## Why are you being asked to take part in this study?

This is a research study. Only people who choose to take part are included in research studies. As you know, you are (or were) very sick and had to be in the intensive care unit in the hospital. Adults and children in intensive care units very often have health problems that make the amount of sugar in your blood either too high or too low. When your blood sugar gets too high or low, it causes other kinds of health problems that we want to prevent. Your doctors and nurses are trying to prevent these problems, and your parent(s)/guardian(s) agreed for you to participate in a study about better ways to keep your blood sugar in a good range. When we talked to your parent(s)/guardian(s) you may have been too sick for us to talk to you about this study. We are asking you whether you are willing to be in this study.

## What is the purpose of this research study?

This study is being done to find out if bringing down your blood sugar when you are very sick will help you get better more quickly.

## What will happen while I am in the study?

If you are in this study, we will check your blood sugar and give you medicine to bring it down if it is too high. A needle is used to place a sensor under your skin. This sensor is a small plastic tube that lets us see what your blood sugar is and if it changes. You will be part of the study while you are in the intensive care unit but no more than 28 days after the study starts. In about 3 months, and then again in a year, someone from the study may telephone your parent(s)/guardian(s) to see how you are doing. The people telephoning your parents for an interview will be from Columbia University. Not everyone who is in the study will be called for the telephone interview. We cannot promise you that being in this study will definitely help you get better, but it may help you get better. What we learn from this study may also help other sick kids.

**Do I have to be in the study?**

You do not have to be in this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don’t want to be in the study or if you join the study and change your mind later and stop.

### **Do my parent(s)/guardian(s) know about this?**

### We explained this study to your parent(s)/guardian(s) and they agreed to let you be in this study. They signed a form that had a lot more information about the study. You can talk with them about it and look at their form before you decide. We can also give you a copy of that form.

## What if you have questions about the study?

If you have questions about the study you can ask to talk to the study doctor, Michael Agus (page 617-355-7243 #1905), or to your own doctor.

**If you sign your name below, it means that you agree to be in this study.**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Subject |  | Date |

**TO BE COMPLETED BY PERSON OBTAINING ASSENT:**

### [ ] Subject giving assent at time of parent/guardian consent:

I have explained this study and the procedures involved to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in terms he/she could understand and that he/she assented to take part in this study.

### [ ] Subject giving assent after parent/guardian consent:

I have explained this study and the procedures involved to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in terms he/she could understand and that he/she assented to take part in this study.

**[ ] Subject unable to give assent:**

I certify that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Assent |  |  |
| Signature of Person Obtaining Assent |  | Date |