

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 are a college student living in certain residence halls or enrolled in a particular Living Learning Community and you have been identified as being a close contact of someone in the study who has recently developed an Acute Respiratory Infection (ARI); we would like to follow you for up to one week to see if you become infected. 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>CONTACT ASSESSMENT</p> <p>If you agree to participate in this part of the study, we will ask you to come to our study clinic in the School of Public Health for a series of up to 7 daily visits.</p> <p>For NEW Study Participants: If you have not previously enrolled in the study, we will first ask you to complete a survey for new study participants. All of your answers will be recorded directly into a secure electronic study database. We will ask you to provide your name, email address, phone number, social media information, and your preferred method of contact so that we can contact you during the study. We will ask you to provide basic information about yourself such as your date of birth, sex, race and ethnicity, and we will ask you some questions about your medical history, influenza vaccinations, and medications. We will also ask you to provide your dorm room number, class schedule, and time spent in certain campus locations (such as your dorm room). At your first study visit we will measure your height and weight, and we will ask you to provide a baseline nail sample that 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. You will be asked to use a sterilized nail clipper to obtain a clipping from each of your fingernails. We estimate that it will take approximately 15-20 minutes to enter your data and answer the enrollment questions in the database and another 5 minutes to provide the nail sample. (Note: if you</p>

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	<p>previously enrolled in the study and already provided a nail sample, you will not repeat these procedures at the initial contact visit.)</p> <p>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>For ALL Participants:</p> <p>At the first visit, you will be asked to complete a contact evaluation questionnaire including questions about the presence of various respiratory disease symptoms, and if present, the date and time of onset, and any related treatments or medications. We will ask you about your stress, recent sleep, exercise, smoking, and alcohol use. We will also ask you about class attendance and time spent in various locations on campus, and to name your closest contacts over the past 24 hours.</p> <p>A professional study staff member (physician, nurse, professional medical technician or highly trained graduate student) or an undergraduate research assistant under physician supervision will measure your temperature using a standard oral thermometer, and will obtain nose and throat swabs. Two nasal swabs will be collected by using a sterile soft-tipped stick (similar to a large Q-tip) to swab the nostrils just inside the opening of your nose, and 2 throat swabs will be collected by using a tongue depressor and swabbing the back of your throat. One set of nose and throat swabs will be combined and tested for a wide variety of respiratory infectious agents within 24 hours to determine if you have an infection. The other set will be saved for later more detailed analysis of the infectious agents, microbiome (the microbes that typically live at the entrance to your respiratory tract), and biomarkers of infection, susceptibility and contagiousness. A study physician, nurse or trained phlebotomist will use a small butterfly needle to collect a small amount (20ml) of your blood from a vein in your arm; this is approximately the amount in 4 teaspoons. The blood will be tested for biomarkers of infection, susceptibility and contagion. We estimate the initial visit should take approximately 30-45 minutes, but could take up to an hour if it is your first study visit and you haven't previously completed the baseline questionnaire.</p> <p>IF we detect targeted respiratory infectious agents in the samples collected from the case subject who named you as a contact, we will ask you to return to our contact assessment lab <u>daily</u> for up to 6 additional visits to test you for signs of ARI. The number of daily follow-up visits is</p>
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	<p>determined by how soon after the nominating case visit you come in for your first contact visit (the quicker this occurs, the more likely you will be eligible for the maximum number of visits). You will be informed about the total number of contact visits that you are eligible for (either 3, 5, or 7) at the initial visit when reviewing this consent form, prior to obtaining your signature. During each of the repeat contact visits we will ask you to complete a short questionnaire updating your symptoms and related treatments and medications, class attendance, time spent in campus locations, and close contacts over the past 24 hours (or since previous visit). We will measure your temperature at each daily visit, and we will collect 2 nose and 2 throat swabs and 20 ml of your blood at the first 2 visits and then every other day thereafter for a maximum of 4 times in 7 days (at the first, second, fourth, and sixth contact visits) or 3 times in 5 days (at the first, second, and fourth visits) or 2 times in 3 days (at the first and second visits). On the alternate days (when you are not having blood drawn and nose and throat swabbed by us), we will ask you to provide 2 self-collected nasal swabs. You will be instructed and assisted by trained study personnel (a physician, nurse, or research assistant under physician supervision) to obtain a nasal swab from each nostril: you will be guided to carefully insert a small, soft, sterile swab that is made specifically for this procedure into your nostril until the stopper along the shaft is just outside the opening of your nose, and to rotate the swab several times to collect a sample from inside your nostril. You will then be asked to place the swab into a collection tube, and to repeat the process for the other nostril. The follow-up visits where you have blood drawn will take approximately 15-25 minutes, whereas the others will be about 10-15 minutes.</p> <p>You may also be randomly selected and asked to temporarily attach a small portable CO₂ monitor to your backpack and to take it with you wherever you go for up to a week to help us measure and understand your environmental exposures. If you want to stop carrying the monitor 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>PLEASE NOTE: If we detect that you have developed an acute respiratory infection, we may stop following you as a contact and invite you to enroll in the case portion of this study (a different consent is required), either instead of or in addition to following you as a contact.</p> <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. Most of the infectious agents we are testing for do not</p>
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	<p>typically require treatment with prescription medication. We will notify you if you develop an infection that should be treated and refer you to a health provider. However, <u>if specimens collected from the subject who named you as a contact do not contain targeted infectious agents, we will stop testing you and will cancel your remaining contact visits.</u></p> <p>STUDY COMPLETION VISIT (after Spring Break):</p> <p>All study participants will be asked to complete a follow-up study visit during the second half of the spring semester, after spring break. You will be asked to complete a follow-up online survey (or complete an identical questionnaire in person) to update some of the information you provided when entering the study, including time spent in various campus locations, recent respiratory symptoms and illness, 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 to provide the following samples: a nail sample , 2 self-collected nasal swabs , and a finger-stick blood sample. The nail and nasal swab samples will be collected and tested in the same manner described previously. To obtain the blood sample, you will be asked to wipe one of your fingers with an alcohol pad and use a sterile, push-button lancet to prick your fingertip. Trained study staff will help massage your finger to form drops of blood and will assist in collecting several drops (0.3 ml) into a capillary blood collection tube. The blood will be used to test 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>
<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</p>

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	<p>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 or gagging sensation, or occasional eye watering or sneezing when the nose and throat 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, when having your blood drawn or providing a finger-stick sample. 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 sight of blood; the staff members who will draw your blood are trained to minimize these risks. The total maximum amount of blood drawn if you are eligible for all seven contact visits (80ml), is much less than the amount typically removed at one time for blood donation (450-500ml). If you are selected and agree to carry a portable CO₂ monitor, this will add a small amount of extra weight (approximately 10 ounces) and may be slightly inconvenient, but poses no other risk.</p>
Potential Benefits	<p>There is a potential benefit to you that <u>if</u> you develop an ARI as a result of your previous contact with someone sick, by participating in this part of the study your infection may be identified early. Although many of the pathogens that cause ARI do not require specific treatment (such as the viruses that cause common colds), 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 spread and identification of biomarkers that can predict contagiousness, in order to limit the spread of respiratory infections like influenza.</p>
Confidentiality	<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</p>

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	<p>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>
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>CONTACT ASSESSMENT</p> <p>You have the potential to earn up to \$350 IF you are eligible for and</p>

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	<p>complete all 7 daily contact visits (see details below):</p> <ul style="list-style-type: none">● You will receive \$50 for completing the initial visit (this includes a \$10 bonus for being on-time and 50% of the compensation payment (up to \$25) will only be paid if you complete the second visit)● You will receive \$60 for the second visit (this includes a \$10 bonus for being on-time; note that 50% of the compensation payment (up to \$30) will only be paid if you complete the third visit)● You will receive \$30 for the third visit (this includes a \$10 bonus for being on-time)● You will receive \$70 for the fourth visit (this includes a \$10 bonus for being on-time; note that 50% of the compensation payment (up to \$35) will only be paid if you complete the fifth visit)● You will receive \$30 for the fifth visit (this includes a \$10 bonus for being on-time)● You will receive \$80 for the sixth visit (this includes a \$10 bonus for being on-time; note that 50% of the compensation payment (up to \$40) will only be paid if you complete the seventh visit)● You will receive \$30 for the seventh visit (this includes a \$10 bonus for being on-time) <p>PLEASE NOTE: if we cancel your remaining contact visits, you will receive full payment for the visit completed prior to this notification.</p> <p>POSSIBLE ADDITIONAL COMPENSATION</p> <p>IF you are selected and agree to carry a portable CO₂ monitor, you will receive an additional \$10 when you return the monitor in person.</p> <p>STUDY COMPLETION VISIT</p> <p>You also have the potential to earn up to \$40 (includes a \$10 on-time bonus) if you complete the follow-up survey or questionnaire and provide your biologic samples at a study completion visit after spring break but before the end of the spring semester.</p> <p>PLEASE NOTE: you must complete the questionnaire AND provide your samples before the end of the spring semester to receive the compensation.</p>
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	<p><i>Because you will 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 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>
Right to Withdraw and Questions	<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 style="text-align: center;">Dr. Donald Milton Room 2234V SPH Building 255 University of Maryland College Park, MD 20742 Telephone: 301-4405-0389 Email: dmilton@umd.edu</p>
Participant Rights	<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</p>

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	<p align="center">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>	
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/Staff Member	Name [Please Print]	
	Date	