



**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>	<p>This research is being conducted by <b>Donald Milton, MD, DrPH, and a team of researchers</b> at the University of Maryland (UMD) 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 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.</p> <p>We are inviting you to participate in the location-tracking part of the study because you have either recently developed ARI symptoms or have been in contact with such a person in the study. Your use of the app will help us to identify contacts who share location and to measure the amount of exposure, particularly when those who are sick may be infectious.</p>
<b>Procedures</b>	If you have not already done so, the first step to participate in this part of the study will be to download the smartphone app from the study website. Once you have downloaded it, you will be asked to register the app with our study by logging in with your UMD directory ID and password and reading and signing

this consent form. Next, we will ask you to enter some personal identifiers into the phone app that will be used to create an encrypted secure ID (similar to the way a password is encrypted). Only the encrypted ID will be transmitted to the study servers. All personal identifiers will be deleted from the app immediately after creating the encrypted ID. The personal identifiers will include several things like your University ID (UID) number, last name, sex, month and date of birth, and the zip code of your permanent/home address. We will also ask you to give us your phone make and model, and phone carrier. We estimate that it will take you no more than 5 minutes to download the app and register with us.

Once you allow the app to have access to location services, the app will start collecting WiFi signal characteristics from your phone such as access points nearby and signal strength, as well as GPS information. The app will send this information to a secure server so that research study personnel can use it to identify your location when you are part of a chain of acute respiratory infection transmission that we are following. We will use your location information to identify the amount of time that you and your close contacts spend together during periods of time when the infected persons are still potentially contagious. The app will run in the background and will not require you to do anything for it to monitor location after it has been activated and given access to location services.

Once activated, we would like you to keep the app continually running on your phone for 5 consecutive days. The amount of time you run the app will be measured by the amount of data sent to the server. Your continued usage will enable you to earn rewards (see details below under compensation). If the app is not sending data to the server, we will occasionally send you a text message letting you know that you may need to restart the app. If you later decide you wish to stop participating or you have run the app for 5 consecutive days, you can turn off the app, stop sharing location information with the app, or choose to uninstall it. You may also reply to the text reminder with an unsubscribe request or contact us by email or phone to unsubscribe. All data collected until the time of leaving the study will be saved unless you inform us by calling/texting 4242-GOTFLU (424-246-8358) or emailing catch@umd.edu or contacting Dr. Milton (see below) and telling us that you wish to

	<p>have us remove all your previously collected data from our database.</p> <p>Please Note: We will periodically post general information about the study to our website, such as the number of enrolled participants and the number and types of infectious agents detected within the study group. Any information posted on the website will be anonymous, with no personally identifiable information about you.</p>
<p><b>Potential Risks and Discomforts</b></p>	<p>It will take a few minutes of your time to download the app and register your phone with our server. There is a small risk to your privacy and confidentiality, because we will be collecting your location data and this data may be possible to use to identify you even though we will not store any personally identifiable data on the location server, as described below under confidentiality. The location data on our server could pose a risk if it were to be hacked and released, extensively analyzed to figure out who it belonged to, and your location at a given time was somehow embarrassing or incriminating. When running, the app is expected to use a small amount of your phone's memory (estimated to be no more than 20 megabytes) and less than 5% of the battery; it should have minimal impact on the function of the phone.</p>
<p><b>Potential Benefits</b></p>	<p>There are no direct benefits of participating in the smartphone app portion of the study. However, participating in this part of the study may increase the likelihood that you will also participate in the case and contact testing components of the companion study, and the possible benefits of that participation would occur if we found that you have an infection that needs treatment. Although most ARIs do not require specific treatment (such as the viruses that cause common colds), we may occasionally identify infections that should be treated or for which early treatment may be advantageous. Hence, there is a small chance that, through your participation as a case or contact, you might benefit from the early detection of a treatable respiratory infection.</p> <p>We hope that, in the future, other people might benefit from this study through improved understanding of how acute</p>

	<p>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 not storing any personally identifying data in connection with the location data. If you decide to participate and use the app, we will assign you a unique ID (created on your phone) that cannot be reversed to get your personal identity without already knowing your identity and how the encryption algorithm works. All subsequent information received from your phone will only be identified by this unique ID.</p> <p>Collaborators within and outside the University of Maryland may conduct analyses on the data for research purposes, but all such 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>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</i></p>

	<p><i>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><b>CONTINUED USE INCENTIVES</b></p> <p>In order to encourage your continued use of the app during the time period of interest, we have a daily reward system. You can earn up to \$2 per day for the next 5 days, pro-rated by the hours of data we receive per day, for a maximum of up to \$10, if you are consistently running the app and contributing location data to the study during the 5 days immediately following your screening, case investigation, or initial contact visit.</p> <p>PLEASE NOTE: We will not make any cash payments. You may choose to receive your rewards via one of two payment methods: 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.</p> <p><i>You will be responsible for any taxes assessed on the compensation you receive during this study.</i></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.</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><b>Dr. Donald Milton</b>  <b>Room 2234V SPH Building 255</b>  <b>University of Maryland 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>If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:</p> <p><b>University of Maryland College Park</b>  <b>Institutional Review Board Office</b>  <b>1204 Marie Mount Hall</b>  <b>College Park, Maryland, 20742</b>  <b>E-mail: irb@umd.edu</b>  <b>Telephone: 301-405-0678</b></p> <p>This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.</p>
<p><b>Statement of consent</b></p>	<p>Your electronic signature indicates that 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, sign the consent by clicking on “Agree”. Otherwise click on Disagree and the smartphone app will not be activated.</p>
<p><b>Electronic Signature</b></p>	<p>{Note to IRB: Only persons logged in with their UMD Directory ID will be able to access this form. If the user clicks on “Agree” they will be allowed to register the app by entering PII and the app will send the users Location Unique ID (LUID) to the server with an indicator of agreement thus verifying the users’ identity. Thus, no additional entry of name in this signature will be required. Clicking on disagree will disable the app.}</p>

<b>CONSENT OF PARTICIPANT</b>	Agree
	Disagree