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Attachment 22.3: BEEA IA Informed Consent Document for the Smartphone App

INFORMED CONSENT DOCUMENT

Study 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, 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. In this part of the study, we will learn about your activities on the farm, and how they vary over time, by asking you to enter information into an application (app) on your smartphone. Your daily activities will provide information on different kinds of tasks that farmers do during a work day. Learning about your activities will help us better understand the relationship between farming activities and health. Your participation will also help us learn if this app is appropriate to use for other similar studies.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 2,200 people in Iowa and North Carolina will take part since the Agricultural Health Study includes participants from these two states. Of this group, approximately 235 people will participate in this part of the study by entering information about their daily activities into the smartphone app.

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Expiration date: 09/30/2016

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HOW LONG WILL I BE IN THIS STUDY?

Your involvement for the smartphone app study will consist of entering your daily activities into the app on 20-30 randomly selected days over a six-month period. Over the course of a selected day, we estimate it will take about 10 minutes to log all your activities.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree, a trained member of our research team will help you install the app on your smartphone and will show you how to use it. A written quick start guide about the app will also be provided. You will be prompted by the app on each of the days you are to enter your farming and non-farming activities. On these selected days, you will track your activities by opening the app, selecting from the pre-programmed activities (or entering a new activity, as needed), and using the start and stop buttons to track the time you spend on each activity. If you agree, you will do this for all your activities over the course of the work day, on each of the days you are prompted.

You already have received mailings and telephone calls from the study field station about the home visit and the smartphone app.

Data Storage for Future Use

The information you enter in the app about your time spent in different activities will be used for this study and possible future research about farming activities and health. If you agree now to future use of this information, but decide in the future that you would like to have it removed from future research, you should contact Dr. Charles Lynch at 319-384-1558. However, if some research with the data has already been completed, the information from that research may still be used.

WHAT ARE THE RISKS OF THIS STUDY?

It is possible, but very unlikely, that there may be a risk of loss of confidentiality of your information collected during this study. In addition to this, there may be other unknown risks, or risks that we did not anticipate, associated with being in 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?

You will receive $100 as a thank you for your participation in the smartphone app study. A personal check in your name will be mailed to you upon completion of the study.

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WHO IS FUNDING THIS STUDY?

The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) is funding this research project. This means that the University of Iowa is receiving payments from DHHS/NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from DHHS/NIH for conducting this study.

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),
- 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. Your consent forms will be stored in securely locked cabinets when not in use. Data will be transmitted in a secure manner and stored on password-protected computers in a secure area. 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.

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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 will be used for research purposes only, and the interpretation is unknown at this time, so we will not be sending any 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. If you experience a research-related injury, please contact: 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, IA 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 22.4: BEEA NC Informed Consent Document for the Smartphone App

INFORMED CONSENT DOCUMENT

Study 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, 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. In this part of the study, we will learn about your activities on the farm, and how they vary over time, by asking you to enter information into an application (app) on your smartphone. Your daily activities will provide information on different kinds of tasks that farmers do during a work day. Learning about your activities will help us better understand the relationship between farming activities and health. Your participation will also help us learn if this app is appropriate to use for other similar studies.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 2,200 people in Iowa and North Carolina will take part since the Agricultural Health Study includes participants from these two states. Of this group, approximately 235 people will participate in this part of the study by entering information about their daily activities into the smartphone app.

OMB #: 0925-0406
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HOW LONG WILL I BE IN THIS STUDY?

Your involvement for the smartphone app study will consist of entering your daily activities into the app on 20-30 randomly selected days over a six-month period. Over the course of a selected day, we estimate it will take about 10 minutes to log all your activities.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree, a trained member of our research team will help you install the app on your smartphone and will show you how to use it. A written quick start guide about the app will also be provided. You will be prompted by the app on each of the days you are to enter your farming and non-farming activities. On these selected days, you will track your activities by opening the app, selecting from the pre-programmed activities (or entering a new activity, as needed), and using the start and stop buttons to track the time you spend on each activity. If you agree, you will do this for all your activities over the course of the work day, on each of the days you are prompted.

You already have received mailings and telephone calls from the study field station about the home visit and the smartphone app.

Data Storage for Future Use

The information you enter in the app about your time spent in different activities will be used for this study and possible future research about farming activities and health. If you agree now to future use of this information, 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 the data has already been completed, the information from that research may still be used.

WHAT ARE THE RISKS OF THIS STUDY?

It is possible, but very unlikely, that there may be a risk of loss of confidentiality of your information collected during this study. In addition to this, there may be other unknown risks, or risks that we did not anticipate, associated with being in 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?

You will receive $100 as a thank you for your participation in the smartphone app study. A personal check in your name will be mailed to you upon completion of the study.

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 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. Your consent forms will be stored in securely locked cabinets when not in use. Data will be transmitted in a secure manner and stored on password-protected computers in a secure area. 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?

The results will be used for research purposes only, and the interpretation is unknown at this time, so we will not be sending any 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 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 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)