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CONSENT FOR AN ADULT TO BE SCREENED FOR ENTRY INTO A RESEARCH STUDY

TITLE: [Ver. 1.9; DMID v. 10.0] Social and Psychological Risk for Infectious Illness

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SOURCE OF SUPPORT: National Institutes of Health: National Institute of Allergy and Infectious Diseases (NIAID)

DESCRIPTION: You have been asked to participate in a research study which will involve testing your blood for antibodies to a specific strain of common cold virus (rhinovirus), completing some questionnaires, and having your blood pressure measured.

PURPOSE, MEANING, AND LIMITATIONS: Dr. Cohen and his colleagues are planning to conduct a study of the relationship between an individual's psychological profile, response to stress, social environment and genetics, and the degree of illness after experimental exposure to a virus (rhinovirus 39) that causes the common cold. You have come to the hospital today because you are interested in obtaining details about that study and, possibly, being considered for participation. You have been invited to participate because you recently gave oral permission for an initial telephone screening interview, passed the screening, and agreed to schedule and attend today's appointment. Your visit today will last about 90 minutes. No procedure or study-related activities will be done with you until you have all of your questions answered, understand what the study involves, and sign this informed consent document.

Because the study involves exposing adult subjects to a virus that causes the common cold (rhinovirus) it is important that all enrolled subjects be in generally good health and that female subjects not be pregnant or anticipate being pregnant at the time when the virus is administered. Also, people who have previously been infected with the particular type of rhinovirus used in the experiment cannot usually be re-infected with the same virus and are not eligible for the study. For these reasons, your time here today is called an initial (first) screening visit with the purpose of familiarizing you with the complete details of the study, and if you remain interested in participation, collecting information about you by questionnaire regarding your demographics. These questionnaires take about 20 minutes to complete. You will also be asked to provide a blood sample (about 1 teaspoon) to

determine if you were previously infected with the rhinovirus type that is used in this study, and have your blood pressure measured. The blood sample will be tested for antibody to the specific strain of common cold virus that will be used in the study. Antibodies are substances made by the body to help prevent repeated infection by the same virus. Subjects with an antibody to the specific strain of common cold virus being used cannot participate in the study. It is expected that about 50% (approximately 1 in every 2 persons) of all those who are screened will not be able to participate. The results of this blood test should be available in about three weeks.

You can be entered into the study only if you are in generally good health, not taking any prescription medication for a chronic illness (there are some exceptions), not pregnant or planning to be pregnant and you are susceptible to infection with the virus used to cause the common cold. If the blood tests show that you have antibodies to the type of virus that we plan to give to you (rhinovirus type 39), you will also be ineligible to participate. Also, it is possible that you may be removed from the research study by the researchers if, for example, you are unable to provide a blood sample due to fainting or inaccessible veins, or if you are unable or unwilling to complete study questionnaires. Elevated blood pressure readings can also lead to removal from the study.

About 3 weeks after this visit, we will inform you as to whether or not you are potentially eligible to participate in the study. At that time, if you are still interested, you will be scheduled for a second screening visit, at which time the study will be described in more detail, your written consent for full study participation will be requested, and, if obtained, you will have medical examinations done to screen you for good health, and if confirmed, given the opportunity to be entered into the study.

At this point, a number of factors can exclude you from continuing in the study. These include:

- Females who are currently lactating (breast-feeding), pregnant or with plans to become pregnant within 3 months of enrollment, who do not agree to use an acceptable method of birth control (abstinence or double barrier contraception) or who are unwilling to take a pregnancy test on the first day in the hotel and at the final visit (Visit 6).
- Currently taking sleeping pills, tranquilizers, steroids, immunosuppressants or other regular medication regimen (with some exceptions, such as birth control)
- Diagnosed psychiatric disorder treated within the last year or psychiatric hospitalization within the past 5 years
- History of cardiovascular (heart) disorder, diabetes or other chronic illness (at study physician's discretion)
- Allergy to eggs/egg products
- Prior hospitalization for flu-like illness
- Asthma or history of asthma, chronic sinusitis or chronic bronchitis
- Previous nasal/otological (ear) surgery (there are some exceptions)
- Antibodies to the challenge strain of virus

RISKS AND BENEFITS: The risks of this "screening" phase of the study are associated with those typical of a blood draw from a vein:

Risks of Having Your Blood Drawn: The physical risks of the blood draws are low and are outlined below. Although unlikely, there is a slight risk that your test results may become known to others. The samples are only tested for rhinovirus antibody and therefore are not linked to your risk for chronic disease or illness, and all samples sent for

testing are coded with a study number. The study code identifying you with the code number is maintained in a locked and secure facility under the direct supervision of one of the Investigators (Dr. Casselbrant).

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

b) 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).

c) 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.

d) 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.

There are no benefits to participating in this screening.

COSTS AND PAYMENTS: Study participation does not make you an employee of the participating hospitals or universities, but you will be compensated for your time. You will be reimbursed $5 for completing this screening to compensate you for your time, parking and transportation. All research and screening procedures will be paid for by the study; neither you nor your insurance company will be charged for these procedures.

NEW INFORMATION: You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

CONFIDENTIALITY: No information will be obtained from or placed into your medical charts, and any collected information will be coded and stored in locked cabinets. Computerized records are password protected. There are, however, some disclosures of your research-related medical information that may occur. In addition to the investigators listed on the first page of this authorization form and their research staff, the following persons may have access to your health information related to your participation in this research study.

- Authorized representatives of the University of Pittsburgh Institutional Review Board for assuring the ethical conduct of research and monitoring the appropriate conduct of this research study.
- Authorized representatives of the sponsor of this study, NIAID, for purposes of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data.
- Authorized representatives of the Office for Human Research Protections (OHRP) may review and/or obtain your identifiable health information for the purpose of ensuring that the research is being conducted according to the Department of Health and Human Services Guidelines.

In unusual cases, the investigators may be required to release your research information in response to a court order. Research investigators may be required under Pennsylvania law to report any suspicion of child abuse to child protection services. If the investigators learn that you or someone with whom you are involved is in serious danger of potential severe harm, they may need to warn those who are in danger and contact other agencies to ensure safety.

Your blood specimen will be labeled with a code number. Information linking this code number to your name will be kept in a separate, secure location at ENT Research Center of Children's Hospital of Pittsburgh. Investigator Dr. Casselbrant assumes overall responsibility for the control of this storage area. Your blood sample will be stored (kept frozen) indefinitely. However, if you choose not to enroll in (provide written informed consent for) the complete study, your blood sample will be kept no longer than 6 years after the end of the study, after which it will be discarded (destroyed). Your blood sample will be assayed (analyzed) only for the purpose of evaluating study

eligibility, not for disease, drugs, alcohol, or other biologic markers, and will not be made available to researchers other than those listed on Page 1.

RIGHT TO REFUSE: You understand that you do not have to take part in this testing. You are free to refuse to participate in this screening, but of course, if you do not participate you cannot be considered for participation in the study. Signing this consent does not commit you in any way to participate in the study but allows you to be considered for such participation. Your decision to withdraw your consent for participation in this research study, or the investigator's decision to remove you from the study will have no effect on your current or future relationship with the University of Pittsburgh, Children's Hospital of Pittsburgh, or Carnegie Mellon University, on your current or future medical care at a UPMC hospital or affiliated health care provider or on your current or future relationship with a health care insurance provider. 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.

COMPENSATION FOR ILLNESS OR INJURY: University of Pittsburgh researchers and their associates who provide services at University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in 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 a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC 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. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

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VOLUNTARY CONSENT AND AUTHORIZATION: All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. I certify that I have read all 5 pages of this form and I understand and agree to its contents. I will receive a copy of this form. 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 (412-268-4727). A copy of this consent form has been 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

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. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date