

Consent and Assent Forms and Information for Families

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 how people spread the flu in a house.
- You are being asked if you want to be in this research study because someone else in your house who goes to school in Oregon or Brooklyn is not feeling well today and they are in a different study called ORCHARDS.
- If you want to be in the study, this is what will happen.
 - Your mom or dad (or guardian) will fill out some paperwork about you today and in a week.
 - Your mom or dad (guardian) or one of our study helpers will put one soft swab in your nose to collect some snot today.
 - Your mom or dad (guardian) will put one soft swab in your nose to collect some snot in one week.
 - Someone from our study will pick up the forms and nasal swabs.
- 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: Evaluation of influenza transmission within households where students are absent from school due to acute respiratory infections

**Research Team Names: Jonathan Temte, MD/PhD (phone: 608-263-3111)
(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 how people spread the flu in a house. You are being asked if you want to be in this research study because someone else in your house who goes to school in Oregon or Brooklyn is not feeling well today and they are in a different study called ORCHARDS.

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.

- You or your parent will complete the top half ("TODAY") of the Household Study Form (attached). You or your parent will complete the bottom half ("FOLLOW-UP") of the Household Study form 7 days later.
- Your parent/guardian or one of our study assistants will collect a nasal swab from you today and your mom or dad (guardian) will collect a nasal swab from you 7 days later. Your parent will put them in the refrigerator until the research team picks them up.
- 7 days from today the research team will pick up the forms and nasal swabs.
- If your brother/sister or other person in your house who is participating in the ORCHARDS study tests positive for influenza, we will test your swabs for the flu as well.
- We will store all of the swabs for many years and may test your swabs for other diseases.

How long does the study last?

You will be in this study for 7 days.

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 your parent puts the swab in your nose.

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?

Your family will be paid with a \$30 gift card.

Will anyone know I am in the study?

- The swab from your nose 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.

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:

UNIVERSITY OF WISCONSIN-MADISON
Parental Consent Form (Parent of children ages 0 - 14)
AND
AUTHORIZATION to Use and/or Disclose Identifiable Health Information for Research

Title of the Study: Evaluation of influenza transmission within households where students are absent from school due to acute respiratory infections

Principal Investigator: Jonathan Temte, MD/PhD
phone: 608-263-3111 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 this research study about transmission of influenza in households. He/she is invited to take part because he/she lives in the same house as a student who is participating in the Oregon CHild Absenteeism due to Respiratory Disease Study (ORCHARDS). This study will include family members of students in the Oregon School District. We will collect samples from 720 participants over a one year period.

Your child's participation in this research study is voluntary. If he/she decides not to participate, the health care provided to him/her 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?

To evaluate transmission of influenza in households from which a student (4K-12) has participated in ORCHARDS.

WHAT WILL MY CHILD'S PARTICIPATION INVOLVE?

- Following the ORCHARDS visit, your child (or you) will complete the identification ("ID") and top half ("TODAY") of the Household Study Form (attached). Your child (or you) will complete the bottom half ("FOLLOW-UP") of the Household Study form 7 days later.
- You or a research assistant will collect a nasal swab (see attached instructions) today and you will collect a nasal swab 7 days later from your child. The nasal swabs will need to be placed into the provided transport vials and Ziploc bags and stored in refrigerator until it is picked up by the research team in 7 days.

- 5-6 days after the home visit, research team will call you to remind you to fill out the bottom half of the form and collect second nasal swab.
- If the student in your household who is participating in the ORCHARDS study tests positive for influenza, we will test your child's specimens for influenza as well.
- We will store your child's specimens for several years and may test your specimens for other respiratory pathogens.
- Your child's participation in this study will last for 7 days.

ARE THERE ANY BENEFITS TO MY CHILD?

Your child is not expected to benefit from participating in this study. His/her participation in this study may benefit other people in the future by helping us learn more about the transmission of influenza in households.

ARE THERE ANY SIDE EFFECTS OR RISKS TO MY CHILD?

The main risk of taking part in this study is that the information that you provide to the study team about your child could become known to someone who is not involved in performing or monitoring this study. However, we do not collect any sensitive personal information. Sometimes a person will find that the nose swab makes them feel mildly uncomfortable. This is a temporary sensation and does not cause any long lasting problems.

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?

At the time of specimen pick up, we will provide your household with a \$30 gift card.

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 your child 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 your child 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 child's 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
- Wisconsin State Laboratory of Hygiene (Public Health Laboratory)

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 HE/SHE STOPS WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE THAT HE/SHE RECEIVES 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 information to be used by and shared with the individuals, companies, or institutions described in this form. The nasal samples will be banked at the Wisconsin State Lab of Hygiene (WSLH) and/or the Centers for Disease

Control and Prevention (CDC) 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 child's 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 your child will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your child's permission, he/she 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 any questions about this study at any time, or if you feel your child was harmed by participating in this study, 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 the 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 contact me for future cold/flu research studies

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 Study: Evaluation of influenza transmission within households where students are absent from school due to acute respiratory infections

Principal Investigator: Jonathan Temte, MD/PhD (phone: 608-263-3111)
(email: jon.temte@fammed.wisc.edu)

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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?

To evaluate transmission of influenza in households from which a student (4K-12) has participated in ORCHARDS.

WHAT WILL MY PARTICIPATION INVOLVE?

- Following the ORCHARDS visit, you will complete the identification (“ID”) and top half (“TODAY”) of the Household Study Form (attached). Your child (or you) will complete the bottom half (“FOLLOW-UP”) of the Household Study form 7 days later.
- You or a research assistant will collect a nasal swab (see attached instructions) today and you will collect a nasal swab 7 days later. The nasal swabs will need to be placed into the provided transport vials and Ziploc bags and stored in refrigerator until it is picked up by the research team in 7 days.

- 5-6 days after the home visit, research team will call you to remind you to fill out the bottom half of the form and collect second nasal swab.
- Parent/guardian will call the ORCHARDS study phone number (608-265-3164) to arrange specimen pick-up.
- If the student in your household who is participating in the ORCHARDS study tests positive for influenza, we will test your specimens for influenza as well.
- We will store your specimens for several years and may test your specimens for other respiratory pathogens.

ARE THERE ANY BENEFITS TO ME?

You are not expected to benefit from participating in this study. Your participation in this study may benefit other people in the future by helping us learn more about the transmission of influenza in households.

WILL I BE PAID FOR MY PARTICIPATION?

At the time of specimen pick up, we will provide your household with a \$30 gift card.

ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

The main risk of taking part in this study is that the information that you provide to the study team could become known to someone who is not involved in performing or monitoring this study. However, we do not collect any sensitive personal information. Sometimes a person will find that the nose swab makes them feel mildly uncomfortable. This is a temporary sensation and does not cause any long lasting problems.

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.

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

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.

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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
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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 PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your 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, you cannot take part in this research study.

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.

HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form you are giving permission for your information to be used by and shared with the individuals, companies, or institutions described in this form. The nasal samples will be banked at the Wisconsin State Lab of Hygiene (WSLH) and/or the Centers for Disease Control

and Prevention (CDC) 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.

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 608-263-3111 or the Project Manager, Shari Barlow at 608-333-2653.

If you are not satisfied with the response of the research team, have more questions, or want to talk with someone about your rights as a research participant, contact the UWMC 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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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 health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

Name of 18 year or older Participant (please print): _____

Signature of 18 year or older of Participant Date

Name of 15 - 17 year old Participant (please print:) _____

Signature of 15 - 17 year old Participant Date

Parent Signature (if age 15 - 17) Date

*Parental permission is required for participants ages 15 - 17

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