

## CONSENT TO PARTICIPATE

### *An investigation by the Centers for Disease Control and Prevention to determine*

### **The risk of food allergic reactions from corn products containing Cry9C**

The Centers for Disease Control and Prevention is conducting an investigation to gather information from people who reported adverse health events after eating corn products containing the genetically engineered protein, Cry9C. Since you reported an adverse event, we would like you to be part of this investigation. Your participation is completely voluntary. Refusing to participate is your right and there is no penalty for doing so. The choice is yours. Before you decide, you should know what is involved and have all your questions answered.

#### **Purpose**

We will interview and collect blood samples from as many of the people who reported adverse reactions as possible. The combined results of the interviews and blood tests will help us better understand whether or not corn products containing Cry9C protein can potentially cause food allergic reactions and what the risk to individuals might be.

#### **What will it involve?**

If you agree, we will take a blood sample right now. It should take about 5-10 minutes. We will take the sample (1 or 2 teaspoons) from a vein in your arm. We will label your blood sample with a unique identification number instead of using your name or other personal information.

A new blood test is being considered for development to detect antibodies against the genetically engineered protein Cry9C. Because of the need to quickly gather information from individuals who reported adverse reactions to corn products containing Cry9C, we are asking questions and collecting blood samples now, even though the blood test is not yet available. If the blood test is not available for use by 31 March 2001 all blood samples will be destroyed, including yours.

If the test is developed, your blood will be tested only for the presence of Cry9C antibodies; it will absolutely not be tested for anything else at any time (such as HIV testing, genetic testing, or drug testing). After the Cry9C antibody testing is complete, any left-over

blood will be destroyed.

#### **Cost**

There is no cost to you.

#### **Benefits**

The goal of this investigation is to help answer the question of whether or not corn products containing the genetically engineered protein Cry9C can potentially cause allergic reactions when eaten by people. The information may help determine if this product is safe for use in human foods and this may indirectly benefit you. Also, if the blood test is developed, we will notify you of your test results if you desire to know.

#### **Risks**

The only risk is that you may have some mild, brief discomfort when we take blood from your arm. A small bruise may also appear. The individual who will take your blood is trained and experienced and will do everything possible to minimize your discomfort.

#### **Confidentiality**

We will keep your test results and what you tell us confidential to the extent allowed by law. We will notify you of your blood test result if you wish to know, and a summary of all the test results will be given to the U.S. Food and Drug Administration. We will not tell anyone else what your test result is.

To protect your privacy, we will not put your name on the questionnaire or blood sample but will use a unique identification number instead. We will also keep all the investigation records and blood sample results in locked files and only investigation staff will be allowed to look at them. When we talk or write about the investigation, we will not include your name or other facts that might identify you.

We are putting your name, telephone number, and address on this consent form now so that we can notify you of your test results and to document your willingness to participate. We will keep this consent

form in a locked file separate from the questionnaires and blood test results.

**For more information**

We will give you a copy of this form to keep. We would be happy to answer any questions about the study or a problem or injury related to the investigation. You may contact the principal investigators, Dr Brad Winterton and Dr Dori Reissman, at the Centers for Disease Control and Prevention at 404-639-2530. If you have any questions now or in the future about your rights as a participant in this investigation, you may contact the

CDC Deputy Associate Director for Science at 800-447-4784, mailbox number 329-4518. Leave a message with your name and number and someone will call you back.

**Voluntary participation**

It is your choice whether or not to participate in this investigation. There is no penalty if you choose not to participate.

**If you agree to volunteer to participate in this investigation, you must sign below. By signing this form, you are saying that:**

1. You have read this entire form or someone read it to you completely.
2. All of your questions have been answered.
3. You are volunteering to be part of this investigation.
4. You know that you have no obligation to answer any questions or to give a blood sample.
5. You will be given a copy of this form to keep.

**I have read this informed consent and agree to participate in this investigation.**

\_\_\_\_\_  
(Signature) \_\_\_\_\_ (Date)

\_\_\_\_\_  
(Printed name)

Street Address: \_\_\_\_\_  
\_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone number: \_\_\_\_\_

**Would you like to be notified of the results of your blood test?      YES      NO**

<b>Parents of children under 18 years old:</b>	
As the parent or legal guardian of this person, I give permission for _____ to participate in this investigation. <span style="float: right;">(Participant's name)</span>	
_____	_____
(Parent or guardian signature)	(Date)
_____	
(Parent or guardian printed name)	

**Consent to release medical records**

CDC report to FDA: Investigation of human illness associated with potential exposure to Cry9c

We would also like your permission to check with any doctors who have given you medical care related to your adverse reaction or other allergies you may have. To do this, we ask you to sign below and also give us the name and address of the doctor or hospital where these records are located. Even if you do not want to give us permission to review your medical records, you may still participate in this investigation by answering the questionnaire questions and giving a blood sample. **By signing below you agree to allow the doctor or hospital listed to share your medical records with us.**

**I have read the above consent to release medical records and agree to allow the doctor/hospital listed below to release my medical records for the purpose of this investigation.**

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Printed name)

Name, address, phone of doctor or hospital

Name, address, phone of doctor or hospital

\_\_\_\_\_  
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## CHILD ASSENT TO PARTICIPATE

### *An investigation by the Centers for Disease Control and Prevention to determine*

#### **The risk of food allergic reactions from corn products containing Cry9C**

You may have heard that the government has recalled some foods that contain corn. That is because there is a concern about whether or not those foods are safe to eat. They contain a new type of corn that is genetically engineered so that insects can't eat it.

We are doing an investigation to find out information about people who have eaten some of those foods. We would like you to be in this investigation. You don't have to unless you want to. It is up to you.

#### **What will happen?**

If you let us, we will take a small amount of blood from a vein in your arm by putting a needle in the vein for a few seconds. First we will rub your skin with alcohol to clean it.

We will also ask you or your parents some questions about your health and things you might have eaten. Your answers are private. We will not tell anyone else outside the investigation.

#### **Will it hurt?**

The needle stick in your skin may hurt a little for a few seconds. The person taking the blood will be very careful.

#### **Benefits**

We are doing this investigation to help answer some important questions.

**We want you to sign your name on this paper to say that you agree to have the blood test done and answer our questions.**

- 1. You know that the blood test is just for this investigation.**
- 2. You know how we will take your blood sample.**
- 3. You know that you do not have to be in this study or answer our questions or have this blood test done if you do not want to.**

\_\_\_\_\_

(Child's signature)

\_\_\_\_\_

(Date)

\_\_\_\_\_

(Child's printed name)

\_\_\_\_\_

(Parent or guardian signature)

\_\_\_\_\_

(Date)

\_\_\_\_\_

(Parent or guardian name)

CDC report to FDA: Investigation of human illness associated with potential exposure to Cry9c

*Unique Identifier*

Street Address: \_\_\_\_\_  
\_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone number: \_\_\_\_\_