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Attachment 18.3: BEEA IA 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: Deb Lande, Study Coordinator, The University of Iowa

Lead Investigator: Jonathan Hofmann, PhD, MPH, 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, saliva, 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, saliva, 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 2200 people in Iowa and North Carolina will take part since this Agricultural Health Study includes participants from these two states. Of this group, approximately 100 people will take part by completing up to three home visits.

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

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HOW LONG WILL I BE IN THIS STUDY?

Your involvement for each home visit will be for about 90 minutes. If you agree to take part in the three home visits, your involvement will be for about 270 minutes total, or 4 ½ hours.

WHAT WILL HAPPEN DURING THIS STUDY?

Study participation will involve completing a maximum of three visits to your home. For each visit, a trained professional will visit your home to collect blood, saliva, and 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. If a dust sample is collected, we will collect your vacuum bag or vacuum waste, and a second questionnaire will apply to that and should take less than 10 minutes to complete. You are free to skip any questions that you prefer not to answer. We will collect about 4 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, saliva, urine, and household dust samples from you. We would like to study your samples in the future, after this study is over.

Blood cells removed from the blood samples, and buccal (mouth) cells removed from your saliva, 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. 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, saliva, urine, and household dust may not even exist at this time. Therefore, we are asking for your permission to store your samples 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, saliva, 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, saliva, 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, saliva, urine, and household dust has already been completed, the information from that research may still be used.

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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 RECEIVE A FINANCIAL INCENTIVE FOR PARTICIPATING?

At each home visit, you will receive $100 as a thank you for your participation in this research study. A personal check in your name for $100 will be provided immediately to you as the phlebotomist completes the home visit. If you agree to take part in the three home visits, you will receive $300 altogether.

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,
- The University of Iowa Institutional Review Board (a committee that reviews and approves research studies)
- Westat, the Agricultural Health Study coordinating center, 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.

To further protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except for the following: The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. You may receive a copy of the Certificate of Confidentiality upon request.

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?

A clinician on the research team (Dr. Charles Lynch) will review your blood tests for red blood cells, white blood cells, platelets, and liver function. 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 this 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 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, Deb Lande, or ask to speak with the principal investigator at The University of Iowa, Charles Lynch, MD, PhD at 319-384-1558.

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, 105 Hardin Library for the Health Sciences, 600 Newton Road, University of Iowa, Iowa City, Iowa, 52242-1098, (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 18.4: BEEA NC Consent Form for Recently Exposed Participants

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: Jonathan Hofmann, PhD, MPH, 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, saliva, 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, saliva, urine samples 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 2200 people in Iowa and North Carolina will take part since this Agricultural Health Study includes participants from these two states. Of this group, approximately 100 people will take part by completing up to three home visits.

OMB #: 0925-0406

Expiration date: 09/30/2016

HOW LONG WILL I BE IN THIS STUDY?

Your involvement for each home visit will be for about 90 minutes. If you agree to take part in the three home visits, your involvement will be for about 270 minutes total, or 4 ½ hours.

WHAT WILL HAPPEN DURING THIS STUDY?

Study participation will involve completing a maximum of three visits to your home. For each visit, a trained professional will visit your home to collect blood, saliva, and 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. If a dust sample is collected, we will collect your vacuum bag or vacuum waste, and a second questionnaire will apply to that and should take less than 10 minutes to complete. You are free to skip any questions that you prefer not to answer. We will collect about 4 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, saliva, urine, and household dust samples from you. We would like to study your samples in the future, after this study is over.

Blood cells removed from the blood samples, and buccal (mouth) cells removed from your saliva, 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. 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, saliva, urine, and household dust may not even exist at this time. Therefore, we are asking for your permission to store your samples 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, saliva, 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, saliva, and urine, 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, saliva, urine, and household 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 receive any direct benefits 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?

At each home visit, you will receive $100 as a thank you for your participation in this research study. A personal check in your name for $100 will be provided immediately to you as the phlebotomist completes the home visit. If you agree to take part in the three home visits, you will receive $300 altogether.

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.

To further protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except for the following: The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. You may receive a copy of the Certificate of Confidentiality upon request.

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?

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 1-800-4AGSTUDY (1-800-424-7883) and speak to the Study Coordinator, Amy Miller, or ask to speak with the principal investigator at Westat, 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 the Westat Human Subjects Protections Office, by calling 1-888-920-7631. Please leave a message with your full name, the name of the research study that you are calling about (the Biomarkers of Exposures and Effects in Agriculture or BEEA Study), and a phone number beginning with the area code. Someone will return your call as soon as possible. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Protections 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 $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)