University of California, Los Angeles
Center for Neurobiology of Stress

CONSENT TO PARTICIPATE IN RESEARCH

Cognitive and Biological Responses in Stress

Drs. Arpana Gupta, Emeran Mayer, Bruce Naliboff, and Jennifer Labus from the Department of Medicine and Gastroenterology at the University of California, Los Angeles (UCLA) are conducting a research study, financed by Danone Research, the study sponsor.

You have been selected as a possible participant in this study because you are a healthy premenopausal Caucasian female, between the ages of 18 to 45, with either a high or a low level of stress. Before you decide whether or not to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read this consent carefully and ask the study doctor or staff about anything that you don't understand, or you want to know more about. Before deciding whether or not you can take part, you might want to talk about it with a relative, friend or your personal doctor. Taking part in this study is entirely voluntary. It is up to you to decide whether or not to take part. We will describe the study and then if you decide to take part in the study, you will be asked to sign this consent. You will be given a copy of this Informed Consent Form.

Why is this study being done?

The main goal of this study is to look at possible cognitive and biological responses involved in stress.

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to do the following:

One video Screening visit (Visit 1):
One comprehensive screening visit will be conducted to assess eligibility and determine if you are interested in the study.

You will review the study with the study coordinator or principal investigator. We will ask you to sign the consent electronically and fill out a few questionnaires by survey monkey or on paper to scan back to us. We will review the questionnaires for any risks or concerns, confirm eligibility, and review your medical history and medications. If all is

determined to be acceptable for enrollment, we will schedule you for an in-laboratory assessment.

You will be given instructions on how to access a link for on-line Survey Monkey questionnaires to complete sometime before the next visit. These questionnaires will ask about food frequency intake over the past year, and other behavioral questionnaires about mood, adversity, stress, anxiety and depression, and some gastronetrological symptoms.

We will give you instructions and collection items to collect a 2-day diet recall and single stool sample at home. These items can be mailed to you. The sample must be collected within about 3-4 days of the stress-testing visit 2. You can return the sample at the next visit or have it picked up by courier. **The sample must be kept cold/frozen**.

In Laboratory Visit (Visit 2):

This will take place within 2 weeks of the initial screening visit. At that in-person center visit (V2) you will be assessed by a trained study coordinator, to include height, weight, vital signs, temperature, waist and hip circumference, and urine pregnancy test.

This visit will collect a single blood sample via finger prick and some brief questionnaires before we begin and after completion of the laboratory behavioral tests described below.

There will be four tests:

1. The first two are attention and cognitive function tests that will last about 15 minutes total. One will assess the speed at which you can organize numbers and letters. The other will assess accuracy in naming colors of words when there is a mismatch between the name of that color (e.g., "blue", "green", or "red") and the color it is written in.
2. The 3rd test will consist of briefly viewing different images and rating them as positive or negative. Some may depict emotional scenes. This task will last about 15 minutes
3. The 4th test will require you to do an arithmatic task and will assess your speed and accuracy in giving responses. The arithmetic portion of this task will last 5 minutes.

During these tasks, you will have two sensors taped on your chest in order to measure heart beats and two sensors on your fingers in order to measure sweating. These measures will be collected while resting 5 minutes before the tasks, while doing the tasks, and then 5 minutes following the tasks.

The sponsor is requesting your full cooperation during this study and attendance at all visits at the scheduled dates, defined by yourself and the study doctor or one of his/her colleagues. During study participation, you must agree to refrain from participating in any

other clinical studies throughout the duration of the present study. In addition, if you need to make changes to medications or medical treatment, we ask that you notify the study doctor or study coordinator so we may consider your continued eligibility and safety in the study.

How long will I be in the research study?

Your participation will take about 6 hour's total. Screening will be about 2 hours, and the stress testing about 2 hours. The online questionnaires and collection of stool sample will take about 2 hours.

Are there any potential risks or discomforts that I can expect from this study?

- Collecting the stool samples may be somewhat uncomfortable or offensive during collection.

- Completing the 2- short cognitive tests may be stressful; however, it only lasts about 15 minutes.

- Watching and rating the images may be stressful by having to look at offensive or upsetting pictures. Each picture will only be viewed for a few seconds we will be in the room with you during the task. It will last a short period of about 15 minutes.

- Completing the arithmetic test may be frustrating and stressful. We will give clear instructions and will be with you during the testing. It will last about 5 minutes.

- Collection of the blood samples may be uncomfortable and in rare instances may cause bruising. The amount of blood taken will be about 2 drops.

- There is a risk of loss of confidentiality. As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see "How will my information be kept confidential?").

- Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

- Sensors for heart rate and skin sweat measures may cause some discomfort when removing or slight irritation. We will assess for allergic response before placing and remove gently after testing.

- **Measures to minimize risks:**
  - You will have your medical history taken and physical examination performed to rule out any study risk factors.

- If you have childbearing potential, you will be asked to practice a medically approved birth control method during the study.
- You will be asked to take a urine pregnancy test. If you are pregnant, you will not be able to participate in the rest of the study activities.
- All procedures will be performed by qualified professionals.
- All discussion with the clinicians will be confidential and respectful.
- You will be provided with the phone number for UCLA page operator and pager numbers of the MD/ PI, to contact in case of an emergency.

Are there any potential benefits if I participate?

You will receive no direct individual benefit from your participation as healthy participant in the study. However, a future health benefit is hoped for by providing relief to individuals with stress.

What other choices do I have if I choose not to participate?
If you chose not to participate in this study and have a high anxiety level, there may be some benefit in counseling to handle stress and learn coping skills under the supervision of trained professionals.

Will I be paid for participating?
You will be paid for your participation in this study. The payment will be prorated as follows according to the extent of your participation in this study:

- **Prescreening eligibility phone/video visit**: for signing the consent, reviewing your medical history and medications, and completing two short questionnaires on-line to determine your eligibility, you will be paid $25.
- **In-person clinic screening:** to include questionnaires online, the modified physical exam, and urine pregnancy test, you will be paid an additional $25.00.
- **Stress testing lab visit**: to include return of the 2-day diet recall and viable stool sample per instructions ($25) completing the on-line diet history and questionnaires links in a timely manner ($40) the finger prick blood sample ($10), and completion of the laboratory stress testing ($100.00) to equal $175.00 total.

The total for completing the whole study will therefore be up to **$225.00**.

You will receive free parking during the time that you will spend in the study activities. You will not be reimbursed for out of pocket expenses, such as transportation fees and parking tickets.

Personal information about you, including your name, address, and social security number, will be released to the UCLA Accounting Office for the purpose of payment.

How Will My Information Be Kept Confidential?

The researchers will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. This signed consent form will

be stored in a locked file that will be accessible only to a very small number of authorized people involved in this project. The research team will carefully follow the coding, storage, and data sharing plan explained below.

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of all your identifiable information will be kept in a password coded file in one of the computers in our office facilities. You will be assigned with a 4-number code that will be used to identify blood and stool samples, data collected during the interviews, assessment of brain activity, etc. Only personnel directly involved with this study will have access to the password secure files and to the code key. No identifiable information about you will be kept with the research data. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be maintained in a secure location at UCLA.

Any specimens (e.g., stool, blood) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

Financial Interest disclosure:

Dr. Emeran Mayer, Co-Investigator on this study has a personal financial interest in the company sponsoring this study (Danone Research) as part of their Advisory Board. A UCLA committee has reviewed these financial interests to help prevent them from affecting the quality and reliability of this study.

USE OF DATA AND SPECIMENS FOR FUTURE RESEARCH

1. My data and/or specimens may be kept for use in present and/or future research to learn about, prevent or treat other health-related problems (for example: diabetes).

YES □ NO □

CONTACT FOR FUTURE RESEARCH

UCLA researchers may contact me in the future to ask me to take part in other research studies.

YES □ NO □

What are my rights if I take part in this study?

- You have a right to have all of your questions answered before deciding whether to take part.
- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

- **The research team:**
  If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

  Dr. Arpana Gupta and/or Dr. Emeran Mayer at

  CHS 42-210 MC737818
  10833 Le Conte Avenue
  Los Angeles, CA 90095-7378
  Tel. (310) 206-0192

- **UCLA Office of the Human Research Protection Program (OHRPP):**
  If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

How do I indicate my agreement to participate?
If you agree to participate in this study, you should sign and date below.

You will be given a copy of this consent form and the Research Participant's Bill of Rights to keep.

SIGNATURE OF STUDY PARTICIPANT

Name of Participant

Signature of Participant | Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent | Contact Number

Signature of Person Obtaining Consent | Date