

Attachment 4: Informed Consent Form



Consent to be in a Research Study

“Factors Influencing the Transmission of Influenza”

1	Who is conducting the study?	NIOSH is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC). NIOSH is partnering with the West Virginia University Health Sciences Center on this study. Under the Occupational Safety and Health Act (29 USC 669), NIOSH is allowed to collect information to conduct research relating to occupational safety and health.
2	What is the purpose?	The purpose of this study is to measure how much influenza virus people with influenza breathe and cough out while they are sick. The information we get in this study will help us learn how to keep diseases from spreading.
3	What will I do?	First, you will be asked to fill out a short questionnaire about your health. Your oral temperature will be taken, and two nasal swabs will be collected from you. Next, you will be asked to don a mask and breathe and cough normally for 40 minutes. While you are doing this, a collection system will collect the cloud of airborne particles that you produce. Finally, 5 ml of blood will be collected from you.
4	When, where, for how long will I be needed?	The study will be conducted at the WVU Medicine clinic. You will be asked to participate in one session, which will take about 95 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.
5	Are there any risks?	During the study, you will be asked to provide a blood sample. 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. Possible risks to your privacy are discussed in item 10 below.

Public reporting burden of this collection of information is estimated to average 15 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 CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0888)

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6	Is my participation voluntary?	The study is voluntary. You may choose to be in the study or not. You may choose to answer any or all questions. You may drop out any time for any reason without consequences to you.
7	What if I’m injured or harmed?	Emergency medical services will be called if you need them. Medical care or compensation will not be provided. If harmed through negligence of a NIOSH employee, you might obtain compensation under Federal Law. If a NIOSH contractor is negligent, you can file a claim with that contractor.
8	Will I receive a token of appreciation after my participation?	You will be given a \$40 gift card as a token of appreciation for your participation. If you decide to leave before completing the study, you will still receive a \$25 gift card for each hour of your participation up to a maximum of \$40 in gift cards.
9	Are there other benefits?	There are no direct benefits to you from participating in this study. However, you will help us to understand more about how influenza spreads from person to person and how we can prevent it, which will help everyone.
10	Will my personal information be kept private?	<p>We will not have access to any of your medical records or personal information other than the information that you provide to us in the health questionnaire and the results from our tests. There is a small risk to the privacy of your personal information from participating in this study. We will make every effort to keep your personally identifiable information secure and will protect it to the extent allowed by law. There are conditions under the Privacy Act where your information may be released to collaborators or contractors, health departments or disease registries, to the Departments of Justice or Labor, or to Congressional offices.</p> <p>Written study records will be kept in a locked file cabinet in the Morgantown NIOSH facility. Only the investigators of the study will have access to records that include test subjects’ names or other data that might allow identification. Electronic records will use a code number only and will not include your name or other information that would allow you to be identified. All personal identifiable information will be destroyed after 20 years.</p>

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11	Will I or anyone else receive study results?	The results of this study do not tell anything about your own health, and thus will not be sent to you or anyone else. The results from all participants will be described in scientific publications and reports, but these will not include information that will allow you to be identified.
12	Who can I talk to if I have more questions?	For questions about the research study, contact the principal investigator, William G. Lindsley at wlindsley@cdc.gov or 304-285-6336. For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board (IRB) in the Human Research Protection Program at 513-533-8591.
13	Your signature	<p>The study was explained to me. My questions were answered. I agree to be in the study.</p> <p>_____</p> <p>Printed name of participant</p> <p>_____</p> <p>Participant signature Date</p> <p>I have accurately described this study to the participant.</p> <p>_____</p> <p>NIOSH representative signature Date</p>