Carnegie Mellon University

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Approved: / /
Biomedical IRB
University of Pittsburgh

CONSENT TO ACT AS A SUBJECT IN AN EXPERIMENTAL STUDY

TITLE: Social Support, Stress, and Susceptibility to Infection

INVESTIGATORS:

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SOURCE OF SUPPORT: National Institute of Mental Health

Subject's Initials: _____

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 about 40 people participating in the study at the same time as you. Over the three year period of the study, there will be a total of 320 participants. About half of them will be male and half female. The age of study participants can range from 18 to 55. The purpose of the current hospital visit is to screen people for acceptance into the study. During this time you will be given a physical, have blood drawn (approximately 5 teaspoons), and be asked to submit a urine specimen for analysis. 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, pregnancy or currently breast feeding, having antibodies to HIV, or abnormal clinical profiles on urinalysis, complete blood count or blood enzymes.

Participation in the study requires a six day stay in a local hotel. Within the four week period prior to the hotel stay, you will undergo an in-person interview about stressful life events and about your relationships with other persons in your social network. The interview is expected to last approximately 2 to 4 hours. Also, within the four week period prior to the hotel stay, you will be required to do the following things: submit one 24-hour urine collection; submit 22 saliva samples collected over a two day period; undergo 6 evening telephone interviews concerning social interactions, mood, and symptoms; and fill out questionnaires regarding social networks and social supports. The evening interviews are expected to last between 10 and 20 minutes each. 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. Upon completion of the study, you will receive $800.

The hotel stay will begin late in the afternoon of a predetermined day and will end six days later (for example, you will report to the hotel late Friday afternoon and will be released the following Thursday at about the same time of day). Two consecutive 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. On one of the floors, there will be two rooms set up with equipment that will be used for various tests. You will be called to the 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 two study floors, and you will not be able to have any visitors. You <u>are allowed</u> to socialize with the other study participants, 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.

During your first day in the hotel you will be asked to fill out some psychological questionnaires and will be given a short interview to update the in-person interview conducted prior to the hotel stay. Also on the first day, you will be given an ear, nose, and throat examination; a nasal washing; checked for signs and symptoms of upper respiratory infection; and asked to collect urine and saliva samples for 24 hours. Twenty-four hours after you arrive at the hotel, you will be exposed to a common cold virus through nose drops. On each of the following five days you will be given an ear, nose, and throat examination; a nasal washing; checked for symptoms and signs of upper respiratory infection; and asked to collect 4 saliva samples. 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.

Subject's Initials: _____

The virus that you will be exposed to is a rhinovirus. This virus is one of a large family of viruses that can cause cold-like symptoms. 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 approximately one-half of the people in this study will develop colds.

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 (approximately 2 teaspoons) will be drawn. You will receive your payment for participation in the study at this last visit.

BENEFITS AND RISKS: Research studies often involve some risks. The risks of this study are that the rhinovirus may cause symptoms including nasal obstruction, nasal discharge, sore throat, cough, and a general feeling of illness. These symptoms are expected to affect approximately one-half of the volunteers and will last for several days (like a common cold). There is a slight chance of developing a sinus (less than 5%) or middle ear (less than 2%) infection. The rhinovirus droplets have been safety tested for other known disease producing viruses and bacteria.

Problems associated with blood drawing are discomfort from the needle (common), fainting at or about the time of blood drawing (infrequent), bruising at the site of blood drawing (infrequent), and infection at the same site (rare). 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. We have run approximately 800 people through similar studies and have had no adverse events.

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. Also, you may develop immunity to this and other rhinovirus subtypes which may give you added protection to these viruses in the future.

COSTS: There are no charges to you for medications and examinations while you are an active participant in the program.

PAYMENT: Study participants are not considered employees of either the hospital or universities. However, you will be compensated for your time. Volunteers who complete all components of the study will receive a total of $800. This includes total payment for all of the components listed on the next page PLUS a $200 bonus. You will receive payment at the last test session. 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. The table on the next page indicates how much you will be paid for each component (or part of a component) that you complete.

Subject's Initials: _____

Study Component	Number of Times or Days	Payment per Time or Day	Total Payment for Component
Screening	1	$10	$10
Interview (in person)	1	$ 25	$ 25
Telephone interviews	6	$ 8.50	$ 51
Saliva collection	2	$ 12	$ 24
24-hour urine collection prior to hotel stay	1	$ 30	$ 30
Days in hotel	6	$ 75	$ 450
Final visit to hospital 3 weeks after hotel stay	1	$ 10	$ 10
Bonus for completing all components of study		$ 200	$ 200
		Total:	$ 800

For example, if you withdraw from the study after having done the screening, in-person interview, and 3 telephone interviews, you would receive $10 + $25 + (3 x $8.50) = $60.50. Payment for volunteers who do not complete the entire study will be available at the time of the final test session.

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.

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.

PRIVACY: Any information obtained from this research will be kept strictly confidential. Only the research team will have access to such information. Knowledge gained from this study may be published in a scientific journal, but your confidentiality will be respected and no names will be used within any reports. However, in unusual circumstances, research records may be inspected by appropriate government agencies or be released in response to an order from a court of competent jurisdiction. All research records will be kept for a period of five years post termination.

COMPENSATION FOR ILLNESS OR INJURY: 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.

Subject's Initials: _____

If you believe that you are injured as the result of the research procedures being performed, please contact immediately the Principal Investigator listed on the cover sheet of this form or the University of Pittsburgh Institutional Review Board (412-692-4376). 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 unlikely event that you should develop such an infection. You should contact the physicians to obtain information about treatment if it is needed.

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VOLUNTARY CONSENT: I have read this form and understand the information it contains. The investigators in charge of the project, Drs. Cohen, Doyle, Frank, and Skoner, will be available if I have any questions. In addition, any questions I may have concerning my rights as a subject in this study can be directed to the Office of the Senior Vice Chancellor for the Health Sciences at 647-9834. My signature means I have freely agreed to take part in this research project.

_____
Subject's Name (please print)

_____
Subject's Signature

_____
Date

INVESTIGATOR'S CERTIFICATION: Based on this conversation, I believe the above person does / does not (circle one) understand what this research involves.

_____
Name of person explaining research Title Date