

University of Maryland College Park

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 either recently developed symptoms of an Acute Respiratory Infection (ARI) or have developed an ARI while being followed as a close contact. 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 epidemics and pandemics of influenza and other ARIs.
Procedures	<p>IN-DEPTH CASE ASSESSMENT</p> <p>If you have cold or flu symptoms and were selected for additional testing or you have a positive virus test through contact testing in our laboratory, are at least 18 years old, and you agree to participate in this part of the study, we will ask you to come to our study clinic and case evaluation lab in the School of Public Health (SPH) for up to two visits approximately one week apart..</p> <p><i>NEW Study Participants: If you have not already enrolled, we will first ask you to join the study (a separate consent form is required, entitled Cohort Consent) and to complete a baseline survey for new study participants. This consent form and survey can be completed on-line prior to your first study visit. In addition, if you haven't already done so, we will ask you to download and use a cell phone app (separate consent required), which tracks your location and the amount of time that 2 or more users spend together. This app will help to assess and measure the exposure between you and your contacts.</i></p> <p><i>ALL Participants:</i></p> <p>At the beginning of the in-depth case visit we will measure and record your oral temperature using a standard thermometer, and if this is your first in-clinic study visit, we will also measure and record your height</p>

University of Maryland College Park

	<p>and weight. We will ask you to complete a set of standard respiratory infection symptom questions and a brief questionnaire, which contains questions about health care visits for evaluation of your symptoms, recent use of cold and flu medications, and use of the phone app. Unless you are a new study participant who joined the study today and just answered the baseline questionnaire, we will ask you about your recent exposures, stress, sleep, exercise, smoking, and alcohol intake. We will also ask about your class attendance and time spent in various campus locations over the past 24 hours, and we will ask you to characterize your contact with up to 4 close contacts during that time period, particularly roommates and household members.. We will provide you with contact recruitment flyers that you can give your contacts to encourage them to enroll in the study, if you would like to do that. In addition, if you haven't already done so, we will ask you to download and use a cell phone app (separate consent required) that tracks your location and the amount of time that 2 or more users spend together. This app will help to assess and measure the exposure between you and your contacts.</p> <p>We will then collect samples from you, including a swab of your cell phone to look for infectious agents. 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 or will help you to 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 for this study and you wish to collect your own samples) in collecting two nasal swabs. These swabs will be collected in the following manner: a soft, sterile swab that is 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 briefly rotated, then withdrawn and placed into a collection tube. This process will be repeated with a second swab to collect a sample from your other nostril, unless there is an obstruction or other reason to avoid sampling, in which case 2 swabs may be obtained from the same nostril. One swab will be tested for a wide variety of respiratory infectious agents within approximately 24 hours to confirm that you have an infection. The other will be saved for a later more detailed analysis of the infectious agents, microbiome (the microbes that typically live at the entrances to your respiratory tract), and biomarkers of infection, susceptibility, and contagiousness. Trained study personnel will also collect a very small amount (up to 0.3 ml) of capillary blood using either a finger-stick,</p>
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University of Maryland College Park

	<p>which obtains capillary blood from the tip of your finger(s), or a new micro-needle capillary blood collection device that obtains blood from your upper arm. For the finger-stick, we may ask you to warm and/or massage one of your fingers prior to personnel wiping it with an alcohol pad and using a sterile, push-button lancet to prick your fingertip. We will then massage or may ask you to help massage your finger to form drops of blood in order to collect several drops into a capillary collection tube. The alternative involves a device that uses multiple micro needles to pierce the skin of your upper arm. For this method, trained study personnel will wipe your preferred upper arm with an alcohol pad and the device will be affixed to the sterilized portion of your arm using the adhesive backing. Once in place, the button on the device will be pushed and the device will be kept in place on your arm for about 3 minutes or until the capillary tube is filled. The blood sample will be used to test for biomarkers of infection, susceptibility, and contagiousness.</p> <p>Depending on funding, there is a possibility that you may be selected and asked if you are willing to provide a relatively small amount of venous blood, instead of providing the capillary blood sample. If you agree, a study physician, nurse or trained phlebotomist will use a small butterfly needle and standard aseptic technique to collect up to 50 ml of your blood from a vein in your arm; this is slightly less than the amount in 3.5 tablespoons and is far less than the amount of blood typically removed at one time for a blood donation (450-500 ml). The venous blood sample will undergo a more detailed analysis for biomarkers of infection, susceptibility, and contagiousness.</p> <p>We will then ask you to sit in a booth with clean, filtered air and breathe into a large funnel or cone, which is part of an apparatus that collects particles in your exhaled breath, coughs, and sneezes. You will sit in the booth for 30 minutes, and during this time you will be asked periodically to talk or recite the alphabet (three times). We will also count the number of times you cough and sneeze while providing the exhaled breath sample, either by direct observation or by asking you to wear a microphone so that we can count your coughs and sneezes later. We estimate the entire visit (including answering questions, swabbing your phone and nose, collecting your blood, and sitting in the booth) will take approximately 60 minutes. If the breath collector is not available, you will have a shorter visit but receive the same compensation.</p> <p>IF you completed a brief case visit for your current illness and are unable to come to the School of Public Health within approximately 24 hours for an in-depth case visit, we will ask you to instead complete a much shorter alternative in-depth visit. This visit may occur in the study clinic</p>
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University of Maryland College Park

	<p>in SPH or may possibly be scheduled as an in-home visit, if clinic personnel are available and site conditions allow. During this visit you will be asked to complete a questionnaire which will ask about your symptoms, medication use, class attendance and location data, as well as your recent stress, sleep, exercise, smoking, and alcohol use (unless you are a new participant who joined the study today and just answered these questions on the baseline survey). You will also be asked to name and characterize your close contacts over the past 24 hours; if any new contacts are identified that are not enrolled in the study, we may ask you to give your contacts a recruitment flyer. During this visit trained study staff will measure and record your oral temperature, obtain a swab of your cell phone to look for infectious agents, and collect (or assist you in collecting) 2 mid-turbinate nasal swabs in the same manner as described previously. If the visit occurs in SPH and it is your first in-clinic visit, we will also measure and record your height and weight. We estimate this visit will take about 20-30 minutes.</p> <p>At the end of your in-depth or alternative case visit we may ask you to take a portable CO₂ monitor home with you (or to allow study personnel to place it in your room) for approximately 1 week to help us measure and understand your environmental exposures. We will ask you to bring it back to the clinic at your 1-week case visit (see below). If you want the monitor to stop collecting data before a week is over, you can return it early; we will retain the data collected unless you specifically request it to be deleted. In the event that you think you have lost the monitor, please notify us; you will not be charged, but can earn compensation if the monitor turns up and you return it.</p> <p>IF we confirm that you are infected with one of several respiratory infectious agents we are studying (e.g. influenza virus) by analysis of the swabs we collect from you, we will also ask you to return to our lab in SPH for a short 1-week case visit approximately 7 days after your in-depth case or alternative visit. At this visit, you will be asked to complete a questionnaire to update your symptoms, related medications, healthcare visits, and course of illness. Your oral temperature will be measured and recorded, and 2 mid-turbinate nasal swabs will be collected and analyzed in the same manner as described previously We estimate this follow-up visit will take about 10-15 minutes.</p> <p>PLEASE NOTE: If we do not detect one of the specific targeted respiratory infectious agents in the swabs collected at your first visit, we will cancel your 1-week follow-up visit, and you will not receive compensation for recruiting your contacts.</p>
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	<p>Your test results may be reported anonymously on our study website to update a summary of the numbers and types of infections detected in the study group. Many of the infectious agents we are testing for do not typically require treatment with prescription medication. We will notify you if you have an infection that should be treated and refer you to a healthcare provider. Otherwise, if you are curious to know what kind of virus we found in your swabs, you are free to call us and talk with one of the senior clinical research staff.</p> <p>STUDY COMPLETION SURVEY and/or VISIT (late Spring Semester):</p> <p>All study participants will be asked to complete a second baseline survey near the end of the spring semester. In addition, if you complete an in-depth case visit or provide a blood sample during the study, we will also invite you to return to the study clinic for a study completion visit during this same timeframe. You will be asked to complete a follow-up on-line baseline survey (or 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 in your room, recent respiratory symptoms and illness, and your sleep, exercise, smoking, and alcohol habits.</p> <p>IF you are eligible for a completion visit (those who complete an in-depth visit or who otherwise provide a blood sample for the study), we will ask you to schedule an appointment in the School of Public Health to measure your height, weight, and oral temperature, and to provide the following samples: a nail sample, 2 mid-turbinate nasal swabs, and a venous blood sample. The nasal swabs will be collected and tested in the same manner as described previously. 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 stress, and other biomarkers relevant to risk of ARI, should such biomarkers become available. A study physician, nurse or trained phlebotomist will use a small butterfly needle and standard aseptic technique to collect a moderately small (20-50 ml, amount depending on funding for more detailed analysis) sample of blood from a vein in your arm. The maximum amount that would be removed (50 ml) is approximately 1.7 fluid ounces or the amount in 10 teaspoons. The blood will be tested for biomarkers of infection, susceptibility and contagiousness. We estimate this entire visit, including updating questions in the database plus sample collection, should take approximately 30-45 minutes.</p>
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University of Maryland College Park

<p>Potential Risks and Discomforts</p>	<p>Your participation in this portion of the study will take time away from other activities or time you may have spent resting and recuperating from your illness; we will try to keep each visit as short as possible and minimize wait times through efficient scheduling of appointments. You may not feel well while participating in this part of the study due to symptoms of your illness, but participation should not exacerbate your symptoms any more than a visit to a health care provider. You may feel some embarrassment when providing information about your recent illness, medical history, and habits, but this will be minimized by collecting the information in a private setting on a computer or tablet and should be no greater than experienced during a doctor visit. 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 study 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.</p> <p>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 providing your capillary blood sample you may feel a small amount of brief pain or discomfort at the site where the lancet needle pricks the skin on your fingertip (if a finger stick is performed) or at the site on your upper arm (if a micro-needle capillary blood collection device is used). If you provide a venous blood sample you may feel some discomfort from having the tourniquet placed around your arm, and you will likely experience a small amount of pain at the site where the needle enters the skin. There is also a very small risk of bruising or infection at the site where the capillary or venous blood samples are taken, and some people become lightheaded or feel faint at the site of blood or when blood is drawn; the staff members who will collect your blood samples are trained to minimize these risks. If you provide a nail sample for the study completion visit, there is a small chance that the skin on your fingers could be nicked, but we will minimize this risk by asking you to clip you own nails with caution and to avoid clipping your nails too short. There is no known risk from breathing warm, humidified HEPA (High Efficiency Particulate Arresting -- removes $\geq 99.94\%$ of particles in the air) filtered air, but you may feel uncomfortable sitting in the booth with your face at the entrance to the large funnel used to collect your exhaled breath, particularly if you suffer from claustrophobia. You may wear headphones and listen to your own entertainment during the session. If</p>
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University of Maryland College Park

	<p>you are selected and agree to place a portable CO₂ monitor in your room, this will add a small amount of extra weight (approximately 10 ounces) when you are transporting it to and from the clinic and may be slightly inconvenient, but poses no other risk.</p> <p>If you schedule an in-home/in-room visit, you will be asked questions about your residence and household to confirm that a visit is feasible, and you may feel slightly uncomfortable about having study personnel come to your home. You may be asked to meet study personnel at the entrance of your building to escort them to your room, apartment, or other suitable private setting. All study personnel will have a study ID badge and will be deployed in teams of two, with at least one person of your same gender whenever possible, to minimize personal safety concerns. If you have a roommate in an on-campus residence hall, you may be required to provide us with your roommate(s) contact information so that we may obtain their permission to allow the visit to take place in your shared room, and if you wish the visit to occur in private, you may need to ask your roommate(s) or others to leave the room or living space. During scheduling you will be asked to verify there is an acceptable place to conduct the visit and collect your samples, such as a table and chair or desk located in a well-lit uncarpeted area. There is a slight risk that surfaces in your residence could be contaminated or that personal items could be damaged in the vicinity where samples are collected. To minimize this risk, we will bring disposable coverings for the sampling area, and you may be asked to clear objects from an area to enable study personnel to obtain your samples using standard sample collection procedures. In the rare instance that a spill occurs, study personnel will follow standard decontamination protocols. IF study personnel determine that your site conditions do not meet our guidelines and safety standards to conduct an in-home visit, your visit may be cancelled or terminated if already underway.</p>
Potential Benefits	<p>There is a potential benefit to you that through your participation in this part of the study, we may be able to identify the respiratory pathogen responsible for your symptoms or illness. Although most of the pathogens that cause ARI do not require specific treatment (such as the viruses that cause common colds) and it would of no benefit to know which one you have, you may benefit from early detection of certain infections such as influenza or strep throat, as this may give you the chance to seek early medical treatment from a healthcare provider, if appropriate.</p> <p>We hope that, in the future, other people might benefit from this study through improved understanding of how acute respiratory infections</p>

University of Maryland College Park

	<p>spread and identification of biomarkers that can predict contagiousness, in order to limit the spread of respiratory infections like influenza.</p>
Confidentiality	<p>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 are eligible, we will seek to enroll your closest contacts and follow them to see if they develop an acute respiratory infection, and it may become obvious to those contacts that you are the case who referred them to the study, even if you do not tell them yourself (for example by giving them a recruiting flyer). We will not voluntarily disclose who you are, but may not be able to prevent disclosure. If one of your contacts develops an infection, we will not tell them what you have or tell you what they have. There are many viruses circulating at the same time and you may have different things. However, if you ask, we will tell you what we found in your own swab. It is up to you whether you want to share that information. Unless disclosure is required by law that requires reporting certain illnesses to the State of Maryland as described below, we will not disclose personally identifiable information about who was infected with what to anyone outside of the research team.</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</p>

University of Maryland College Park

	<p>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>
Medical Treatment	<p><i>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 any injury sustained as a result of participation in this research study, except as required by law.</i></p>
Compensation	<p>IN-DEPTH CASE ASSESSMENT</p> <p>You have the potential to earn up to \$100, IF you are eligible for and complete both visits (see details below):</p> <ul style="list-style-type: none"> ● You will receive up to \$75 for completing the in-depth case visit (this includes a \$10 bonus for being on-time to your appointment). <p>NOTE: If you do NOT complete the in-depth visit but instead complete a shorter alternative to the in-depth visit, you will receive up to \$35 (this includes a \$10 bonus for being on-time for your in-clinic appointment; for an in-home visit you will receive \$25).</p> <ul style="list-style-type: none"> ● You will receive \$25 (includes a \$10 on-time bonus) for completing the 1week case visit within 6-8 days of your in-depth or alternative case visit, <u>IF eligible because your swabs are</u>

positive for a targeted infection.

ADDITIONAL COMPENSATION

You may also qualify for additional compensation (see details below):

- You have the potential to earn a BONUS of up to **\$40** if close contacts you name become enrolled in the study within 1 day of your initial case visit. (For each of the first four of your named contacts that become enrolled within 1 day, you will be compensated **\$10**.)
- IF you are selected and agree to provide a venous blood sample at your in-depth visit, you will receive an additional **\$25**
- IF you are selected and agree to place a portable CO₂ monitor in your room, you will receive an additional **\$10** when you return the monitor to study personnel.

STUDY COMPLETION SURVEY and/or VISIT

You also have the potential to earn up to **\$60** IF you complete the follow-up baseline survey or questionnaire and provide your biologic samples (IF eligible) at a study completion visit (see details below):

- You will receive **\$10** for completing the baseline follow-up survey either on-line or at the completion visit
- IF you are eligible (i.e. you have completed an in-depth visit), you will receive **\$50** (this includes a \$10 bonus for being on-time) when you provide your samples at a study completion visit

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.

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.

You will be responsible for any taxes assessed on the compensation you

University of Maryland College Park

	<p><i>receive during this study.</i></p> <p>You may choose to receive compensation payments via one of two payment vehicles 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 participation or non-participation in this study.</i></p> <p>Special notice for research assistants: If you are a student working on the study and are 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 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 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</i></p>

University of Maryland College Park

	<i>Maryland, College Park IRB procedures for research involving human subjects.</i>	
	<i>[Consent Form Quiz, see attachment 1 below, will be inserted here in the electronic version of this consent document.]</i>	
Statement of Consent	<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>	
Signature and Date	NAME OF PARTICIPANT [Please Print]	
	SIGNATURE OF PARTICIPANT	
	DATE	
Witness/Study Personnel	Name [Please Print]	
	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. I have been selected to participate because I have cold and flu symptoms or a positive virus test.	<input type="checkbox"/>	<input type="checkbox"/>
2. I may be asked to complete a second visit in approximately one week.	<input type="checkbox"/>	<input type="checkbox"/>
3. No blood samples are collected at the in-depth visit.	<input type="checkbox"/>	<input type="checkbox"/>
4. I will be asked to identify my 4 closest contacts and estimate the amount of time spent with each of them over the past 24 hours.	<input type="checkbox"/>	<input type="checkbox"/>