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University of Pittsburgh
Institutional Review Board
IRB #990609
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CONSENT TO ACT AS A SUBJECT IN AN EXPERIMENTAL STUDY

TITLE: Understanding Shared Psychobiological Pathways
Project 1. Psychobiological Pathways: Risks for Respiratory Illness—Rhinovirus Trial

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SOURCE OF SUPPORT: National Heart, Lung, and Blood Institute

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DESCRIPTION: You have been asked to participate in a research project for the purpose of learning more about how psychological factors such as social support, stress, and self-esteem, and health relevant behaviors such as exercise influence susceptibility to upper respiratory infection. There will be between 20 and 40 people participating in the study at the same time as you. Over the four year period of the study, there will be a total of between 160-220 participants. About half of them will be male and half female. The age of study participants can range from 21 to 55.

The purpose of the current hospital visit is to screen people for acceptance into the study. During this time you will have blood drawn (approximately 3 teaspoons). This blood will be tested for antibody to the viruses that will be used in the study. Persons with antibody to the common cold virus being used in the current trial will not be eligible to participate in the study at this time. It is expected that about 60% of the persons screened will have the antibody and therefore will not be eligible to participate. The results of this blood test should be available in about three weeks. In addition to the blood test, you will also be asked to complete a short questionnaire today. The estimated time required for you to complete this questionnaire is 10 to 15 minutes. Your blood sample will be stored (kept frozen) for up to two years, after which it will be discarded (destroyed). This sample may be tested for antibody to any of the study viruses (common cold or influenza virus) used in this research. If you are ineligible for the current trial because you have antibody to the virus currently being used, but later testing of your frozen blood sample shows that you do not have antibody to a virus that will be used in a future trial, you may be contacted in the future, to ask if you would like to participate in a future trial. Frozen blood samples will be tested only for antibody to study viruses, not for disease, drugs, alcohol, genetic material (DNA), or other biologic markers, and will not be made available to researchers other than those listed on Page 1. These blood specimens will be stored in a secure location at Rangos Research Center of Children's Hospital of Pittsburgh; investigator Dr. William Doyle assumes overall responsibility for the control of this storage area. If you are contacted in the future as a result of this testing, you are under no obligation to participate in a future trial. If you are eligible to participate in a future trial, you will be asked to sign an additional consent form at that time. You will also be asked to have another blood sample (about 1 teaspoon) drawn, to ensure that in the time period between the current trial and the future trial, you have not been exposed to the study virus. None of that blood sample will be frozen/stored.

Persons who do not have antibody to the study virus (a cold virus) used in the current trial will be scheduled to return to the hospital to complete the screening process. At that time, you will be given a physical, have blood drawn (about 6 or 7 teaspoons), and be asked to submit a urine specimen for analysis. Your blood sample will be tested to rule out the following: human immunodeficiency virus (HIV); high cholesterol (a possible indicator of heart problems); abnormal metabolic functioning (when substances in your blood that are necessary for good health are present, but at unusually high [or low] levels); and abnormalities related to your blood (anemia, infection, clotting problems). There are a number of things that exclude people from participation in the study. Examples are: previous nasal or middle ear surgery, history of asthma or heart problems, allergy to eggs or egg products, pregnancy or currently breast feeding, having antibodies to HIV, or abnormal clinical profiles on urinalysis, complete blood count or blood enzymes.

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At that time, you will be asked to sign a separate consent form for the HIV testing. The results of the HIV test will not be made part of a medical chart/record. You will also be asked to complete some questionnaires. The estimated time required for you to complete all questionnaires, over the length of the study, is three hours. To rule out pregnancy, female subjects will take a urine dipstick pregnancy test on the second day of hotel cloister, prior to infection with the study virus.

Participation in the study requires a six-day stay in a local hotel. Within the two month period prior to the hotel stay, you will be required to do the following things: submit one 24-hour urine collection; submit 14 saliva samples collected over a two day period; undergo 14 evening telephone interviews concerning social interactions, mood, symptoms, and health practices; and fill out questionnaires regarding social networks and social supports. Saliva sample collection involves holding a small roll of dental cotton in your mouth for about a minute, for 7 scheduled times per day, for two days (with a day off in between). You then cap the sample and write your ID number and other information on its label. You will be required to attend two training sessions at Children's Hospital of Pittsburgh. At one of these sessions you will fill out some questionnaires and receive training for the evening telephone interviews. (The evening telephone interviews are expected to last approximately 15 minutes each. You will be required to do an interview every evening for 14 consecutive days.) At the other session you will receive training for the saliva and urine collection and complete additional questionnaires. (None of the questionnaires are diagnostic tools; rather they measure normal variations in feelings, thoughts, and behaviors among persons.) Approximately three weeks after the week in the hotel, you will be required to come back to the hospital to give another blood sample. The blood sample will be tested for antibody to the study virus; the amount of antibody in the sample reveals how strongly your immune system reacted to being challenged with this virus while you were in the hotel.

The hotel stay will begin late in the afternoon of a predetermined day and will end 6 days later (for example, you will report to the hotel late Friday afternoon and will be released 6 days later on the following Thursday at about the same time of day). One or two floors of the hotel will be dedicated to our study. Each study participant gets a private room equipped with bed, dresser, table and chair, television set, telephone, and bathroom facilities. There will be other rooms set up with equipment that will be used for various tests. You will be called to these testing rooms at various times throughout each day in the hotel. Some of the testing will be done in your own room. You will be served 3 meals per day. You will not be permitted to leave the study floor(s), and you will not be able to have any visitors. You are allowed to socialize with the other study participants on your floor, but participants are not allowed in each others' rooms and must maintain a minimum distance of 3 feet from each other to avoid infecting one another. You are NOT allowed to socialize or otherwise have physical contact with subjects housed on other floors, because these subjects may be infected with a different rhinovirus strain than you. Under the controlled conditions in the hotel, your risk of becoming infected by the second cold virus strain is very low. In our daily lives, exposure to multiple viruses that cause colds occurs often, without serious consequence. If dual exposure does occur, the overall risk to your health is minimal. However, dual infection can increase the severity of your symptoms. Violation of the restrictions listed above can result in expulsion from the study. Violation of the restriction regarding

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leaving the study floor(s) will result in both expulsion from the study and forfeiture of the (\$250) bonus for successfully completing all components of the study.

During your first day in the hotel you will be asked to fill out several questionnaires. Also on the first day, you will be given a nasal washing; a general physical examination; an ear, nose, and throat examination; and have your waist measured. In addition, you will be checked for signs and symptoms of upper respiratory infection, asked to collect urine and saliva samples for 24 hours, and have blood drawn (about 7 or 8 teaspoons). Blood is drawn only once during your hotel stay (prior to inoculation with the study virus), through venipuncture in your non-dominant arm. Twenty-four hours after you arrive at the hotel, you will be exposed to one of two cold viruses through nose drops. On each of the following five days you will be given a general physical examination; an ear, nose, and throat examination; a nasal washing; and checked for symptoms and signs of upper respiratory infection. The daily physical and ENT exam include the following: assessment of any abnormality related to your skin, neck, lymph nodes, lungs, heart, abdomen, joints, and body temperature; and ear/nose/throat examinations of your external-, middle-, and inner ear functioning. You will also receive a chest exam: the study physician will assess your breathing, and listen to your heart and breath sounds using a stethoscope. ENT testing includes measurements of congestion severity, nasal or sinus discharge, and the rate of mucosal clearance/progression through your sinuses, as well as visualization of your eardrum on a television monitor. You will also be asked to complete a short questionnaire on each of the days in the hotel. On the last day in the hotel you will be given an exit physical examination.

The virus that you will be exposed to is a cold virus. The two cold viruses used in the study are strains of rhinovirus that can cause common cold-like symptoms. You will be exposed to only one of them. You will be allowed to take only acetaminophen [Tylenol (R)] after you are exposed to the virus. If you use acetaminophen, you must record the time and amount consumed. We expect that about one-half (50%) of the people in this study will develop symptoms.

You will be asked to report to the hospital three weeks after the end of the hotel stay. At the last hospital visit a small amount of blood (about one and a half teaspoons) will be drawn. The blood sample will be tested for antibody to the study virus; the amount of antibody in the sample reveals how strongly your immune system reacted to being challenged with this virus while you were in the hotel. You will receive your payment for participation in the study at this last visit.

In summary, during the study, you will complete written questionnaires 7 times. Each questionnaire will take about 30 to 45 minutes to complete, except for the questionnaire on your first visit, which will take about 10-15 minutes. You will complete questionnaires at the following times: at your two screening visits (Visits 1

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and 2; each last 60-90 minutes total, including the informed consent process, blood draw, & physical), a session during which you will be trained for the daily evening interviews (Visit 3; lasts 60-90 minutes total, including training), and a session during which you will be trained for the collection of saliva and urine (Visit 4; lasts 60-90 minutes total, including training). Evening interviews (after Visits 1-4; prior to hotel) are orally administered by an experimenter over the phone, occur over 14 consecutive evenings, and require 10-15 minutes of your time per evening (at about the same time each day). Calls will be made to your home or other previously-arranged location. At your last visit (Visit 5, after the hotel stay), you will have your final blood draw and receive your subject payment check. This visit lasts 15-30 minutes, and does not involve any questionnaires. All visits, with the exception of the hotel stay, are made to either Children's Hospital of Pittsburgh or Rangos Research Center (part of Children's Hospital; both in Oakland on Fifth Avenue).

Protection against risk. As noted above, appropriate medical care is readily available throughout the study. During your stay in the hotel you will have daily examinations by a physician so that any potential illness problems would be spotted quickly. The physician will check your blood pressure, and skin, neck, lymph nodes, lungs, heart, abdomen and joints for abnormalities. You will also have ear tests and examinations to monitor for abnormal pressure or otitis media as well as a nasal examination. If you develop any complications that may be related to a secondary bacterial infection, you will be treated with medicines as is common practice. A physician is available 24-hours a day during trials and appropriate care will be provided if necessary. An exit physical exam is given to all volunteers at the end of the stay in the hotel to assure that there are no secondary infections or other signs of continuing illness. If your illness is not resolved by that time, you may be asked to return to the Hospital for additional follow-up, testing and treatment. If chest congestion or signs and symptoms of clinical bronchitis are discovered at your physical exam, you may receive a chest X-ray. Also, the emergency rooms of the University of Pittsburgh Health Center and the Allegheny General Hospital are available to you in case of emergency.

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BENEFITS AND RISKS: Research studies often involve some risks. As with any investigational study, there may be adverse events or side effects that are currently unknown and it is possible that certain of these unknown risks could be permanent, serious or life-threatening. Being infected with the cold virus, and having your blood drawn, during this study may result in the following symptoms, which are categorized below according to the risk that you have of experiencing them:

Risks of Being Infected with the Cold Virus:

Risks of this study that are LIKELY (occur in more than 25% of people, or more than 25 out of 100 people) include: Nasal obstruction, nasal discharge, sinus pain, sore throat, cough, chest congestion, sneezing, headache, and a general feeling of illness.

Risks that are COMMON (occur in 10% to 25% of people, or 10 to 25 out of 100 people) include: Chills, back pain, earache.

Risks that are INFREQUENT (occur in 1% to 10% of people, or 1 to 10 out of 100 people) include: Dizziness (unrelated to blood drawing), sinus infection, fainting (unrelated to blood drawing), hands trembling, middle ear infection.

Risks that are RARE (occur in less than 1% of people, or less than 1 out of 100 people) include: Pneumonia, bronchitis.

Risks of Having Your Blood Drawn:

Risks that are LIKELY (occur in more than 25% of people, or more than 25 out of 100 people) include: (None).

Risks that are COMMON (occur in 10% to 25% of people, or 10 to 25 out of 100 people) include: Discomfort from the needle (during blood drawing).

Risks that are INFREQUENT (occur in 1% to 10% of people, or 1 to 10 out of 100 people) include: Bruising at the site of blood drawing, fainting at or about the time of blood drawing.

Risks that are RARE (occur in less than 1% of people, or less than 1 out of 100 people) include: Infection at the site of blood drawing.

Symptoms you experience as a result of being infected with the study virus will last for several days (like a cold). Illness is most often judged to be of mild to moderate degree. Under the controlled conditions in the

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hotel, and with your adherence to the restriction (see page 4) to not visit other study floors or have physical contact with subjects on those floors, your risk of becoming infected with the second cold virus strain is very low. In our daily lives, exposure to multiple viruses that cause colds occurs often, without serious consequence. If dual exposure does occur, the overall risk to your health is minimal.

However, dual infection (with the second cold virus strain, in trials using two different cold viruses) can increase the severity of your symptoms. The virus droplets have been safety tested for other known disease-producing viruses, bacteria and other infectious agents. The risk of contracting HIV (the virus that causes AIDS) and/or hepatitis from inoculation with the virus droplets is negligible. In addition, it is possible in any experiment that harmful effects which are not now known could occur. We will take every precaution to watch for and prevent any harmful side effects. Participants will be carefully followed during the period of illness. A doctor will be on call 24-hours-a-day during the hotel quarantine period.

If your pregnancy test (administered immediately prior to infection with the study virus) proves to be positive, you will be removed from the research study. To avoid risk to the fetus, it is important that you not be pregnant when we conduct this study. We also advise that you (or your female sexual partner) not become pregnant for two weeks after infection with the study virus. Avoiding sexual activity is the only certain method to prevent pregnancy. However, if you choose to be sexually active after infection with the virus and for two weeks thereafter, you should use an appropriate “double barrier” method of birth control (such as female use of a diaphragm, intrauterine device [IUD], or contraceptive sponge, in addition to male use of a condom) or the female should be using prescribed “birth control” pills, injections, or implants. If you choose to be sexually active during the two-week period after being infected with the study virus, you understand that even with use of these birth control measures pregnancy could still result. The risks of receiving the study virus while pregnant include potential loss of pregnancy or possible birth defects.

If you participate in this study, you will receive the benefit of knowing that you have participated in a scientific study designed to better understand the common cold (rhinovirus). Also, you may develop immunity to this and other rhinovirus subtypes, which may give you added protection to these viruses in the future. Also, if you desire, we will provide you with feedback from your evening telephone interviews on your health practices, mood, and social interactions. In addition, you will be tested for HIV infection and counseled regarding HIV infections at no cost to you. There may be emotional discomfort or stress associated with knowledge of the results of this test.

ALTERNATIVE TREATMENTS: None.

NEW INFORMATION: You will be promptly notified if any new information develops during the conduct of this research study that may cause you to change your mind about continuing to participate. You will be promptly notified if any new information, either good or bad, about rhinoviruses #39 or #16 develops during the course of this study and which may cause you to change your mind about continuing to participate.

COSTS: There are no charges to you for any of the medical examinations, medications, or procedures described above in the Description section of this document.

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PAYMENT: Study participants are not considered employees of either the hospital or universities. However, you will be compensated for your time and may receive up to \$820 for your participation in the study. The following table lists the various components of the study and how much you will be paid for completing each one.

<u>Study Component</u>	<u>Number of Times or Days</u>	<u>Payment per Time or Day</u>	<u>Transportation Reimbursement</u>	<u>Total Payment for Component</u>
1. Follow-up screening for people who do not have antibodies to the virus	1	\$5	\$4	\$9
2. Training session for saliva and urine collection	1	\$20	\$4	\$24
3. Training session for phone interviews	1	\$20	\$4	\$24
4. Evening telephone interviews	14	\$4	-----	\$56
5. Saliva collection prior to hotel stay	2	\$25	-----	\$50
6. 24-hour urine collection prior to hotel stay	1	\$25	\$4	\$29
7. Days in hotel	6	\$50	\$4	\$304
8. Final visit to hospital 3 weeks after hotel stay	1	\$10	\$4	\$14
Bonus 1 for successfully completing all components of study				\$250
Bonus 2 for successfully completing all 14 phone interviews				\$60
			TOTAL	\$820

You will receive payment at the last test session (component 8 in the table). If you withdraw prior to the end of the study you will receive partial payment as determined by what components of the study you have completed. For example, if you withdraw from the study after having done the two training sessions (components 2 and 3 in the table) and 4 evening telephone interviews, you would receive $\$24 + \$24 + (4 \times \$4) = \64 . Payment for volunteers who do not complete the entire study will be available at the time of the final test session.

As indicated in the table, you may also receive two bonuses. You will receive Bonus 1 (\$250) if you successfully complete all of the components of the study. You will receive Bonus 2 (\$60) if you successfully complete the 14 evening telephone interviews according to the schedule that you will receive at the training session. (The telephone interviews are conducted every evening for 14 consecutive evenings.) Subjects who complete all of the components of the study and earn both bonuses will receive \$820.

Please Note: If you incur any charges at the hotel that are not covered by the study (for example, long-distance telephone calls) and do not pay for them before checking out, the check that you receive at the last test session will have these charges subtracted from it.

For CMU employees only: Subject payment for current part- or full-time CMU employees will automatically be added to your CMU employee paycheck. Taxes (approx. 30%) will automatically be withdrawn; depending on your annual income, you may receive some of this back when you file your IRS tax return. **Subject's Initials:** _____

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RIGHT TO WITHDRAW: You are free to refuse to join the study and may withdraw at any time. We reserve the right to remove you from the study if it becomes apparent that you are unable or unwilling to complete any of the tasks required in the study. Such tasks include: attendance at, and completion of, two (2) screening appointments; attendance at and completion of two (2) appointments to learn how to collect saliva and urine samples, and conduct telephone interviews; saliva sample collection (for a total of 3 days) and drop-off; urine sample collection (over a 24-hour period) and drop-off; completion of all psychological questionnaires; completion of fourteen (14) evening telephone interviews; attendance at and completion of hotel cloister (6 days); completion of medical and other instructions while cloistered; and attendance at and completion of a final (post-hotel) appointment. Your doctor may be an investigator in this research study, and as an investigator, is interested both in your medical care and in the conduct of this research. Before entering this study or at any time during the research, you may discuss your care with another doctor who is in no way associated with this research project. You are not under any obligation to participate in any research study offered by your doctor. Your current and future care at a UPMC HS facility and any other benefits for which you qualify will be the same whether you complete the study or withdraw. If you withdraw after being infected with the study virus, and develop an ear or sinus infection as a result, study physicians will treat this infection without cost to you. If you withdraw or are withdrawn from the study, and previously agreed to have part of your blood sample frozen and stored (to test at a later date for study virus antibodies which may indicate your eligibility for our future projects), this stored blood specimen will be destroyed.

PRIVACY: All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. Only the researchers listed on the first page of this form and their staff will have access to your research records. Your research records will be destroyed when such is approved by the sponsor of this study or, as per University policy, at 5 years following study completion, whichever should occur last. If you agree to have part of your blood sample stored (to test at a later date for study virus antibodies which may indicate your eligibility for our future projects), your stored blood specimen will be assigned a code number; information linking this code number to your name will be kept in a separate, secure location.

Any information about you obtained from this research will be kept as confidential (private) as possible. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release). In unusual cases, your research records may be released in response to an order from a court of law. It is also possible that authorized representatives of the Food and Drug Administration, the study sponsor (National Heart, Lung, and Blood Institute), and/or the University Research Conduct and Compliance Office may inspect your research records. If the researchers learn that you or someone with whom you are involved is in serious danger or harm, they will need to inform the appropriate agencies as

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required by Pennsylvania law. The fact that you are participating in a research study and that you are undergoing certain research procedures (but not the results of the procedures) may also be made known to individuals involved in insurance billing and/or other administrative activities associated with the conduct of the study.

COMPENSATION FOR ILLNESS OR INJURY: Carnegie Mellon University and University of Pittsburgh investigators and their associates who provide services at the UPMC Health System (UPMC HS) recognize the importance of your voluntary participation to their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research.

If you believe that you are injured as the result of the research procedures being performed, please contact immediately the Principal Investigator or one of the co-investigators listed on the first page of this form. Emergency medical treatment for injuries solely and directly relating to your participation in this research will be provided to you by hospitals of the UPMC HS. It is possible that the UPMC HS may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. You will not receive monetary payment for, or associated with, any injury that you suffer in relation to this research.

Study physicians will treat ear or sinus infections without cost to you, in the event that you should develop such an infection. You should contact the physicians to obtain information about treatment if it is needed. This treatment will be available without cost to you if you are exposed to a virus as part of the study, whether or not you complete the entire study.

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VOLUNTARY CONSENT: I certify that I have read the preceding and I understand its contents. Any questions I have pertaining to the research have been, and will continue to be answered by the investigators listed at the beginning of this consent form at the phone numbers given. Any questions I have concerning my rights as a research subject will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668), or the IRB Chair at Carnegie Mellon University, Dr. Ann Baldwin Taylor (412-268-4727). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this project.

Subject's Name (please print)

Subject's Signature

Date

Please read the following statement. If you agree, write your initials at the end of the statement. For more information, see page 2 of this consent form (the "Description" section):

"I agree to have part of my first blood sample frozen, stored, and tested at a later date, for antibodies to other (cold or flu) viruses to be used in this project. The purpose of this test is to determine if I will be eligible for participation in a future study. I understand that only study investigators (listed on page 1) will have access to my sample, that my sample will not be used to test for anything other than antibody to study viruses, and that my sample will be destroyed no later than two years from today's date."

(Write your initials if you agree with this statement _____)
(initials)

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date