

ATTACHMENT 23

BEEA Consent Mailing Cover Letter, Pre-Visit Preparation Show Card, and Urine Collection Instructions

- 23A. BEEA Consent Mailing Cover Letter for Iowa Respondents
- 23B. BEEA Consent Mailing Cover Letter for North Carolina Respondents
- 23C. BEEA Pre-Visit Prep Show Card for Iowa Respondents
- 23D. BEEA Pre-Visit Prep Show Card for North Carolina Respondents
- 23E. BEEA Urine Collection Instructions for Iowa Respondents
- 23F. BEEA Urine Collection Instructions for North Carolina Respondents

Attachment 23A: BEEA IA Consent Mailing/Urine Kit Cover Letter (Both Groups)

Study of Biomarkers of Exposures and Effects in Agriculture

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 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, {STREET ADDRESS/CITY/STATE/ZIP} on {DATE} at {TIME} for a home visit for the BEEA Study. Before the appointment, please take some time to review the enclosed materials, which include an information sheet, directions for collection of the urine sample, and a consent form. The consent form describes the contents of 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, 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.

***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 23B: BEEA NC Consent Mailing/Urine Kit Cover Letter (Both Groups)

Study of Biomarkers of Exposures and Effects in Agriculture

Date

Dear Mr. <name or names entered here>,

I want to thank you for taking the time to speak with us recently and for 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, {STREET ADDRESS/CITY/STATE/ZIP} on {DATE} at {TIME} for a home visit for the BEEA Study. Before the appointment, please take some time to review the enclosed materials, which include an information sheet, directions for collection of the urine sample, and a consent form. The consent form describes the contents of 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 Margaret Hayslip, study coordinator toll free at 800424-7883. 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

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Attention BEEA Study Participants!

It is important that you make the following preparations for your study visit:

Consent Form

Please take some time to review the consent form so you can be prepared to complete it with the interviewer. The interviewer will address any questions or concerns you may have at the beginning of your visit, or you may also call us at the number below.

Prescription Medications

We will be asking you about the prescription medications you take regularly. Please assemble them in their original containers so they are ready to review with the interviewer.

Pesticide Use in the Past 12 Months

We will be asking you about pesticides you have used in the past 12 months. This includes use of herbicides, insecticides, fungicides, fumigants, or other chemicals used to kill plants, insects, fungi, molds, or rodents. Do not include antibiotics, sanitizers, antimicrobial soaps, or fertilizers. For each product, we will ask for the product name, active ingredient, and EPA registration number, as well as about total days of use, and dates of most recent use. Please use the back of this card to help you prepare this information.

Urine Sample Collection

Please review the Directions for Urine Collection and the materials in the collection kit. It is very important that you collect the urine sample on the morning of your visit.

Please call us at 1-800-217-1954 if you have any questions.

In preparation for your interview, please record the product name, active ingredient, and EPA registration number of the pesticides you personally mixed, loaded, handled or applied in the past 12 months. This information is available from the product label. We will collect this information at your visit.

Product Name	Active Ingredient	EPA Registration #

Attachment 23C: 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.



Attention BEEA Study Participants!

It is important that you make the following preparations for your study visit:

Consent Form

Please take some time to review the consent form so you can be prepared to complete it with the interviewer. The interviewer will address any questions or concerns you may have at the beginning of your visit, or you may also call us at the number below.

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Urine Sample Collection

Please review the Directions for Urine Collection and the materials in the collection kit. It is very important that you collect the urine sample on the morning of your visit.

Please call us at 1-800-424-7883 if you have any questions.

In preparation for your interview, please record the product name, active ingredient, and EPA registration number of the pesticides you personally mixed, loaded, handled or applied in the past 12 months. This information is available from the product label. We will collect this information at your visit.

Product Name	Active Ingredient	EPA Registration #

Public reporting burden for this collection of information is estimated to average five minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other 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 23E. 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 23F: 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!