

ATTACHMENT 21

BEEA Introductory Letter and Brochure Content

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- 21B. BEEA Introductory Letter for North Carolina Respondents
- 21C. BEEA Brochure/Fact Sheet Content for Iowa Randomly Selected Respondents
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Attachment 21A: BEEA Introductory Letter - Iowa
**Study of Biomarkers of Exposures and Effects in Agriculture
IA Introductory Letter (Both Groups)**

Date

To: Mr. <name or names entered here>
From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

Thank you for your participation in the Agricultural Health Study (AHS). We appreciate the time you have already taken over the years to complete the study interviews and questionnaires.

A new study is underway for the AHS that is designed to measure biologic effects in relation to different farming exposures and activities. You are one of nine people in Iowa who will take part in a pilot test of this study. Overall, 1,600 Agricultural Health Study members will be enrolled over the next five years of the study. The study is being funded by the National Cancer Institute.

This study will examine the properties of blood and urine that may be related to environmental or occupational factors and life-style characteristics. Improving our understanding of these relationships will help us in our evaluation of possible links between pesticide exposure and disease. We are particularly interested in cancers. We believe our long-term study of rural Iowans may help us better understand these illnesses and eventually prevent them.

We plan to call you within the next few weeks to determine if you are truly eligible to participate in this study. Up to 5 call attempts will be made at different times of the day and at different days to reach you. Among the questions we will ask are three aimed toward improving our understanding of your cancer screening practices. The call will take 10 minutes or less.

Once we determine your eligibility for the study and you tell us that you are interested in participating, we will schedule a home visit with you. Prior to the home visit, you will receive materials from us including two copies of the consent document, a reminder card for key elements of the questionnaire, and urine collection materials. At the time of the home visit we will obtain your signed consent to participate in this study. We will also conduct a 20-minute interview to obtain information about your recent medication use, medical conditions, smoking status, alcohol consumption, and pesticide use during the current/previous growing season. We will ask you to provide about 3 tablespoons of blood and a first morning sample of urine.

All of the information we collect will be used only for research purposes and will be kept strictly confidential. However, federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Neither your name nor any personal information will ever appear in any reports generated from this study. The physical risks associated with the study are minimal and include those associated with blood collection. Rarely, there may be swelling or bruising. It is also possible, but very unlikely, that there may be a risk of loss of confidentiality of your information collected during this study. You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because of the knowledge gained.

You should not have any costs for being in this study. You will be paid \$75.00 for being in this research study.

We want you to know that your participation in any activity of the Agricultural Health

Privacy Act Notification: 42 U.S.C. 285a of the Public Health Service Act authorizes collection of this information. It will be used to evaluate the role of agricultural exposures and other factors in the development of cancer, neurological disease, birth defects and other chronic diseases. All information is voluntary and if you decide not to provide all or any part of the requested information you will not be penalized or lose any benefits for which you otherwise qualify. We will keep your participation in this research study confidential to the extent permitted by law.

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Attachment 21A: BEEA Introductory Letter - Iowa

Study is always voluntary. Be assured that there will be no penalties if you decide not to respond, either to the information collection as a whole or to any particular question.

If you have any questions, concerns or do not want to participate, please contact Ellen Heywood, study coordinator at 1-800-217-1954. Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study. If you have questions or concerns about your rights as a research subject please contact the Human Subjects Office, 300 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. This study's IRB number is 201002777. Again, we want to thank you for your assistance in making the Agricultural Health Study an important and successful study of health in the agricultural community. We look forward to speaking with you soon.

***Privacy Act Notification:** 42 U.S.C. 285a of the Public Health Service Act authorizes collection of this information. It will be used to evaluate the role of agricultural exposures and other factors in the development of cancer, neurological disease, birth defects and other chronic diseases. All information is voluntary and if you decide not to provide all or any part of the requested information you will not be penalized or lose any benefits for which you otherwise qualify. We will keep your participation in this research study confidential to the extent permitted by law.*

**Study of Biomarkers of Exposures and Effects in Agriculture
NC Introductory Letter (Both Groups)**

Date

Dear Mr. <name or names entered here>,

Thank you for your participation in the Agricultural Health Study (AHS). We appreciate the time you have already taken over the years to complete the study interviews and questionnaires.

A new study is underway for the AHS that is designed to measure biologic effects in relation to different farming exposures and activities. You are one of 1,600 Agricultural Health Study members whom we plan to call over the five years of the study. We plan to call you within the next few weeks to find out if you may be eligible for this part of the AHS. The call will take 10 minutes or less.

This part of the AHS will examine the properties of blood and urine that may be related to environmental or occupational factors and life-style characteristics. Improving our understanding of these relationships will help us in our evaluation of possible links between pesticide exposure and disease. We are particularly interested in cancers. We believe our long-term study of rural Iowans may help us better understand these illnesses and eventually prevent them.

When we call we would also like to ask you several questions about your history of cancer screening practices. These questions do not relate to this new study within the AHS, but are aimed toward improving our understanding of cancer screening among participants in the Agricultural Health Study.

We want you to know that your participation in any activity of the Agricultural Health Study is always voluntary. Be assured that there will be no penalties if you decide not to respond, either to the information collection as a whole or to any particular question. As always, your answers to questions are confidential to the extent provided by law. Identifiers will be stored in locked files or in password-protected computerized files available only to authorized research staff.

If you have any questions or concerns, please contact Margaret Hayslip, study coordinator toll free at 1-800-424-7883. Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study. If you have questions or concerns about your rights as a research subject please contact the Battelle Institutional Review Board toll-free at (877) 810-9530 ext. 500. Again, we want to thank you for your assistance in making the Agricultural Health Study an important and successful study of health in the agricultural community. We look forward to speaking with you soon.

Sincerely,

Charles Knott, MPA, PMP
Director, North Carolina Field Station

Privacy Act Notification: 42 U.S.C. 285a of the Public Health Service Act authorizes collection of this information. It will be used to evaluate the role of agricultural exposures and other factors in the development of cancer, neurological disease, birth defects and other chronic diseases. All information is voluntary and if you decide not to provide all or any part of the requested information you will not be penalized or lose any benefits for which you otherwise qualify. We will keep your participation in this research study confidential to the extent permitted by law.

**Attachment 21C. BEEA Iowa Brochure/Fact Sheet Content (Random Select Group)
Study of Biomarkers of Exposures and Effects in Agriculture -**

Purpose: The study will look for biologic changes associated with farming practices and exposures. In this study, we will collect information by a questionnaire and also collect urine and blood samples. We will use these samples to measure effects of certain factors in the farming environment.

Who can participate: Farmers who are enrolled in the Agricultural Health Study will be asked to participate. To determine if any biologic changes we see are related to farming, we will compare those actively applying specific chemicals or performing other farming activities to those who are not. Participation is voluntary and can be discontinued at any time.

What is required of participants: Study participation will involve completing a home visit. Participants will be asked to provide a urine sample. A person trained to collect blood will visit your home to collect blood samples and the urine sample you have already collected, and administer a short questionnaire. You will receive telephone calls from the study field station in order to schedule the home visit. Again, participation is strictly voluntary and samples will be taken only from those who provide written consent.

Use of the data: The National Institutes of Health and the University of Iowa are working together on this study. The data collected in this study will be used for research purposes only to determine biologic changes that occur as a result of farming practices or pesticide exposures. Study records will be kept strictly confidential as provided by law. The information will be used for scientific purposes only without identifying participants by name.

Benefits: Although there is little direct benefit to your participation in the study, findings may benefit the health of farmers in the future. Several tests will be done using your blood and urine samples. The laboratory tests are for biomedical research only and will not be useful to evaluate your own health.

Compensation: It will take time and effort for you to give urine and blood samples and complete the questionnaire during a home visit. We will offer you \$75 for your participation in the home visit.

For more information: Contact Ellen Heywood, Field Coordinator, Iowa Agricultural Health Study, N251 OH, Dept of Epidemiology, College of Public Health, University of Iowa, Iowa City, IA 52242. Phone: **1-800-217-1954** E-mail: ellen-heywood@uiowa.edu.

**Attachment 21D. BEEA NC Brochure/Fact Sheet Content (Random Select Group)
Study of Biomarkers of Exposures and Effects in Agriculture -**

Purpose: The study will look for biologic changes associated with farming practices and exposures. In this study, we will collect information by a questionnaire and also collect urine and blood samples. We will use these samples to measure effects of certain factors in the farming environment.

Who can participate: Farmers who are enrolled in the Agricultural Health Study will be asked to participate. To determine if any biologic changes we see are related to farming, we will compare those actively applying specific chemicals or performing other farming activities to those who are not. Participation is voluntary and can be discontinued at any time.

What is required of participants: Study participation will involve completing a home visit. Participants will be asked to provide a urine sample. A person trained to collect blood will visit your home to collect blood samples and the urine sample you have already collected, and administer a short questionnaire. You will receive telephone calls from the study field station in order to schedule the home visit. Again, participation is strictly voluntary and samples will be taken only from those who provide written consent.

Use of the data: The National Institutes of Health and the Battelle are working together on this study. The data collected in this study will be used for research purposes only to determine biologic changes that occur as a result of farming practices or pesticide exposures. Study records will be kept strictly confidential as provided by law. The information will be used for scientific purposes only without identifying participants by name.

Benefits: Although there is little direct benefit to your participation in the study, findings may benefit the health of farmers in the future. Several tests will be done using your blood and urine samples. The laboratory tests are for biomedical research only and will not be useful to evaluate your own health.

Compensation: It will take time and effort for you to give urine and blood samples and complete the questionnaire during a home visit. We will offer you \$75 for your participation in the home visit.

For more information: Contact Margaret Hayslip, Field Coordinator, Battelle Agricultural Health Study, 100 Capitola Drive, Suite 200, Durham, NC 27713. Phone: **1-800-424-7883** E-mail: hayslipm@battelle.org.

Attacment 21E: BEEA IA Brochure/Fact Sheet Content (Recent Exposure Group)
Study of Biomarkers of Exposures and Effects in Agriculture -

Purpose: The study will look for biologic changes associated with farming practices and exposures. In this study, we will collect information by a questionnaire and also collect urine and blood samples. We will use these samples to measure effects of certain factors in the farming environment.

Who can participate: Farmers who are enrolled in the Agricultural Health Study will be asked to participate. To determine if any biologic changes we see are related to farming, we will compare those actively applying specific chemicals or performing other farming activities to those who are not. Participation is voluntary and can be discontinued at any time.

What is required of participants: Study participation will involve completing three home visits. At each visit, participants will be asked to provide a urine sample. A person trained to collect blood will visit your home to collect blood samples and the urine sample you have already collected, and administer a short questionnaire. One visit will be scheduled for the off-season, whereas two will be scheduled within a three week window of applying specific pesticides. You will receive telephone calls from the study field station in order to schedule the home visits. Again, participation is strictly voluntary and samples will be taken only from those who provide written consent.

Use of the data: The National Institutes of Health and the University of Iowa are working together on this study. The data collected in this study will be used for research purposes only to determine biologic changes that occur as a result of farming practices or pesticide exposures. Study records will be kept strictly confidential as provided by law. The information will be used for scientific purposes only without identifying participants by name.

Benefits: Although there is little direct benefit to your participation in the study, findings may benefit the health of farmers in the future. Several tests will be done using your blood and urine samples. The laboratory tests are for biomedical research only and will not be useful to evaluate your own health.

Compensation: It will take time and effort for you to give urine and blood samples and complete the questionnaire during a home visit. We will offer you \$75 for each home visit.

For more information: Contact Ellen Heywood, Field Coordinator, Iowa Agricultural Health Study, N251 OH, Dept of Epidemiology, College of Public Health, University of Iowa, Iowa City, IA 52242. Phone: **1-800-217-1954** E-mail: ellen-heywood@uiowa.edu.

Attachment 21F: BEEA NC Brochure/Fact Sheet Content (Recent Exposure Group)
Study of Biomarkers of Exposures and Effects in Agriculture -

Purpose: The study will look for biologic changes associated with farming practices and exposures. In this study, we will collect information by a questionnaire and also collect urine and blood samples. We will use these samples to measure effects of certain factors in the farming environment.

Who can participate: Farmers who are enrolled in the Agricultural Health Study will be asked to participate. To determine if any biologic changes we see are related to farming, we will compare those actively applying specific chemicals or performing other farming activities to those who are not. Participation is voluntary and can be discontinued at any time.

What is required of participants: Study participation will involve completing three home visits. At each visit, participants will be asked to provide a urine sample. A person trained to collect blood will visit your home to collect blood samples and the urine sample you have already collected, and administer a short questionnaire. One visit will be scheduled for the off-season, whereas two will be scheduled within a three week window of applying specific pesticides. You will receive telephone calls from the study field station in order to schedule the home visits. Again, participation is strictly voluntary and samples will be taken only from those who provide written consent.

Use of the data: The National Institutes of Health and Battelle are working together on this study. The data collected in this study will be used for research purposes only to determine biologic changes that occur as a result of farming practices or pesticide exposures. Study records will be kept strictly confidential as provided by law. The information will be used for scientific purposes only without identifying participants by name.

Benefits: Although there is little direct benefit to your participation in the study, findings may benefit the health of farmers in the future. Several tests will be done using your blood and urine samples. The laboratory tests are for biomedical research only and will not be useful to evaluate your own health.

Compensation: It will take time and effort for you to give urine and blood samples and complete the questionnaire during a home visit. We will offer you \$75 for each home visit.

For more information: Contact Margaret Hayslip, Field Coordinator, Battelle Agricultural Health Study, 100 Capitola Drive, Suite 200, Durham, NC 27713. Phone: **1-800-424-7883** E-mail: hayslipm@battelle.org.