

ATTACHMENT 4

Phase III Buccal Script and Verbal Consent Following Contact Letter

- 4A. Phase III Buccal Script and Verbal Consent for North Carolina Respondents
- 4B. Phase III Buccal Script and Verbal Consent for Iowa Respondents with Prostate Cancer
- 4C. Phase III Buccal Script and Verbal Consent for Iowa Respondents with NHL

Attachment 4A:

Phase III Buccal Cell Collection Script and Consent for North Carolina Respondents

VERBAL CONSENT FOR BUCCAL CELL COLLECTION (Interviewer's Script)

Public reporting burden for this collection of information is estimated to average five minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0406). Do not return the completed form to this address.

Thank you for your participation in the Agricultural Health Study. We appreciate your help and would like to make an additional request. This request is voluntary and will provide very important information to the study. We would like to obtain a sample of loose cells from your mouth. This is called a buccal cell sample. This only takes a few minutes of your time, and is done simply by swishing mouthwash in your mouth and then expelling it into a container. Everything you need to collect the sample—including mouthwash, container, and complete instructions—will be mailed to you. A consent form will also be included in the kit, as well as materials for mailing the sample back to us. We will also enclose \$5 for your time and effort in collecting and mailing the sample. As soon as we receive the sample, the cells will be put in a freezer for long-term storage and will be used for later laboratory analysis. Would you be willing to participate in the buccal cell collection?

(IF YES) >> Thank you. We will mail the buccal cell kit to you within the next few days along with the \$5. Please read the instructions that are included carefully. If possible, we would like to ask you to complete this activity and mail it out as soon as you can. Also, don't forget to sign and return the consent form along with the buccal cell sample. Thank you for your participation.

(IF NO)>> Do you have any questions or concerns about the buccal cell collection that I could answer for you? (ANSWER ANY QUESTIONS AND RECORD REPLY)

(IF R STILL REFUSES)>> Thank you for your time and your past participation.

Attachment 4B:

Phase III Buccal Cell Collection Script-Consent Following Letter to Iowa Residents with Prostate Cancer

BUCCAL SCRIPT FOLLOWING LETTER

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Introduction

"Hello, this is _____ from the Agricultural Health Study. May I speak to _____?"

"I am calling you about the letter that we sent you recently about collecting cheek cells for a study of prostate cancer and pesticide exposure. Do you recall getting that letter?"

IF DOES NOT REMEMBER GETTING LETTER, OFFER TO
RE-SEND AND CONTINUE WITH THE SCRIPT.

"[As we state in the letter] You are one of about 1,000 members of the Agricultural Health Study who have been selected to be contacted about a study of prostate cancer. Because you have already contributed a tremendous amount of information about your pesticide exposure in previous interviews and questionnaires, this new study will have a head-start in understanding the relationship of prostate cancer to pesticide exposure. The study will include people who have not been diagnosed with prostate cancer as well as people who have had this disease. These two groups will then be compared.

"We would like to obtain a sample of loose cells from your mouth. This is called a buccal (or cheek) cell sample. This only takes a few minutes and is done simply by swishing plain Scope mouthwash in your mouth and then expelling it into a container . . . it's extremely simple and quick. This is totally voluntary, but is really important to the study.

"We'll mail everything you need, along with materials for you to mail it back to us. We'll also enclose a \$5 check for your time and effort in collecting and mailing the sample. When we get samples back from study participants, we store them. We'll later analyze the samples to identify genetic differences between people that may explain why some develop certain diseases and some don't.

"Would you be willing to participate in this study?"

IF HESITATING→ "Do you have any questions or concerns that I could answer for you?"

ANSWER ANY QUESTIONS.

IF YES→ "Great! We'll mail the kit out to you within the next few days. Will that work for you?"

IF REQUESTED TO HOLD MAILING: "When would you like that mailed?"

"Should we mail that to ^address ^city, ^state ^zip?"

IF NO: What address should we use?

"You'll find some instructions with the kit. Please read those carefully. It would help us greatly if you could complete them and mail them back to us as soon as you can. Also, it's really important that you sign the consent form and mail it back to us along with the mouth rinse sample."

"Thank you again for all that you've done for us. Goodbye!"

IF NO→ "Okay, not a problem. We really appreciate all the other things that you've done for us. Goodbye!"

Attachment 4C:

Phase III Buccal Cell Collection Script-Consent Following Letter for Iowa Residents with NHL

BUCCAL SCRIPT FOLLOWING LETTER

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Introduction

"Hello, this is _____ from the Agricultural Health Study. May I speak to _____?"

"I am calling you about the letter that we sent you recently about collecting cheek cells for a study of non-Hodgkin lymphoma and pesticide exposure. Do you recall getting that letter?"

IF DOES NOT REMEMBER GETTING LETTER, OFFER TO RE-SEND AND CONTINUE WITH THE SCRIPT.

"[As we state in the letter] You are one of about 500 members of the Agricultural Health Study who have been selected to be contacted about a study of non-Hodgkin lymphoma. Because you have already contributed a tremendous amount of information about your pesticide exposure in previous interviews and questionnaires, this new study will have a head-start in understanding the relationship of non-Hodgkin lymphoma to pesticide exposure. The study will include people who have not been diagnosed with non-Hodgkin lymphoma as well as people who have had this disease. These two groups will then be compared.

"We would like to obtain a sample of loose cells from your mouth. This is called a buccal (or cheek) cell sample. This only takes a few minutes and is done simply by swishing plain Scope mouthwash in your mouth and then expelling it into a container . . . it's extremely simple and quick. This is totally voluntary, but is really important to the study.

"We'll mail everything you need, along with materials for you to mail it back to us. We'll also enclose a \$5 check for your time and effort in collecting and mailing the sample. When we get samples back from study participants, we store them. We'll later analyze the samples to identify genetic differences between people that may explain why some develop certain diseases and some don't.

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ANSWER ANY QUESTIONS.

IF YES→ "Great! We'll mail the kit out to you within the next few days. Will that work for you?"

IF REQUESTED TO HOLD MAILING: "When would you like that mailed?"

"Should we mail that to ^address ^city, ^state ^zip?"

IF NO: What address should we use?

"You'll find some instructions with the kit. Please read those carefully. It would help us greatly if you could complete them and mail them back to us as soon as you can. Also, it's really important that you sign the consent form and mail it back to us along with the mouth rinse sample."

"Thank you again for all that you've done for us. Goodbye!"

IF NO→ "Okay, not a problem. We really appreciate all the other things that you've done for us. Goodbye!"