

Vanderbilt University Institutional Review Board
Proposal for Research Using Human Participants
Assent Document for Research Study

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Version Date: 13FEB2012

Title of Study: TrialNet Natural History Study of the Development of Type One Diabetes (Screening)

Institution/Hospital: Vanderbilt Eskind Diabetes Clinic

Screening for Risk of Developing Type 1 Diabetes (T1D)

This assent form is for children ages 7 to 12 years.

Printed Name of volunteer _____ **Age** _____ **Birthday** _____

We want to tell you about a research study.

Somebody in your family has diabetes. You may have a greater chance of getting diabetes too. Diabetes happens when your body doesn't make enough insulin. Insulin is needed so that your body can use the food that you eat to give you energy to run and play. Without enough insulin, we don't grow well and sometimes we get sick. Family members of people with diabetes sometimes get diabetes more often than other people.

We would like to find out more about your risk of getting diabetes. To do this, we would need to give your arm a little poke to do a blood test. We can use some special cream or spray to help it not hurt. We need one tube of blood and that is about 2 teaspoons. It shouldn't make you sick for us to take the blood because your body will make new blood to replace it. You have a very important job and that is to hold still. If you can do that, it will be very fast. Your arm may be a little sore or get a little bruise. The blood test will help to know your chance of getting diabetes so that you can know early and hopefully keep you from getting very sick.

Sometimes we need to check the blood a second time to get more information. We are asking you to come back for a second test if we need to re-check your blood. If you come back, it would be the same test just like before. If we find that you may have more of a chance of getting diabetes, we will ask you and your parents if you want to stay in this study. We might also save some of your blood sample to test later.

If we find out that you do not have a good chance of getting diabetes, you still might have a chance of getting it later. So we are asking you to come back once a year until your 18th birthday to repeat the same blood test. You and your parents can change your mind and stop any time you want.

Please ask Dr. Bill Russell or a member of the research team any questions you might have.

It is your choice to have this done. You can say "no". You can say "not now, maybe later". Nobody can make you do this. If you say YES, you may be helping us know how to keep people from getting diabetes. Only people doing the research will get your information, but you or your parents can tell people if you want to.

We will not do these tests unless you say YES. You can say STOP any time you want. The study team won't be upset with you. Sign your name below if you agree to do the blood tests.

My Name

Date

Signature of person obtaining assent

Printed name of person obtaining assent

