

University of Maryland College Park

Page 1 of 6

Initials _____ Date _____

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, Ashok Agrawala, PhD, and a team of researchers at the University of Maryland School of Public Health with funding from the U.S. Defense Advanced Research Projects Agency. We are inviting you to participate in this research project because you are part of the group we wish to study. 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.
Procedures	<p>If you have not already done so, the first step to participate in this study will be to download the smartphone app from the appropriate App Store. 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. We will then ask you to provide the research team with your name, sex, date of birth, dorm room, email address, University ID, phone number, phone make and model, and phone carrier using the app. We estimate that it will take you no more than 10 minutes to download the app and register with us.</p> <p>Once you have registered with our study, you may be asked by your phone to allow the app to have access to location services. If you agree, 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 there is potential that you are part of a chain of acute respiratory infection transmission that we are following.</p> <p>{The following text will be included in the consent form ONLY if the user is a member of the Index Cohort – as identified by their University directory ID used to login and access the consent form.} [If you come down with cold or flu symptoms, we want you to notify us quickly. We may use the app as a means of periodically contacting you to ask you if you are feeling well to help you let us know. If you are ill, we may then invite you to come to the research clinic in the School of Public Health to test for infection and ask you to identify recent close contacts (persons you are aware of having been in close contact and who might become</p>

University of Maryland College Park

Page 2 of 6

Initials _____ Date _____

	<p>infected). We will use the location information collected by the app to identify contacts to whom you might have transmitted the infection, even if you may not have been aware of who they were or that they were near you (e.g. in a classroom, common room, or dining hall).]</p> <p>When we have identified cases of acute respiratory infection among app users, we will use your location information to identify the amount of time that you spent with the infected persons during periods of time when they were potentially contagious. If you are identified as a close contact and at risk of getting infected, we will contact you and invite you to enroll in follow-up testing over several days to see if you become infected. We may use the app to contact you.</p> <p>Before being enrolled as a case or a contact of a case, you will be asked to read and sign additional consent forms, which fully explain in more detail what you would be asked to do. 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>Once activated, we would like you to keep the app continually running on your phone. Your usage will be tracked, and your continued usage will enable you to be entered in to monthly and end of semester prize drawings; the more time that you use the app, the greater your chances of winning. If you later decide you wish to stop participating, you can turn off the app, stop sharing location information with the app, or choose to uninstall it. All data collected until the time of leaving the study will be saved unless you inform us by calling [Study Phone Number Goes Here] or emailing [Study Email Address Goes Here] or contacting Dr. Milton (see below) and telling us that you wish to have us remove all your previously collected data from our database.</p> <p>During the academic year, we will send you short periodic emails to keep you informed about what is going on with the study and remind you about possible opportunities to participate in additional parts of the study.</p>
Potential Risks and Discomforts	<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, as we will be collecting a small amount of personal data from you; All personal identifier data will be kept in a separate, secure data center from that containing the location data, as described below</p>

University of Maryland College Park

Page 3 of 6

Initials _____ Date _____

	<p>under confidentiality. The location data on our server could pose a risk if it were to be hacked and released 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>
Potential Benefits	<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 components of this study, and 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 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 personally identifying data in an encrypted database maintained on a secure server in a high security data center. If you decide to participate and use the app, we will follow National Institutes of Health guidelines and assign you a global unique identifier (GUID, similar to an ID number). All subsequent information received from your phone will only be identified by this number and will be stored on a separate encrypted database on another secure server separate from the one holding personally identifiable information. Very few study staff will have authorized access to the database linking your personal information to the GUID. We will also apply for a Certificate of Confidentiality from the U.S. Department of Health and Human Services, National Institutes of Health that will allow us to avoid compelled "involuntary disclosure" (e.g. subpoenas) of names and other identifying information.</p> <p>Collaborators 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</p>

University of Maryland College Park

Page 4 of 6

Initials _____ Date _____

	<p>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>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>SMART PHONE APP INSTALLATION & REGISTRATION</p> <p>You will receive \$10 if you download the app from the App Store and register your phone with our study. This compensation payment will be made via an electronic transfer of funds to a Terrapin Express account linked to your University identification number (UID), which allows purchase at over 50 locations on campus.</p> <p>Please Note: If you subsequently delete the app and then download and register again a second time, you will NOT receive a second payment.</p> <p>CONTINUED USE INCENTIVES</p> <p>Based on the amount of time you leave the app running, you will be entered into small monthly prize drawings (worth approximately \$25), and 2 Grand Prize drawings for \$500 (one drawing at the end of each semester). Grand Prize money will be loaded onto a University issued debit card, which is accepted both on and off campus. The longer you use the app the greater will be your chances of receiving the prizes.</p> <p>PLEASE NOTE: We will not make any cash payments other than by electronic means. All winners will need to come to the School of Public Health in order to claim prizes, and if you are a Grand Prize winner you will be required to provide your name, address, and social security number (required by the University for tax reporting purposes on all research participants who earn more than \$100).</p> <p><i>You will be responsible for any taxes assessed on the compensation you receive during this study.</i></p>

University of Maryland College Park

Page 5 of 6

Initials _____ Date _____

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 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 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, confirm your UMD directory ID below and</p>

University of Maryland College Park

Page 6 of 6

Initials _____ Date _____

	sign the consent by clicking on “Agree”. Otherwise click on Disagree and the smartphone app will not be activated.	
Electronic Signature and Date	UMD Directory ID	[Populated from CAS login]
	SIGNATURE OF PARTICIPANT	Agree Disagree
	DATE	[Automatic date-time stamp]