University of Maryland College Park

Initials _____ Date _____

Project Title	Contagious Phenotypes of Acute Respiratory Infection: Identification, Characterization, and Biomarkers (Prometheus@UMD, GotFlu? 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 School of Public Health with funding from the U.S. Defense Advanced Research Projects Agency's Prometheus Program. We are inviting you to participate in this part of the research project because you have previously enrolled in the baseline assessment part of this research study and you have been identified as being a close contact of someone in the study who has recently developed an Acute Respiratory Infection (ARI), and we would like to follow you over the next week to see if you become infected. 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	**CONTACT ASSESSMENT** If you have already enrolled in the baseline part of this study and agree to participate in this part of the study, we will ask you to come to our contact assessment lab in the School of Public Health for a series of up to 7 daily visits. At the first visit, you will be asked to complete a contact evaluation questionnaire including questions about the presence of various respiratory disease symptoms, and if present, the date and time of onset, and any related treatments or medications. We will ask you about your stress, recent sleep, exercise, smoking, and alcohol use. We will also ask you about class attendance and time spent in various locations on campus, and to name your closest contacts over the past 24 hours. A study physician, nurse, or trained research assistant under physician supervision will measure your temperature using a standard oral thermometer, and will obtain nose and throat swabs. Two nasal swabs will be collected by using a sterile soft-tipped stick (similar to a large Q-tip) to swab the nostrils inside your nose — the same type as used to collect the baseline samples, and 2 throat swabs will be collected by using a tongue depressor and swabbing the back of your throat. One set of nose and throat swabs will be combined and tested for a wide variety of respiratory infectious agents within 24 hours to confirm that you have an infection. The other set 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 contagiousness. A study physician,

	nurse or trained phlebotomist will use a small butterfly needle to collect a small amount (20ml) of your blood from a vein in your arm; this is approximately the amount in 4 teaspoons. The blood will be tested for biomarkers of infection and contagion. We estimate this visit should take approximately 20-30 minutes. IF we detect respiratory infectious agents in the samples collected from the case subject who named you as a contact, we will ask you to return to our contact assessment lab daily for up to 6 additional visits to test you for signs of ARI. During each of these repeat visits we will ask you to complete a short questionnaire updating your symptoms and related treatments and medications, class attendance, time spent in campus locations, and close contacts over the past 24 hours (or since previous visit). We will measure your temperature and collect 2 nose and 2 throat swabs at each daily visit. but we will only collect 20 ml of your blood three additional times (at the second, fourth, and sixth contact visits). The visits where you have blood drawn will take approximately 15-25 minutes, whereas the others will be about 10-15 minutes. PLEASE NOTE: If we detect signs of infection in you or your specimens, we will stop following you as a contact and will instead invite you to enroll in the case portion of this study (a different consent is required). 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. Most of the infectious agents we are testing for do not typically require treatment with prescription medication. We will notify you if you develop an infection that should be treated and refer you to a health provider. However, if specimens collected from the subject who named you as a contact do not contain infectious agents, we will stop testing you and will cancel your remaining contact visits.
Potential Risks and Discomforts	Your participation in this portion of the study will take time away from other activities or rest; we will try to keep each visit as short as possible and minimize wait times through efficient scheduling of appointments. You may feel some slight embarrassment when providing information about your recent habits, but this will be minimized by answering the questions in a private setting on a computer or tablet. You may experience some pressure or discomfort or a gagging sensation when the nose and throat swabs are collected. In rare instances swabbing inside the nose may cause very minor bleeding. When having your blood drawn, you may feel some discomfort from having a tourniquet placed around your arm, and a small amount of pain at the site where the needle enters the skin. There is also a slight risk of bruising or infection at the site, and some people become lightheaded or feel faint when having blood drawn; the staff

	members who will draw your blood are trained to minimize these risks. The total maximum amount of blood drawn over the seven visits (80ml), is much less than the amount typically removed at one time for blood donation.
Potential Benefits	There is a potential benefit to you that if you develop an ARI as a result of your previous contact with someone sick, by participating in this part of the study your infection may be identified early. Although many of the pathogens that cause ARI do not require specific treatment (such as the viruses that cause common colds), 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 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.
Confidentiality	Any potential loss of confidentiality will be minimized by storing all data a secure HIPAA compliant database maintained on a secure server operated by the University of Maryland Libraries. 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 peer ambassador liaisons will only have access to records for participants that they personally entered and will not be able to access data on other participants. If you decide to participate in the study, you will be assigned a subject ID number which will be used to access your records in the database. 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 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 Pertussis and Legionellosis, both of which will be tested for in samples that we collect. Pertussis, also known as whooping cough, is a highly contagious bacterial respiratory infection that can be prevented through proper vaccination, and Legionellosis is a bacterial infection that can cause pneumonia or flu-like illness. 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	You have the potential to earn up to **$405** IF you are eligible for and complete **all 7 daily visits** (see details below): ● You will receive **$60** for completing the initial visit (this includes a $10 bonus for being on-time and 50% of the compensation payment (up to $30) will only be paid if you complete the second visit) ● You will receive **$70** for the second visit (this includes a $10 bonus for being on-time; note that 50% of the compensation payment (up to $35) will only be paid if you complete the third visit) ● You will receive **$30** for the third visit (this includes a $10 bonus for being on-time) ● You will receive **$80** for the fourth visit (this includes a $10 bonus for being on-time; note that 50% of the compensation payment (up to $40) will only be paid if you complete the fifth visit) ● You will receive **$35** for the fifth visit (this includes a $10 bonus for being on-time) ● You will receive **$90** for the sixth visit (this includes a $10 bonus for being on-time; note that 50% of the compensation payment (up to $45) will only be paid if you complete the seventh visit) ● You will receive **$40** for the seventh visit (this includes a $10 bonus for being on-time) *Because you will 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 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.
Right to Withdraw and Questions	*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.* *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:* **Dr. Donald Milton** **Room 2234V** **SPH Building 255** **University of Maryland** **College Park, MD 20742** **Telephone:301-4405-0389** **Email: dmilton@umd.edu**
Participant Rights	*If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:* **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** *This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human*

	subjects.	
Statement of Consent	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. 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	**Name [Please Print]**	
	Date	