



Institutional Review Board

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CONSENT TO PARTICIPATE

Project Title	Contagious Phenotypes of Acute Respiratory Infection: Identification, Characterization, and Biomarkers {Characterizing And Tracking College-community 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 (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 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. We are inviting you to participate in this part of the research project because you have either recently joined the study, or recently developed symptoms of an Acute Respiratory Infection (ARI)..
Procedures	<ul style="list-style-type: none">❖ BASELINE, SCREENING, and CASE FOLLOW-UP SAMPLE COLLECTION The first time you meet study criteria to provide biological samples, either for baseline testing or when you are sick, you will be asked to review and sign this consent form. This will take approximately 15 minutes at the beginning of your first visit. You may become eligible to provide samples more than once during the study; we will review study procedures with you at the start of any subsequent visit(s) covered by this form prior to collecting your samples. ❖ WHEN TO COLLECT SAMPLES? Trained study personnel will collect samples from you throughout the study year whenever you are eligible and agree to provide samples in the following scenarios.<ul style="list-style-type: none">➤ At study entry: Baseline Sample Visit After enrolling in the study we will ask you to come to our research clinic in the School of Public Health (SPH) to provide a set of baseline samples. At that time

you will be asked to answer a standard set of respiratory symptom questions, and trained study personnel will measure your oral temperature. If we suspect that you have an ARI, we may ask you to reschedule for a later date and/or ask you to provide samples for a Case Screening Visit instead (see below). In most instances the visit will continue, and study personnel will measure your height and weight and will collect nail samples, two nasal swabs, and a blood sample as described below. We estimate this visit will take approximately 20-30 minutes (plus an additional 15 minutes if you need to review and sign this form).

➤ **When you are sick:**

1. Case Screening Visit

Once you have enrolled in the wearable portion of the study, you will be asked to promptly come to the SPH research clinic to provide samples for screening each time you have new cold or flu-like symptoms and you meet study criteria. You will be asked to complete a brief online questionnaire about your symptoms, medications and healthcare visits related to your illness, and to name and characterize up to 4 of your closest contacts over the previous 24 hours, particularly roommates and household members. You will 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). Trained study personnel will measure your oral temperature and will collect two nasal swabs as described below to test for signs of infection. We will also measure your height and weight if it is your first in-clinic study visit. We estimate this visit will take approximately 15-20 minutes, plus a few extra minutes if you need to download the location tracking app on your phone.

After your visit 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.

2. Case Follow-up Visit

If screening test results indicate you are infected with influenza, adenovirus, or one of the other respiratory infectious agents we are studying, we will ask you to return to the research clinic for a follow-up visit the next day. You will be asked to answer a questionnaire about your symptoms and medications, recent health habits, contacts, and time spent in your residence over the past 24 hours and to provide 2 nasal swabs for testing to confirm your infection. This case follow-up visit should only take about 15-20 minutes.

Depending on funding, you may be invited to participate in a more in-depth investigation of your case instead of the short follow-up visit. In this situation

you would be asked to read and sign a separate consent form, answer similar questionnaires and provide blood and exhaled breath samples for testing in addition to your nasal swabs. You would also be asked to take home a small portable indoor air monitor to help us understand your environmental exposures and to come back for a short visit approximately 1 week later to provide additional nasal swabs and return the monitor.

➤ **At the end of the study: Study Completion Visit**

If you provide a blood sample at any study visit, you will be invited to return to SPH research clinic near the end of the spring semester to provide a set of samples as described below and to have your oral temperature, height, and weight measured. You will also be emailed a link 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. The survey should take approximately 10-15 minutes to complete and the visit should take approximately 20-30 minutes.

❖ **WHAT SAMPLES TO COLLECT?**

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

Visit/Procedure		Procedures and Samples Collected					Est. time (min)
		Height & Weight	Nail Sample	Oral Temp	Nasal Swabs	Venous Blood Sample	
Review and sign consent form							10-15
At study entry (if not sick)	Baseline Sample Visit at Study Entry	✓	✓	✓	✓	✓	20-30
When you are sick	Case Screening Visit	✓*		✓	✓		15-20**
	Case Follow-up Visit			✓	✓		15-20
At the end of study	Study Completion Visit	✓	✓	✓	✓	✓	20-30

* only measured if this is your first study visit.

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

➤ **Oral Temperature**

	<p>We will place the tip of a 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.</p> <p>➤ Nail Samples</p> <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>➤ Nasal Swabs</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 to determine if you have an infection; this will usually be done within 24 hours, especially if you are sick. 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>➤ Venous Blood Sample</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 (amount depending on funding for more detailed analysis) will be removed. The maximum amount that would be removed at any one visit (30 ml) is approximately the amount in 2 tablespoons. The blood sample will be used to test for biomarkers of infection, susceptibility and contagiousness.</p>
<p>Potential Risks and Discomforts</p>	<p>Your participation 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</p>

	<p>the server will be housed in a secure data center as described below under confidentiality.</p> <p>When you provide a nail sample, 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 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.</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.</p>
<p>Potential Benefits</p>	<p>There are no direct benefits to providing baseline samples at study entry and at the end of the study, however completing a baseline sample visit early in the study may increase the likelihood that you will participate in ARI case and contact testing, which could yield useful information if you develop an infection. There is a potential benefit to you that through your participation in ARI screening, 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 with prescription medication (such as the viruses that cause common colds) and it would be 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. We will notify you if you have an infection that should be treated; otherwise, if you are curious to know what we found in your swabs, you are free to contact us and talk with one of the senior clinical research staff.</p> <p>We hope that, in the future, other people might benefit from this study through improved understanding of how acute respiratory infections spread and identification of biomarkers that can predict contagiousness, in order to limit the spread of respiratory infections like influenza.</p>
<p>Confidentiality</p>	<p>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</p>

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 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. 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.

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.

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.

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.

Medical Treatment *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.*

Compensation The chart below outlines the amount of compensation you can earn by completing the various visits and/or surveys covered in this consent form.

Visit/Survey	Compensation
Baseline Sample Visit at Study Entry	\$50 (includes \$10 on time bonus)
Case Screening Visit	\$25 (includes \$10 on time bonus)
Case Follow-up Visit	\$25 (includes \$10 on time bonus)
Contact Tracing and Smartphone Location Tracking App	\$2/day pro-rated by hours of usage over the 5 days after your screening visit for a maximum total compensation of \$10
Study Completion Survey	\$10
Study Completion Visit	\$50 (includes \$10 on time bonus)

PLEASE NOTE: If you are eligible and choose to provide samples at a study completion visit, you must answer the study completion survey to receive compensation for the visit; both must be done before the end of the spring semester.

	<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>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.</i></p> <p><i>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: 301-405-0389 Email: dmilton@umd.edu</p>
<p>Participant Rights</p>	<p><i>If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:</i></p> <p style="text-align: center;">University of Maryland College Park Institutional Review Board Office 1204 Marie Mount Hall</p>

	College Park, Maryland, 20742 E-mail: irb@umd.edu Telephone: 301-405-0678	
	<i>This research has been reviewed according to the University of 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>Possible future sample usage We are asking you for your permission to keep and use your samples for future studies. If you agree, please sign your initials below. _____ YES _____ NO</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]	

Consent form quiz

[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 need to provide my SSN to receive compensation. True False

2. I will be asked to provide blood samples at all study visits. True False

3. If I complete a screening visit and my samples are positive, I will be asked to return the next day for a follow-up visit. True False

4. I will be asked to list my 4 closest contacts at screening and follow-up visits, and my contacts may be recruited for contact testing. True False