

ASSENT FORM TO BE IN A RESEARCH STUDY

Participant's Name _____ Medical Record # _____

Why would we like to speak with you?

We want to talk with you about being a part of something called a research study. A research study is when doctors collect information to learn more about a disease. Doctors who do research are also called researchers.

If you have any questions during our talk about this study, you can ask them. Don't worry about waiting until the person talking stops speaking to you. You can stop them at any time and ask your question.

Doctors at the University of Virginia are doing this research study to learn more about children who have lost their smell after an illness. After we tell you about this research study, we will ask you if you'd like to be in this research study or not. If you decide to be in this research study, you will be asked to sign this paper and you can take a copy of it home with you.

It's okay to say 'NO' if you don't want to be in the study. It is also okay to be in the study now and leave it at any time. You should speak with your parent/guardian about your decision.

Why are we doing this research study?

You are being asked to join this study because you have trouble with your sense of smell after you had a sickness. The researchers are looking at whether sniff training can help people get better at smelling. This will help researchers learn more about smell loss and possible ways to help it.

We will be getting information from lots of boys and girls like you.

In this research study, there will be about 75 people at UVA who have lost their smell after a sickness.

What will happen to you if you are in the research study?

If you say yes, this is what you will be asked to do:

1. Come back to this office 4 times over the course of 52 weeks (about 1 year).
2. You will be asked to answer questions about feeling lonely, how good your life feels, and how well you think. Also, you will complete smell tests in which you will sniff different smells and answer questions about them.
3. You will also have to complete sniff training at home. You will sniff four smells twice a day in the morning and at night. This will last up until the 5 and a half month visit. You will be placed into one of three groups by chance, like picking a number from a hat. Each group has smells that may be a little different or stronger. One of the groups could be a "control group." This group would not get the same sniff training as the other groups. The control group will help us learn if sniff training really works.

What things may bother or hurt you about being in this study?

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks.

There are some small risks associated with this study. The biggest risk is that your information might not stay private. If this happens, we will check what went wrong and make it right. Another risk is that you might not like some of the smells during the sniff training. You might not like having to do “sniff” training for about 5 or 6 months. If you are in the control group, you might not get the active sniff training. This means your sense of smell may not get better during the study, and it could stay the same. This study will not treat your sense of smell, and it does not replace your regular doctor's care.

You may not like answering some of the questions we ask.

If you are pregnant or think you might be pregnant, please tell us so we may talk about this with you.

It is important that you contact the study doctor right away if you think you may be pregnant, if you have missed a period or it is late, or if you have a change in your usual menstrual cycle (heavier or lighter bleeding than usual or bleeding between periods).

Will you be paid for being in this study?

You will receive up to \$150 for being in this research study. This money will go into your bank account. If you do not have your own bank account, the money will go into your parent or guardian's bank account for you.

Can you do something else instead?

Yes. Your doctor will tell you and your parents what other treatment(s) you may have instead.

Do you have to be in this research study?

No and no one will be upset with you if you don't want to be in this research study. If you don't want to be in this research study, just tell us. If you want to be in the research study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you.

Please talk this over with your parents before you decide whether or not to be in the research study. Your parents have said that it is okay with them if you want to be in the research study. Even though your parents have said it is okay with them, you can still say 'No'.

What if you have questions?

You may ask questions at any time. You can ask now or later. You may talk to the doctor or someone else. Your parents/guardians have the information on who you or they may call after you go home.

What about your privacy?

The doctor will talk about you and the research study with your parent/guardian, but will not talk about it with anyone else except the people working here. If the doctor needs to talk to anyone else about you he/she will ask you and your parent/guardian if it is OK.

Saying Yes or No to being in this research study

You can say yes or no. If you say yes, remember:

1. You can stop being in the study any time you want to
2. You can call the doctor any time you have any questions
3. Besides your parents/guardian, your information will only be shared with the doctor and nurses in this study

If you sign this paper, it means that you have read this and you have talked with someone about it. It also means you have had all your questions for today answered and you want to be in the research study. If you don't want to be in the study, don't sign this paper.

Please ask as many questions as you need to make sure you understand the study before you sign this form. Being in the study is up to you, and no one will be upset if you don't sign this paper or if you change your mind later.

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

Parent(s)/Guardian has signed Main informed consent ___Yes ___ No

Name of Person Obtaining Consent of the Parent(s)/Legal Guardian_____

Signature of Person Obtaining Consent of the Parent(s)/Legal Guardian_____

Assent from Child (10-14 years of age)

CHILD
(SIGNATURE)

CHILD
(PRINT NAME)

DATE

Person Obtaining Assent of the Child (10-14 years of age)

By signing below you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

PERSON OBTAINING ASSENT OF
THE CHILD
(SIGNATURE)

PERSON OBTAINING ASSENT
OF THE CHILD
(PRINT NAME)

DATE

Consent from Impartial Witness

If this assent form is read to the minor subject because the minor subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The minor subject may place an X on the Assent from Child Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the minor subject who has had the opportunity to ask any questions he/she had about the study. I also agree that the minor subject freely gave their assent to participate in this trial.

IMPARTIAL WITNESS
(SIGNATURE)

IMPARTIAL WITNESS
(PRINT)

DATE