Meeting Date: November 21, 2007

Assent Form

Development of Algorithms for a Prototype Closed Loop Insulin Pump

You are being asked to be in a research study. Before you decide whether you want to be in it, we want to tell you about it so you can ask any questions. A research study is something like a science project at school but harder to do. When doctors want to learn more about how to help kids with diabetes like you, they do a research study.

We are conducting a study to evaluate the Navigator Continuous Glucose Monitor (Navigator CGM). The Navigator has a small sensor that is inserted just underneath the skin. We can numb your skin before we inject the sensor. The sensor is worn for up to 120 hours (5 days). The sensor is then replaced. The sensor measures the blood sugar every minute and shows your blood sugar on a receiver that is similar in size to a pager (beeper). The wireless receiver can be worn on a belt or carried in a pocket or purse.

1. What will happen to me in this study?

If you want to be in this study then the following will happen:

- You will be asked to come to Stanford University Medical Center. While you are there the research staff will talk to you about the study and give you a medical exam. You will also learn about the Navigator system and how to use it.
- At the first visit the following will happen:
  - You will have a small Navigator sensor inserted under your skin. The sensor is worn for 5 days and then replaced. You will practice wearing the Navigator for 3 days to 2 weeks before your hospital stay. This will allow the study staff to review your blood sugar levels and make changes to your insulin, if needed.
  - You will be given computer software to download your Navigator at home.
- You will then have a 10-12 hour overnight hospital visit. At the hospital visit, the following will happen:
  - You should arrive at the hospital between 7:30pm and 8:30pm. Before arriving you should eat your dinner meal at home between 5:30pm and 6:30pm. Your dinner meal should be a microwavable meal with a known amount of carbohydrate, fat and protein. During the 1-3 days prior to the CRC visit when you are wearing the Navigators keep a written log of your carbohydrate intake, exercise and all medications taken.
  - A nurse will put a small plastic tube (IV) into your arm that will be used to draw many small blood samples during the visit. Special cream may be used before the

needle is put in your arm so that it will not hurt. Sometimes the plastic tube falls out and it has to be restarted.

- Once your blood sugar is greater than 100 mg/dl the research staff will increase your basal insulin dose in your pump to lower your blood sugar.
- No bedtime snack will be given if your BG is greater than 100 mg/dl at bedtime. If you are less than 100 mg/dl at bedtime you will be given a 15g carbohydrate snack without a bolus of insulin.

Your pump will be turned off (suspended) for 1 ½ hours to see what happens to your blood sugar. During this time blood will be taken from the tub (IV) in your arm every 10 to 30 minutes. If you go too low, they will treat you with food or IV sugar. If you go too high, they will restart your insulin pump. In either case the test period will end and you will be allowed to eat a meal/snack.

- You will be observed in the hospital overnight to make sure your blood sugar remains between 60 - 300 mg/dl. Blood sugar and ketone testing will continue during this time.
- In the morning you will be given breakfast.
- The tube will then be removed from your arm and the Navigator will also be removed. The research staff will download your insulin pump and Navigator devices, and you can go home.
- You have the option of continuing to use the Navigator at home for 13 weeks. The Navigator will be used in addition to your home blood sugar meter. A minimum of 4 blood sugar tests is required each day. All Navigator sensor values must be confirmed with a fingerstick before you make any diabetes management changes. Also, you must do a blood sugar test anytime the Navigator sensor does not match how you are feeling.
- You will have the option of returning to Stanford for an appointment or completing a phone consult 7-12 days later. You are required to return to Stanford for the final 13 week follow up appointment. All study supplies will be returned to the study staff at this final appointment.

2. Can anything bad happen to me?

Taking part in a research study involves some risks. The most likely risks of this study are listed below. This study may include risks that are unknown at this time.

Finger Sticks
When you do a finger stick it may hurt when the lancet goes into your finger but not for long. There is a small risk of infection.

IV

A small plastic tube (IV) will be placed in your arm for taking blood samples. This will remain in for approximately 8 hours and will be taken out just before you leave the hospital. When the needle goes into a vein, it may hurt for a short time. A small amount of bleeding under the skin may happen and cause a bruise. We can apply numbing cream before inserting the IV.

Continuous Glucose Sensor (Navigator)

The continuous glucose sensor (Navigator) may cause pain when the sensor is inserted into the skin. We can apply numbing crème before inserting the sensor to prevent discomfort. The site where you inserted the sensor may get itchy, red, or start bleeding. A microscopic (very small) piece of the sensor membrane may occasionally be left under the skin after the sensor is removed. This poses no health or safety risk.

Low Blood Sugar

Having diabetes increases your risk of having low blood sugar. Since we will be watching you closely and testing your blood sugar a lot during this study, a serious low blood sugar is not expected to happen.

High Blood Sugar

Having diabetes increases your risk of having high blood sugar. Since we will be watching you closely and testing your blood sugar and ketones a lot during this study, a serious high blood sugar is not expected to happen.

3. Can anything good happen to me?

The information gathered from wearing the device 1-3 days before coming into the hospital and the information gathered if you choose to wear the device for an additional 13 weeks may help with your diabetes management.

We think that a closed loop insulin pump will have an important part in the management of diabetes in children. However, it is possible that you will not directly benefit from being a part of this study.

4. Do I have other choices?

You have the choice to NOT be part of the study.

5. Will anyone know I am in the study?

We will not use your name to identify you as a study subject. You will be given a code number that will be used to identify you. No one outside of Stanford will know you are part of the study.

6. **What happens if I get hurt?**

The research staff will help you find medical treatment but this study does not provide financial assistance for additional medical or other costs.

7. Who can I talk to about the study?

If you get hurt while taking part in this study please call Bruce Buckingham, MD or Darrell Wilson, MD at 650-723-5791.

8. What if I do not want to do this?

You can stop being in the study at any time without getting in trouble. Your doctor will continue to see you for your routine medical care.

If you are not happy about this study or if you have any questions please contact: Stanford Institutional Review Board (IRB) to speak to someone other than your doctor at (650)-723-5244 or toll free at 1-866-680-2906 or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401.

Do you understand this study and are you willing to participate?

☐ *YES* ☐ *NO*

_____ _____

Signature of Child Date

_____ _____

Signature of person obtaining consent Date

☐ *YES* *I received a copy of my signed assent/consent form*

Signature of Child Date

☐ *NO* *I did not receive a copy of my signed assent/consent form*

Signature of Child Date