UNIVERSITY OF WISCONSIN-MADISON

Parental Consent Form (Parent of children ages 4 - 14) AND AUTHORIZATION to Use and/or Disclose Identifiable Health Information for Research

Title of the Study: ORegon CHild Absenteeism due to Respiratory Disease Study (ORCHARDS)

Principal Investigator: Jonathan Temte, MD/PhD
phone: 608-263-3011, email: jon.temte@fammed.wisc.edu

Mailing address: Dept. of Family Medicine, 1100 Delaplaine Ct., Madison, WI 53715

INVITATION

Your child is being invited to participate in a research study about school absenteeism and influenza surveillance in the Oregon School District.
Your child has been asked to participate because he/she has symptoms such as a sore throat, fever or other respiratory symptoms, which could be due to influenza (the “flu”).
This study will include Kindergarten through 12th grade students in the Oregon School District. We will collect samples from 500 students each year over a 3 year period.
This research is being conducted in participant's homes.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the research is to determine the causes of school absences across the Oregon school district over a three-year period and to compare when influenza is occurring in the Oregon School District to when it is occurring in surrounding areas and across Wisconsin.

WHAT WILL MY CHILD’S PARTICIPATION INVOLVE?

If you decide to allow your child to participate in this research, he/she will be asked to answer some simple questions about his/her current illness and have two samples taken from his/her nose and/or throat using a soft swab. One sample will be tested for influenza today. The other sample will be sent to the Wisconsin State Laboratory of Hygiene, where it will be tested for influenza and other viruses using research tools. Some samples may be frozen and kept at the Wisconsin State Lab of Hygiene. Some samples may even be tested at the Centers for Disease Control and Prevention in Atlanta.
Your child’s participation will last approximately 30 minutes today.
We will also collect the following information about your child for this research study: First and last name, birth date, home address, phone number, email address, sex, race/ethnicity, birth date, and information including when the illness began, exposure to similar illnesses, recent travel, exposure to farm animals, symptoms of this illness,

severity of this illness, and whether he/she received influenza vaccine. We will also verify his/her immunizations through the Wisconsin Immunization Registry.

ARE THERE ANY BENEFITS TO MY CHILD?

You will receive your child's rapid influenza results by phone within 48 hours of the sample collection. If you would like us to provide the results in writing so that you can share them with your child's health care provider, we can arrange for that. This may allow the health care provider to better diagnose your child's current illness and provide appropriate treatments. You will also receive your child's influenza test results from the Wisconsin State Lab of Hygiene in the mail within 2 weeks of the sample collection.

ARE THERE ANY SIDE EFFECTS OR RISKS TO MY CHILD?

The main risk of taking part in this study is that your study information could become known to someone who is not involved in performing or monitoring this study.
Sometimes a person will find that the nose or throat swab makes them feel mildly uncomfortable or causes a gagging sensation. This is temporary and does not cause any long lasting problems. These samples will be obtained by a trained and skilled research associate.
All University of Wisconsin System (UWS) employees shall report child abuse or neglect immediately if the employee, in the course of employment, observes an incident or threat of child abuse or neglect, or learns of an incident or threat of child abuse or neglect, and the employee has reasonable cause to believe that child abuse or neglect has occurred or will occur.

WILL MY CHILD BE COMPENSATED FOR THEIR PARTICIPATION?

Your child will receive a $20 gift card for participating in all parts of this study.

HOW WILL MY CHILD'S CONFIDENTIALITY BE PROTECTED?

All paper data sheets will be kept in locked filing cabinets in the UW Department of Family Medicine. Contact sheets with name, address, phone number, and email will be kept separate from other data, with other information identified with a Subject ID Number. The coded information collected from you during this study will be used by the researchers and research staff associated with the University of Wisconsin Madison, but will not include any data that could identify you as an individual. The study sponsor, the Centers for Disease Control and Prevention as well as the Wisconsin Department of Public Health and the Wisconsin State Laboratory of Hygiene may also have access to the data. While there will probably be publications as a result of this study, your name will not be used. Only group characteristics will be published.

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:

• UW-Madison regulatory and research oversight boards and offices
• Accounting and billing personnel at the UW-Madison

Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research:

• Centers for Disease Control and Prevention
• Wisconsin Department of Public Health

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information

with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and its affiliates, it is not shared in a way that can identify an individual.

IS MY CHILD'S PERMISSION VOLUNTARY AND MAY HE/SHE CHANGE HIS/HER MIND?

Your child's permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, your child cannot take part in this research study.

Your child may completely withdraw from the study at any time. Your child also may choose to cease participation or skip any questions that he/she does not feel comfortable answering.

IF YOUR CHILD DECIDES NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU RECEIVE FROM THE UW-MADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.

HOW LONG WILL MY PERMISSION TO USE MY CHILD'S HEALTH INFORMATION LAST?

By signing this form you are giving permission for your child's health information to be used by and shared with the individuals, companies, or institutions described in this form. The nasal and/or throat samples will be banked at the Wisconsin State Lab of Hygiene and/or the Centers for Disease Control and Prevention for future research purposes. Future research would be limited to the detection of pathogens (viruses and bacteria) not included within our usual testing procedures. Both the WSLH and the CDC will store these samples in a secure location. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this or subsequent research studies. You may withdraw your permission at any time by writing to the person whose name is listed below:

Jonathan Temte, MD/PhD
Dept. of Family Medicine, 1100 Delaplaine Ct, Madison, WI 53715

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish for your child to participate. If you have questions about the study at any time, or if you feel your child was harmed by participating in this study,you should contact the Principal Investigator Jonathan Temte, MD/PhD at 608-263-3111 or the Project Manager, Shari Barlow at 608-333-2653.

If you are not satisfied with response of the research team, have more questions, or want to talk with someone about your rights as a research participant, contact the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

AGREEMENT TO PARTICIPATE IN THIS STUDY AND PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my child's health information will be used. I have had a chance to ask questions about the

research study, including the use of my child's health information, and I have received answers to my questions. I agree to allow my child to participate in this research study, and permit the researcher to use and share my child's health information as described above.

Name of Participant (please print):______________________________

____ ______________
Parent/Guardian Signature Date

☐ Please leave a message on my voice mail with my child's rapid influenza results if I do not answer.

☐ Please contact me for future cold/flu research studies

ORCHARDS

Oral Assent for Children ages 4 - 6

Assent script

- You are being asked if you want to be in a research study. A research study is a way to find out about something. We are trying to find out about why kids miss school.
- We want to know 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 child between the ages of 4 – 6 and you go to school in Oregon or Brooklyn and you are not feeling well today.
- If you want to be in the study:
  - I will ask you some questions about how you are feeling today.
  - It will take a few minutes to ask all of my questions
  - I 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. (Show child the swabs that will be used).
  - It will only take a few seconds to collect some snot or spit
  - It will take about 30 minutes to do everything
- Your mom or dad (or guardian) has said that it is ok for you to be in this study.
- It is okay to say "No" if you don't want to be in the study. You can say "no" even if your parents say it's OK for you to be in this study. No one will be mad at you if you don't want to be in the study. If you say "Yes" you can also change your mind and quit being in the study at any time without getting in trouble.
- Do you have any questions?

- Do you want to be in this study?

Name of Child _________________

Did child give oral consent? _______ (yes or no)

Date ___________________

ORCHARDS
University of Wisconsin-Madison
Assent Form Ages 7 - 14

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

Research Team Names Jonathan Temte, MD/PhD (phone: 608-263-3011) (email: jon.temte@fammed.wisc.edu)

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 why kids miss school. We want to know 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.
- 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.

How long does the study last?
You will only be in this study during my time here today, about 30 minutes.

Can I stop being in the study? You may stop being in the study at any time and no one will be mad at you.

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 and that is ok.

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 be given a gift card for $20.

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 at 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: ______

UNIVERSITY OF WISCONSIN-MADISON

Subject ASSENT/Parental CONSENT (ages 15 – 17)/CONSENT (ages 18 & Older) to Participate in Research
And
AUTHORIZATION to Use and/or Disclose Identifiable Health information for Research

Title of the Study: ORegon CHild Absenteeism due to Respiratory Disease Study (ORCHARDS)
Participants ages 15 and older

Principal Investigator: Jonathan Temte, MD/PhD (phone: 608-263-3011)
(email: jon.temte@fammed.wisc.edu)

Mailing Address: Dept. of Family Medicine, 1100 Delaplaine Ct, Madison, WI 53715

INVITATION

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Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

This research is being conducted in participant's homes.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the research is to determine the causes of school absences across the Oregon school district over a three-year period and to compare when influenza is occurring in the Oregon School District to when it is occurring in surrounding areas and across Wisconsin.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research you will be asked to answer some simple questions about your current illness and have two samples taken from your nose and/or throat using a soft swab. One sample will be tested today. The other sample will be sent to the Wisconsin State Laboratory of Hygiene, where it will be tested for influenza and other viruses using research tools. Some samples may be frozen and kept at the Wisconsin State Lab of Hygiene. Some samples may even be tested at the Centers for Disease Control and Prevention in Atlanta.

Your participation will last about 30 minutes today.

We will also collect the following information about you for this research study:

First and last name, birth date, home address, phone number, email address, sex, race/ethnicity, birth date, and information including when your illness began, exposure to similar illnesses, recent travel, exposure to farm animals, symptoms of your illness, severity of your illness, and whether you received influenza vaccine. We will also verify your immunizations through the Wisconsin Immunization Registry.

ARE THERE ANY BENEFITS TO ME?

If you are between the ages of 14 – 17, your parent or guardian will receive your rapid influenza results by phone within 48 hours of the sample collection. If your parent would like us to provide the results in writing, that can be arranged so that the results can be shared with your health care provider. This may allow the health care provider to better diagnose your current illness and provide appropriate treatments. Your parent or guardian will also receive your influenza test results from the Wisconsin State Lab of Hygiene in the mail within 2 weeks of sample collection.

If you are 18 or older, you will receive the information listed in the above paragraph. You may choose to share the information with your parent or guardian if you wish.

WILL I BE PAID FOR MY PARTICIPATION?

You will receive a $20 gift card for participating in all parts of this study.

ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

The main risk of taking part in this study is that your study information could become known to someone who is not involved in performing or monitoring this study. Sometimes a person will find that the nose or throat swab makes them feel mildly uncomfortable or causes a gagging sensation. This is temporary and does not cause any long lasting problems. These samples will be obtained by a trained and skilled research associate.

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HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

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• Accounting and billing personnel at the UW-Madison

Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research:

• Centers for Disease Control and Prevention
• Wisconsin Department of Public HealthPeople outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and its affiliates, it is not shared in a way that can identify an individual.

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You may completely withdraw from the study at any time. You also may choose to cease participation or skip any questions that you do not feel comfortable answering.

IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU RECEIVE FROM THE UW-MADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.

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WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, or if you feel you were harmed (your child was harmed) by participating in this study, contact the Principal Investigator Jonathan Temte, MD/PhD at 608-263-3011 or the Project Manager, Shari Barlow at 608-333-2653.

If you are not satisfied with the response of research team, have more questions, or want to talk with someone about your rights as a research participant, contact the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

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Name of Participant (please print):___________________________

____________________________________ _____________

Signature of Participant Date

☐☐I am 18 years or older and understand that I will receive the information and laboratory tests results

☐ Please leave a message on my voice mail with my rapid influenza results if I do not answer.

☐☐I am 15-17 years old and understand that test results will be shared with my parents

______________________________ ____________
Parent Signature (if age 15 – 17) Date
*Parental permission is required for participants ages 15 – 17

☐ Please leave a message on my voice mail with my child’s rapid influenza results if I do not answer.

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.
Signature of person obtaining consent and authorization:

______________________________ ____________
Signature Date

☐ Please contact me (my child) for future cold/flu research studies