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CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: [Ver. 1.4; DMID v. 10.0] Social and Psychological Risk for Infectious Illness: Hair Collection Substudy

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Why is this research being done?

You have been asked to participate in a research project designed to learn more about the possible role of chronically high levels of cortisol (as measured by cortisol deposition in hair) in immune response and susceptibility to the common cold. We will study whether cortisol levels as measured prior to exposure to the study common cold virus influence who develops a cold. Cortisol is an important hormone in your body, affecting immune system function and inflammatory response to infection. While cortisol is a helpful part of your body's response to stress, higher and more prolonged levels of cortisol in the bloodstream (like those associated with chronic stress) have been shown to have negative effects, such as lowered immunity and inflammatory responses in the body, slowed wound healing, and other health effects. Hair sample collection is a relatively non-invasive method by which to measure long-term levels of cortisol.

Before agreeing to enroll in this study and provide hair samples, it is important that you read and understand all of the information included in this consent document and ask any and all questions that come to mind about the study. The following describes what will be done on all who present for enrollment and are accepted for study participation. 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.

Who is being asked to take part in this research study?
You are being asked to participate because you are participating in the parent study (The Pitt-CMU Cold Study). We plan to study approximately 15 healthy adults aged 18-55 at the same time as you, and a total of approximately 80 participants over the 3-year period of study. About half of the participants will be male and half female. Like you, all will be susceptible to infection with the study virus (rhinovirus type 39) and all will be in good health.

What procedures will be performed for research purposes?
All procedures and tests are being done for research purposes. No information about you will be obtained from pre-existing medical or physician records, and no information about you will be added to your medical or physician records. If you are accepted for study participation and complete the study, your total time commitment will be about 20 minutes. Of this 20-minute period (2 occasions [10 minutes each], spread over a period of approximately 2 months), you will spend a total of about 10 minutes completing questionnaires. Hair samples will be collected during your regularly-scheduled visits for the parent study, Social and Psychological Risk for Infectious Illness ('The Pitt-CMU Cold Study'). Participation in the hair collection substudy does not require additional visits beyond those for the Cold Study.

Screening Procedures:
Procedures to determine if you are eligible to take part in a research study are called "screening procedures."

There are a number of factors that can exclude you from participating in the study. Examples include:

- You do not have enough hair on your head to provide a sample of many strands, which together total about a pencil's-width across (diameter)
- Your hair is not long enough to provide a sample at least 1¼ inches in length
- You do not pass the Health Screening visit physical examination (Visit 2, Pitt-CMU Cold Study), or you are eliminated from participation in the parent study for any reason. .

Experimental Procedures:
If you qualify to take part in this research study, you will undergo the experimental procedures listed below. These procedures will take place in Pittsburgh at Children's Hospital and at a local hotel.

Pre-Hotel ('Pre-Cloister') Hair Collection

At Visit 2 of the parent study (Pitt-CMU Cold Study), (Visit 2 is the Health Screening visit done at the CHP) we will do the following in addition to the physical examinations, urine and blood tests and other activities that are part of this visit.

- Collect a hair sample to determine the level of the hormone cortisol. The results of this test are not used to disqualify people from this study or the parent study (Pitt-CMU Cold Study). Because these tests are not done by an accredited clinical laboratory and have no direct implications for your health, the results of the tests will not be provided to you. To give this sample you will be asked to allow a research assistant or study technician to collect using small scissors a sample of hair consisting of many small strands, which together total about a pencil's-width across, from the back of your head close to your scalp. If there is not enough hair on the back of your head, the sample may be collected from another location on your scalp.
- You will be asked to complete a questionnaire (requires about 5 minutes to complete). The questionnaire asks you to provide demographic and health behavior information, and information about your hair care, hair treatments and products that you may use on your hair.

The hair collection process will take about 5 minutes, typically while you wait for other activities to begin during this visit. Hair samples will be labeled with only your study ID number, not your name, and are typically destroyed during laboratory analysis shortly after the end of the study. Hair samples will only be available to investigators and experimenters listed on Page 1 of this form.

Hotel ('Cloister') Hair Collection

On Hotel Day 0 of the parent study (The Pitt-CMU Cold Study), which is the full 24-hour day before virus exposure, we will do the following:

- Collect the second (final) hair sample, using the same procedure described in Visit 2 of the parent study above.
- You will also be asked to complete a questionnaire identical to the one you completed at Visit 2 (requires about 5 minutes to complete). This questionnaire will ask you to update any information which may have changed since your first study visit.

The hair collection process lasts about 5 minutes, typically while you wait for other activities to begin at Hotel Day 0.

What are the possible risks, side effects, and discomforts of this research study?

Risks of Hair Sample Collection: The risks associated with study participation relate to the collection of hair samples.

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: (None.)
c) Risks that are INFREQUENT (occur in 1% to 10% of people, or 1 to 10 out of 100 people) include: (None.)
d) Risks that are RARE (occur in less than 1% of people, or less than 1 out of 100 people) include: Minor scalp laceration (a cut) during sample collection; infection related to same.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

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

What are possible benefits from taking part in this study?

There is no guarantee of direct benefit from your participation in this research study. You may benefit indirectly by knowing that you have participated in a research study designed to better understand the factors that make people susceptible to the common cold.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

All procedures conducted in this study are for research purposes only, therefore neither you nor your insurance company will be charged for any of the procedures performed as part of this research study.

Will I be paid for participating in the study?

Study participation does not make you an employee of the participating hospitals or universities, but you will be compensated for your time. At the final visit of the parent study (Pitt-CMU Cold Study), approximately 3-5 weeks after the hotel stay, you will receive remuneration for your study participation. This remuneration may be taxable and will be reported to the Internal Revenue Service (IRS). Because final visits are scheduled over an approximately 2-week period, participants will not all receive their checks on the same day. The table lists the various components of the study and how much you will be reimbursed for completing each part.

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

Study Component	Number of Times or Days	Payment per Time or Day	Total Payment for Component
1. Hair sample collection (#1); questionnaire. (Takes place during Screening Visit 2 of Pitt-CMU Cold Study)	1	$30	$30
2. Hair sample collection (#2); questionnaire. (Takes place during Hotel (Cloister) Day 0 of Pitt-CMU Cold Study)	1	$30	$30
		TOTAL	$60

If you withdraw or are withdrawn from this or the parent study prior to the end of the study you will receive partial payment as determined by what parts of the study you have completed. For example, if you withdraw/ are withdrawn after having completed Hair sample collection (#1) (part 1in the table), you would receive $30. Subjects who complete all of the components of the study will receive $60. Payment for volunteers who do not complete the entire study will be available at the time of the final test session of the parent study (Pitt-CMU Cold Study). If you withdraw from the study or are withdrawn by the investigators, you will receive a pro-rated monetary amount consistent with the above-listed schedule.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh and CMU researchers and their associates who provide services at 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 or one of the experimenters 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. Every attempt will be made to bill the research project directly; however, in cases where this is administratively impossible, you will be reimbursed for testing/treatment ordered by the study physician. You will not receive any monetary payment for, or associated with, any injury that you suffer in relation to this research.

Who will know about my participation in this research study?

Only members of the study staff who directly interact with you will know that you have participated in this study. Any information about you obtained from this research will be kept as confidential (private) as possible. 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. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release). Research results about you will not be released to any third party (e.g., personal physicians, insurance companies, relatives) without your prior written authorization.

Will this research study involve the use or disclosure of my identifiable medical information?

All information concerning you will be recorded only in research charts/files. No information will be placed in your medical records/physician office records and no use of such records will be made by the study investigators.

Who will have access to identifiable information related to my participation in this research study?

Only the Principal Investigator of this study (Dr. Cohen), the parent study physician (Dr. Casselbrant), and a designated member of our staff (CMU Project Director) will have access to the study code (allowing identification of your records), and only researchers listed on the first page of this form and their staff will have access to your coded research results. 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 study sponsor (Pittsburgh Mind-Body Center), and/or the University Research Conduct and Compliance Office may inspect your research records. While PMBC understands the importance of maintaining the confidentiality of your identifiable research information, the University of Pittsburgh and CMU cannot guarantee the confidentiality of this information after it has been obtained by those agencies. If during the course of this study, the researchers learn that you or someone with whom you are involved is in serious danger or harm, they are required by Pennsylvania law to inform appropriate agencies. 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 reimbursement and/or other administrative activities associated with the conduct of the study.

For how long will the investigators be permitted to use information and samples collected from me in this research study?

The investigators will use and store your information and samples in accordance with University policy. Your hair samples will only be tested for cortisol. Your hair samples will not be tested for disease, drugs, or alcohol. The results of the cortisol analyses will not be made part of your medical record. The results of the tests will only be made available to the researchers listed on Page 1 of this consent form and only in coded form. Only the individuals listed on Page 1 will have access to your hair samples. Hair samples from those who complete the study will be destroyed during the laboratory analysis process, typically shortly after the end of your participation in the parent (Cold) study. If you withdraw or are withdrawn from the study prior to infection with the study rhinovirus at Hotel Day 0 of the parent study, your hair sample(s) will be destroyed shortly after the end of the study. If you agree to participate in the research project, use of your biological samples will be under the control of the principal investigator of this research project. Your hair samples will be stored in a secure location at CMU and assigned a code number, with information linking this code number to your name kept in a separate, secure location.

May I have access to my medical information that results from my participation in this research study?

There is no information collected in this study that will be included in your medical records.

Is my participation in this research study voluntary?

Your decision to participate is entirely up to you. Feel free to discuss study participation with your physician and others in whom you trust. Your decision with respect to participation will have no effect on your current or future relationship with the University of Pittsburgh, Children's Hospital, and CMU, 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. Deciding not to participate in this study does not disqualify you from continued participation in the parent study (The Pitt-CMU Cold Study).

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study. To formally withdraw your consent for participation in this study you should provide a written, dated notice of this decision to the Principal Investigator of this research study at the address listed on the first page of this form.

If you withdraw, the following materials collected from you may be kept by the investigators listed on Page 1 for up to 6 years after the end of this research project: your signed consent form, and your questionnaires.

The investigators reserve the right to remove you from the study for any reason, including if it becomes apparent that you are unable or unwilling to complete any of the following tasks required by the study: 1) undergo hair sample collection on 2 occasions; and 2) complete 2 demographic, health behavior, and hair-care questionnaires.

Before entering this study or at any time during the research, you may discuss your care with a healthcare provider who is in no way associated with this research project. 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 CMU, 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.

No guarantees have been made as to the results of your participation in the study.

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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 6 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.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date