



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). 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 a variety of physiologic variables such as heart rate, movement, breathing, and sweating 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.

Procedures

USING A WEARABLE HEALTH-MONITORING DEVICE

Overview:

If you are at least 18 years of age, willing to participate in screening for infections, and you have a smartphone which is compatible with our wearable App, you are eligible to enroll in the wearable device portion of the study.

Enrolling in this part of the study will involve: a) downloading and installing an App from the App Store or Google Play Store and pairing the wearable device or devices with your smartphone; b) using the App and wearing the device(s) consistently; c) answering a questionnaire about medications and other drugs or substances at the start and end of this part of the study, and questions about the usability of the device(s) at the end of the study. You may be able to keep the device at the end of the study, depending on the device you receive.

Device Details:

If you agree to participate, we will give you one complete device or a set of wearable health-monitoring devices, along with the corresponding charger, if applicable. These devices will track some or all of the following parameters, depending on which device is used: a) vital signs, such as heart rate, respiratory rate, temperature, blood pressure, and peripheral capillary oxygen saturation (SpO₂); b) HRV (Heart Rate Variability); c) calculated cardiac parameters such as stroke volume, cardiac index, cardiac output, and systemic vascular resistance; d) skin perspiration and sweat composition, including electrolytes, metabolites, and proteins; e) skin conductance; f) motion evaluation, including rest, physical activity, and falls; and g) stress levels. One or more wearable devices may be utilized in the study, including Spire Health Tags, the Empatica Embrace 2 Wristband, and the Biobeat Watch (specific product details below). The device you receive will depend on funding, device availability, and compatibility of your smartphone. If you are interested in using and testing more than one type of device and devices are available, we may occasionally give you a second device.

Spire Health Tag a small (approx. 1" x 2" x 3/16") wearable personal health-monitoring device. 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 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 (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.

Embrace 2 Wristband is an FDA cleared device which is small (approx. 1.5" x 1.2" x 0.4"), light-weight (0.5 Oz), and commercially available (\$249 for Wristband and \$29 for charging hub from <https://www.empatica.com/store/embrace2/>). It is worn the same way as a watch and is water resistant to 1 meter. The device must be in contact with healthy skin on your wrist so that it can monitor your electrodermal activity, skin temperature and movement/location. Embrace2 is made of biocompatible materials that can be worn snugly and comfortably for long periods of time. We will ask you to place Embrace 2 on your wrist and to wear it for as many hours as possible every day and especially during the time you are sleeping. The device has a battery life of 48 hours before it needs to be recharged, which can be done in approximately 1 hour by using the charging dock; the process is similar to charging your phone or an Apple Watch.

Biobeat Watch is an FDA cleared device which is small (33.4 x 35.4 mm) and allows continuous non-invasive accurate medical-grade monitoring of vital signs and other clinically relevant parameters. The Biobeat watch and charging hub are commercially available from Biobeat website (<https://www.biobeat.cloud/>). It is worn on your wrist and must be in contact with your skin so that it can monitor your activity, temperature, and movement/location, but it is NOT waterproof so cannot be worn during swimming or showering. We will ask you to wear the Biobeat watch on your wrist as many hours as possible

every day, and especially during the time you are sleeping. The device has a battery life of approximately 3 days before it needs to be recharged, which takes approximately 3-4 hours.

Device Set-Up and Use:

When you enroll we will give you a research instructional sheet for your device that includes setup directions for using the health device and the App while participating in this study. This sheet will contain details about how to answer the registration questions so that you are not providing your personal information. During your visit we will also ask you to complete a short questionnaire about your use of various medications and substances to compare to the data collected with 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 15-20 minutes to download and activate the app, answer the brief questionnaire, and set-up the device for use.

We want you to wear your device as many hours as you can during the study, not only during the day but also at night, as your sleep data is very important. You will need to have the wearable 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 device. The device will provide you with feedback on your heart rate, activity, sleep patterns, etc. similar to that provided by a Fitbit or other commercial activity monitor, but in order for you to receive daily rewards, you will need to wear your wearable device and upload data for a minimum of approximately 18 hours each day. Thus, we recommend that you wear your device and connect your phone to WiFi as much as possible, and also suggest that you ensure the device has enough battery and the app is uploading data efficiently before you go to bed.

Your regular participation, which includes answering the daily text question about cold and flu symptoms, is essential to the success of this study. We may notify you about your rewards status in our daily text message. The data collected from your wearable device 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.

We may periodically contact you to troubleshoot or to remind you to wear the device if compliance reports show that significant data is missing. If you need to contact customer support for any technical problems, you should follow the steps provided in the instructional sheet for your particular device. If you wish to stop participating in the wearable portion of the study, you will have the ability to turn off the wearable app at any point or you can choose to uninstall it, and you can also choose to stop wearing the device. You may respond to a reminder about the health device not sending data with a request to opt out of this portion of the study, and you will no longer receive reminders about the device. 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.

At the end of the study you will be asked to complete a study completion survey, which will contain the same questions about your use of medications and substances that were asked when you enrolled to use the wearable, along with added questions about your experience using the device (e.g. was it uncomfortable, too much of a hassle, etc.). You will receive a link to this questionnaire by email or 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 10 minutes.

Once the study is over (or you decide to stop contributing data to the wearable part of the study), you will need to return the Biobeat watch to us so it can be recycled. Health Tag and Embrace 2 Wristband users will have the option to keep these devices. Please note that your wearable device is locked to the research study. If you wish to continue using the device (except Biobeat watch), you will need to contact the company to assist you in converting the app and your account to commercial mode. The wearable devices used in the study cannot be transferred to another user and have no resale value.

Potential Risks and Discomforts

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 device as short as possible and will email you the wearable health device 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.

Using the wearable health devices as directed may require a small change in your lifestyle and habits as you adapt to wearing it, such as replacing your watch with the Biobeat Watch or the Embrace 2 Wristband and wearing it while sleeping. For the Health Tags changes may include moving tags to different pieces of clothing or 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 wearable devices are small and light-weight, and the material used on the side against skin is soft, sweat-proof, and hypoallergenic. There is a small risk of skin irritation which can occur if sweat collects under the Embrace 2 Wristband or if a Health Tag slips and the adhesive becomes exposed. There have also been rare reports of contact dermatitis in Biobeat watch users who have sensitive skin. You can minimize these risks by only placing the device against healthy skin, by cleaning the Embrace 2 wristband regularly, and by always applying new adhesives or changing the Health Tags as directed. The exposure to radiofrequency is similar to wearing a fitness tracker that connects with a phone via Bluetooth.

You will be asked to have the wearable health 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 and the battery. A significant amount of data will need to be regularly uploaded, and data storage on your phone will be minimized by regularly sending accumulated data from the app to the cloud.

	<p>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>
Potential Benefits	<p>If used and worn regularly, you may benefit from some of the information you can receive from the wearable device, such as information about your vital signs, activity, and sleep patterns. You may find this information to be helpful. Please note that data collected from your device will be used for research purposes only; vital signs and other parameters will not be directly monitored by study staff or used for diagnostic purposes. If you have a concern</p>

about information provided by the device, you may want to contact your healthcare provider.

Participants using Health Tags and the Embrace 2 Wristband will be allowed to keep these devices and continue using them after the study is over, however you will need to contact the company to assist in converting the app and account to commercial mode. (Health Tags and Embrace 2 Wristbands used in this study are locked to study participants, and hence have no resale value.)

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.

Confidentiality

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. The device contains an onboard processor for interpreting sensor data and for encrypting and securely transmitting data and alerts over a Bluetooth connection to a paired smartphone or tablet.

You have been 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 access to the records and be able to link your wearable health device data to other personal identifying study data. When you register the wearable app, you will be given a separate unique code or will be asked to follow specific directions to avoid providing any personally identifying information about yourself. If you need to contact customer service to obtain technical support, you will be instructed to only use identifiers provided by the study 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).

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

WEARABLE USE INCENTIVES

You will receive **\$20** in appreciation for your agreement to enroll in the wearable portion of the study after installing the wearable app and pairing the device with your phone.

You will also be entered into a **daily rewards system**: each day that you wear the device and contribute data to the study for a minimum number of hours (approximately 18 hours), you will earn \$1, with a random day of \$5 every month, for **cumulative rewards totalling up to \$35/month/device**.

NOTE: The minimum threshold to earn awards may be adjusted up or down and customized for each device, as we get experience with what is feasible for a motivated participant to do based on data we collect during the first few weeks of the study. We will notify you if we change the set point for earning reward compensation for your type of device.

Reward compensation earned will be paid biweekly except for Biobeat wearers who will be paid monthly. Please note compensation process may take up to a week after payment submitted.

DEVICE RETENTION and END OF STUDY COMPENSATION

Depending on the device you have received, you will have the option to keep and continue using the device after the study is over, or you will be required to return the device and will receive compensation for doing so (see details below).

- Participants with Spire Health Tags (retail value \$299/ set of 8) will be able to keep and continue to use these devices. However you will need to contact the company to convert the app to commercial mode, and you may incur a fee for certain levels of continued use or replacement Tags. The tags are registered to your phone and cannot be transferred. Therefore, they have no resale value.
- Participants with Embrace 2 Wristbands (retail value \$278/ wristband and charger) will also be able to keep and continue using these devices. The wristband is registered to your phone and cannot be transferred. Therefore, it has no resale value.
- Biobeat watch users will be required to return the watch and will receive **\$250 upon returning the device**. The device is

registered to your phone and cannot be transferred. Therefore, it has no resale value.

- All wearable participants will receive **\$10** after completing the online study completion survey (which includes wearable survey questions) near the end of the spring semester. Please note: you must complete the questionnaire before the end of the spring semester to receive this compensation.

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.

You will be responsible for any taxes assessed on the compensation you receive during this study.

You will receive compensation payments via a University issued debit card onto which funds will be electronically transferred. If you lose or damage your debit card, you will have two options to resolve the issue; a) we will issue you another debit card, but a small amount of processing fee will be charged based on the debit card company policy; b) you can contact debit card company to mail you a new card, and then you will need to update your debit card information with us to ensure you receive compensation on the correct card. We will not make any cash payments other than by electronic means.

<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>

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>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]	
	DATE	

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. If I want to earn compensation for using the wearable, it doesn't matter how many hours a day I wear it or whether my phone remains charged and with me.

True False

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

True False

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

True False

4. At the end of the study I will have the option to keep and continue using Spire Health Tags and the Embrace 2 Wristband, but NOT the Biobeat Watch, which must be returned.

True False