

Attachment 17: BEEA Letters
(Intro, Cover, Reminder, Results, Show Cards)

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OMB NO.: 0925-0406
EXPIRATION DATE: XX/XX/2016

Attachment 17.1:
Study of Biomarkers of Exposures and Effects in Agriculture
Pre-Screening Initial Contact Letter (Both Groups)

Date

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

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

A new study is underway for the AHS that is designed to measure biologic effects in relation to different farming exposures and activities. Overall, 1,600 Agricultural Health Study members will be enrolled over the next five years of the study. The study is being funded by the National Cancer Institute and the US Environmental Protection Agency.

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

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

Once we determine your eligibility for the study and you tell us that you are interested in participating, we will schedule a home visit with you. Prior to the home visit, you will receive materials from us including two copies of the consent document, a reminder card for key elements of the questionnaire, and urine collection materials. At the time of the home visit we will obtain your signed consent to participate in this study. We will also conduct a 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 3 tablespoons of blood and a first morning sample of urine. This will take about 30 minutes. In all, the visit would take about an hour 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 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

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

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Attachment 17.1:

study because of the knowledge gained.

You should not have any costs for being in this study. You will receive \$75.00 as a thank you for your participation in the main portion of the research study. You will not 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 Ellen Heywood, study coordinator at 1-800-217-1954. Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study. If you have questions or concerns about your rights as a research subject please contact the Human Subjects Office, 300 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. This study's IRB number is 201002777. Again, we want to thank you for your assistance in making the Agricultural Health Study an important and successful study of health in the agricultural community. We look forward to speaking with you soon.

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Attachment 17.2:
Study of Biomarkers of Exposures and Effects in Agriculture
NC Introductory Contact Letter (Both 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 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, 1,600 Agricultural Health Study members 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 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 the next few weeks to determine if you are truly eligible to participate in this study. Up to 5 call attempts will be made at different times of the day and at different days to reach you. Among the questions we will ask are three aimed toward improving our understanding of your cancer screening practices. The call will take 10 minutes or less.

Once we determine your eligibility for the study and you tell us that you are interested in participating, we will schedule a home visit with you. Prior to the home visit, you will receive materials from us including two copies of the consent document, a reminder card for key elements of the questionnaire, and urine collection materials. At the time of the home visit we will obtain your signed consent to participate in this study. We will also conduct a 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 3 tablespoons of blood and a first morning sample of urine. This will take about 30 minutes. In all, the visit would take about an hour 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 \$75.00 as a thank you for your participation in the main portion of the research study. You will not receive a

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Attachment 17.2:

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 Sharon Zack of the Westat Human Subjects Office, 1-800-937-8281, or e-mail IRB@westat.com. 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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OMB NO.: 0925-0406
EXPIRATION DATE: 5/31/2013

Attachment 17.3:

Study of Biomarkers of Exposures and Effects in Agriculture Consent Mailing Letter (Both Groups)

Date

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

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, 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 have provided two copies of the consent form. Please sign both – one will be collected by the study examiner at your home visit and the other you may keep 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 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 Ellen Heywood, study coordinator at 1-800-217-1954. Please specify that you are calling about the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study. If you have questions or concerns about your rights as a research subject please contact the Human Subjects Office, 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

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

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EXPIRATION DATE: 5/31/2013

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:

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

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, 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 have provided two copies of the consent form. Please sign both – one will be collected by the study examiner at your home visit and the other you may keep 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 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 as a research subject please contact Sharon Zack of the Westat Human Subjects Office, by calling 1-800-937-8281, or e-mail **IRB@westat.com**. 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 Pre-Visit Preparation Showcard

aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0406). Do not return the completed form to this address.

Agricultural Health Study
Study of Biomarkers of Exposures and Effects in Agriculture

Attachment 17.7: BEEA IA 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:

- 2 copies of the Informed Consent Form
- Screw top collection container
- 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. Read and sign both copies of the Informed Consent Form. We will collect one copy at your home visit (the other copy is yours to keep).
2. To help you remember to collect your wake-up urine sample on the day of your home visit, leave the urine collection bottle on the toilet seat lid the night before.
3. When you wake up in the morning, 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 brown paper bag.
6. Store the sample in the refrigerator.
7. We will pick up the sample at your home visit.

THANK YOU FOR YOUR HELP!

Agricultural Health Study
Study of Biomarkers of Exposures and Effects in Agriculture

Attachment 17.8: BEEA NC 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:

- 2 copies of the Informed Consent Form
- Screw top collection container
- 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. Read and sign both copies of the Informed Consent Form. We will collect one copy at your home visit (the other copy is yours to keep).
2. To help you remember to collect your wake-up urine sample on the day of your home visit, leave the urine collection bottle on the toilet seat lid the night before.
3. When you wake up in the morning, 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 brown paper bag.
6. Store the sample in the refrigerator.
7. We will pick up the sample at your home visit.

THANK YOU FOR YOUR HELP!

Attachment 17.9:

**Study of Biomarkers of Exposures and Effects in Agriculture
Pre-Visit Reminder Letter (Both Groups/All Visits)**

Date

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

This letter is to remind you about our appointment at your home, {STREET ADDRESS/CITY/STATE/ZIP} on {DATE} at {TIME} for a home visit for the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study.

We will be calling you within the next week to confirm the appointment and answer any questions you have.

Please review the information sheet on preparation for the home visit carefully and follow the instructions precisely. Note that for the duration of the visit, we will need quiet, uninterrupted time with you, and an area with a table such as a kitchen or dining room. If you have any questions about the instructions, please ask them when we call you before the visit.

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 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 52242-1098300 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (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.

Attachment 17.10:

**Study of Biomarkers of Exposures and Effects in Agriculture
Pre-Visit Reminder Letter (Both Groups/All Visits)**

Date

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

This letter is to remind you about our appointment at your home, {STREET ADDRESS/CITY/STATE/ZIP} on {DATE} at {TIME} for a home visit for the Biomarkers of Exposures and Effects in Agriculture (BEEA) Study.

We will be calling you within the next week to confirm the appointment and answer any questions you have.

Please review the information sheet on preparation for the home visit carefully and follow the instructions precisely. Note that for the duration of the visit, we will need quiet, uninterrupted time with you, and an area with a table such as a kitchen or dining room. If you have any questions about the instructions, please ask them when we call you before the visit.

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 BEEA Study. If you have questions or concerns about your rights as a research subject please contact Sharon Zack, of the Westat Human Subjects Office, by calling 1-800-937-8281, or e-mail **IRB@westat.com**. 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 17.11: BEEA IA Scheduling Letter for First Post-Diazinon Application Visit (Recent Exposure Group only)

Study of Biomarkers of Exposures and Effects in Agriculture
(to be sent in advance of the “month out” call)

Date

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

I want to thank you for participating in the Agricultural Health Study’s Biomarkers of Exposures and Effects in Agriculture (BEEA) Study and for taking the time to complete the first home visit with us. You may recall that you consented to receiving two additional visits to your home: one within a day after you complete diazinon use, and one about three weeks later. You noted previously that you thought that you would {apply/make the decision about applying} diazinon in <month >.

We will be calling you within the next week to verify your schedule for applying diazinon and to find out when you may be ready to schedule the next home visit. The call will take 5 minutes or less.

If you have any questions or concerns, please contact Ellen Heywood, study coordinator at 1-800-217-1954. Please specify that you are calling about the BEEA Study. If you have questions or concerns about your rights as a research subject please contact the Human Subjects Office, 300 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail **irb@uiowa.edu**. 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 17.12: BEEA NC Scheduling Letter for First Post-Diazinon Application Visit
(Recent Exposure Group only)**

Study of Biomarkers of Exposures and Effects in Agriculture
(to be sent in advance of the “month out” call)

Date

Dear Mr. <name or names entered here>,

I want to thank you for participating in the Agricultural Health Study’s Biomarkers of Exposures and Effects in Agriculture (BEEA) Study and for taking the time to complete the first home visit with us. You may recall that you consented to receiving two additional visits to your home: one within a day after you complete diazinon use, and one about three weeks later. You noted previously that you thought that you would {apply/make the decision about applying} diazinon in <month >.

We will be calling you within the next week to verify your schedule for applying diazinon and to find out when you may be ready to schedule the next home visit. The call will take 5 minutes or less.

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

Sincerely,

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



Dear Mr.,xxxxx

We would like to thank you once again for taking the time and effort to participate in the Agricultural Health Study (AHS) and the Study of Biomarkers of Exposures and Effects in Agriculture (BEEA). I hope we were able to answer any questions you had about our research, but if you have additional questions or concerns, please do not hesitate to contact us at any time. We are conducting the BEEA study because we are interested in changes that may occur in the blood and urine when people are exposed to occupational and environmental chemicals and substances. We are also interested in differences in other body processes that are affected by lifestyle and the environment. The material in the blood and urine samples that we collected will allow us to study these differences in relation to cancer risk, and help understand the causes of cancer and other chronic diseases.

I am enclosing a copy of the clinical lab results which were done as part of our home visit. Your [INSERT RELEVANT MEASUREMENT] was slightly elevated. You might wish to have this test repeated by your local physician.

Thank you again for your interest and participation in our research. Without the help of individuals such as you our work would not be possible. We truly appreciate the time and effort on your part to be a part of this study. Please feel free to contact us at any time if you have questions with which we can be of assistance.

Sincerely,

Neil Caporaso, MD
National Cancer Institute
Genetic Epidemiology Branch
6120 Executive Blvd. MSC 7236
Rockville, MD 20850-7236
(301) 496-4377
caporason@mail.nih.gov

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OMB NO.: 0925-0406
EXPIRATION DATE: XX/XX/2016

Attachment 17.14:

**Study of Biomarkers of Exposures and Effects in Agriculture
Contact the Field Station Letter (Both Groups)**

Date

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

Thank you for your participation in the Agricultural Health Study (AHS). We appreciate the time you have already taken over the years to complete the study 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 a little over an hour of your time. You will receive \$75.00 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 no longer in service. Could you please call [study coordinator], study coordinator, at <insert 800#> 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 17.15:

**Study of Biomarkers of Exposures and Effects in Agriculture
NC “Contact Us” Letter (Both 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 a little over an hour of your time. You will receive \$75.00 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 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.