

Attachments 17.1-17.19: BEEA Supplementary Participant Materials Letters (Intro Letter, Pre-Visit Mailing Letter, Urine Directions, Results Letters)

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Attachment 17-1: BEEA IA Introductory Letter for Randomly Selected and Recently Exposed Group Participants

Date

To: Mr. <name or names entered here>
From: Charles Lynch, M.D., Ph.D.
Director, Agricultural Health Study in Iowa

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. Overall, 2,200 Agricultural Health Study members and controls will be enrolled over the next several years of the study. The study is being funded by the National Cancer Institute.

This study will examine the properties of blood, saliva, and urine as well as dust samples from a subset of households 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 a couple of 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, with the possibility of completing two additional home visits for a select number of participants. 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 30-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 4 tablespoons of blood, saliva, and a first morning sample of urine. This will take about 30 minutes. In all, the visit would take about 1.5 to 2 hours of your time.

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. There should be no risk for answering the questions regarding the cancer screening practices. 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.

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You should not have any costs for being in this study. You will receive \$100.00 for each visit as a thank you for your participation in the main portion of the research study. You will not receive financial incentive for answering the questions regarding cancer screening practices.

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.

If you have any questions, concerns or do not want to participate, please contact Deb Lande, 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, 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. 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.

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Attachment 17-2: BEEA NC Introductory Letter for Randomly Selected and Recently Exposed Group Participants

Date

To: Mr. <name or names entered here>

From: Marsha Dunn, MPH

Director, Agricultural Health Study in North Carolina

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. Overall, 2,200 Agricultural Health Study members and controls will be enrolled over the next several years of the study. The study is being funded by the National Cancer Institute and the US Environmental Protection Agency.

This study will examine the properties of blood, saliva, and urine as well as dust samples from a subset of households 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 may help us better understand these illnesses and eventually prevent them.

We plan to call you within a couple of 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, with the possibility of completing two additional home visits for a select number of participants. 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 30-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 4 tablespoons of blood, saliva, and a first morning sample of urine. This will take about 30 minutes. In all, the visit would take about 1.5 to 2 hours of your time.

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 Westat 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 main portion of 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. There should be no risk for answering the questions regarding the cancer screening practices. 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 receive \$100.00 for each visit as a thank you for your participation in the main portion of the research study. You will not

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receive a financial incentive for answering the questions regarding cancer screening practices.

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.

If you have any questions, concerns or do not want to participate, please contact Amy Miller, study coordinator, at 1-800-4AGSTUDY (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 Westat Human Subjects Protections Office, 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. 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.

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Attachment 17-3: BEEA IA Consent Mailing Cover Letter for Randomly Selected, Recently Expose, and Control Group Participants

Date

To: Mr. <name or names entered here>
From: Charles Lynch, M.D., Ph.D.
Director, Agricultural Health Study in Iowa

I want to thank you for taking the time to speak with us recently and for expressing interest in participating in the Agricultural Health Study's Study of Biomarkers of Exposures and Effects in Agriculture (BEEA).

This letter is to confirm our appointment at your home, {address}, on
{Day of week, DATE}
{TIME}

for a home visit for the BEEA Study. Before the appointment, please take some time to review the enclosed materials, which include a home visit preparation sheet, directions for collection of the urine sample, a questionnaire concerning collection of the vacuum dust sample, and a consent form. The consent form describes what will happen during the home visit, foreseeable benefits and risks (such as possible bruising after a blood draw), an explanation of the study's confidentiality procedures and who to contact for answers to questions about the home visit. We will collect the signed consent form at your visit, and you may also request a copy for your records.

We will be calling you within the next week to confirm the appointment and verify receipt of these materials. We will be happy to answer any questions you have at that time. Please read the information sheet on preparation for the home visit and the vacuum dust sample questionnaire carefully and follow the instructions precisely. If you have any questions about the instructions, please ask them when we call you.

If you have any questions or concerns, please contact Deb Lande, 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, 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. 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.

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Attachment 17-4: BEEA NC Consent Mailing Cover Letter for Randomly Selected, Recently Exposed, and Control Group Participants

Date

To: Mr. <name or names entered here>

From: Marsha Dunn, MPH.

Director, Agricultural Health Study in North Carolina

I want to thank you for taking the time to speak with us recently and for expressing interest in participating in the Agricultural Health Study's Study of Biomarkers of Exposures and Effects in Agriculture (BEEA).

This letter is to confirm our appointment at your home, {address}, on
{Day of week, DATE}
{TIME}

for a home visit for the BEEA Study. Before the appointment, please take some time to review the enclosed materials, which include a home visit preparation sheet, directions for collection of the urine sample, a questionnaire concerning collection of the vacuum dust sample, and a consent form. The consent form describes what will happen during the home visit, foreseeable benefits and risks (such as possible bruising after a blood draw), an explanation of the study's confidentiality procedures and who to contact for answers to questions about the home visit. **We will collect the signed consent forms at your visit, and you may also request a copy for your records.**

We will be calling you within the next week to confirm the appointment and verify receipt of these materials. We will be happy to answer any questions you have at that time. Please read the information sheet on preparation for the home visit and the vacuum dust sample questionnaire carefully and follow the instructions precisely. If you have any questions about the instructions, please ask them when we call you.

If you have any questions or concerns, please contact Amy Miller, study coordinator at 1-800-4AGSTUDY (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 **and welfare** as a research **participant** 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.** 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.

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Attachment 17-5: BEEA IA Consent Mailing Cover Letter for Recently Exposed Group - Air Monitoring Visit

Date

To: Mr. <name or names entered here>
From: Charles Lynch, M.D., Ph.D.
Director, Agricultural Health Study in Iowa

I want to thank you for taking the time to speak with us recently and for expressing interest in participating in the Agricultural Health Study's Study of Biomarkers of Exposures and Effects in Agriculture (BEEA).

This letter is to confirm our appointments for the BEEA Study

Farm Visit: at {address}, on {Day of week, DATE} at {TIME}

Home Visit: at {address}, on {Day of week, DATE} at {TIME}

Before the appointments, please take some time to review the enclosed materials, which include a home visit preparation sheet, directions for collection of the urine sample, a questionnaire concerning collection of the vacuum dust sample, and two consent forms. The consent forms describe what will happen at each type of visit, foreseeable benefits and risks (such as possible bruising after the home visit blood draw), an explanation of the study's confidentiality procedures and who to contact for answers to questions about the home visit. We will collect the signed consent form at your visit, and you may also request a copy for your records.

We will be calling you a few days before the first visit to confirm the appointment and verify receipt of these materials. We will be happy to answer any questions you have at that time. You do not have to do any preparation for the air monitoring visit, but prior to the home visit please read the information sheet on preparation for the home visit and the vacuum dust sample questionnaire carefully and follow the instructions precisely. If you have any questions about the instructions, please ask them when we call you.

If you have any questions or concerns, please contact Deb Lande, 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, 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. Again, we want to thank you for your assistance in making the Agricultural Health Study an

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important and successful study of health in the agricultural community. We look forward to speaking with you soon.

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Attachment 17-6: BEEA NC Consent Mailing Cover Letter for Recently Exposed Group -Air Monitoring Visit

Date

To: Mr. <name or names entered here>
From: Marsha Dunn, MPH.
Director, Agricultural Health Study in North Carolina

I want to thank you for taking the time to speak with us recently and for expressing interest in participating in the Agricultural Health Study's Study of Biomarkers of Exposures and Effects in Agriculture (BEEA).

This letter is to confirm our appointments **for the BEEA Study**

Farm Visit: at {address}, on {Day of week, DATE} at {TIME}

Home Visit: at {address}, on {Day of week, DATE} at {TIME}

Before the appointments, please take some time to review the enclosed materials, which include a home visit preparation sheet, directions for collection of the urine sample, a questionnaire concerning collection of the vacuum dust sample, and **two** consent forms. The consent forms describes what will happen **at each type of** visit, foreseeable benefits and risks (such as possible bruising after a blood draw), an explanation of the study's confidentiality procedures and who to contact for answers to questions about the home visit. **We will collect the signed consent forms at your visits, and you may also request copies for your records.**

We will be calling you within the next week to confirm the appointment and verify receipt of these materials. We will be happy to answer any questions you have at that time. **You do not have to do any preparation for the air monitoring visit, but prior to the home visit,** please read the information sheet on preparation for the home visit and the vacuum dust sample questionnaire carefully and follow the instructions precisely. If you have any questions about the instructions, please ask them when we call you.

If you have any questions or concerns, please contact Amy Miller, study coordinator at 1-800-4AGSTUDY (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 **and welfare** as a research **participant** please contact of 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.** 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.

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DIRECTIONS FOR URINE COLLECTION

Please follow the directions below. You may request help reading the instructions from a member of your household, but **please do not permit anyone else to handle the collection materials.**

Here is a list of what you should find in the package we mailed to you:

- 1 Liter screw top collection container
- 1 leak-proof plastic bag containing 1 piece of absorbent tissue
- Brown paper bag

If you have not received all of these materials, please call us at 1-800-217-1954. Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study.

1. To help you remember to collect your urine sample, leave the collection container on the toilet seat lid the night before your home visit.
2. Collect the sample only when you wake and get up for the day.
3. Wash your hands before opening the collection container.
4. Urinate directly into the container.
5. Replace the top on the collection container and screw it on tightly. Place the sample inside the leak-proof plastic bag with the absorbent tissue and then inside the brown paper bag.
6. Store the sample in a refrigerator or at a refrigerated temperature.
7. We will collect the sample at your home visit.

THANK YOU FOR YOUR HELP!

DIRECTIONS FOR URINE COLLECTION

Please follow the directions below. You may request help reading the instructions from a member of your household, but **please do not permit anyone else to handle the collection materials.**

Here is a list of what you should find in the package we mailed to you:

- 1 liter screw top collection container
- 1 leak-proof plastic bag containing 1 piece of absorbent tissue
- Brown paper bag

If you have not received all of these materials, please call us at 1-800-424-7883. Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study.

1. To help you remember to collect your urine sample, leave the collection container on the toilet seat lid the night before your home visit.
2. Collect the sample only when you wake and get up for the day.
3. Wash your hands before opening the collection container.
4. Urinate directly into the container.
5. Replace the top on the collection container and screw it on tightly. Place the sample inside the leak-proof plastic bag with the absorbent tissue and then inside the brown paper bag.
6. Store the sample in a refrigerator or at a refrigerated temperature.
7. We will collect the sample at your home visit.

THANK YOU FOR YOUR HELP!

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Attachment 17-11a: BEEA IA Sample Letter to Subject for Communication of Lab Test Results that are Normal (REG and Control Groups)

Date:

To: Mr. [Subject's name]
From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

Thank you for your participation in the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

When you signed a consent form for this study, you indicated that you were interested in receiving the results of the clinical tests run on your blood. A standard panel of complete blood cell count was performed on a blood sample collected from you on [month/day/year]. As you can see from the accompanying report, your levels of platelets (PLT), white blood cells (WBC), and red blood cells (RBC) were all within the normal range for people in your sex and age group. Platelets are important in assisting your blood to clot when you bleed. Mean platelet volume (MPV) is the average size of platelets found in your blood. White blood cells are important in fighting infectious organisms. Your red blood cells carry oxygen to your tissues and contain hemoglobin (HB) to help them perform this task.

These red blood cells are a major constituent of your blood, and the volume of your blood occupied by these cells is measured by the hematocrit (HCT). The mean cell volume (MCV), mean cell hemoglobin (MCH), and mean cell hemoglobin concentration (MCHC) are also each specific to your red blood cells. The red blood cell distribution width (RDW and RDWSD) is a measure of variability in red blood cell size. Nucleated red blood cells (NRBC) are immature cells that normally do not enter your blood. All of these red blood cell indices were within the normal range in your blood.

Your white blood cells consist of neutrophils (NEUT), lymphocytes (LYMPH), monocytes (MONO), eosinophils (EOS), basophils (BASO), and immature granulocytes (IMMATURE GRAN). Immature granulocytes are considered normal up to 2% of your WBC count. Thus, these WBC types were all within the normal range in your blood.

Liver function tests are lab blood tests designed to provide information about the state of your liver. The parameters measured included total protein, albumin, alkaline phosphatase, total bilirubin, direct bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT). Results of these tests were normal.

In summary, the results of your routine blood tests are all normal. If you have any questions or concerns, please contact Dr. Charles Lynch at (319-384-1558). Please specify that you are calling about the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

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Attachment 17-11b: BEEA IA Sample Letter to Subject for Communication of Lab Test Results that are Essentially Normal (REG and Control Groups)

Date:

To: Mr. [Subject's name]
From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

Thank you for your participation in the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

When you signed a consent form for this study, you indicated that you were interested in receiving the results of the clinical tests run on your blood. A standard panel of complete blood cell count was performed on a blood sample collected from you on [month/day/year]. As you can see from the accompanying report, your levels of platelets (PLT), white blood cells (WBC), and red blood cells (RBC) were all within the normal range for people in your sex and age group [with the exception of the [type(s) of measure], which was/were slightly [above/below] the normal range]. Platelets are important in assisting your blood to clot when you bleed. Mean platelet volume (MPV) is the average size of platelets found in your blood. White blood cells are important in fighting infectious organisms. Your red blood cells carry oxygen to your tissues and contain hemoglobin (HB) to help them perform this task.

These red blood cells are a major constituent of your blood, and the volume of your blood occupied by these cells is measured by the hematocrit (HCT). The mean cell volume (MCV), mean cell hemoglobin (MCH), and mean cell hemoglobin concentration (MCHC) are also each specific to your red blood cells. The red blood cell distribution width (RDW and RDWSD) is a measure of variability in red blood cell size. Nucleated red blood cells (NRBC) are immature cells that normally do not enter your blood. All of these red blood cell indices were within the normal range in your blood [with the exception of the [type(s) of measure], which was/were slightly [above/below] the normal range].

Your white blood cells consist of neutrophils (NEUT), lymphocytes (LYMPH), monocytes (MONO), eosinophils (EOS), basophils (BASO), and immature granulocytes (IMMATURE GRAN). Immature granulocytes are considered normal up to 2% of your WBC count. Thus, these WBC types were all within the normal range in your blood [with the exception of the [type(s) of measure], which was/were slightly [above/below] the normal range]. [INCLUDE THE FOLLOWING IF PERFORMED: A drop of your blood was used to make a peripheral smear. This was examined and reported to have [report what was stated on report]].

Liver function tests are lab blood tests designed to provide information about the state of your liver. The parameters measured included total protein, albumin, alkaline phosphatase, total bilirubin, direct bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT). Results of these tests were normal [with the exception of the [type(s) of measure], which was/were slightly [above/below] the normal range].

In summary, the results of your routine blood tests are essentially normal. Your [types of measure] were slightly [above/below] the normal range, but we ran many tests here and are not surprised to find [number] out of the normal range. The normal range represents a 95% confidence interval. Thus, if you ran 20 tests, we would expect one to be outside the normal range by chance alone. This is what I believe has occurred with your [type of measure]. If you have any questions or concerns, please contact Dr.

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Charles Lynch at (319-384-1558). Please specify that you are calling about the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

Attachment 17-11c: BEEA IA Sample Letter to Subject for Communication of Lab Test Results that are Abnormal When Health Care Provider to be Contacted (REG and Control Groups)

Date:

To: Mr. [Subject's name]
From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

Thank you for your participation in the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

When you signed a consent form for this study, you indicated that you were interested in receiving the results of the clinical tests run on your blood. A standard panel of complete blood cell count was performed on a blood sample collected from you on [month/day/year]. As you can see from the accompanying report, your levels of platelets (PLT), white blood cells (WBC), and red blood cells (RBC) were all within the normal range for people in your sex and age group [with the exception of the [type(s) of measure], which was/were [above/below] the normal range]. Platelets are important in assisting your blood to clot when you bleed. Mean platelet volume (MPV) is the average size of platelets found in your blood. White blood cells are important in fighting infectious organisms. Your red blood cells carry oxygen to your tissues and contain hemoglobin (HB) to help them perform this task.

These red blood cells are a major constituent of your blood, and the volume of your blood occupied by these cells is measured by the hematocrit (HCT). The mean cell volume (MCV), mean cell hemoglobin (MCH), and mean cell hemoglobin concentration (MCHC) are also each specific to your red blood cells. The red blood cell distribution width (RDW and RDWSD) is a measure of variability in red blood cell size. Nucleated red blood cells (NRBC) are immature cells that normally do not enter your blood. All of these red blood cell indices were within the normal range in your blood [with the exception of the [type(s) of measure], which was/were [above/below] the normal range].

Your white blood cells consist of neutrophils (NEUT), lymphocytes (LYMPH), monocytes (MONO), eosinophils (EOS), basophils (BASO), and immature granulocytes (IMMATURE GRAN). Immature granulocytes are considered normal up to 2% of your WBC count. Thus, these WBC types were all within the normal range in your blood [with the exception of the [type(s) of measure], which was/were [above/below] the normal range]. [INCLUDE THE FOLLOWING IF PERFORMED: A drop of your blood was used to make a peripheral smear. This was examined and reported to have [report what was stated on report]].

Liver function tests are blood tests designed to provide information about the state of your liver. The parameters measured included total protein, albumin, alkaline phosphatase, total bilirubin, direct bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT). Results of these tests were normal [with the exception of the [type(s) of measure], which was/were [above/below] the normal range].

{Add the following paragraph regarding lymphocyte subset test results if abnormal: Lymphocyte subset blood tests were performed. These consist of B-cells and types of T-cells, which are important in maintaining your health status. These were all within the normal range in your blood [with the exception of the [type(s) of measure], which was/were [above/below] the normal range]}.

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In summary, some of the results of your routine blood tests are outside of clinically-defined normal ranges. In particular this applies to [list abnormal tests]. There are many reasons why such abnormal tests could occur. When you enrolled in this study you indicated that you wanted any such test results sent to:

[List name and address of Health Care Provider]

We have done this and included this letter and its accompanying results in the mailing to your health care provider. We recommend that you consult with your health care provider to discuss your blood test results further. If you have any questions or concerns, please contact Dr. Charles Lynch at (319-384-1558). Please specify that you are calling about the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

Attachment 17-11d: BEEA IA Sample Letter to Subject for Communication of Lab Test Results that are Abnormal When Health Care Provider is Not to be Contacted (REG and Control Groups)

Date:

To: Mr. [Subject's name]
From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

Thank you for your participation in the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

When you signed a consent form for this study, you indicated that you were interested in receiving the results of the clinical tests run on your blood. A standard panel of complete blood cell count was performed on a blood sample collected from you on [month/day/year]. As you can see from the accompanying report, your levels of platelets (PLT), white blood cells (WBC), and red blood cells (RBC) were all within the normal range for people in your sex and age group [with the exception of the [type(s) of measure], which was/were [above/below] the normal range]. Platelets are important in assisting your blood to clot when you bleed. Mean platelet volume (MPV) is the average size of platelets found in your blood. White blood cells are important in fighting infectious organisms. Your red blood cells carry oxygen to your tissues and contain hemoglobin (HB) to help them perform this task.

These red blood cells are a major constituent of your blood, and the volume of your blood occupied by these cells is measured by the hematocrit (HCT). The mean cell volume (MCV), mean cell hemoglobin (MCH), and mean cell hemoglobin concentration (MCHC) are also each specific to your red blood cells. The red blood cell distribution width (RDW and RDWSD) is a measure of variability in red blood cell size. Nucleated red blood cells (NRBC) are immature cells that normally do not enter your blood. All of these red blood cell indices were within the normal range in your blood [with the exception of the [type(s) of measure], which was/were [above/below] the normal range].

Your white blood cells consist of neutrophils (NEUT), lymphocytes (LYMPH), monocytes (MONO), eosinophils (EOS), basophils (BASO), and immature granulocytes (IMMATURE GRAN). Immature granulocytes are considered normal up to 2% of your WBC count. Thus, these WBC types were all within the normal range in your blood [with the exception of the [type(s) of measure], which was/were [above/below] the normal range]. [INCLUDE THE FOLLOWING IF PERFORMED: A drop of your blood was used to make a peripheral smear. This was examined and reported to have [report what was stated on report]].

Liver function tests are lab blood tests designed to provide information about the state of your liver. The parameters measured included total protein, albumin, alkaline phosphatase, total bilirubin, direct bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT). Results of these tests were normal [with the exception of the [type(s) of measure], which was/were [above/below] the normal range].

{Add the following paragraph regarding lymphocyte subset test results if abnormal: Lymphocyte subset blood tests were performed. These consist of B-cells and types of T-cells, which are important in maintaining your health status. These were all within the normal range in your blood [with the exception of the [type(s) of measure], which was/were [above/below] the normal range]}.

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In summary, some of the results of your routine blood tests are outside of clinically-defined normal ranges. In particular this applies to [list abnormal tests]. There are many reasons why such abnormal tests could occur. We recommend that you consult with your health care provider to discuss your blood test results further. If you have any questions or concerns, please contact Dr. Charles Lynch at (319-384-1558). Please specify that you are calling about the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

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**Attachment 17-11e: BEEA IA Sample Letter to Subject's Physician for
Communication of Abnormal Lab Test Results (REG Group)**

Date:

To: Dr. [Name]
From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

The Agricultural Health Study is a cohort study of almost 90,000 licensed pesticide applicators and their spouses in Iowa and North Carolina. The study is sponsored by the National Institutes of Health, the National Institute of Environmental Health Sciences, and the Environmental Protection Agency. We are currently conducting a substudy within the cohort, called the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**. Your patient, [Subject's name], is participating in this study. The contact information we have for this patient is as follows:

[Contact Information]

A standard panel of complete blood cell count (CBC) with automated differential, liver function tests, and [if applicable, state "lymphocyte subset tests"] were performed on a blood sample collected from [Subject's name] on [month/day/year]. Some of the results of these lab tests were outside of clinically-defined normal ranges and considered abnormal. As requested and authorized by the patient when he enrolled in this study, we are providing you the letter sent to him and its accompanying results. We recommended that he consult with you to discuss his test results further.

If you have any questions or concerns, please contact Dr. Charles Lynch at (319) 384-1558. Please specify that you are calling about the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

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**Attachment 17-11f: BEEA IA Sample Letter to Subject's Physician for
Communication of Abnormal Lab Test Results (Control Group)**

Date:

To: Dr. [Name]
From: Charles Lynch, M.D., Ph.D.
Director, Iowa Field Station

The **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study** is a research study currently being conducted in Iowa and North Carolina to investigate biologic changes associated with farming practices and exposures. The study is sponsored by the National Cancer Institute, the National Institute of Environmental Health Sciences, and the Environmental Protection Agency. Your patient, [Subject's name], is participating in this study. The contact information we have for this patient is as follows:

[Contact Information]

A standard panel of complete blood cell count (CBC) with automated differential, liver function tests, and [if applicable, state "lymphocyte subset tests"] were performed on a blood sample collected from [Subject's name] on [month/day/year]. Some of the results of these lab tests were outside of clinically-defined normal ranges and considered abnormal. As requested and authorized by the patient when he enrolled in this study, we are providing you the letter sent to him and its accompanying results. We recommended that he consult with you to discuss his test results further.

If you have any questions or concerns, please contact Dr. Charles Lynch at (319) 384-1558. Please specify that you are calling about the **Biomarkers of Exposures and Effects in Agriculture (BEEA) Study**.

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Attachment 17-12: BEEA IA “Contact Us” Letter for Randomly Selected and Recently Exposed Groups

Date

To: Mr. <name or names entered here>
From: Charles Lynch, M.D., Ph.D.
Director, **Agricultural Health Study in Iowa**

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 telephone interviews and questionnaires.

We recently sent you a letter to invite you to take part in a new study designed to measure biologic effects in relation to different farming exposures and activities. We would like to tell you more about the study and find out if you may be eligible for the study and interested in participating. If so, we will schedule a home visit with you which will take **about 90 minutes** of your time, **with the possibility of completing two additional home visits for a select number of participants**. You will receive **\$100.00 for each visit** as a thank you for your participation in this research study.

We tried to reach you to determine if you are truly eligible to participate in this study. **Unfortunately, your telephone number was no longer in service. Could you please call Deb Lande, study coordinator, at 1-800-217-1954 to let us know whether or not you are interested in participating in this study, or if you have any questions? Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study.**

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.

Attachment 17-13: BEEA NC “Contact Us” Letter for Randomly Selected and Recently Exposed Groups

Date

To: Mr. <name or names entered here>
From: Marsha Dunn, MPH.
Director, Agricultural Health Study in North Carolina

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 telephone interviews and questionnaires.

We recently sent you a letter to invite you to take part in a new study designed to measure biologic effects in relation to different farming exposures and activities. We would like to tell you more about the study and find out if you may be eligible for the study and interested in participating. If so, we will schedule a home visit with you which will take about 90 minutes of your time, with the possibility of completing two additional home visits for a select number of participants. You will receive \$100.00 for each visit as a thank you for your participation in this research study.

We tried to reach you to determine if you are truly eligible to participate in this study. **Unfortunately, your telephone number was no longer in service. Could you please call Amy Miller, study coordinator, at 1-800-4AGSTUDY (1-800-424-7883) to let us know whether or not you are interested in participating in this study, or if you have any questions? Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study.**

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.

Attachment 17-14: BEEA IA Introductory Letter for Control Group Participants

Date:

To: Mr. <name or names entered here>
From: Charles Lynch
Director, Agricultural Health Study in Iowa

We are writing to ask you to consider participating in an important study that our group is doing in Iowa and North Carolina, looking at the possible health effects of farming. The participants in the study are both farmers and non-farmers.

The study, called Biomarkers of Exposure and Effect in Agriculture (BEEA), is funded by the National Cancer Institute.

Farmers are exposed to chemicals and other substances that may affect their health. In our study we are measuring the possible effects of those different exposures. We want to know if they affect farmers' risk of getting cancer and other chronic diseases.

A comparison group of non-farmers, who are similar in age and live in the same area as the farmers in the study, can help us understand if any health changes we might see in the farmers are related to farming or something else.

You are receiving this letter because we randomly picked your name from a list of men age 50 and older who are registered voters in your area. We hope to enroll 200 non-farmers in the next several years in our study.

We will call you in the next couple of weeks to see if you are eligible and want to be in the study. The call will take 10 minutes or less. If you do volunteer for the study, the caller will schedule a home visit.

Prior to the home visit we will send you materials including a consent form, a card highlighting key elements of the visit, a questionnaire, and a container you would use for collecting a urine sample.

The home visit takes about 90 minutes. During the visit, a trained professional will:

- Ask you about your work history, general health, and any recent use of tobacco, alcohol, or medications;
- Take a blood and a saliva sample;
- Take a sample of dust from your home; and
- Ask you to read and sign a consent form that describes your rights as a study participant and confirms that you want to be in the study.

You will receive \$100 as a thank you for your participation in the home visit portion of the research study. You will not have any costs for being in this research study.

The only physical risks from participating in the study are possible swelling or bruising from the blood draw, which occurs rarely.

***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.*

All of the information we collect will be used for research purposes only and will be kept strictly confidential. Federal agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records from the study. Your name and personal information won't be in any reports that come out of this study. It's possible, although very unlikely, that the privacy of your information could be compromised.

You won't directly benefit from being in the study. However, we hope that people will benefit in the future from knowledge that comes from the study.

Your participation in any part of this study is voluntary. There would be no penalties for not responding to the questionnaire or to any question.

If you have questions, concerns or don't want to participate, please call Deb Lande, study coordinator, at 1-800-217-1954). Please say 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 study participant 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.

Thank you for considering helping us better understand the health of our farmers. 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.*

Attachment 17-15: BEEA NC Introductory Letter for Control Group Participants

Date:

To: Mr. <name or names entered here>

From: Marsha Dunn, MPH

Director, Agricultural Health Study in North Carolina

We are writing to ask you to consider participating in an important study that our group is doing in Iowa and North Carolina, looking at the possible health effects of farming. The participants in the study are both farmers and non-farmers.

The study, called Biomarkers of Exposure and Effect in Agriculture (BEEA), is funded by the National Cancer Institute and the U.S. Environmental Protection Agency.

Farmers are exposed to chemicals and other substances that may affect their health. In our study we are measuring the possible effects of those different exposures. We want to know if they affect farmers' risk of getting cancer and other chronic diseases.

A comparison group of non-farmers, who are similar in age and live in the same area as the farmers in the study, can help us understand if any health changes we might see in the farmers are related to farming or something else.

You are receiving this letter because we randomly picked your name from a list of men age 50 and older who are registered voters in your area. We hope to enroll 200 non-farmers in the next several years in our study.

We will call you in the next few weeks to see if you are eligible and want to be in the study. The call will take 10 minutes or less. If you do volunteer for the study, the caller will schedule a home visit.

Prior to the home visit we will send you materials including a consent form, a card highlighting key elements of the visit, a questionnaire, and a container you would use for collecting a urine sample.

The home visit takes about 90 minutes. During the visit, a trained professional will:

- Ask you about your work history, general health, and any recent use of tobacco, alcohol, or medications;
- Take a blood and a saliva sample;
- Take a sample of dust from your home; and
- Ask you to read and sign a consent form that describes your rights as a study participant and confirms that you want to be in the study.

You will receive \$100 as a thank you for your participation in the home visit portion of the research study. You will not have any costs from being in this research study. The only physical risks from participating in the study are possible swelling or bruising from the blood draw, which occur rarely.

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.

All of the information we collect will be used for research purposes only and will be kept strictly confidential. Federal agencies and the Westat Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records from the study. Your name and personal information won't be in any reports that come out of this study. It's possible, although very unlikely, that the privacy of your information could be compromised.

You won't directly benefit from being in the study. However, we hope that people will benefit in the future from knowledge that comes from the study.

Your participation in any part of this study is voluntary. There would be no penalties for not responding to the questionnaire or to any question.

If you have questions, concerns or don't want to participate, please call Amy Miller, study coordinator, at 1-800-4AGSTUDY (1-800-424-7883). Please say that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study.

If you have questions or concerns about your rights and welfare as a study participant please contact the Westat Human Subjects Protections Office, 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.

Thank you for considering helping us better understand the health of our farmers. 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.*

Attachment 17-18: BEEA IA “Contact Us” Letter for Control Group Participants

Date

To: Mr. <name or names entered here>
From: Charles Lynch
Director, Agricultural Health Study in Iowa

We recently sent you a letter to invite you to take part in an important scientific study being conducted in Iowa and North Carolina. The study is designed to measure biologic effects in relation to different farming exposures and activities, and includes both farmers and non-farmers. We invited you to participate in this study because your name was randomly picked from a list of men age 50 and older who are registered voters in your area.

We would like to tell you more about the study and find out if you may be eligible for the study and interested in participating. If so, we will schedule a home visit with you which will take about 90 minutes of your time. You will receive \$100.00 as a thank you for your participation in this research study.

We tried to reach you to determine if you are truly eligible to participate in this study. **Unfortunately, your telephone number was not in service. Could you please call Deb Lande, study coordinator, at 1-800-217-1954 and leave a message to let us know whether or not you are interested in participating in this study, or if you have any questions? Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study and please leave an updated telephone number so we may return your call.**

Again, we want to thank you for your assistance with this important study of health in the agricultural community. We look forward to speaking with you soon.

Attachment 17-19: BEEA NC “Contact Us” Letter for Control Group Participants

Date

To: Mr. <name or names entered here>

From: Marsha Dunn, MPH.

Director, Agricultural Health Study in North Carolina

We recently sent you a letter to invite you to take part in an important scientific study being conducted in Iowa and North Carolina. The study is designed to measure biologic effects in relation to different farming exposures and activities, and includes both farmers and non-farmers. We invited you to participate in this study because your name was randomly picked from a list of men age 50 and older who are registered voters in your area.

We would like to tell you more about the study and find out if you may be eligible for the study and interested in participating. If so, we will schedule a home visit with you which will take about 90 minutes of your time. You will receive \$100.00 as a thank you for your participation in this research study.

We tried to reach you to determine if you are truly eligible to participate in this study. **Unfortunately, your telephone number was not in service. Could you please call Amy Miller, study coordinator, at 1-800-4AGSTUDY (1-800-424-7883) and leave a message to let us know whether or not you are interested in participating in this study, or if you have any questions? Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study and please leave an updated telephone number so we may return your call.**

Again, we want to thank you for your assistance with this important study of health in the agricultural community. We look forward to speaking with you soon.