

INFORMED CONSENT FORM FOR BUCCAL CELL COLLECTION

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

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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

Attachment 14B: Buccal Cell Collection Informed Consent Form for North Carolina

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