

Telephone script to obtain varicella laboratory specimens

Hello. My name is _____ with the WV Division of Infectious Disease Epidemiology. I would like to invite you to participate in a project that is being conducted by the Bureau for Public Health and the Centers for Disease Control and Prevention. This project will help us to learn about chickenpox now that doctors are giving children the shot. We have been informed that your child has chickenpox. As a result, we are hoping that you will allow us to obtain specimen samples from your child's rash. If you agree, the chickenpox surveillance nurse will meet you at your local health department to obtain specimen samples from your child's rash (this is a fast procedure without pain). We will also provide you with the results of the laboratory test. Are you willing to allow us to obtain rash specimens from your child?

(Yes-Continue, No-Thank the parent for his/her time and give them our telephone number (304-558-5838) in case they have future questions/concerns)

Thank you for agreeing to participate in this important project. At this time, we will schedule a time for our staff to meet you at your local health department or a local school based health center.

Visit Date: ____/____/_____ Visit Time: _____AM/PM

Consent to Obtain Laboratory Specimens

INTRODUCTION

The West Virginia Bureau for Public Health and the Centers for Disease Control and Prevention (or CDC) are participating in a project about students with chicken pox. This disease is usually mild, but can sometimes be very harmful. This project will help to show us how well the chicken pox shot is working. Our project will include school-age children who live in West Virginia. Some children were given 1 shot. Other children were given 2 shots. Some children are now sick with chicken pox. Some children are not sick. We want to see if children who got 2 shots are better protected against chicken pox than children who got only 1 shot.

We would like to include your child because s/he may have chicken pox disease. You can help today by allowing us to collect samples from your child to test for the chicken pox virus. We will provide you with the result of the specimen testing.

PROCEDURES

It is your choice to allow us to obtain rash specimens. We will ask you if we can do 3 things:

- 1) Collect samples from your child's chicken pox rash to test for the chicken pox virus. Trained staff members will take specimen samples from your child. This is commonly done for rashes and is a very simple process. To get the samples, they will scrape your child's chicken pox rash with a glass slide. If the rash has formed scabs, the staff member may lift 1 or 2 scabs off with tweezers. They may also wipe the rash with a Q-tip. Collection of the samples will take approximately 5-10 minutes. The samples will be tested in the lab for chicken pox and results of the test will be sent to your doctor. This process will not affect your child's health at all. However, your child does not have to provide any samples that s/he does not want to. No explanation will be necessary.
- 2) We will call you in about three weeks to see if your child's rash has healed. We will call at a time that works for you and ask a few more questions about the rash. No other samples will be needed.
- 3) Use the information you gave us on the phone about your child and chicken pox for the project.

BENEFITS AND RISKS

There is only 1 direct benefit of this project to you and your child. You will know for sure if your child has chicken pox. If s/he was sick with chicken pox, it is evidence to your doctor that s/he will not get another chicken pox infection. This project will also help the health department and CDC to evaluate the effectiveness of the chickenpox vaccine. The findings from this study will benefit the general public and will help guide how the chicken pox shot is used to prevent disease in the US. The risk to your child participating in this project is small. Your child may feel some discomfort when samples are taken from his/her rash. There may also be some bleeding or oozing of clear fluid after the samples are taken. If this occurs a band-aid will be placed on the area.

COSTS / PAYMENTS

There will be no charge to you or your insurance for any tests done in this project. No payments will be made to you or your child for participation in this project.

CONFIDENTIALITY

By signing this form, you are allowing the project staff to use the information you give us about your child and chicken pox. You are also allowing the staff to collect samples from your child's chickenpox rash. Your child's personal information will be kept private as required by law. Hard copy records with your child's name will be stored in locked file cabinets. After 5 years, all hard copy records will be destroyed. Electronic records will be kept in a password protected database. Only project team and the West Virginia Bureau for Public Health staff will be allowed to see your child's records. Anything that could identify your child will be removed before it is examined and will not appear in the project findings.

YOUR RIGHTS AS A VOLUNTEER

You are free to decide if your child takes part in this project. This will not affect your child’s health-care now or in the future.

Do you have any questions? All of your questions should be answered before you agree to have your child take part in this project.

CONTACT INFORMATION

If you have questions about this project, you can contact West Virginia Department of Health & Human Resources at (304)-558-5838. Ask for the Varicella Project Team.

YOUR CONSENT

Do you agree to voluntarily give your consent to obtain rash specimens from your child?

_____ Yes, I agree to allow the project team to obtain rash specimens from my child.

Initial

_____ No, I do not agree to allow the project team to obtain rash specimens from my child.

Initial

Participant’s Name

Parent/Guardian’s Name

Parent/Guardian’s Signature

Date

Project Team Member’s Signature

Date