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<b>Project Title</b>	Contagious Phenotypes of Acute Respiratory Infection: Identification, Characterization, and Biomarkers {Characterizing And Tracking College Health (CATCH) – the Virus Study}
<b>Purpose of the Study</b>	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 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 5 days 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.
<b>Procedures</b>	<p><b>CONTACT ASSESSMENT</b></p> <p>If you 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 in the School of Public Health for a series of up to 5 daily visits. In rare instances (if you are unable to come to the clinic and only if staffing and your site conditions allow), you may be able to arrange for an in-home/in-room contact visit.</p> <p><i><b>NEW Study Participants:</b> 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 then 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><b>ALL Participants:</b></p> <p>At the first contact 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, unless you are a new study participant who joined the study earlier today and just answered</p>

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	<p>these questions on the baseline survey. 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, and we will measure and record your height and weight if this is your first in-clinic study visit.</p> <p>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 measure your temperature using a standard oral thermometer, and will obtain two mid-turbinate nasal swabs. Prior to obtaining these 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 2 swabs from the mid-turbinate area inside your nose. The nasal swabs will be collected in the following manner: a small, 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 typically 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 two swabs may be collected from the same nostril. One swab will be tested for a wide variety of respiratory infectious agents within 24 hours to determine if you have an infection. The other 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 and standard aseptic technique to collect a relatively small amount (20-50 ml, amount depending on funding for more detailed analysis) of your 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 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 enrolled and 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 4 additional visits to test you for signs of ARI. The number of daily follow-up visits is 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</p>
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	<p>eligible for the maximum number of visits and compensation). You will be informed about the total number of contact visits that you are eligible for (either 2, 3,4, or 5) 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 or assist you in collecting 2 nasal swabs at every daily contact visit for up to 5 consecutive days. We will use a small butterfly needle to obtain a very small amount (up to 6 ml) of your blood from a vein in your arm <u>at each daily follow-up visit except the last one</u> (i.e. at visits 2-4 if eligible for 5 visits, visits 2 &amp; 3 if eligible for 4, etc.) for a maximum of up to 4 consecutive daily blood draws removing a total of no more than 38-68 ml venous blood over 4 days (amount depending on funding). The contact follow-up visits where you have blood drawn will take approximately 15-25 minutes, whereas the last visit will only be about 10-15 minutes.</p> <p>You may also be randomly selected and asked to take a small portable CO<sub>2</sub> monitor home with you and to place it in your room for approximately a week to help us measure and understand your environmental exposures. 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>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 in-depth 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 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>
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	<p><b>STUDY COMPLETION VISIT (late Spring Semester):</b></p> <p>All contact study participants 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 online 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 various campus locations, recent respiratory symptoms and illness, and your sleep, exercise, smoking, and alcohol habits.</p> <p>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 20-50 ml (amount depends on funding) venous blood sample. The nasal swab and blood samples will be collected and tested in the same manner 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. We estimate this entire visit, including updating questions in the database plus sample collection, should take approximately 30-45 minutes.</p>
<p><b>Potential Risks and Discomforts</b></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</p>

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	<p>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 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 five contact visits (and additional funding is approved) is 68 ml, which is much less than the amount typically removed at one time for blood donation (450-500ml). If you are selected and agree to place a portable CO<sub>2</sub> monitor in your room, this will add a small amount of extra weight (approximately 10 ounces) when you are transporting it back and forth from the clinic to your home/room 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 chance 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 use 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>
<b>Potential Benefits</b>	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

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	<p>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>
<b>Confidentiality</b>	<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,</p>

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	<p>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>
<b>Medical Treatment</b>	<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>
<b>Compensation</b>	<p><b>CONTACT ASSESSMENT</b></p> <p>You have the potential to earn up to <b>\$300</b> IF you are eligible for and complete <b>all 5 daily contact visits</b> (see details below):</p> <ul style="list-style-type: none"><li>● You will receive <b>\$50</b> 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)</li><li>● You will receive <b>\$60</b> 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), unless this is your last visit, see below*</li><li>● You will receive <b>\$70</b> for the third 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 fourth visit), unless this is your last visit, see below*</li><li>● You will receive <b>\$80</b> for the fourth 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 fifth visit), unless this is your last visit, see below*</li><li>● *You will receive <b>\$40</b> for the fifth visit or the LAST visit, if you are eligible for fewer than 5 visits when you enroll (this includes a</li></ul>

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	<p style="text-align: center;">\$10 bonus for being on-time)</p> <p>PLEASE NOTE: 1) If we cancel your remaining contact visits, you will receive full payment for the visit completed prior to this notification.</p> <p>2) You will not be eligible to receive a \$10 on-time bonus for any in-home/in-room visit.</p> <p><b>POSSIBLE ADDITIONAL COMPENSATION</b></p> <p>IF you are selected and agree to place a portable CO<sub>2</sub> monitor in your room, you will receive an additional <b>\$10</b> when you return the monitor to study personnel.</p> <p><b>STUDY COMPLETION VISIT</b></p> <p>You also have the potential to earn up to <b>\$60</b> 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"><li>• You will receive \$10 for completing the baseline follow-up survey, either on-line or as part of the completion visit</li><li>• You will receive \$50 (this includes a \$10 bonus for being on-time) when you provide your samples at the study completion visit</li></ul> <p>PLEASE NOTE: you must complete the questionnaire and provide your samples before the end of the spring semester to receive the compensation. You can receive compensation for the survey without providing samples at a completion visit, but <u>the survey must be completed in order to receive compensation for the study completion visit.</u></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</i></p>
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	<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>
<b>Right to Withdraw and Questions</b>	<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;"><b>Dr. Donald Milton Room 2234V SPH Building 255 University of Maryland College Park, MD 20742 Telephone: 301-405-0389 Email: <a href="mailto:dmilton@umd.edu">dmilton@umd.edu</a></b></p>
<b>Participant Rights</b>	<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;"><b>University of Maryland College Park Institutional Review Board Office 1204 Marie Mount Hall College Park, Maryland, 20742 E-mail: <a href="mailto:irb@umd.edu">irb@umd.edu</a> Telephone: 301-405-0678</b></p> <p><i>This research has been reviewed according to the University of</i></p>

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	<i>Maryland, College Park IRB procedures for research involving human subjects.</i>	
	<b><i>[Consent Form Quiz, see attachment 1 below, will be inserted here in the electronic version of this consent document.]</i></b>	
<b>Statement of Consent</b>	<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>	
<b>Signature and Date</b>	<b>NAME OF PARTICIPANT [Please Print]</b>	
	<b>SIGNATURE OF PARTICIPANT</b>	
	<b>DATE</b>	
<b>Witness/Study Personnel</b>	<b>Name [Please Print]</b>	
	<b>Date</b>	

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**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 identified as a contact of a participant with cold or flu symptoms.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I will give blood samples daily, including the last visit.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I may be asked to participate as a case if my samples are positive.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I can withdraw from this research study at any time.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. My remaining visits may be cancelled, if the swabs from the participant who listed me as a contact are not positive for one of the targeted infections. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. My identity as a participant will be kept confidential except as required by law.   | <input type="checkbox"/> | <input type="checkbox"/> |