Building Related Asthma Research in Public Schools (New)

Principal Investigator:

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Appendix E: Consent Forms

1: Consent Form for Questionnaires and Spirometry

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

CENTERS FOR DISEASE CONTROL AND PREVENTION

U.S. PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We will explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

I. DESCRIPTION

School Study

Jean M. Cox-Ganser, Ph.D. NIOSH, Division of Respiratory Disease Studies, Field Studies Branch

You are being asked to take part in a NIOSH research study of schools. The full study is for three years. If you consent to take part this year, you do not have to participate the next two years. We will ask you every year if you want to participate. The purpose of this three-year study is to understand changes in respiratory health and environmental measures in relation to dampness over time.

The benefits to you from participating in the study include the free medical test described below. Your participation may also benefit your co-workers, and possibly other people, as a result of what is learned from this study. NIOSH will send you and your doctor (if you wish) all results from your medical test.

II. CONDITIONS OF THE STUDY

1. The study will include the following procedures:

A. Questionnaires

A.1. Current Worker Health Questionnaire: You will be asked to complete a questionnaire about your work history, health history, and health-related activities. The questionnaire will be given at the school during school hours by a NIOSH employee. It should take about 45 minutes. If you have asthma or asthma-like symptoms that improve when you are away from the school, you will be asked to take part in a medical test to look at lung function changes over time.

A.2. Former Worker Health Questionnaire (if applicable): If you stop working at the school this year, we will call you by telephone next spring to complete a short questionnaire about your health. It should take about 10 minutes.

B. Lung function test (spirometry): You will be asked to breathe in as deeply as you can and then blow out as quickly and completely as possible through a tube that you place in your mouth. You will be asked to do this at least 3 times, and possibly several more times. The testing will take place at the school during school hours. This test typically takes 10 to 20 minutes.

2. This lung function test may be tiring, and you may feel momentary light headedness, faintness, or chest discomfort. If, at any time, you feel unable to continue, the test will be terminated. Another disadvantage, besides the slight discomfort and inconvenience described above, is that a test result may be outside the range of "normal" even though nothing is wrong. This could result in a recommendation for further medical evaluation that, ultimately, may not have been necessary. If you have any comments or questions about the test, you should contact Jean M. Cox-Ganser, Ph.D. at (800) 232-2114.

3. The lung function spirometry test is a standard medical test; there is no alternative procedure.

4. Injury or harm from your participation in this project is unlikely. But if it results, medical care is not provided, other than emergency treatment. If you are injured through negligence of a NIOSH employee you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Public Health Service Claims Office: 301-443-1904. If you are injured or harmed through the negligence of a NIOSH contractor, your claim would be against the contractor, not the Federal government. If an injury or harm should occur to you as the result of your participation, you also should contact Jean M. Cox-Ganser, Ph.D., at (800) 232-2114 or Cherie F. Estill, Chair, NIOSH Human Subjects Review Board at (513) 533-8591.

5. If you have questions about this research, you should contact Dr. Jean M. Cox-Ganser, Tel (800) 232-2114. If you have questions about your rights as a member of this study, contact Cheryl F. Estill, Chair NIOSH Human Subjects Review Board, 513-533-8591.

6. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

7. NIOSH will provide you and your doctor (if you wish) with all results from your medical test. Overall study results (without names or other identifying information) will be prepared and will be available upon request.

III. USE OF INFORMATION

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control and Prevention (CDC), a government agency in the Department of Health and Human Services. We collect this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep information about you, including your results from this study, along with your social security number (if applicable), because of three laws passed by Congress. These laws are:

1. The Public Health Service Act (42 U.S.C 241)
2. The Occupational Safety and Health Act (29 U.S.C. 669)
3. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. It is up to you. If the information we are collecting is maintained and retrieved by personal identifiers, such as your name and social security number, it will become part of the CDC record system and we will protect it to the extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources. These conditions under which we might release this information are listed in Appendix A (the Privacy Act).

IV. SIGNATURES

I have read this consent form and received a copy of the conditions for data release under the Privacy Act (Appendix A). I agree to participate in this study.

PARTICIPANT NAME _____ Age _____ Date _____
(print)

_____
(signature)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE _____ Date _____
(signature)

cc: Participant

Appendix A for Consent for Questionnaires and Spirometry

The Information you provide will become part of the CDC Privacy Act System, 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records" and may be disclosed to

- **Appropriate state or local heath departments to report communicable diseases;**
- **A State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for confidentiality;**
- **Private contractors assisting NIOSH;**
- **Collaborating researchers under certain circumstances to conduct further investigations;**
- **One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;**
- **The Department of Justice or the Department of Labor in the event of litigation;**
- **Congressional offices assisting an individual in locating his or her records;**

You may request an accounting of the disclosures made by NIOSH.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.

REQUEST AND AUTHORIZATION FOR RELEASE OF INFORMATION

I, _____, request and permit the project officer to inform the following physicians or health care facilities (whose names and addresses I have entered below) of any significant findings from this study that concern me.

1. My personal physician(s):

   Dr. _____

   Street _____

   City _____State_____Zip_____

   _____

2. Other physician or health care facilities:

   Dr. _____

   Street _____

   City _____State_____Zip_____

   _____
   Participant_____Date_____

2: Consent Form for Serial Spirometry

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

CENTERS FOR DISEASE CONTROL AND PREVENTION

U.S. PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in this medical test which is part of a NIOSH research study. We will explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

I. DESCRIPTION

School Study

Jean M. Cox-Ganser, Ph.D. NIOSH, Division of Respiratory Disease Studies, Field Studies Branch

You have been asked to participate in this medical test which is part of a NIOSH research study. The purpose of this medical test is to look for changes in lung function over time in relation to work.

The benefits to you from participating in the study include the free medical test described below. Your participation may also benefit your co-workers, and possibly other people, as a result of what is learned from this study. NIOSH will send you and your doctor (if you wish) all results from your medical test.

II. CONDITIONS OF THE STUDY

1. This portion of the study will include the following procedure:

A. Serial spirometry: You will be given a hand-held spirometer to test your lung function. We will train you to use it. There will be two three-week periods. One three-week period will be during the school year, and another three-week period will be during the summer holiday. You will be asked to blow into the spirometer five sessions a day. There will be at least three blows each session. In addition, you will be asked to answer a few questions directly into the spirometer. The questions include: where you are, any respiratory symptoms, use of medicine, and cigarette smoking. You will be asked to give us your telephone number so that we can call to

help you if the quality of your blows fall or you forget to do the sessions. The total time required for this test, each day, is about 30 minutes.

2. This lung function test may be tiring, and you may feel momentary light headedness, faintness, or chest discomfort. If, at any time, you feel unable to continue, please stop the session. If you have any comments or questions about the tests, you should contact Jean M. Cox-Ganser, Ph.D. or Nancy Sahakian, M.D. at (800) 232-2114.

3. This procedure is a standard medical test; there is no alternative procedure.

4. Injury or harm from your participation in this project is unlikely. But if it results, medical care is not provided, other than emergency treatment. If you are injured through negligence of a NIOSH employee you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Public Health Service Claims Office: 301-443-1904. If you are injured or harmed through the negligence of a NIOSH contractor, your claim would be against the contractor, not the Federal government. If an injury or harm should occur to you as the result of your participation, you also should contact Jean M. Cox-Ganser, Ph.D., at (800) 232-2114 or Cherie F. Estill, Chair, NIOSH Human Subjects Review Board at (513) 533-8591.

5. If you have questions about this serial spirometry test, you should contact Jean M. Cox-Ganser, Ph.D. or Nancy Sahakian, M.D. at (800) 232-2114. If you have questions about your rights as a member of this study, contact Cheryl F. Estill, Chair NIOSH Human Subjects Review Board, 513-533-8591.

6. Your participation is voluntary and you may withdraw your consent and your participation in this portion of the study at any time without penalty or loss of benefits to which you are otherwise entitled.

   For your inconvenience, you will be reimbursed with a gift certificate to a local store for $25 for each of the three-week periods, up to a total of $50. No gift certificates will be given until your hand-held spirometer has been returned to NIOSH.

7. NIOSH will provide you and your doctor (if you wish) with all results from your medical test. Overall study results (without names or other identifying information) will be prepared and will be available upon request.

III. USE OF INFORMATION

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control and Prevention (CDC), a government agency in the Department of Health and Human Services. We collect this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep information about you, including your results from this study, along with your social security number (if applicable), because of three laws passed by Congress. These laws are:

4. The Public Health Service Act (42 U.S.C 241)
5. The Occupational Safety and Health Act (29 U.S.C. 669)
6. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. It is up to you. If the information we are collecting is maintained and retrieved by personal identifiers, such as your name and social security number, it will become part of the CDC record system and we will protect it to the extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources. These conditions under which we might release this information are listed in Appendix A (the Privacy Act).

IV. SIGNATURES

I have read this consent form and received a copy of the conditions for data release under the Privacy Act (Appendix A). I agree to participate in this study.

PARTICIPANT NAME _____ Age _____ Date _____
(print)

_____
(signature)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE _____ Date _____
(signature)

cc: Participant

Appendix A for Consent for Serial Spirometry

The Information you provide will become part of the CDC Privacy Act System, 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records" and may be disclosed to

- **Appropriate state or local heath departments to report communicable diseases;**
- **A State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for confidentiality;**
- **Private contractors assisting NIOSH;**
- **Collaborating researchers under certain circumstances to conduct further investigations;**
- **One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;**
- **The Department of Justice or the Department of Labor in the event of litigation;**
- **Congressional offices assisting an individual in locating his or her records;**

You may request an accounting of the disclosures made by NIOSH.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.

REQUEST AND AUTHORIZATION FOR RELEASE OF INFORMATION

I, _____, request and permit the project officer to inform the following physicians or health care facilities (whose names and addresses I have entered below) of any significant findings from this study that concern me.

1. My personal physician(s):

   Dr. _____

   Street _____

   City _____State_____Zip_____

   _____

2. Other physician or health care facilities:

   Dr. _____

   Street _____

   City _____State_____Zip_____

   _____
   Participant_____Date_____