ATTACHMENT 14

Phase III Buccal Cell Consent Form

14A. Phase III Buccal Cell Consent Form for Iowa Respondents
14B. Phase III Buccal Cell Consent Form for North Carolina Respondents

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APPROVED BY: IRB-01
IRB ID #: 200612708
APPROVAL DATE: 3/31/08
EXPIRATION DATE: 3/31/09

The Agricultural Health Study (AHS)

Informed Consent Form

Study Title: Buccal (Mouth) Cell Collection for the AHS

Principal Investigator: Charles Lynch, M.D., Ph.D., University of Iowa

Lead Investigator: Michael Alavanja, Dr. P.H., National Institutes of Health

Co-Investigators: Aaron Blair, Ph.D., National Cancer Institute; Dale Sandler, Ph.D., National Institute of Environmental Health Sciences; Charles Knott, M.P.A., Battelle Centers for Public Health Research and Evaluation

Study Purpose: The purpose of this study is to collect buccal (mouth) cells from participants in the Agricultural Health Study. We are inviting you to participate in this research study because you are a participant in the Agricultural Health Study. The collection of this sample will supplement the questionnaire information you have already provided to us. We are interested in the way people process cancer causing substances, such as those coming from environmental exposures. We are also interested in differences in other body processes that are affected by lifestyle and the environment. The material in the buccal cell samples will allow us to study these differences in relation to cancer risk, and help understand the causes of cancer.

Number of Participants: Approximately 1,000 people will take part in the collection of buccal cell samples for the Agricultural Health Study at the University of Iowa.

Study Procedures: We are asking you to collect loose cells from your mouth by swishing about one tablespoon of mouthwash in your mouth and then discharging it into the container provided. This should take only 5 minutes of your time.

Risks and Benefits: There is no known physical risk associated with this collection of cells from your mouth. There may be a risk of loss of confidentiality of your information collected during this study. Please refer to the section below entitles "Future Research Studies and Confidentiality" which describes the protections in place to protect your confidentiality.
Although you will receive no personal benefit, we hope that the knowledge gained from this research may eventually benefit others.

Costs and Payments: You will not have any costs from being in this study. All costs of collecting and mailing back the samples are covered by the study. You will be paid $5 for being in this study.

Funding for this Study: The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) is funding this research project. This means that the University of Iowa is receiving payments from DHHS/NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from DHHS/NIH for conducting this study.

Future Research Studies and Confidentiality: The buccal cell sample you give us will be used to study genes that may play a part in why some people develop cancer. They will be used only to study cancer and other chronic diseases that may be related to agricultural exposures. The exact studies that will be performed are not all known at this time but are likely to include the following: 1) the study of differences in genes that may be related to how people process disease-causing substances; and 2) the study of how the effects of diet, lifestyle, the environment, occupational exposures, race/ethnicity, age and other factors may be related to these genes. We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, federal government regulatory agencies, auditing departments of the University of Iowa, and the University of Iowa Institutional Review

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Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. In order to protect the confidentiality of these genetic studies, we have provided multiple safeguards so that test results cannot be linked directly to you. As you can see on the collection container, a bar code is being used to identify you. At no time will your name and address be given to anyone outside your research team. All information will be kept confidential to the extent provided by law. Your name will not be used in any reports. The study results will be reported in statistical summary form only. Iowa Field Station personnel, who have access to your personal identifiers, will not be given your genetic test results.

Research Results: The results of this study will be used for research purposes only. We do not plan to inform participants of their results for any genetic tests, because, for almost all tests, we will not know how to interpret individual risk or benefit. We will provide you with summary findings through periodic communications about research activities of the Agricultural Health Study.

Voluntary Participation: Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

Additional Information: If you have any questions about any part of this activity or if you experience a research-related injury, please call our toll-free number at 1-800-217-1954 to contact the principal investigator at the University of Iowa, Charles Lynch, M.D., Ph.D.

If you have any questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 340 College of Medicine Administration Building, The University of Iowa, Iowa City, IA 52242, (319)335-6564, or email irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This informed consent is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 03/31/2009.

_____ _____

(Signature of Subject) (Date)

INFORMED CONSENT FORM FOR BUCCAL CELL COLLECTION

Study Title: Buccal (Mouth) Cell Collection for the Agricultural Health Study

Principal Investigator Michael Alavanja, Dr. P.H., National Institutes of Health

Co-Investigators: Aaron Blair, Ph.D., National Cancer Institute; Dale Sandler, Ph.D., National Institute of Environmental Health Sciences; Charles Lynch, M.D., Ph.D., University of Iowa; Charles Knott, M.P.A., Battelle Centers for Public Health Research and Evaluation

Study Purpose: The purpose of this study is to collect buccal (mouth) cells from participants in the Agricultural Health Study. The collection of this sample will supplement the questionnaire information you have already provided to us when you enrolled in the study at your pesticide licensing/training facility and/or during the last interview approximately 5 years ago. We are interested in the way people process cancer-causing substances, such as those coming from environmental exposures and diet. We are also interested in differences in other body processes that are affected by lifestyle and the environment. The material in the buccal cell samples will us to study these differences in relation to cancer risk, and help understand the causes of cancer.

Study Procedures and Risks/Benefits: We are asking you to collect loose cells from your mouth by swishing one tablespoon of Scope mouthwash in your mouth and then discharging it into the container provided. This is a one-time procedure that should take only 5 minutes of your time. There is no known physical risk associated with this procedure. All costs of collecting and mailing back the samples are covered by the study. Although you will receive no immediate benefit, the knowledge gained from this research may eventually benefit you and others.

Compensation: Participants who agree to provide a buccal cell sample are mailed $5.00 with the kit to compensate for their time and inconvenience.

Future Research Studies and Confidentiality: The buccal cell sample you give us is being collected for use in future research. The exact studies that will be performed are not all known at this time but are likely to include the following: 1) the study of differences in genes that may be related to how people process disease-causing substances; 2) the study of how the effects of diet, lifestyle, the environment, race/ethnicity, age and other factors may be related to these genes. In order to protect the confidentiality of these genetic tests, we have provided multiple safeguards so that test results cannot be linked directly to you. At no time will your name and address be given to anyone outside our research team. All information will be kept strictly confidential to the

extent provided by law. Your name will not be used in any reports. The study results will be reported in statistical summary form only.

Research Results: We do not plan to inform participants of their results for any genetic tests. If the research yields findings that are of any possible medical benefit, we will provide you with that information through a newsletter. In the event you then want to determine the relevance of those research findings to you, we will refer you, upon your request, to certified health professionals outside the research study, who can assist you.

Additional Information: If you have any question about any part of this activity, please call your toll-free number at 1-800-424-7883. If you have concerns about your rights as a research participant, or complaints about your treatment in this study, contact Ms. Brigette Brevard at (919) 544-3717.

By agreeing to participate in this study, you do not waive any rights that you may have regarding access and disclosure of your records. For further information on those rights, please contact Dr. Michael Alavanja Dr. P.H., Principal Investigator, at (301) 435-4720.

I certify that I have read the above information, that I understand the risks and benefits involved, that I have been given satisfactory answers to any questions about the project and that my permission is freely given. I have been advised that I am free to withdraw (take away) my consent and can refuse to take part further in the study at any time without it making any difference to my care in the future.

I give my consent to be part of this study with the understanding that such consent does not take away any of my legal rights, nor does it release the investigator or the institution or any employee or agent thereof from liability for negligence. I understand that if I am injured in the course of this research, I alone may be responsible for the costs of treating my injuries.

_____	_____	_____
Signature of Participant	Participant's Name (Please print)	Date