

ORCHARDS
2019-2020 School Year
University of Wisconsin-Madison
Assent Form Ages 7 - 14

Research Study Title ORegon CHild Absenteeism due to Respiratory Disease Study (ORCHARDS)

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What is this study about?

We are doing a research study. A research study is a way to find out about something. This study is being done to find out what causes kids to get sick and why they miss school. You are being asked if you want to be in this research study because you are a student between the ages of 7 – 14 who goes to school in Oregon or Brooklyn and is not feeling well today.

What will I need to do if I am in this study?

If you want to be in the study, this is what will happen:

- The researcher will ask you some questions. The questions will be about how you are feeling today and if you've been around people who are sick at school or at home
- The researcher will put one soft swab in your nose and one more soft swab further back in your nose or your throat to collect some snot or spit.
- If your family participates in the Household Study, your mom or dad (guardian) will collect a nasal swab from you in one week. You or your parent (guardian) will fill out some paperwork about you at that time and someone from the study will pick up everything up.

How long does the study last?

You will be in this study during my time here today, about 30 minutes.

If your family participates in the Household Study, you will be in the study for 7 days.

By agreeing to be in this study today, you could do other ORCHARDS visits this year if you become sick again between now and August 31, 2020.

Can I stop being in the study?

You can stop being in the study at any time and no one will be mad at you. If you decide to be in the study today, you do not have to be in the study later this year, even if you get sick again. It is always your choice.

Will anything bad happen to me if I am in the study?

- It might feel funny or hurt a little bit when we put the swab in your nose or throat.

- The swab in your nose or throat might make you feel like gagging.

What good things might happen to me if I am in the study?

We do not think being in this study will help you. You may feel good knowing that what we find out from this study may help other people someday.

Will I be given anything for being in this study?

- If you decide to be in this study, you will get a gift card for \$20.
- If your family participates in the Household Study, your family will receive a \$50 gift card.

Will anyone know I am in the study?

- When we get the snot or spit from your nose, it will be put in a test tube and we will write your Study Number on it, not your name.
- When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.
- We will only tell your parents or guardian about your answers if we think they need to know something you have told us. We will tell them if you are feeling really sad or are not feeling well.
- If we find that you have influenza (the “flu”), we will let your parent or guardian know this information and they may want to share that information with your doctor.

Who can I talk to about the study?

If you have any questions about the study or any problems, you can talk to your parents, guardian or anyone on the research team. You can contact the study Project Manager, Shari Barlow at 608-333-2653 or shari.barlow@fammed.wisc.edu.

What if I do not want to do this?

You don’t have to be in this study. It is up to you. You can decide whether or not you want to be in this study, and you can stop being in it if you want to. If you say okay now, but change your mind later, that’s okay too. Just tell me.

Child Authorization:

Your mom or dad (or guardian) has said that it is ok for you to be in this study.

I have been told about the study and what I will need to do if I agree to be a part of it. I agree to be in this study. I have been told that I can stop at any time. I asked and got answers to my questions. I can keep a copy of this paper.

If you would like to be in the study, please fill out the lines below.

Child’s Printed Name: _____

Child’s Signature or Initials: _____ Date: _____

Person Obtaining Assent/Consent:

I have discussed this research study with the child using language that is understandable and appropriate. I believe I have fully informed the participant of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assented to participate in this study.

Name of Person Obtaining Assent/Consent: _____

Signature: _____ Date: _____