



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 Health (CATCH)- the Virus Study}
Purpose of the Study	<p>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 and the Biomedical Advanced Research and Development Authority. We are inviting you to participate in this part of the research project because you have a compatible smartphone and have expressed an interest in helping us to evaluate a wearable health-monitoring device for detection of Acute Respiratory Infection (ARI). The purpose of this part of the research project is to monitor heart rate, respiration, and activity (movement) through a wearable device and to correlate these metrics with symptoms and lab data in order to determine which, if any, metrics can be used to help detect and ultimately help mitigate or prevent future epidemics and pandemics of influenza and other ARIs.</p>
Procedures	<p>USING A WEARABLE HEALTH-MONITORING DEVICE</p> <p>If you are at least 18 years of age and have recently enrolled in the CATCH study, do not currently have a cold or flu symptoms, and you have an iPhone version 6 or higher, you are eligible to enroll in the wearable device portion of the study.</p> <p>Overview: Enrolling in the Spire Health Tag portion of the study will involve: a) downloading and installing an app from the Apple App Store and attaching the Health Tags to your underwear; b) using the app and wearing the devices consistently; c) answering an additional questionnaire about medications and other drugs or substances at the start and end of this part of the study and questions about usability of the devices at the end of the study. You may keep the tags and app at the end of the study.</p> <p>Details: If you agree to participate, we will give you a pack of 8 small (approx. 1” x 2” x 3/16”) wearable personal health-monitoring devices, called Spire Health Tags. The tags are commercially available (\$299 for pack of 8 from https://spire.io/) health monitors for placement on the undergarments you wear most such as underwear, bras, and pajamas. They have an adhesive backing to attach them semi-permanently on the inside waistband of men’s</p>

underwear or the wing of a bra. The device must be in contact with skin on your torso so that it can monitor your breathing and heart rate. We will ask you to place one Tag on each undergarment you regularly wear and to wear a garment with one of these devices for as many hours as possible every day attached (especially during the time you are sleeping). The Health Tags can safely go through the washer/dryer. They have a long-lasting battery that doesn't require recharging. If necessary, the Tags can be removed from your clothes and reapplied to other garments by using adhesive remover wipes and extra adhesive strips provided with the pack of Tags, and we can provide additional remover and adhesive if needed. If you are having difficulty with Tag usage, please let us know so we can help find a solution, including possibly some extra tags.

We will provide you with special research setup instructions for using the Health Tags and the app in this study. The pack of Tags also contains basic consumer directions for downloading and setting up the app and Tags – please be sure to follow the research instructions. First, you will need to download the free Spire Health Tag App from the Apple Apps Store. Then, you will need to follow the research instructions to create an account with Spire.io. The research setup instructions will give you details on how to answer the registration questions so that you do not provide personally identifiable information to Spire and so that we can link your Health Tag data with your subject-ID. Then, you will need to provide your height, weight (these need not be exact). It is important that you provide your sex (or gender identity) so that the app displays the gender appropriate instructional video on how to attach the tags to your underwear. Finally, you need to connect the app and one of the Health Tags via Bluetooth. Once you attach one tag, the entire pack will automatically be connected.

If you wish to do the set-up during your clinic visit, study personnel can assist you in downloading the app and getting a Tag paired to the app. Then, when you get home, we ask that you apply the Tags to your selected garments and to start using them that night or the next day.

Before you leave the clinic, we will ask you to complete an additional short questionnaire about your use of various medications and substances that can affect the data we will collect from the device such as your breathing and activity levels; your answers will be recorded directly into the secure electronic study database. We estimate it will take 10-15 minutes to download and activate the app, answer the brief questionnaire, and set-up the Tags for use. We will ask you to complete the questionnaire again at the end of the study along with questions about your experience using the Tags.

You will need to have the Spire App running continuously in the

background and your phone nearby and charged with Bluetooth running so that the app can collect the data from the Tag. Each tag can only store 45 minutes of data, so if you are away from your phone for more than 45 minutes, your phone battery is dead, or you are not running the app, you will lose data and not receive credit toward the daily and weekly raffles.

We recommend that you connect your phone to WiFi as much as possible every day and when you are sleeping to ensure that the data transfer from the app to the Spire cloud server occurs seamlessly. You may choose to turn off your cellular data to protect your data plan, as long as you are frequently attached to WiFi. We will receive reports about the number of hours/day you are wearing the device and providing data, and your continued usage of the Tags will enable you to be entered into daily and weekly prize drawings (see details below under compensation).

Your regular participation by answering the daily text question about cold and flu symptoms is essential to the success of this study. We may notify you about your incentive drawing status in our daily text message asking about your symptoms. The data collected from your Health Tags will be analyzed in conjunction with your symptom data in response to the daily text messages and your laboratory data on confirmed ARIs to see if we can detect onset of colds and flu, possibly even before you realize you are getting ill.

The Spire Health Tag App provides users with feedback on heart rate, activity, and sleep patterns similar to that provided by a Fitbit or other commercial activity monitor – but with additional information on breathing and more detail about sleep. The commercial version of the app has a feature called “LiveInsights” that sends notifications via the app and can make the tag vibrate to alert users about stressful breathing patterns, sleep, exercise, etc. We ask that you not use this feature, if you find that it has not been disabled during the study.

We may periodically (no more than twice a month) contact you to troubleshoot or to remind you to wear the tags if compliance reports show that significant data is missing. These reminders may be sent to you via an email and/or text message and will contain our study email address and phone number to report issues to us. If you need to contact Spire for technical customer support, you should identify yourself as a participant in the study and you will need to provide the information used to register the Spire App (your study ID number and the study email address plus your study ID number); this information can be found in the app by looking at your user profile.

If you wish to stop participating in the Health Tag study, you will have the ability to turn off the Health Tag app at any point or you can choose to

	<p>uninstall it, and you can also choose to stop wearing the devices. You may respond to a reminder about the Tags not sending data with a request to opt out of this portion of the study, and you will no longer receive reminders about the Tags. All data collected until that time will be saved, unless you notify us that you wish to have all previously collected data removed from the database.</p> <p>At the end of the Health Tag study, you will be asked to complete the questionnaire on use of medications and substances with added questions about your impression of the acceptability of the wearable device (e.g. was it uncomfortable, too much of a hassle, etc.). You will receive a link to this questionnaire by email to text message and will be able to complete it outside the clinic at a convenient time. We estimate you should be able to complete this survey in approximately 5 minutes or less.</p> <p>Once the study is over (or you decide to stop contributing data to the wearable part of the study), you can choose to return the Tags to us so they can be recycled, throw them away, or keep them and continue to use them until the batteries no longer work. If you wish to continue using the tags, you will need to contact Spire to assist you in converting the app and your Spire account to commercial mode. If interested, you will be able to purchase replacement tags through a subscription.</p>
<p>Potential Risks and Discomforts</p>	<p>Your participation in this portion of the study may take a small amount of time away from other activities; we will try to keep the visit where you pick up the Tags as short as possible and will email you the Health Tag completion survey so that you can complete it at a time convenient for you. You may feel some slight embarrassment when providing information about your medication, drug, or substance use, 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 some 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>Using the Health Tag devices as directed may require a small change in your lifestyle and habits as you adapt to wearing the device, such as possibly needing to change your laundry routine (i.e. doing laundry more frequently to ensure tagged articles of clothing are available to wear), or wearing a different article of clothing to bed so that a tag can be worn during sleep. The device is small and light-weight, and the microsuede material on the side placed against the skin is soft, sweat-proof, and</p>

	<p>hypoallergenic, and the adhesive is hypoallergenic so that there is minimal risk of irritating your skin. There is a small risk of skin irritation if the device slips and the adhesive becomes exposed; you can minimize this risk by always applying the Tags to articles of clothing before wearing them. The exposure to radiofrequency is similar to wearing a fitness tracker that connects with a phone via Bluetooth.</p> <p>You will be asked to have the Health Tag app continuously running in the background of your phone with Bluetooth turned on, and this will use a small amount of your phone’s memory (100MB) and the battery (2-3% battery use per day maximum). A significant amount of raw data will need to be regularly uploaded to the cloud (if not uploaded for 24 hours would require 30MB of your phone’s memory); data storage will be minimized by regularly sending accumulated data from the app to the cloud. The estimated amount of data sent may be up to a maximum of 1GB per month, although usually less than that and newer compression algorithms are expected to reduce the maximum to 500 MB/month early in the study. Risk of this data transfer impacting your phone data plan will be minimized by having your phone connected to WiFi as much as possible including all time spent on campus or at home, and you can choose to turn off your cellular data to prevent this data transfer from impacting your phone’s data plan if WiFi is not available.</p>
<p>Potential Benefits</p>	<p>If you regularly wear the Health Tags you may benefit from some of the information you can receive from the device, such as information about your activity and sleep patterns. You may find this information to be helpful, and you will be allowed to keep the device and continue using it after the study is over. We hope that the data collected in this portion of the study may be useful to develop algorithms to help identify pre-symptomatic individuals who subsequently become infected with influenza and other respiratory pathogens, with the hope that this information can be applied to help prevent the spread of influenza and other ARIs.</p>
<p>Confidentiality</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 to the clinical research database while working in the clinic under senior staff supervision.</p> <p>If you decide to participate in this part of the study, you will be assigned a subject ID number which will be used to access your records in the database, and only Dr. Milton and his designated research staff will have</p>

	<p>access to the records and be able to link your Health Tag data to other personal identifying study data. Your subject ID number plus the study email address and a fake date of birth will be used to register the Spire Health Tag App, and if you need to contact Spire to obtain technical support you will only use these identifiers to help protect your confidentiality. However, if you are seeking support by calling or emailing you may be revealing your personal phone number (unless caller ID is blocked) or return email address (unless a temporary, masking, or anonymous email system is used).</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, 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>
<p>Medical Treatment</p>	<p>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</p>

	<p>any injury sustained as a result of participation in this research study, except as required by law.</p>
<p>Compensation</p>	<p>VALUE OF THE SPIRE HEALTH TAGS and CONTINUED USE INCENTIVES</p> <p>At the end of the study you will have the option to keep and continue to use the set of Health Tags, and this 8-pack set has a retail value of \$300.</p> <p>In addition, each day that you wear a Tag and contribute data to the study for a minimum number of hours (approximately 20 hours), you will be entered into a daily prize drawing for \$20, as well as cumulative weekly prize drawings. Two \$100 prizes will be awarded each week.</p> <p>NOTE: Persons working on the study are not eligible for the prize drawings, but they can earn a \$20 bonus at the end of the spring semester by consistently wearing the Tags and contributing data (by meeting a threshold of at least 20 hours per day on at least 80% of days during the last 3 months of the semester).</p> <p>END OF STUDY SURVEY</p> <p>You will receive \$10 if you complete the online wearable device follow-up questionnaire near the end of the spring semester.</p> <p>PLEASE NOTE: you must complete the questionnaire <u>before</u> the end of the spring semester to receive this compensation.</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 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. We</p>

	<p>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. 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 this study and 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 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>
	<p><i>[Consent Form Quiz, see attachment 1 below, will be inserted here in the electronic version of this consent document.]</i></p>
<p>Statement of Consent</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>

	If you agree to participate, please type your name and sign below.	
Signature and Date	NAME OF PARTICIPANT [Please Print]	
	SIGNATURE OF PARTICIPANT	
	DATE	
Witness/Study Personnel	NAME [Please Print]	
	DATE	

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. If I want to be entered into daily and weekly prize drawings, it doesn't matter how many hours a day I wear the Tag or whether my phone remains charged and with me.

2. In order to collect data from my Tag, the Spire App needs to be constantly running in the background of my phone and Bluetooth must be turned on.

3. If my phone is not regularly connected to WiFi, data collected from the Tag may be stored on my phone until it is transferred to the cloud and the transfer may impact my phone's data plan.