**Persistence of Viable Influenza Virus in Aerosols**

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

Section B

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December 2010

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# Section B. Data Collection Procedures

## *B1. Respondent Universe and Sampling Methods*

Volunteer subjects will be recruited from local health care clinics, primarily including the student health service at West Virginia University. Flyers and advertizing posters will be placed in the waiting rooms of the clinics, and a recruiter will be available in the waiting area to explain the study and answer any questions that potential participants may have. For the convenience of the participants, all testing will be carried out in the clinics at the time of recruitment. This study will not interfere with the normal operation of the clinics. The study participants must meet the following eligibility criteria:

- Male or female adult ages 18 to 35.
- Symptoms of influenza-like illness (fever, headache, fatigue, cough, sore throat, muscle aches).
- Symptoms present for 72 hours or less.
- Not vaccinated against influenza during the current season.
- No other respiratory illness such as severe asthma, COPD or tuberculosis.
- Otherwise good health with no underlying illnesses.
- Not pregnant.
- No medical condition or illness that would make it difficult or uncomfortable for them to perform the test procedure.

Because it is not possible to accurately screen participants for influenza at the clinic in a timely manner, all eligible subjects with febrile respiratory illness who volunteer will be allowed to participate in the study.

## *B2. Procedures for the Collection of Information*

***Study Design***

The objective of this study is to measure the amount of viable influenza virus in airborne particles that are produced by patients when they cough, and the size and quantity of the particles carrying the virus. The project will be carried out in three phases, with one phase being conducted each year during influenza season:

*Phase 1:* Forty subjects will be asked to cough three times into a piston-style medical spirometer, and the cough aerosol particles will then be collected using aerosol samplers (aerosol samplers are devices that separate airborne particles by size and collect them).

*Phase 2:* Forty subjects will be asked to sit in an examination room and cough three times through an ultrasonic spirometer in a specified direction. An array of aerosol samplers located throughout the examination room will collect the cough aerosol particles.

*Phase 3:* Forty subjects will be asked to sit in an examination room for 20 minutes while they cough and breathe normally. An array of aerosol samplers located throughout the examination room will collect the cough and breathing-generated aerosol particles.

This work will be carried out when influenza activity is reported to be elevated in the community. Volunteers will be screened initially using a health questionnaire to verify that they have influenza-like symptoms and that they meet the health requirements for the study. If the volunteer is eligible and chooses to participate in the study, they will be asked to read and sign the informed consent form. A nurse or medical technician will measure the subject's oral temperature, and collect three nasal swabs which will be tested for influenza virus. The volunteer will then be asked to carry out one of the tasks described in the test phases above.

### *Apparatus*

The test apparatus for Phase 1 is shown in Figure 1 below. Before each test, the piston spirometer is purged and partially filled with 5 liters of clean dry air. When the patient coughs into the system mouthpiece, the cough flows through an ultrasonic spirometer which measures the cough volume and flow rate. The cough then flows through a valve and into the piston spirometer, displacing the piston to the right. When the subject has finished coughing, the valve is closed and the aerosol sampler is turned on. The cough aerosol is pulled out of the spirometer and collected by the aerosol sampler. As the aerosol sampler draws air, the piston moves to the left until no air remains in the spirometer. After the cough aerosol has been collected, a viral preservation media is added to the sample tubes containing the cough aerosol particles and the samples are placed on ice. After returning to the lab, any virus in the samples is then cultured by allowing it to infect Madin Darby canine kidney (MDCK) cells grown in tissue

culture flasks. The presence of infectious virus is evaluated using a standard viral plaque assay.

For Phase 2, the ultrasonic spirometer will also be used, but the subject will cough directly into the room and the cough aerosol will be collected using an array of aerosol samplers. Aerosol samples will be processed in the same manner as described for Phase 1.

For Phase 3, the subject will not be required to cough into any apparatus, but will only be asked to sit quietly and breathe and cough normally for 20 minutes. Aerosol samples will be processed in the same manner as described for Phase 1.

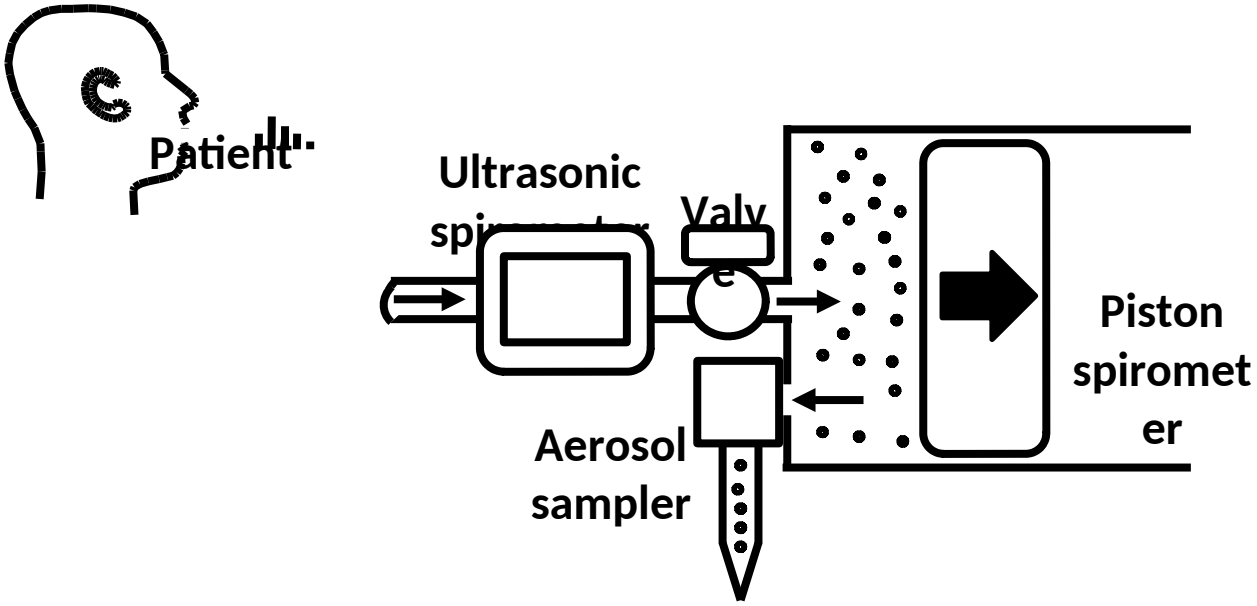


**Figure 1: Cough aerosol particle collection system.**

## *B3. Methods to Maximize Response Rates and Deal with Nonresponse*

We will continue to recruit until each phase of the study has been completed. Respondents will be encouraged to participate in the study by incentive payments as described in Section A9. Previous experience with recruiting paid volunteers has indicated that this should not be a problem.

## *B4. Tests of Procedures or Methods to be Undertaken*

The health questionnaire and informed consent forms used in this study are very similar to those used in a previous NIOSH study, "Experimental and Theoretical Study of Early Detection and Isolation of Influenza" (OMB No. 0920-07AW). The

cough aerosol collection system was also used in the previous study and has been adapted for use in the present work.

## *B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data*

The data collection procedures were designed by the project officer, who will also perform the data collection and analysis:

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