



SUBJECT ASSENT FORM Children aged 7-13 years

Assent Form – PET/CT Study for Neuroendocrine Tumours

INVITATION

I am being invited to be part of a research study. A research study tries to find better treatments to help children like me. It is up to me if I want to be in this study. No one will make me be part of the study. Even if I agree to be part of the study, I can change my mind later. No one will be mad at me if I choose not to be part of this study.

WHAT ARE WE DOING IN THIS STUDY?

In this study we want to see how a scan called a Positron Emission Tomography scan, or “PET scan”, works in children like me who might have a tumour. The results of the PET scan will be compared to other tests that me, and children like me, have had. I am being invited to be part of this study because my doctor would like to know if the PET scan will help us know if I have a tumour inside my body.

WHAT WILL HAPPEN IN THIS STUDY?

If I agree to be in this study, I will be asked to come see the study doctor one time for about three hours in order to have the PET scan.

When I come to have my PET scan, the study staff will talk to me and my parents or guardian. If I want to be in the study, I will be weighed and my blood pressure will be taken by putting a cuff around my arm. The cuff will squeeze my arm a bit but will not hurt. If I am a child who has diabetes, I will get a needle poke in my finger so that the sugar in my blood can be measured. If the sugar in my blood is measured to be too high, the test won't work properly.

The study staff will then poke a needle into my arm or hand to put a drug into my body called ^{18}F -6-L-fluorodihydroxyphenylalanine, or “FDOPA”. The FDOPA is a type of drug that will move into my body and it can tell my study doctor if there are any tumours in my body. An hour after the FDOPA is put into my body I will be asked to lie still in the PET scanner for about 30 minutes. While I am lying still, pictures of my entire body will be taken.

WHO IS DOING THE STUDY?

Dr. Don Wilson and doctors from the Children's Hospital will be doing this study. They will answer any questions I have about the study. I can also call **Dr. Wilson** at **604-707-5979**, if I am having any problems or if there is an emergency and I cannot talk to my parents.

CAN ANYTHING BAD HAPPEN TO ME?

If I am a child who is diabetic, the needle poke that I will get in my finger will hurt a little. The needle poke that I will get in my arm or hand when the study drug is being put into my body will also hurt a little, but the hurt will go away after a short while. A special cream called Ametop Gel can be put on my skin to help numb my arm so the needle will hurt less. Sometimes after the needle is taken out of the arm there is a small bruise and sore spot, but this bruise and sore spot will go away after a day or two.

WHAT SHOULD I DO IF I AM NOT FEELING WELL?

The study drug should not make me feel any different. If the study drug or the scan makes me feel bad or I notice strange feelings during or after the study, I should tell my parents or guardian right away. I can also call the study doctor: **Dr. Wilson** at **604-707-5979**. I can call at any time to tell the study doctor how I feel.

COULD I GET BETTER BY BEING IN THE STUDY?

Being in this study will not make me feel better. The doctors might find out something that may help my treatment and that might also help other children like me later.

ARE THERE ANY OTHER TREATMENTS FOR ME?

I do not have to be in this study. There are other types of scans that could help give my doctor more information about whether I have a tumour or not. I can ask my doctor or my parents about the other scans.

WHO WILL KNOW I AM IN THE STUDY?

Only my doctors and the people who are involved in the study will know I am in it. When the study is finished, the doctors will write a report about what was learned. This report will not say my name or that I was in the study. My parents and I do not have to tell anyone I am in the study if we don't want to.

WHEN DO I HAVE TO DECIDE?

I have as much time as I want to decide to be part of the study. I have also been asked to discuss my decision with my parents.

ASSENT (AGREEMENT) TO PARTICIPATE IN THIS STUDY

I have had a chance to read this assent form. I was allowed to ask questions about being in this study and to talk to my family about being in this study. All of my questions have been answered. I can stop participating in this study at any time I want. If I put my name at the end of this form, it means that I agree to be in this study.

Subject's Signature

Printed name

Date