Attachment 18:
BEEA Consent Forms

1**8**.1**).** BEEA Consent form for Iowa Randomly Selected Respondents
1**8**.2**).** BEEA Consent form for North Carolina Randomly Selected Respondents
1**8**.3**).** BEEA Consent form for Iowa Recently Exposed Respondents
1**8**.4**).** BEEA Consent form for North Carolina Recently Exposed Respondents

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Attachment 18.1:

INFORMED CONSENT DOCUMENT

Project Title: **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**

Principal Investigator: Charles Lynch, MD, PhD, The University of Iowa

Research Team Contact: Ellen Heywood, Study Coordinator, The University of Iowa

Lead Investigator: Michael Alavanja, DrPH, National Institutes of Health

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are a participant in the Agricultural Health Study.

The purpose of this research study is to investigate the changes that may occur in the blood and urine when people are exposed to occupational and environmental chemicals and substances. We are also interested in differences in other body processes that are affected by lifestyle and the environment. The material in the blood and urine samples will allow us to study these differences in relation to cancer risk, and help understand the causes of cancer and other chronic diseases.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1100 people will take part in this study conducted by investigators at the University of Iowa. Another 500 people from North Carolina will take part since the Agricultural Health Study includes participants from these two states.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for no more than 90 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

Study participation will involve completing a home visit. You 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 questionnaire that will take about 30 minutes. The questionnaire will address recent medication use, medical conditions, smoking status, alcohol consumption, and pesticide use during the current/previous growing season. You are free to skip any questions that you prefer not to answer. We will collect about 3 tablespoons of blood. You already have received mailings and telephone calls from the study field station in order to schedule the home visit.

Blood/Data Storage for Future Use

As part of this study, we are obtaining blood and urine samples from you. We would like to study your blood and urine data in the future, after this study is over.

Blood cells removed from the blood samples will likely be used to make a cell line and DNA. Cell lines are produced by growing blood cells in a laboratory and allow us to have a source of the DNA without having to redraw your blood. These blood cells can be stored for decades or more. The cell lines and DNA and data will be made available to researchers trying to learn more about the cause of diseases.

The tests we might want to use to study your blood and urine may not even exist at this time. Therefore, we are asking for your permission to store your blood and urine so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding how occupational and environmental exposures and lifestyle characteristics cause cancer and other chronic diseases, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood and urine might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your blood and urine, but decide in the future that you would like to have it removed from future research, you should contact Dr. Charles Lynch at 319-384-5006. However, if some research with your blood and urine has already been completed, the information from that research may still be used.

Audio Recording

One aspect of this study involves making an audio recording of you. This aspect is the computer-assisted personal interview. The recording will be used for quality control purposes to ensure we have correctly captured your responses to the interview questions. It will be destroyed once the quality control activity is completed. Research personnel at the Iowa Field Station directly involved with this study will have access to this recording.

[ ] Yes [ ] No I give you permission to make an audio recording of me during this study.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in 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.

WHAT ARE THE BENEFITS OF 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.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I RECEIVE A FINANCIAL INCENTIVE FOR PARTICIPATING?

You will receive $75 as a thank you for your participation in this research study. A personal check in your name will be provided immediately to you as the phlebotomist completes the home visit.

WHO IS FUNDING THIS STUDY?

The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) is funding this research study. 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.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your

participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Iowa Field Station working with the Agricultural Health Study,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)
- NIH, the sponsor

To help protect your confidentiality, we will provide multiple safeguards. A study number will identify you in the database. As you can see on the collection containers, a bar code is being used to identify you. Your consent forms will be stored in securely locked cabinets when not in use. Computerized data will be entered into password-protected computers, stored in a secure area, and transmitted in a secure manner. Training sessions and annual signed confidentiality pledges will emphasize and remind research personnel the importance of keeping all data strictly confidential. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. All statistical analyses and publication of study results will involve grouped data.

IS BEING IN THIS STUDY VOLUNTARY?

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.

WILL I RECEIVE RESEARCH RESULTS?

The results of this study will be used for research purposes only and their clinical interpretation is unknown at this time, so we will not be sending any of the individual results to you.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please call our toll-free number at 1-800-271-1954 and speak to the Study Coordinator, Ellen Heywood, or ask to speak with the principal investigator at The University of Iowa, Charles Lynch, MD, PhD. If you experience a research-related injury, please contact: Charles Lynch, MD, PhD at 319-384-5006.

If you have 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, Iowa, 52242, (319) 335-6564, or e-mail 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.

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This Informed Consent Document 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 $STAMP_EXP_DT.

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

Attachment 18.2:
INFORMED CONSENT DOCUMENT

Project Title: **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**

Principal Investigator: Marsha Dunn, MPH, Westat

Research Team Contact: Amy Miller, North Carolina Study Coordinator, Westat

Lead Investigator: Michael Alavanja, DrPH, National Institutes of Health

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are a participant in the Agricultural Health Study.

The purpose of this research study is to investigate the changes that may occur in the blood and urine as well as dust samples from a subset of households when people are exposed to occupational and environmental chemicals and substances. We are also interested in differences in other body processes that are affected by lifestyle and the environment. The material in the blood, urine and dust samples will allow us to study these differences in relation to cancer risk, and help understand the causes of cancer and other chronic diseases.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1600 people in Iowa and North Carolina will take part since the Agricultural Health Study includes participants from these two states.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for no more than 90 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

Study participation will involve completing a home visit. You will be asked to provide a urine sample and possibly a dust sample. A person trained to collect blood will visit your home to collect blood and possibly dust samples and the urine sample you have already collected, and administer a questionnaire that will take about 30 minutes. The questionnaire will address recent medication use, medical conditions, smoking status, alcohol consumption, and pesticide use during the current/previous growing

season. You are free to skip any questions that you prefer not to answer. We will collect about 3 tablespoons of blood. You already have received mailings and telephone calls from the study field station in order to schedule the home visit.

Blood/Data Storage for Future Use

As part of this study, we are obtaining blood and urine samples and possibly dust samples from you. We would like to study your blood, urine and dust data in the future, after this study is over.

Blood cells removed from the blood samples will likely be used to make a cell line and DNA. Cell lines are produced by growing blood cells in a laboratory and allow us to have a source of the DNA without having to redraw your blood. These blood cells can be stored for decades or more. The cell lines and DNA and data will be made available to researchers trying to learn more about the cause of diseases.

The tests we might want to use to study your blood, urine and dust samples may not even exist at this time. Therefore, we are asking for your permission to store your blood, urine and dust so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding how occupational and environmental exposures and lifestyle characteristics cause cancer and other chronic diseases, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood and urine might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your blood, urine and dust, but decide in the future that you would like to have it removed from future research, you should contact Marsha Dunn at 1-800-4AGSTUDY (1-800-424-7883). However, if some research with your blood, urine and dust has already been completed, the information from that research may still be used.

Audio Recording

One aspect of this study involves making an audio recording of you. This aspect is the computer-assisted personal interview. The recording will be used for quality control purposes to ensure we have correctly captured your responses to the interview questions. It will be destroyed once the quality control activity is completed. Research personnel from the North Carolina Field Station, Westat, who are directly involved with this study will have access to this recording.

[ ] Yes [ ] No I give you permission to make an audio recording of me during this study.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in 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.

WHAT ARE THE BENEFITS OF 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.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I RECEIVE A FINANCIAL INCENTIVE FOR PARTICIPATING?

You will receive $75 as a thank you for your participation in this research study. A personal check in your name will be provided immediately to you as the phlebotomist completes the home visit.

WHO IS FUNDING THIS STUDY?

The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) is funding this research study. This means that Westat 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.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- Westat does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a Westat employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Federal government regulatory agencies, Westat staff working with the Agricultural Health Study,
- The Westat Institutional Review Board (a committee that reviews and approves research studies), and

- NIH, the sponsor.

To help protect your confidentiality, we will provide multiple safeguards. A study number will identify you in the database. As you can see on the collection containers, a bar code is being used to identify you. Your consent forms will be stored in securely locked cabinets when not in use. Computerized data will be entered into password-protected computers, stored in a secure area, and transmitted in a secure manner. Training sessions and annual signed confidentiality pledges will emphasize and remind research personnel the importance of keeping all data strictly confidential. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. All statistical analyses and publication of study results will involve grouped data.

IS BEING IN THIS STUDY VOLUNTARY?

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.

WILL I RECEIVE RESEARCH RESULTS?

The results of this study will be used for research purposes only and their clinical interpretation is unknown at this time, so we will not be sending any of the individual results to you.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please call our toll-free number at 1-800-4AGSTUDY (1-800-424-7883) and speak to the Study Coordinator, AmyMiller, or the principal investigator at Westat, Marsha Dunn. If you experience a research-related injury, please contact: Marsha Dunn at 1-800-4AGSTUDY.

If you have 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 1-800-937-8281, or e-mail IRB@westat.com. 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 Document 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 _____.

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

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Attachment 1**8.3**: BEEA Iowa Consent Form for Recently Exposed Participants

INFORMED CONSENT DOCUMENT

Project Title: Biomarkers of Exposures and Effects in Agriculture (BEEA) Study

Principal Investigator: Charles Lynch, MD, PhD, The University of Iowa

Research Team Contact: Ellen Heywood, Study Coordinator, The University of Iowa

Lead Investigator: Michael Alavanja, DrPH, National Institutes of Health

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are a participant in the Agricultural Health Study. We are interested in changes that may occur in the blood and urine when people are exposed to occupational and environmental chemicals and substances. We are also interested in differences in other body processes that are affected by lifestyle and the environment. The material in the blood and urine samples will allow us to study these differences in relation to cancer risk, and help understand the causes of cancer and other chronic diseases.

The purpose of this research study is to collect blood and urine samples from participants in the Agricultural Health Study and administer a short questionnaire for biomedical research. The collection of these samples and additional questionnaire will supplement the questionnaire information you have already provided to us.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1100 people will take part in this study conducted by investigators at the University of Iowa. Another 500 people from North Carolina will take part since the Agricultural Health Study includes participants from these two states. Of this group, approximately 33 people from Iowa and 17 people from North Carolina will take part by completing three home visits.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for no more than 90 minutes of your time.

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WHAT WILL HAPPEN DURING THIS STUDY?

Study participation will involve completing three visits to your home. You will be asked to provide a urine sample. At each visit, a person trained to collect blood will come to your home to collect blood samples and the urine sample you have already collected, and administer a questionnaire that will take about 20 minutes. You are free to skip any questions that you prefer not to answer. We will collect about 2-3.5 tablespoons of blood at each visit. You already have received mailings and telephone calls from the study field station in order to schedule this home visit.

Tissue/Blood/Data Storage for Future Use

As part of this study, we are obtaining blood and urine samples from you. We would like to study your blood and urine data in the future, after this study is over.

Blood cells removed from the blood samples will likely be used to make a cell line and DNA. Cell lines are produced by growing blood cells in a laboratory and allow us to have a source of the DNA without having to redraw your blood. These blood cells can be stored for decades or more. The cell lines and DNA and data will be made available to researchers trying to learn more about the cause of diseases.

The tests we might want to use to study your blood and urine may not even exist at this time. Therefore, we are asking for your permission to store your blood and urine so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding how occupational and environmental exposures and lifestyle characteristics cause cancer and other chronic diseases, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood and urine might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your blood and urine, but decide in the future that you would like to have it removed from future research, you should contact Dr. Charles Lynch at 319-384-5006. However, if some research with your blood and urine has already been completed, the information from that research may still be used.

Audio Recording

One aspect of this study involves making an audio recording of you. This aspect is the computer-assisted personal interview. The recording will be used for quality control purposes to ensure we have correctly captured your responses to the interview questions. It will be destroyed once the quality control activity is completed.

[ ] Yes [ ] No I give you permission to make an audio recording of me during this study.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in 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.

WHAT ARE THE BENEFITS OF 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.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. A personal check in your name for $75 will be provided immediately to you as the phlebotomist completes each home visit.

WHO IS FUNDING THIS STUDY?

The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) is funding this research study. 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.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Iowa Field Station working with the Agricultural Health Study,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will provide multiple safeguards. A study number will identify you in the database. As you can see on the collection containers, a bar code is being used to identify you. Your consent forms will be stored in securely locked cabinets when not in use. Computerized data will be entered into password-protected computers, stored in a secure area, and transmitted in a secure manner.

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Training sessions and annual signed confidentiality pledges will emphasize and remind research personnel the importance of keeping all data strictly confidential. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. All statistical analyses and publication of study results will involve grouped data.

IS BEING IN THIS STUDY VOLUNTARY?

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.

WILL I RECEIVE RESEARCH RESULTS?

As part of this study, we will use your blood sample to measure your complete blood count (CBC) and white blood cell (WBC) counts. A clinician on the research team (Dr. Neil Caporaso) will review your CBC and WBC measurements. If your results indicate something of potential clinical significance (e.g., anemia or an infection), we will send you a letter with additional information about the results and recommendations for medical follow-up. The results of other tests will be used for research purposes only and their clinical interpretation is unknown at this time, so we will not be sending any other individual results to you.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please call our toll-free number at 1-800-271-1954 and speak to the Study Coordinator, Ellen Heywood, or ask to speak with the principal investigator at The University of Iowa, Charles Lynch, MD, PhD.

If you have 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, Iowa, 52242, (319) 335-6564, or e-mail 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.

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This Informed Consent Document 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 $STAMP_EXP_DT.

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

FOR IRB USE ONLY
APPROVED BY:
IRB ID #:
APPROVAL DATE:
EXPIRATION DATE:

Attachment 1**8.4**: BEEA NC Consent Form for Recently Exposed Participants

The Agricultural Health Study (AHS)
Informed Consent Form (Recent Exposure Group)

Study Title: Study of Biomarkers of Exposures and Effects in Agriculture

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

Co-Investigators: Laura Beane-Freeman, Ph.D.: Jonathan Hofmann, Ph.D.; Ola Landgren, M.D., Ph.D.; Neil Caporaso, M.D.; Sharon Savage, M.D.: National Cancer Institute
Charles Knott, M.P.A., Battelle Centers for Public Health Research and Evaluation;
Charles Lynch, M.D., Ph.D., University of Iowa

Study Purpose: The purpose of this study is to collect blood and urine samples from participants in the Agricultural Health Study and administer a short questionnaire for biomedical research. We are inviting you to participate in this research study because you are a participant in the Agricultural Health Study. The collection of these samples and additional questionnaire will supplement the questionnaire information you have already provided to us. We are interested in changes that may occur in the blood and urine when people are exposed to occupational and environmental chemicals and substances. We are also interested in differences in other body processes that are affected by lifestyle and the environment. The material in the blood and urine samples will allow us to study these differences in relation to cancer risk, and help understand the causes of cancer and other chronic diseases.

Number of Participants: Approximately 1600 people will take part in the collection of biospecimens for the Agricultural Health Study. Of this group, approximately 50 people will take part by completing three home visits.

Study Procedures: We are asking you to allow a person trained to collect blood to make three visits to your home to collect blood and urine samples 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. At each visit we will collect about 2-3.5 tablespoons of blood. Each visit should take no more than 90 minutes of your time.

Risks and Benefits: The physical risks associated with the study are minimal and only include those associated with blood collection. It is possible, but unlikely, that 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. Please refer to the section below entitled “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 samples are covered by the study. You will be paid $75 for each visit completed at your home.

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 Battelle North Carolina Field Station 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 blood and urine you give us will be used to study how occupational and environmental exposures and life-style characteristics cause cancer and other chronic diseases. They will also be used only to study cancer and other chronic diseases that may be related to agricultural exposures and life on the farm and in rural areas. The exact studies that will be performed are not all known at this time but are likely to include the following: 1) factors in the blood and urine that may be

associated with environmental or occupational exposures or life-style characteristics; and 2) factors in the blood and urine that may be associated with certain cancers or other chronic diseases. Blood and urine will also be used to study why genes may play a part in why some people develop cancer and some do not.

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APPROVED BY:
IRB ID #:
APPROVAL DATE:
EXPIRATION DATE:

Blood samples and genetic materials will be shipped to and stored at a central processing laboratory in Frederick, MD, and will be sent to other laboratories for specific analyses. After analyses, the samples will be returned to the processing laboratory for long-term storage. The Mayo Medical Laboratories in Rochester, MN, will also receive blood samples to measure your complete blood count (CBC) and white blood cell (WBC) counts.

We will keep your participation in this research study confidential to the extent permitted by law. 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 containers, a bar code is being used to identify you.

The Agricultural Health Study research team has a Certificate of Confidentiality to protect your privacy in this study. This certificate says that we do not ever have to give your name or any other personal information about you to anyone who is not working on the study. For example, even a court of law would not be able to find out what you said. 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. Battelle Field Station personnel, who have access to your personal identifiers, will not be given your laboratory test results.

Research Results: A clinician on the research team (Dr. Neil Caporaso) will review your CBC and WBC measurements. If your results indicate something of potential clinical significance (e.g., anemia or an infection), we will send you a letter with additional information about the results and recommendations for medical follow-up. The results of other tests will be used for research purposes only and their clinical interpretation is unknown at this time, so we will not be sending any other individual results to you.

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.

To withdraw your participation and/or to have your specimens (blood, urine) destroyed, please write to Dr. Michael Alavanja at alavanjm@exchange.nih.gov with your specific request.

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 1-800-424-7883 to contact the principal investigator at Battelle, Charles Knott, M.P.A., PMP.

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.

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 EXPIRATION DATE: 00/00/20__.

Subject's Name (printed): _____

_____ _____

(Signature of Subject) (Today's date)