Persistence of Viable Influenza Virus in Aerosols

Request for Office of Management and Budget Review and Approval
for Federally Sponsored Data Collection

Attachment 10:
Informed Consent Form
for Phase 3

Project Officer: William G. Lindsley, PhD
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Form Approved
OMB No. 0920-xxxx
Exp. Date xx/xx/20xx

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
1095 Willowdale Road
Morgantown, WV 26505-2888

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:* Persistence of Viable Influenza Virus in Aerosols

2. *Project Officer:* William G. Lindsley, PhD
Biomedical Engineer (Research)
National Institute for Occupational Safety and Health
1095 Willowdale Road, MS 4020
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 that people with influenza produce when they cough. The information we get in this study will help us learn how to keep diseases from spreading by coughing. You will receive a test for influenza and the results will be provided to you. Aside from this, 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 questions about your health, including any respiratory problems or illnesses you may have. Your oral temperature will be taken, and a nasal swab

will be taken from you to test you for the influenza virus. Next, you will be asked to sit quietly in an examination room for 20 minutes while coughing and breathing normally. The entire session will take about 30 minutes. 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.

If your health care provider performed a rapid influenza test on you, the results of your test will be provided to us. If your health care provider did not perform a rapid influenza test on you, we will administer the test and give the results to you and your health care provider. Aside from this, we will not have access to any of the information you may have given to your health care provider.

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 Claims Office of the General Law Division of OGC at (202) 233-0233. 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 be reimbursed $25 for your time and inconvenience for each session of this study in which you participate. If you decide to leave before completing the study, you will be reimbursed at a rate of $25 per hour for the time you spend in the study.

7. Notification of results: You will receive a test for influenza and the results will be provided to you at the end of each session. Aside from this, 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, 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, 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). The information you provide to us will be retained for three years and then destroyed.

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;
- 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.