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Attachment 15.1: Phase IV Iowa Buccal Informed Consent Document

INFORMED CONSENT DOCUMENT

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.,
Co-Investigators: Laura Beane Freeman, Ph.D., National Institutes of Health; Gabriella Andreotti Ph.D., M.P.H., National Institutes of Health

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 in previous studies. 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 5,000 people will take part in the collection of buccal cell samples for the Agricultural Health Study.

Study Procedures and Risks/Benefits: 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 Incentives: 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 receive $5 as a thank you for your participation in this study.

OMB #: 0925-0406
Expiration date: 09/30/2016

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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. 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.

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. 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, 105 Hardin Library for the Health Sciences, 600 Newton Road, University of Iowa, Iowa City, IA 52242-1098, (319)335-6564, or email irb@uiowa.edu.

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.

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

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

INFORMED CONSENT DOCUMENT

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

Principal Investigator: Marsha Dunn, MPH, Westat

Lead Investigator: Michael Alavanja, Dr. P.H., and Laura Beane Freeman, Ph.D., National Institutes of Health;

Co-Investigators: Gabriella Andreotti Ph.D., M.P.H., National Institutes of Health

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 in previous studies. 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.

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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 1-800-4AGSTUDY. If you have any questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact Sharon Zack of the Westat Human Subjects Office, by calling 1-888-920-7631, or e-mail IRB@westat.com.

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.

Do not sign this form if date is on or after _____.

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