

ATTACHMENT 15

Phase III Buccal Collection Kit Cover Letters, Directions, and Answers to Frequently Asked Questions (FAQs)

- 15A. Phase III Buccal Cell Kit Cover Letter for Iowa Respondents
- 15B. Phase III Buccal Cell Kit Directions for Iowa Respondents
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- 15G. Phase III Buccal Cell Kit Collection FAQs for North Carolina Respondents



**Agricultural Health Study
Iowa Field Station**

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[Date]

To: Agricultural Health Study Participant

From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

Thank you for participating in our follow-up interview for the 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 15B:
Phase III Buccal Cell Collection Directions for Iowa Respondents**

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 15C:
Phase III Buccal Cell Answers to Questions for Iowa Respondents with Prostate
Cancer**

**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 prostate cancer, while others 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 prostate cancer.
- ***What about cloning—what could be done with these cells?*** These cells will not 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 they use a mouthwash with alcohol in it to better preserve the sample, but we will accept the sample with any mouthwash of their 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.
- ***I'm in the middle of [planting, harvest].*** We know you are very busy right now, but if you put the kit right next to the sink where you brush your teeth in the morning, it will be right there and will take only a few minutes of your time. If at all possible, please do it as soon as you can. We would greatly appreciate it.

Attachment 15D:
Phase III Buccal Cell Answers to Questions for Iowa Respondents with NHL

**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 non-Hodgkin lymphoma, while others 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 non-Hodgkin lymphoma.
- ***What about cloning—what could be done with these cells?*** These cells will not 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 they use a mouthwash with alcohol in it to better preserve the sample, but we will accept the sample with any mouthwash of their 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.
- ***I'm in the middle of [planting, harvest].*** We know you are very busy right now, but if you put the kit right next to the sink where you brush your teeth in the morning, it will be right there and will take only a few minutes of your time. If at all possible, please do it as soon as you can. We would greatly appreciate it.

**Attachment 15E:
Phase III Buccal Cell Kit Cover Letter for North Carolina Respondents**

**COVER LETTER FOR BUCCAL CELL COLLECTION
(AFTER CATI OR OTHER DATA COLLECTION ACTIVITY)**

<AHS LETTERHEAD>

<DATE>

Dear <Name>,

Thank you for participating in our [follow-up interview/data collection task] for the 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.

As we discussed on the phone, we would like for you 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 Instructions for Buccal Cell Collection and Mailing*). The cells will be kept in a freezer for long-term storage, and will be used for later laboratory analysis. 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 *along with the signed consent form*. We have enclosed \$5 for your time in collecting and mailing the buccal cell sample. If we have not received the kit back in about 3 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 1-800-4AG-STUDY. 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.

Sincerely,

Charles Knott
North Carolina Director



The purpose of this simple procedure is to collect some loose cells from your mouth. Please follow the instructions 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 enclosed envelope:

- Two 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

INSTRUCTIONS FOR BUCCAL CELL COLLECTION

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 sample.
3. Open the bottle of mouthwash and fill the enclosed container with mouthwash to the red line.
4. Swish the mouthwash from the 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 container. Replace the top on the container and screw it on tightly. You may keep the remaining portion of mouthwash for your own use.

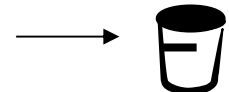
1. Sign Informed Consent 

2.  one hour!

3. Fill to red line 

4. Swish for  45 seconds

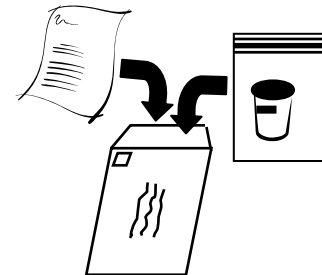
5. Spit and Close the top tightly



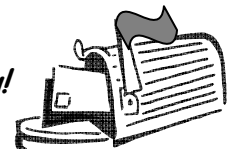
INSTRUCTIONS FOR MAILING

Prepare the collection container for mailing as follows:

1. Make sure the Informed Consent Form with your signature is placed in the padded envelope.
2. Place the collection container into the leak-proof plastic bag. Keep the absorbent sheet in the bag. 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. Seal the envelope.
4. Mail the samples within 24 hours of collection.



Thank you!



If you have any questions or concerns, please call us at 1-800-424-7883.

**Attachment 15G:
Phase III Buccal Cell Collection FAQs for North Carolina Respondents**

BUCCAL CELL COLLECTION FAQs

Do what?

- We would like for you to collect a sample of cheek cells. To do that, all you would do is rinse your mouth with mouthwash and return a sample to us. Everything you would need and the directions are provided. It's quick and easy to do.

Why participate?

- The buccal cell (cheek cell) collection is this study's most important contribution to science. There has never been a project of this magnitude for collecting genetic information that can help scientists understand why some people get cancer and other diseases and why others don't. This is really on the cutting edge of new discoveries in science. By completing the buccal cell sample, you are making a very important contribution to science, a contribution that will help us learn what we can do to promote good health for ourselves and our families.

Genes?

- We plan to study a wide range of genes that are important in how the body protects itself from tissue damage. These samples will be used to study genes that may play a part in why some people develop cancer and other diseases but others do not.

Consent form?

- The consent form has a lot more information than we give over the telephone. After you read it, you can decide how important it is. If you have questions and want to call us, a telephone number is included; however, we cannot use your sample without your signed consent.

Will this help?

- Knowing more about factors that promote good health can help everyone, especially in generations to come. You may not personally receive any direct benefits, but your participation will help with research that may uncover causes of diseases and risks.

Individual results?

- Usually in studies such as these, the individual results are not very meaningful, and for that reason study results cannot be given back to each individual. It is only when we look at groups of people, such as farmers as a whole, that we can get a good picture of what common genetic characteristics are important in predicting who might be at a greater risk of disease. We will let you know the overall results through newsletters and other publications.

Confidentiality?

The collection bottle for the buccal cell sample has a label that identifies participants through a barcode. For the protection of participants, names are not given. Your name and address will be separated from the data you provide. You cannot be named in any reports. If more than one individual in the household is asked to provide a sample, the two bottles will be labeled as “his” or “hers” to prevent confusion. In the Agricultural Health Study, personal information is never presented with a name.

Why farmers?

- Medical research suggests that while agricultural workers may be healthier, they may experience higher rates of leukemia, myeloma, non-Hodgkin’s lymphoma, and other cancers than people in more urban areas. Also, chronic diseases like asthma, neurological and kidney disease may be related to agricultural exposures.

Why AHS?

- This study is different from other studies because it focuses on health, not just your health, but on the health of your family. The primary goal of the Agricultural Health Study is to investigate the effects of environmental, occupational, and dietary factors on health.

Cloning?

- These cells will never be used for cloning. In fact, government-funded studies prohibit cloning experiments.

RESPONSES TO COMMON OBJECTIONS

No longer farming /Retired

- We especially need to include you because you no longer farm. The scientists will learn more about long-term effects of past exposures by studying individuals who are retired or who no longer farm. Occupational experiences and health conditions over a long period of time, and not just for the present time, are of interest. Your participation is very valuable.

Too sick

- I'm so sorry to learn about your illness. We wouldn't ask you for the buccal cell (cheek cell) sample if it weren't so important. It is important that the scientists be able to study the cells from individuals who are ill as well as those who are not, to evaluate individual differences. By comparing individuals who are diseased with those who are disease free, more can be learned about the role genes play in protecting us from diseases. If you feel up to doing this or if others help you, your sample would be very valuable. If others help, we would ask that only you handle the collection bottle.

Never farmed

- For buccal cell samples to be more representative, we need to include study participants with different work and health histories. We need everyone to participate. In addition, there are many factors that are of interest to the study such as diet and family health.

No time

- The buccal cell (cheek cell) collection is simple, easy, and important. It takes 5 minutes or less and is very important to science and to the study. You simply swish, spit, sign the consent form, and mail. We will send you all the supplies needed, including a pre-addressed and stamped envelope to return the sample.

Can't use mouthwash

- You can spit directly into the container and then fill the container to the red line with the mouthwash. That way you will not have to swish with mouthwash, but the cells in the saliva will be preserved. The buccal cell collection is very important to the study, and we would very much appreciate your participation.

Look it over

- We would be glad to mail a kit to you. We will enclose \$5 in the kit to provide for any inconvenience. You can then decide whether to take part after you receive the kit.

I already did that. Did you get my sample?

- Let me check our records:

IF YES: Yes, I see here that we received your buccal cell sample in Phase 2, several years ago. Thank you! Since scientists are interested in changes in genetic structure that occur over a period of time, another sample *now* will be even more valuable to the study (as a comparison). We will send you a packet with everything provided. As you may recall, it just takes a few minutes to do

the mouthwash rinse, sign the consent, and return the sample in the mail. We would appreciate your help for this important part of the study. May we send you a kit?

IF NO: Our records do not indicate that we have a buccal cell sample from you. (It may have been lost in the mail, or at the lab, or there may have not been enough liquid in the container when it was received at the lab.) Again, this is the most important part of the study for understanding how genetic factors influence health, so we would like to send you another kit. It just takes a few minutes to do the mouthwash rinse, sign the consent, and return the sample in the mail. We would appreciate your help for this important part of the study. May we send you a kit?