



**Institutional Review Board**

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**CONSENT TO PARTICIPATE**

<b>Project Title</b>	Contagious Phenotypes of Acute Respiratory Infection: Identification, Characterization, and Biomarkers {Characterizing And Tracking College-community 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 (DARPA) and the Biomedical Advanced Research and Development Authority (BARDA). The purpose of this research project is to identify chemical biomarkers (measurable substances within a person) and physiological biomarkers (such as heart rate, movement, breathing, or sweating measured by a wearable device) that can indicate which individuals, when exposed to viruses and bacteria that cause ARIs, 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. We are inviting you to participate in this part of the research project because you have been identified as being a close contact of a study participant 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.
<b>Procedures</b>	<p>❖ <b>CONTACT SURVEILLANCE SAMPLE COLLECTION</b></p> <p>If you are at least 18 years old and you agree to participate, we will ask you to come to the SPH research clinic in the School of Public Health for a series of up to 5 consecutive daily visits. At the beginning of the first visit in each series you will be informed about the total number of contact surveillance visits that you are eligible for (either 2, 3, 4, or 5), and you will be asked to review and sign this consent form with trained study personnel prior to providing any biological samples.</p> <p>If you are new to the study, you will be asked to complete a short online survey to provide your name, email address, phone number, social media information, your preferred method of contact so that</p>

we can contact you during the study, and your basic information about yourself such as your date of birth, sex, race and ethnicity. We will ask you questions about your medical history, influenza vaccinations, respiratory symptoms and medications, stress, and your habits regarding sleep, exercise, smoking, and alcohol use. We will also ask about your dorm room number or local address, the number of persons who share your living space, and time spent in your room or residence and certain locations on campus, to assess your exposure to exhaled breath from other building occupants in these locations. You will have the ability to complete the survey prior to your first visit by reading and signing this form on-line, but we will also review the form and give you an opportunity to ask questions when you arrive.

At the first contact visit we will ask you to take home a small portable indoor air monitor and to place it in your bedroom or other shared room in your residence for several days and to return it at your last contact visit. The monitor measures temperature, relative humidity, and CO<sub>2</sub>; this will help us evaluate and understand your environmental exposures. If you want the monitor to stop collecting data, you can return it early, however 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 you will not earn full compensation for your contact visits unless you return it. You will also be asked to download and use a smartphone app that tracks your location and the amount of time that 2 or more users spend together (a separate consent form is required). You will be asked to use the app over the next 5 days to help assess and measure the exposure between you and the person with the ARI during that period.

At each contact surveillance visit you will be asked to complete an online questionnaire about your close contacts, symptoms, medications, class attendance, and time spent in your residence and various campus locations over the past 24 hours, and at the first visit in the series you will also be asked about your recent exercise, sleep, stress, smoking and alcohol use, unless you just joined the study and answered these questions earlier the same day.

Trained study personnel will measure your oral temperature and collect nasal swabs and other biological samples from you at each

visit as described and specified below. If you are new to the study we will also measure your height and weight at the first visit. We estimate the first contact visit in a series will take approximately 45-60 minutes, and subsequent contact visits in the series will take approximately 20-30 minutes, except for the last visit, which will only take approximately 10-15 minutes.

**PLEASE NOTE:**

- If the 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 surveillance visits.
- If we detect that you have developed an acute respiratory infection, we will ask you to return and complete one more contact visit of your series to confirm your infection, but we may cancel any remaining visits thereafter. If your initial positive test result occurs on your last scheduled contact visit, we will ask you to return the next day for a short contact follow-up visit: you would be asked to complete the same set of questions as the previous day and provide one set of nasal swabs (i.e. repeat the last visit).
- If you develop an ARI and funding is approved, we may ask you to complete a longer, special visit to investigate your case instead of the contact visit. In this situation you would be asked to read and sign a separate consent form, answer additional questionnaires and provide blood and exhaled breath samples for testing in addition to your nasal swabs.
- If you develop an ARI during contact surveillance testing, your contacts may be recruited and invited to participate in contact testing to see if they develop a respiratory infection. We will provide you with contact recruitment flyers that you can give to your contacts to encourage them to enroll in the study, if you would like to do that. If you live in one of our targeted residence halls, we may also recruit and invite persons who live in close proximity to your room for testing.
- 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 healthcare provider.

❖ **STUDY COMPLETION SURVEY AND VISIT**

If you complete at least one contact visit, you will be invited to return to the research clinic for a study completion visit near the

end of the spring semester to have your oral temperature, height and weight measured and to provide follow-up samples as described below. You will also be emailed a link and will be asked to complete a follow-up survey prior to the visit to update some of the information you provided when entering the study, including time spent in your room or residence, recent respiratory symptoms and illness, recent stress, and your sleep, exercise, smoking, and alcohol habits. We will also ask you about your experience using the wearable device if you have at least one provided by the study. The survey should take approximately 10-15 minutes to complete and the visit should take approximately 20-30 minutes.

❖ **SAMPLE COLLECTION: procedure description and schedule by visit type**

The following procedures and samples will be performed or collected at your study visit, according to the visit schedule in the chart below.

Visit	Procedures and Samples Collected					Time (minutes)
	Height & Weight	Nail Sample	Oral Temp	Nasal Swabs	Venous Blood Sample	
First Contact Surveillance Visit	✓*	✓*	✓	✓	✓	45-60***
Second and Later Contact Surveillance Visit			✓	✓	✓	20-30
Last Contact Surveillance Visit			✓	✓		10-15
Contact Follow-up Visit**			✓	✓		10-15
Study Completion Visit	✓	✓	✓	✓	✓	20-30

\* only included if you are new to the study and this is your first visit.

\*\*if you test positive for ARI on your last contact visit, you will be asked to complete a Contact Follow-up Visit the next day.

\*\*\*if you need to download and setup the smartphone location tracking app, this may take an additional 5-10 minutes.

➤ **Oral Temperature**

We will place the tip of the standard oral thermometer probe under your tongue on one side of your mouth next to the back molar, and this will be repeated on the other side of your mouth.

➤ **Nail Samples**

	<p>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.</p> <p>➤ <b>Nasal Swabs</b></p> <p>We will use a small penlight to look inside your nostrils, and then collect or instruct and assist you in collecting two mid-turbinate nasal swabs. A small, soft, contoured swab made specifically for this procedure will be inserted approx. 1.5-2” into your nostril (stopper ensures proper depth), rotated once, then withdrawn and placed into a collection tube. A second swab will be used to obtain a sample from 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. The swabs will be tested for a wide variety of respiratory infectious agents within 24 hours to determine if you have an infection, and some of the sample 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.</p> <p>➤ <b>Venous Blood Sampling</b></p> <p>We will use a small butterfly needle and standard aseptic technique to collect a relatively small amount of your blood from a vein in your arm. Between 10-30 ml (0.67-2 tablespoons; amount depending on funding for more detailed analysis) will be removed at the first contact visit in a series as well as the study completion visit. No more than 10 ml will be removed at subsequent contact surveillance visits in a series, except for the last visit in the series where no blood will be drawn. The blood sample will be used to test for biomarkers of infection, susceptibility and contagion.</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; we will minimize this risk by asking you to clip your own nails 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.</p> <p>When having your blood drawn, 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 blood is taken, and some people become lightheaded or feel faint at the sight of blood or when blood is drawn; the staff members who will collect your blood sample are trained to minimize these risks. The total maximum amount of blood that would be drawn if you are eligible for all five contact visits (and additional funding is approved) is 60 ml, which is much less than the amount typically removed at one time for blood donation (450-500ml).</p> <p>Placing a portable indoor air monitor in your residence 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><b>Potential Benefits</b></p>	<p>There is a potential benefit to you that if 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>
<p><b>Confidentiality</b></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</p>

to the clinical research database while working in the clinic under senior staff supervision. You have been assigned a subject ID number which will be used to access your records in the database.

Please note that your name and email address may briefly appear in a list of potential study participants that is seen by other case and/or contact participants when they are attempting to search for and name their closest contacts on study questionnaires; the presence of your name on this list does NOT confirm to others that you are an enrolled participant but is indicative that you have been targeted for possible study participation.

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. If we detect that you have an infection, 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.

If you develop an ARI, we may 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. 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.

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>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>To help us protect your privacy, we have a Certificate of Confidentiality from the U.S. Department of Health and Human Services, National Institutes of Health. This Certificate will allow us to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example if there is a court subpoena. We will use the Certificate to resist any demands for information that would identify you and any of the data we collect about you except as explained below.</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><b>Medical Treatment</b></p>	<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>
<p><b>Compensation</b></p>	<p>You have the potential to earn up to <b>\$300</b> if you are eligible for and complete all 5 daily contact surveillance visits as specified in the chart below, and you may have the opportunity to earn additional compensation.</p> <p>You also have the potential to earn up to <b>\$60</b> if you answer the study completion survey and provide samples at a completion visit.</p>

Visit/Survey	Compensation
<b>Contact Surveillance-- First Visit in a Series</b>	<p style="text-align: center;">\$50 (includes \$10 on-time bonus and \$25 escrow for returning indoor air monitor) Only 50% of the compensation will be paid if you do NOT complete the next visit.</p>
<b>Contact Surveillance-- Second and Later Visits and Last Visit in a Series</b>	<p style="text-align: center;">Day 2: \$60* Day 3: \$70* <u>Day 4: \$80*</u> Day 5 or LAST day, if eligible for fewer than 5 visits: \$40 (All amounts shown include a \$10 on time bonus)  *Only 50% of the compensation will be paid if you do NOT complete the next visit.</p>
<b>Contact Follow-up Visit**</b>	<p style="text-align: center;">**If an infection is detected on your last visit, you are eligible to complete Contact Follow-up Visit: \$25</p>
<b>Contact Tracing and Smartphone Location Tracking App</b>	<p style="text-align: center;">\$2/day pro-rated by hours of usage over the 5 days after initial contact visit for a maximum total compensation of \$10</p>
<b>Study Completion Survey</b>	<p style="text-align: center;">\$10</p>
<b>Study Completion Visit</b>	<p style="text-align: center;">\$50 (includes \$10 on time bonus)</p>

Please note the following:

- If you are new to the study, you will also receive an additional \$10 in compensation for completing the online survey when you agree to participate in the study.
- If we cancel your remaining contact visits, you will receive full payment for the last visit completed prior to this notification, unless you do not return the indoor air monitor.
- The indoor air monitor must be returned in order to receive full payment for your visit(s). If you do not return the monitor, \$25 will be deducted from your compensation.
- Compensation earned for contact visits will be paid approximately 1 week after the last visit in the series is completed.
- If you decide to provide samples at a study completion visit, you must answer the study completion survey to receive compensation

	<p>for the visit; both must be done before the end of the spring semester.</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 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><b>Right to Withdraw and Questions</b></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 style="text-align: center;"><b>Dr. Donald Milton</b>  <b>Room 2234V, SPH Building 255</b>  <b>University of Maryland</b>  <b>College Park, MD 20742</b>  <b>Telephone: 301-405-0389</b>  <b>Email: dmilton@umd.edu</b></p>

<p><b>Participant Rights</b></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;"><b>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</b></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;"><b><i>[Consent Form Quiz, see attachment 1 below, will be inserted here in the electronic version of this consent document.]</i></b></p>
<p><b>Statement of Consent</b></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><b>Class schedules</b> In order to identify potential transmission in the classroom, we would like to ask, if you are a University of Maryland student, for your permission to obtain your class schedules for the current academic year from the registrar. Please place your initials on the appropriate line below.  <input type="checkbox"/> YES                      <input type="checkbox"/> NO                      <input type="checkbox"/> Not Applicable</p> <p><b>Possible future sample usage</b> We are asking you for your permission to keep and use your samples for future studies. If you agree, please sign your initials below.  <input type="checkbox"/> YES                      <input type="checkbox"/> NO</p> <p><b>Possible future study opportunities</b> There may be an opportunity for you to enroll in future studies, and we would like to be able to notify you if such an opportunity develops. Please place your initials on the appropriate line below to indicate whether we have your permission to contact you for future studies.  <input type="checkbox"/> YES                      <input type="checkbox"/> NO</p> <p>If you agree to participate, please type your name and sign below.</p>

<b>Signature and Date</b>	<b>NAME OF PARTICIPANT</b> [Please Print]	
	<b>SIGNATURE OF PARTICIPANT</b>	
	<b>DATE</b>	
<b>Witness/Study Personnel</b>	<b>NAME</b> [Please Print]	

**Consent form quiz for on-line completion**

[Note to IRB: if a respondent answers any of the questions incorrectly, they will be prompted to try again until selecting the correct answer before allowing the participant to type their name in the signature block]

1. My participation in this research study is voluntary, and I can withdraw at any time.  
 True  False
2. I will be asked to come to the School of Public Health for a series of daily visits.  
 True  False
3. My identity as a participant will be kept confidential except as required by law.  
 True  False
4. I don't need to provide my social security number to receive compensation.  
 True  False

**Consent form quiz for in-person completion**

[Note to IRB and study personnel: if a participant answers any of the following questions incorrectly, study personnel will discuss these responses and review information with the participant to ensure they understand the key concepts and can select the correct answer]

1. I will be asked to give blood samples daily, including the last visit.  True  False
2. If my swabs test positive at the last visit, I will be asked to come back for a follow-up visit the next day.  True  False
3. My compensation will be reduced if I don't return the indoor air monitor.  True  False
4. There's a chance that my remaining contact visits may be cancelled.  True  False