d. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1e. _____ mg/dL at bedtime	☐ **Not Used**	**1f. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1g. _____ mg/dL pre-exercise	☐ **Not Used**	**1h. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1i. _____ mg/dL bedtime after exercise	☐ **Not Used**	**1j. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**

H. 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)***:**
   - ☐ Change in basal/intermediate 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 Navigator Pilot Study
Follow-up Visit Form

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

2. Visit Type: ☐**1 week** ☐**3 weeks** ☐**7 weeks** ☐**13 weeks** ☐**26 weeks**

3a. ☐**Visit was missed and will not be made up** **3b. Reason:** _____

A. Hypoglycemia Assessment

1. Did the subject have any symptomatic episodes of hypoglycemia in the last 7 days? ☐Yes ☐No
If Yes,
a. How many episodes? _____

b. How many were verified with a blood glucose test? _____

2. How many severe (i.e. caused the subject to faint or have a seizure) episodes of hypoglycemia did the subject have since the last scheduled contact? _____

2a. 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. Current Insulin to Carb Ratios and Bolus Insulin Doses

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

1a. Breakfast Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

1b. Lunch Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

1c. Dinner Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

1d. Bedtime Snack Insulin to Carb Ratio: 1 unit per ___ grams of carbohydrates ☐ **Not Used**

2. Usual Meal Bolus Doses: Breakfast: _____ **Lunch:** _____ **Dinner:** _____ **Snack:** _____ **Bedtime Snack:** _____

C. 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)*

- ☐ Change in basal/intermediate 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

D. 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 _____

E. Skin Assessment

1. Acute Assessment

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

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

		Adhesive Area			Sensor Insertion Area				
	Insertion Area (R/L, Location*)	Erythema (0-4)	Edema (0-4)	Total***	Erythema (0-4)	Induration (0-4)**	Total***	# Days Since Removal	Comment
1									
2									
3									
4									
5									
6									
7									
8									

*****Location: Abd-UQ Abd-LQ Arm Buttock/Hip

**Induration: 0= No induration, 1= <2mm, 2= 3 to 5mm, 3= 6 to 10mm, 4= >10mm

*******Total=erythema score + edema/induration 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 Navigator use? ☐Yes ☐No

a. If Yes, record the locations that are affected and complete all information for only those locations:

	Location*	Scabbing Present?	Scabbing # Sites	Dry Skin Present?	Hypo/Hyper pigmentation Area**	Scarring Area**	Comment
1		☐Yes ☐No		☐Yes ☐No			
2		☐Yes ☐No		☐Yes ☐No			
3		☐Yes ☐No		☐Yes ☐No			
4		☐Yes ☐No		☐Yes ☐No			
5		☐Yes ☐No		☐Yes ☐No			
6		☐Yes ☐No		☐Yes ☐No			
7		☐Yes ☐No		☐Yes ☐No			
8		☐Yes ☐No		☐Yes ☐No			

*****Location: Abd-UQ Abd-LQ Arm Buttock/Hip

**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

F. HbA1c *(7, 13, and 26-week visits only)*

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

COMMENTS

Follow-up Visit Navigator Form

G. Navigator Use

1. How many days per week are you using the Navigator? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

a. If <7, indicate reason (select any of the following that apply):

- ☐ Skin irritation
- ☐ Alarms 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. Did the subject have any problems while using the Navigator since the last contact? ☐ Yes ☐ No

If Yes, did any of the following occur?

- ☐ Problem connecting transmitter to receiver
- ☐ Inserter not intact upon opening packet
- ☐ Inserter attachment to support mount not straight and secure
- ☐ Problem placing support mount on skin
- ☐ Inserter fired improperly
- ☐ Problem removing inserter from support mount
- ☐ Sensor did not insert properly
- ☐ Too much bleeding at the area of sensor insertion (more than 1 drop)
- ☐ Problem attaching transmitter to support mount
- ☐ The sensor was pulled out accidentally
- ☐ The subject removed the sensor due to discomfort
- ☐ The sensor stopped working early
- ☐ Other _____

H. Targets and Corrections for Insulin Dose Response Guidelines

1. Target glucose levels and bolus correction targets:

1a. _____ mg/dL during the day	☐ **Not Used**	**1b. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1c. _____ mg/dL overnight	☐ **Not Used**	**1d. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1e. _____ mg/dL at bedtime	☐ **Not Used**	**1f. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1g. _____ mg/dL pre-exercise	☐ **Not Used**	**1h. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**
1i. _____ mg/dL bedtime after exercise	☐ **Not Used**	**1j. Correction factor: 1 unit per _____ mg/dL above ____ mg/dL**	☐ **Not Used**

I. 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)***:**
   - ☐ Change in basal/intermediate 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 Navigator 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 Navigator

☐ 2. Subject encountered a problem or had a question related to the HGM

☐ 3. Subject had a skin reaction **[If checked please detail in section C]**

☐ 4. Subject experienced hyperglycemia

☐ 5. Subject experienced a hypoglycemic event

☐ 6. Subject encountered a problem or had a question related to downloading the Navigator

☐ 7. Reminder for upcoming scheduled visit

☐ 8. Subject requested additional supplies

☐ 9. Other **[If checked please detail in section C]**

C. Additional Information

DirecNet Navigator Pilot Study
Non-Protocol Visit

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

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

☐ 1. Subject encountered a problem or had a question related to the Navigator

☐ 2. Subject had a skin reaction [If checked please complete section B]

☐ 3. Other [If checked please detail in section C]

B. Skin Assessment – Complete if Question #A.2 Above is Checked:

1. Acute Assessment

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

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

		Adhesive Area			Sensor Insertion Area				
	Insertion Area (R/L, Location*)	Erythema (0-4)	Edema (0-4)	Total***	Erythema (0-4)	Induration (0-4)**	Total***	# Days Since Removal	Comment
1									
2									
3									
4									
5									

*****Location: Abd-UQ Abd-LQ Arm Buttock/Hip
**Induration: 0= No induration, 1= <2mm, 2= 3 to 5mm, 3= 6 to 10mm, 4= >10mm
*******Total=erythema score + edema/induration 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 Navigator use? ☐**Yes** ☐**No**

a. If Yes, record the 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
1		☐Yes ☐No		☐Yes ☐No			
2		☐Yes ☐No		☐Yes ☐No			
3		☐Yes ☐No		☐Yes ☐No			
4		☐Yes ☐No		☐Yes ☐No			
5		☐Yes ☐No		☐Yes ☐No			

*****Location: Abd-UQ Abd-LQ Arm Buttock/Hip
**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

C. Comment

DirecNet Navigator 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.

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 Navigator temporarily ☐discontinued Navigator permanently
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 an 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 Navigator Pilot Study
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)*

- ☐ Patient not eligible / enrollment visit not completed
- ☐ Enrollment visit completed, but patient withdrew prior to CRC Admission
- ☐ Patient requested withdrawal after CRC Admission
- ☐ Loss to Follow-up
- ☐ Patient declined optional 2nd 13 weeks

B. COMMENTS
