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REDI-US STUDY INFORMED CONSENT TO PARTICIPATE IN RESEARCH

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1. STUDY DESCRIPTION

You have been invited to participate in a study of the natural occurrence of respiratory illnesses (e.g., cold and flu) among UC Berkeley students. This research study – the REDI-US Study – is being conducted by the UC Berkeley Center for Infectious Disease Preparedness and is funded by the Centers for Disease Control and Prevention (CDC).

Your name was randomly selected from a list of undergraduate and graduate students registered at least half time at Berkeley. Enrollment in the REDI-US study will be offered on a first-come basis to eligible students, and will be closed after the first 3,000 people sign up.

The following information is provided to help you decide whether you wish to participate in the REDI-US Study. Participation in this research study is completely voluntary, and any information you provide will be kept confidential. If you agree to participate, you may withdraw from the study at any time.

2. STUDY PROCEDURES

Description of Participation: This study will be conducted during this year's annual cold and flu season. Your participation in each of the following steps is voluntary.

- a) During enrollment, you will be asked to fill out an initial online survey to provide demographic and other basic information about yourself. This survey should take 15-20 minutes to complete.
- b) Throughout the study period, you will be asked to fill out a weekly online survey to provide information on any respiratory illness symptoms you experienced during the past week, as well as adherence to any preventive measures. This survey should typically take 3-5 minutes to complete each week.
- c) You may be provided information on measures you can take to prevent contracting and/or transmitting respiratory infections. These measures are part of standard practice in the prevention of infectious respiratory diseases.

- d) Should you develop any respiratory illness symptoms prior to the next weekly survey, you will be asked to proactively report your symptoms online. This should take no longer than 2 minutes of your time.
- e) You will be asked to complete a 15-20 minute survey at the end of the study.

Length of Participation: Enrollment and the initial survey (15-20 minutes) are scheduled to take place during the second half of October 2007. The weekly surveys (3-5 minutes each) will begin on November 6th, 2007 and continue through April 8th, 2008. The final survey will take place during the week of April 14th, 2008 (15-20 minutes).

If the cold and flu season is particularly late this year (lasting beyond the week of April 14th, 2008) we may ask you to extend your study participation for a few more weeks. However, this is not likely, and you may decline to extend your participation.

Testing: During the study, we will ask *some* participants to be tested for influenza. The testing meeting will take approximately 5-10 minutes, and will involve a trained professional gently swabbing the inside of one of your nostrils with a foam swab. If you are one of the selected participants, we will set up a convenient time and place to do this test; we can either meet you at the Tang Center (2222 Bancroft Way), or at your residence. We will share the results of the test with you within 24 hours. Declining the test will not affect your participation in the study.

Household and Close Contacts: During the study, you will be asked to list your household and close contacts. If you are not comfortable providing your contacts' names, you may decline to do so and it will not affect your participation in the study in any way.

Should you provide the names and contact information for your household and close contacts, some of these individuals *may* be invited to participate in the study on a limited basis. Their participation will help us determine the role of household and close contacts in the transmission of respiratory infections. We will not tell them why they have been selected, and your identity and participation in the study will remain confidential at all times. Their participation, like yours, will be completely voluntary.

3. POSSIBLE DISCOMFORTS

Respiratory Illness Test: The influenza test used in this study is conducted with a nasal swab, which may cause minor discomfort for you (it may tickle, but is unlikely to be painful). The results of the test will be kept confidential.

Providing Household and Close Contact Information: Providing the names of your household and close contacts may be uncomfortable for you. If this is the case, you are free to decline to provide some or all names of household and close contacts.

4. POSSIBLE BENEFITS

Reduced Risk: Through your participation in this study, you may learn about measures you can take to prevent contracting and/or transmitting respiratory infections.

Meaningful Research: Your participation may help identify ways to reduce infectious respiratory illnesses on campus and in the broader community. Results from this study will also help UC Berkeley and other campuses prepare for outbreaks of respiratory infections and other infectious disease emergencies, including pandemic influenza.

5. CONFIDENTIALITY

Participation in research may involve a loss of privacy, but your data will be handled as confidentially as possible. All surveys will be provided online through a secure survey service. Your name and contact information will be retained separately from your survey answers with only a unique identification number linking the two. Similarly, the results from your flu test, should you be selected for one, will be identified only with a unique ID. In order to prevent access to identifying data by anyone but REDI-US researchers, the file containing your name and contact information will be encrypted and stored in a locked room at CIDP. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

After the study, a small number of participants may be randomly selected for a focus group and invited to provide more detailed feedback about their study experience. Your name and contact information will be retained for this purpose for a short period following the last study survey. Invited individuals may decline to participate in the focus group. All of your identifying information, including your name and contact information, will be destroyed after study analyses are complete (anticipated for December 2008).

6. DISCONTINUING STUDY PARTICIPATION

You may decline to sign this form and not participate in this study. Even if you agree to participate, you are free to withdraw at any time. You can end your participation by notifying the researchers at the contact information provided below, or you may choose just to stop filling out the weekly surveys. If you do withdraw from this study, it will not affect your relationship with this Center, the services it may provide to you, or the University of California, Berkeley.

7. FINANCIAL CONSIDERATIONS

Participation Thank-You Gifts: There will be no costs to you for your participation in this study. To thank you for your contribution to this research study, you will receive \$1 towards the incentive of your choosing (Amazon.com Gift Certificates, Napster music downloads, or Starbucks Cards) for each survey you complete. If you complete all surveys during the course of the study, you will receive a bonus \$10 towards your incentives at the end of the study period, for a total possible value of \$35.

Additionally, your name will be entered into an end-of-study raffle drawing for each survey you complete. You can choose to enter either the:

- Long odds drawing (one drawing for a \$500 Visa Gift card) – or –
- Short odds drawings (ten drawings for \$50 Visa Gift cards).

All participants will also receive a free digital thermometer, which we will ask you to use to assess your temperature if you are sick with a respiratory illness.

Additional Raffle Drawings: You may be invited to enter additional weekly raffle drawings (\$25 Visa Gift cards) as a thank you for time spent learning about measures to prevent contracting and/or transmitting respiratory infections.

Testing: If you are selected and agree to be tested for influenza, you will receive an additional \$5 towards your chosen incentive upon completion of the test. There will be no cost to you for the test.

8. QUESTIONS ABOUT PARTICIPATION

If you have any questions about the study, you can reach REDI-US researchers at (510) 643-4921, or by email at redius@berkeley.edu. If you have any questions regarding your treatment or rights as a participant in this research project, please contact the University of California at Berkeley’s, Committee for Protection of Human Subjects at (510) 642-7461, or by email at subjects@berkeley.edu.

You can download an electronic copy of this informed consent document for storage or printing by clicking [here](#).

9. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I voluntarily choose to participate, but I understand that my consent does not take away my legal rights in the case of negligence. I also understand my participation in every step of this study is completely voluntary. My refusal to participate at any point will not affect my relationship with the University of California, Berkeley, or the Center for Infectious Disease Preparedness.

I consent to the above terms and agree to participate in this research study.

Type/Print Participant's Name

Date