Attachment 10: Respondent Consent Form for Non-employees of NIOSH

National Institute for Occupational Safety and Health (NIOSH)
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

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

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I. DESCRIPTION

1. *Title:* Aerosol Generation by Cough

2. *Project Officer:* William G. Lindsley, PhD
Biomedical Engineer (Research)
National Institute for Occupational Safety and Health
1095 Willowdale Road, MS 2015
Morgantown, WV 26508
304-285-6336

3. *Project Purpose and Benefits:* The purpose of this study is to measure the size and number of small droplets produced by people when they cough. The information we get in this study will help us learn how to keep diseases from spreading by coughing. This study also will help us design better face masks to protect people. The results of this study do not tell anything about your own health, and will not directly benefit you.

II. CONDITIONS OF THE STUDY

1. *Test procedures:* At the beginning of the session, you will be asked to answer a few written questions about your health, including any respiratory problems or illnesses you may have. One of us will then explain the procedure to you. You will be asked to sit with your head and shoulders inside a box with clear sides. The box will blow air down over you during the test. First, you will be asked to sit quietly for 10 minutes. Next, you will be asked to exhale completely, inhale as much as possible, seal your lips around a disposable cardboard mouthpiece, and

cough. We would like for you to cough hard using as much of the air in your lungs as you can. After you cough, you will be asked to sit quietly for about 10 minutes while we analyze your cough. You will be asked to cough again twice more for a total of 3 coughs. The entire session will take about 1 hour. If you are willing, you may be asked to participate in up to 5 sessions. You can wear contact lenses or glasses during these tests. You can eat and drink before and after the test. During the test you may not eat, drink, smoke, or chew gum.

2. Risks or discomforts: During the study, you will be asked several times to take a deep breath and cough hard. There is a slight possibility that this may cause you to become dizzy or faint. Other than this, you should not be at any risk or experience any discomfort during this study. If you have any comments or problems because of the test procedures, you should call William G. Lindsley at 304-285-6336.

3. Alternative procedures: There are no different tests or procedures that will provide the information we need for our study.

4. Possibility of injury: It is very unlikely that you will be hurt as a result of these tests. However, if you are hurt, we will not provide medical care 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 you should contact the Public Health Service Claims Office at 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 William G. Lindsley at 304-285-6336. You can also contact Cheryl F. Estill, Chair, NIOSH Human Subjects Review Board, 4676 Columbia Parkway, Cincinnati, OH 45225, 513-533-8591.

5. Questions: If you have questions about this research, you can contact William G. Lindsley at 304-285-6336. If you have questions about your rights as a member of this study, you can contact Cheryl F. Estill, Chair, NIOSH Human Subjects Review Board, 4676 Columbia Parkway, Cincinnati, OH 45225, 513-533-8591.

6. Participation is voluntary: Your participation in this study is completely voluntary. You may withdraw your consent and end your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled. You will receive compensation of $20.00 for each session of this study in which you participate. If you decide to leave before completing the study, you will be compensated at a rate of $20 per hour for the time you spend in the study.

7. Notification of results: Your test results from this study don't tell anything about your own health. For this reason, we will not send you a copy of your test results.

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 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 I agree to participate in this study.

PARTICIPANT		AGE		DATE	
	(signature)				

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

REPRESENTATIVE		DATE	

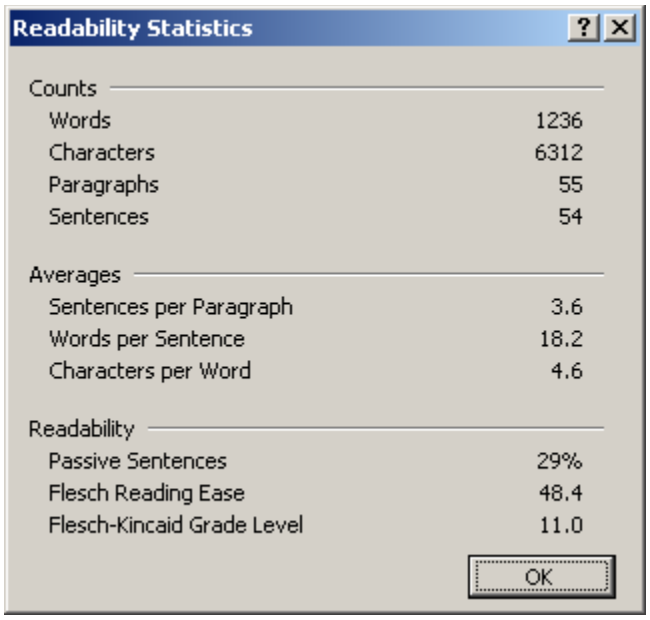
	(signature)		

Appendix A

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.


Readability Statistics
Counts
Words 1236
Characters 6312
Paragraphs 55
Sentences 54
Averages
Sentences per Paragraph 3.6
Words per Sentence 18.2
Characters per Word 4.6
Readability
Passive Sentences 29%
Flesch Reading Ease 48.4
Flesch-Kincaid Grade Level 11.0
OK