



Initials: _____ Date: _____

Institutional Review Board

1204 Marie Mount Hall • 7814 Regents Drive • College Park, MD 20742 • 301-405-4212 • irb@umd.edu

CONSENT TO PARTICIPATE

Project Title	Contagious Phenotypes of Acute Respiratory Infection: Identification, Characterization, and Biomarkers {Characterizing And Tracking College Health (CATCH)- the Virus Study}
Purpose of the Study	This research is being conducted by Donald Milton, MD, DrPH and a team of researchers at the University of Maryland with funding from the U.S. Defense Advanced Research Projects Agency. We are inviting you to participate in this part of the research project because you have enrolled in the study early and have no current symptoms of illness. The purpose of this research project is to identify biomarkers (measurable substances within a person) that can indicate which individuals, when exposed to viruses and bacteria that cause Acute Respiratory Infections (ARI), are likely to become contagious and spread the ARI to others, and to improve our understanding of how ARI are transmitted so that we may better prepare to mitigate or prevent future epidemics and pandemics of influenza and other ARIs.
Procedures	<p>BASELINE SAMPLE COLLECTION</p> <p>If you are at least 18 years of age and have recently enrolled in the study, have no current symptoms of respiratory illness within the past week and are not currently being recruited as a contact, and you agree to participate in this part of the study, we will invite you to come to our study clinic in the School of Public Health for up to 2 visits: once at the time of study entry and a second visit near the end of the spring semester.</p> <p>STUDY ENTRY BASELINE SAMPLE VISIT</p> <p>Study personnel will first ask you to answer a standard set of respiratory symptom questions, unless you just enrolled in the study and completed these questions today as part of the baseline survey, and will use a standard thermometer to measure and record your oral temperature. Based on this data, there is a slight chance that study personnel may determine you are no longer eligible for the visit today and will ask you to reschedule for a later day, but if that occurs you may be invited to complete a different type of visit instead. In most instances the visit will proceed, and study personnel will measure and record your height and weight and will collect the following samples: a nail sample, two nasal swabs, and a venous blood sample.</p> <p>To collect the nail sample, you will be asked to use a sterilized nail clipper to obtain a clipping from each of your fingernails. The nail sample will be stored for later use to measure your cortisol level, a biomarker of chronic</p>

stress, and other biomarkers relevant to risk of ARI, should such biomarkers become available. A professional study staff member (physician, nurse, professional medical technician or highly trained graduate student) or a trained undergraduate research assistant under physician supervision will collect 2 mid-turbinate nasal swabs. Prior to obtaining the swabs, trained study personnel may use a small penlight to look inside your nostrils, and they will collect or will instruct and assist you (if you previously had the procedure done and you wish to collect your own samples) in collecting two nasal swabs. These swabs will be collected in the following manner: a small, soft, contoured swab made specifically for this procedure will be inserted into your nostril until the stopper along the shaft is just outside the opening of your nose, the swab is rotated to obtain a sample from inside your nose, then the swab is withdrawn and placed into a collection tube. This process will be repeated with a second swab to obtain a sample from inside the other nostril, unless there is an obstruction or other reason to avoid sampling, in which case two swabs may be collected from the same nostril. These swabs will be used to test for a wide variety of respiratory infectious agents and a detailed analysis of your microbiome (microbes that typically live at the entrances to your respiratory tract), and biomarkers of infection, susceptibility, and contagiousness. A study physician, nurse or trained phlebotomist will use a small butterfly needle and standard aseptic technique to collect a relatively small amount (20-50 ml, amount depending on funding for more detailed analysis) of blood from a vein in your arm. The maximum amount that would be removed (50 ml) is slightly less than the amount in 3.5 tablespoons. The blood will be tested for biomarkers of infection, susceptibility and contagiousness. We estimate that the visit may take approximately 25-35 minutes.

STUDY COMPETITION VISIT (late spring semester)

Regardless of whether or not you participate in case or contact testing during the study, you will be asked to return to the study clinic for a study completion visit near the end of the spring semester. You will be asked to complete a follow-up on-line baseline survey (or to complete an identical questionnaire in person at the visit) to update some of the information you provided when entering the study, including time spent in your room, recent respiratory symptoms and illness, recent stress, and your sleep, exercise, smoking, and alcohol habits.

We will ask you to schedule an appointment in the School of Public Health to measure your height and weight and oral temperature, and to provide the following samples: a nail sample, 2 mid-turbinate nasal swabs, and a moderately small (20-50 ml) venous blood sample. These are the same samples that were obtained at the study entry baseline visit, and they will be collected and tested in the same manner as described previously. We

	<p>estimate this entire visit, including updating questions in the database plus sample collection, should take approximately 20-30 minutes.</p>
<p>Potential Risks and Discomforts</p>	<p>Your participation in this portion of the study will take time away from other activities or rest; we will try to keep each visit as short as possible and minimize wait times through efficient scheduling of appointments. You may feel some slight embarrassment when providing information about your medical history and habits, but this will be minimized by collecting the information in a private setting on a computer or tablet. There is a small risk to your privacy and confidentiality, as we will be collecting a variety of personal information from you; we will do our best to keep your personal information confidential and limit access to only essential personnel. All data will be transmitted between the tablet or computer used to enter the data and the server via encrypted connections and the server will be housed in a secure data center.</p> <p>During nail sampling there is a small chance the skin on your fingers could be nicked, but we will minimize this risk by asking you to clip your own nails with caution and to avoid clipping your nails too short. You may experience some mild pressure or discomfort, a tickling sensation, or occasional eye watering or sneezing when the nasal swabs are collected. In rare instances swabbing inside the nose may cause very minor bleeding. When having your blood drawn, you may feel some discomfort from having a tourniquet placed around your arm; you will likely experience a small amount of pain at the site where the needle enters the skin. There is also a slight risk of bruising or infection at the site, and some people become lightheaded or feel faint when having blood drawn or at the site of blood; the staff members who will draw your blood are trained to minimize these risks. The maximum amount of blood that would be drawn at each visit (50 ml) is far less than the amount typically removed at one time for a blood donation (450-500 ml).</p>
<p>Potential Benefits</p>	<p>There are no direct benefits to participating in the baseline sample collection part of the study. However, joining the study and participating in an early visit where you provide baseline samples at study entry may increase the likelihood that you will also participate in the case and contact components of this study, and possible benefits of that participation would occur if we detected that you were infected with pathogens that can and should be treated or for which early treatment may be advantageous. Although most of the pathogens that cause ARI do not require specific treatment (such as the viruses that cause common colds), we may occasionally identify pathogens that can and should be treated or for which early treatment may be advantageous.</p> <p>We hope that, in the future, other people might benefit from this study through improved understanding of how acute respiratory infections spread and identification of biomarkers that can predict contagiousness, in order to limit the spread of respiratory infections like influenza.</p>

<p>Confidentiality</p>	<p>Any potential loss of confidentiality will be minimized by storing all data in an encrypted database maintained on a secure server housed in a high security data center. Only essential study personnel will have access to this data. Access to data elements will also be controlled so that only staff with an operational need for particular information will have access to sensitive information (for example social security numbers), and undergraduate research assistants will only have access to the clinical research database while working in the clinic under senior staff supervision.</p> <p>If you decide to participate in the study, you will be assigned a subject ID number which will be used to access your records in the database. All biologic samples will be labeled with a unique sample ID that can only be linked to your subject ID number by Dr. Milton and his designated research staff.</p> <p>Collaborators within and outside the University of Maryland may conduct analyses on samples or data for research purposes, but all such samples or data will always be de-identified. If we write a report or article about this research project or post information on the study website, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law.</p> <p>The Code of Maryland Regulations (COMAR) 10.06.01.03 C, requires reporting to the Maryland Department of Health and Mental Hygiene of certain illness including personally identifiable information in the event of “any grouping or clustering of patients having similar disease, symptoms, or syndromes that may indicate the presence of a disease outbreak,” that poses a danger to public health. It also requires reporting of cases of Measles, Mumps, Pertussis and Legionellosis, which will be tested for in samples that we collect. Measles is a highly contagious virus that causes respiratory infection and rash, and Mumps is a somewhat less contagious viral illness that typically causes swollen tender salivary glands. Pertussis, also known as whooping cough, is a highly contagious bacterial respiratory infection, and Legionellosis is a bacterial infection that can cause pneumonia or flu-like illness. Measles, Mumps, and Pertussis can all be prevented through proper vaccination.</p> <p>Any unanticipated problems involving risks to participants or others such as unexpected or serious adverse events, non-compliance, audits, and investigation reports will be promptly reported to the University of Maryland Institutional Review Board, as well as both the U.S. Department of the Navy and Space and Naval Warfare Systems Center Pacific Human Research Protection Programs.</p>
<p>Medical Treatment</p>	<p>The University of Maryland does not provide any medical, hospitalization or other insurance for participants in this research study, nor will the University of Maryland provide any medical treatment or compensation for</p>

	<p>any injury sustained as a result of participation in this research study, except as required by law.</p>
<p>Compensation</p>	<p>STUDY ENTRY BASELINE SAMPLE COLLECTION VISIT You will receive up to \$ 50 (includes a \$10 bonus for being on-time for your appointment) if you complete this visit.</p> <p>STUDY COMPLETION SURVEY and/or VISIT You have the potential to earn up to \$60 if you complete the follow-up baseline survey or questionnaire and provide your biologic samples at a study completion visit (see details below).</p> <ul style="list-style-type: none"> • You will receive \$10 for completing the baseline follow-up survey, either on-line or as part of the study completion visit • You will receive \$50 (this includes a \$10 bonus for being on-time) when you provide your samples at the study completion visit <p>PLEASE NOTE: You must complete the questionnaire and provide your samples before the end of the spring semester to receive the compensation, and you must complete the survey in order to receive compensation for the study completion visit.</p> <p><i>Because you have the potential to earn more than \$100 as a research participant in this study, you must provide your name, address, and SSN to receive compensation. If you decline to provide this information you can still participate in the study, but you will not be able to receive compensation.</i></p> <p><i>You will be responsible for any taxes assessed on the compensation you receive during this study.</i></p> <p>You may choose to receive compensation payments via one of two payment methods: a) the Terrapin Express account linked to your University identification number (UID), which allows purchase at over 50 locations on campus and for which the Bursar's Office will mail a check to your permanent address on cancellation of the account, or b) a University issued debit card onto which funds will be electronically transferred. We will not make any cash payments other than by electronic means.</p>
<p>Right to Withdraw and Questions</p>	<p><i>Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify. Your academic standing as a student or employability at UMD will not be affected by your</i></p>

	<p><i>participation or non-participation in this study.</i></p> <p>Special notice for research assistants: If you are a student working on this study and earning course credit for your work, your grade will not be affected by your decision to participate (or not participate) in this portion of the study.</p> <p><i>If you decide to stop taking part in the study, if you have questions, concerns, or complaints, or if you need to report an injury related to the research, please contact the investigator:</i></p> <p style="text-align: center;">Dr. Donald Milton Room 2234V SPH Building 255 University of Maryland College Park, MD 20742 Telephone: 301-405-0389 Email: dmilton@umd.edu</p>	
<p>Participant Rights</p>	<p><i>If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:</i></p> <p style="text-align: center;">University of Maryland College Park Institutional Review Board Office 1204 Marie Mount Hall College Park, Maryland, 20742 E-mail: irb@umd.edu Telephone: 301-405-0678</p> <p><i>This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.</i></p>	
	<p style="text-align: center;">[Consent Form Quiz, see attachment 1 below, will be inserted here in the electronic version of this consent document.]</p>	
<p>Statement of Consent</p>	<p>Your signature indicates that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You will be sent a copy of this signed consent form via email, which you may print.</p> <p>If you agree to participate, please type your name and sign below.</p>	
<p>Signature and Date</p>	<p>NAME OF PARTICIPANT [Please Print]</p>	
	<p>SIGNATURE OF PARTICIPANT</p>	
	<p>DATE</p>	
<p>Witness/Study Personnel</p>	<p>NAME [Please Print]</p>	

	DATE	
--	-------------	--

ATTACHMENT 1

CONSENT FORM QUIZ

[Note to Staff: If the participant answers any of the following questions incorrectly, you must discuss these responses and review the correct answer with participant.]

- | | TRUE | FALSE |
|--|--------------------------|--------------------------|
| 1. No blood samples are collected at this visit. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I will be asked to complete a similar visit at the end of spring semester. | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. In order to receive compensation, I will be asked to provide my social security number. | <input type="checkbox"/> | <input type="checkbox"/> |