

Attachment 16: Phase IV Buccal Cell Collection Information

(Kit Letter, Collection Directions/Instructions, FAQs, etc.)

16.1). Phase IV Iowa Buccal Cell Kit Cover Letter

16.2). Phase IV Iowa Buccal Cell Directions

16.3). Phase IV Iowa Buccal Cell Kit Re-mail Cover Letter

16.4). Phase IV North Carolina Buccal Cell Kit Cover Letter

16.5). Phase IV North Carolina Buccal Cell Directions

16.6). Phase IV North Carolina Buccal Cell Kit Re-mail Cover Letter

16.7). Phase IV Buccal Cell FAQs for Both Sites



Attachment 16.1: Phase IV Buccal Iowa

Agricultural Health Study- Iowa

University of Iowa • 2500 Crossspark Road, Suite W240 • Coralville IA 52241 •
1.800.217.1954

www.aghealth.org

[date]

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To: Agricultural Health Study Participant

From: Charles Lynch, M.D., Ph.D.
Director, Agricultural Health Study -Iowa

Thank you for your continued participation in Agricultural Health Study. You are an essential member of this study, which is designed to learn about how occupation and environmental factors affect an individual's health. Thanks to your participation, this now is the largest one of its kind in the United States.

As we discussed on the phone, we would like to collect a sample of loose cells from your mouth. This is done simply by swishing mouthwash in your mouth and then expelling it into the accompanying container (see the enclosed DIRECTIONS FOR MOUTHWASH). The cells will be kept in a freezer for long-term storage, and will be used for later laboratory analysis that will involve genetic testing. This will take only a few minutes of your time and will provide very important information for the study. Once you collect this sample, please return it as soon as possible in the padded envelope enclosed. **If we have not received the kit back in a few weeks, we may contact you to see if you have any questions or concerns.**

We will continue to inform you about the study's progress on various aspects of research through periodic communications. If you have any questions, please call us at **1-800-217-1954**. We will be glad to assist you.

We truly value your continued participation in this landmark study of agricultural workers and their families. Because you have already provided us with valuable information no other person can take your place.

Thank you once again for your time and support.

Attachment 16.2: Phase IV Buccal Iowa

DIRECTIONS FOR MOUTHWASH

The purpose of this simple procedure is to collect some loose cells from your mouth. Please follow the directions below. You may request help reading the instructions from a member of your household, but **please do not permit anyone else to handle the collection materials.**

Here is a list of what you should find in the envelope we mailed to you:

- 2 copies of the Informed Consent Form
- Screw top collection container
- Plastic bottle of mouthwash
- Leak-proof plastic bag with a small absorbent sheet (in case anything spills)
- Pre-stamped mailing envelope

If you have not received all of these materials, please call us at 1-800-217-1954

1. Read and sign one copy of the Informed Consent Form (the other copy is yours to keep).
2. Do not eat or rinse your mouth for one hour before collecting the saliva sample.
3. Open the bottle of mouthwash and fill the enclosed screw top collection container half full of mouthwash (to the red fill line).
4. Swish the mouthwash from the collection container around in your mouth vigorously for 45 seconds. **Watch the clock while you do this.**
5. Holding the container close to your mouth, spit the mouthwash back into the collection container. Replace the top on the collection container and screw it on tightly. You may keep the remaining portion of mouthwash for your own use.

MAILING INSTRUCTIONS

Prepare the collection container for mailing as follows:

1. Place the collection container into the leak-proof plastic bag. Do not remove the absorbent sheet.
2. Remove any air from the bag and seal the bag.
3. Place the plastic bag and its contents into the padded envelope that is addressed to the biorepository.
4. **Make sure the consent form with your signature is placed in the padded envelope.**
5. **Try to mail the sample within 24 hours of collection.**

If you have any questions or concerns, please call us at 1-800- 217-1954.



Attachment 16.3: Phase IV Buccal Iowa

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[Date]

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Enclosed is the replacement buccal cell kit that we discussed with you over the phone. Directions are included. As we discussed, please read, sign, date and return one copy of the consent form with your sample.

Should you have any questions, please call us at **1-800-217-1954**.

Thank you again for your participation.

Attachment 16.4: Phase IV Buccal North Carolina
Buccal Kit Mailing Cover Letter

[date]

To: *Agricultural Health Study Participant*

From: Marsha Dunn, MPH
Director, Agricultural Health Study –North Carolina

Thank you for your continued participation in Agricultural Health Study. You are an essential member of this study, which is designed to learn about how occupation and environmental factors affect an individual's health. Thanks to your participation, this now is the largest one of its kind in the United States.

As we discussed on the phone, we would like to collect a sample of loose cells from your mouth. This is done simply by swishing mouthwash in your mouth and then expelling it into the accompanying container (see the enclosed DIRECTIONS FOR MOUTHWASH). The cells will be kept in a freezer for long-term storage, and will be used for later laboratory analysis that will involve genetic testing. This will take only a few minutes of your time and will provide very important information for the study. Once you collect this sample, please return it as soon as possible in the padded envelope enclosed. **If we have not received the kit back in a few weeks, we may contact you to see if you have any questions or concerns.**

We will continue to inform you about the study's progress on various aspects of research through periodic communications. If you have any questions, please call us at **1-800-4AGSTUDY**. We will be glad to assist you.

We truly value your continued participation in this landmark study of agricultural workers and their families. Because you have already provided us with valuable information no other person can take your place.

Thank you once again for your time and support.

Attachment 16.5: Phase IV Buccal North Carolina

DIRECTIONS FOR MOUTHWASH

The purpose of this simple procedure is to collect some loose cells from your mouth. Please follow the directions below. You may request help reading the instructions from a member of your household, but **please do not permit anyone else to handle the collection materials.**

Here is a list of what you should find in the envelope we mailed to you:

- 2 copies of the Informed Consent Form
- Screw top collection container
- Plastic bottle of mouthwash
- Leak-proof plastic bag with a small absorbent sheet (in case anything spills)
- Pre-stamped mailing envelope

If you have not received all of these materials, please call us at 1-800-4AGSTUDY

1. Read and sign one copy of the Informed Consent Form (the other copy is yours to keep).
2. Do not eat or rinse your mouth for one hour before collecting the saliva sample.
3. Open the bottle of mouthwash and fill the enclosed screw top collection container half full of mouthwash (to the red fill line).
4. Swish the mouthwash from the collection container around in your mouth vigorously for 45 seconds. **Watch the clock while you do this.**
5. Holding the container close to your mouth, spit the mouthwash back into the collection container. Replace the top on the collection container and screw it on tightly. You may keep the remaining portion of mouthwash for your own use.

MAILING INSTRUCTIONS

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1. Place the collection container into the leak-proof plastic bag. Do not remove the absorbent sheet.
2. Remove any air from the bag and seal the bag.
3. Place the plastic bag and its contents into the padded envelope that is addressed to the biorepository.
4. **Make sure the consent form with your signature is placed in the padded envelope.**
5. **Try to mail the sample within 24 hours of collection.**

If you have any questions or concerns, please call us at 1-800-4AGSTUDY.

Attachment 16.6: Phase IV Buccal North Carolina

[Date]

Enclosed is the replacement buccal cell kit that we discussed with you over the phone. Directions are included. As we discussed, please read, sign, date and return one copy of the consent form with your sample.

Should you have any questions, please call us at **1-800-4AGSTUDY**.

Thank you again for your participation.

Attachment 16.7: Phase IV Buccal FAQs

AHS: BUCCAL CELL COLLECTION ANSWERS TO QUESTIONS

- **What are you going to test for?** We are looking for genes that may help us identify groups of people that may be at a higher risk of developing cancer, while other exposed to the same toxins don't. We'll be combining this genetic information with information from questionnaires about exposures. Then we'll try to determine what genetic and exposure patterns are associated with cancer.
- **What about cloning—what could be done with these cells?** These cells will never be used for cloning; they can only be used for this study. Government-funded studies prohibit cloning experiments.
- **I would like the test results.** To protect the confidentiality of your sample, we immediately disassociate your name and other identifying information from the sample and store it by ID number only. That would make it very difficult to get back to you with results. Also, with the little that is known about genetic markers at this point, your individual results would be meaningless anyway. They simply don't know what is normal or abnormal yet and don't know which genes contribute to most diseases yet. The purpose of collecting the samples is to try to learn more about these things.
- **I would like to be informed as to what tests are going to be performed on the cells and when they are testing.** We will keep you informed through newsletters and other publications on the types of analyses we are doing as a whole, and will let you know the overall results for the study.
- **What do you mean by environmental exposures?** This refers to all of the different things your body comes into contact with, particularly as the result of where you live and your occupation. It includes chemicals, such as pesticides, as well as sunlight, grain dust, and other elements in your environment.
- **What do you mean by other body processes?** We mean for example, how the body defends itself against infection, how the nervous system is affected and any effects on the reproductive system.
- **I do not want to sign a release form or anything else, but I will send you the sample.** We cannot use any material you send us unless you consent to its use. We appreciate the fact that you are willing to participate,

and would ask you to reconsider signing the consent form. You are free to withdraw your consent at any time by simply notifying us that you wish to withdraw from the study and have your materials removed.

- **Why do you need these samples, can't you draw blood instead?** Collecting cells this way is easier on our study participants. Many people do not like to give blood, and we can get good information for our purposes from the cheek cells if the instructions are followed carefully.
- **What do I have to gain by this if I can't receive any results?** Although you personally may not receive any direct benefits, your participation is helping all farmers and their families, by helping us with research that may uncover the causes of disease that farmers are more likely to have. This understanding of farmers' risks may also help us understand the risks to the general population.
- **Okay to collect the sample when I have a cold or other illness?** Yes, this should not affect the sample.
- **Okay to collect the sample when I'm taking antibiotics or other medicines?** Yes
- **Can I substitute my own mouthwash, rather than use the Scope we send me?** We prefer that you use a mouthwash with alcohol in it to better preserve the sample, but we will accept the sample with any mouthwash of your choosing.
- **If you send it to me now, I may not get to it for a while. Is that okay?** Yes. It helps us if you can complete it and send it in soon, but if it does take awhile, that will be fine too.