Official Title:	Neural Mechanisms of Cost and Benefit Integration During Decision-Making, Aim 2: Acute & Lifetime Stress
NCT Number:	NCT04060966
Study Number:	18-01945
Document Type:	Informed Consent Form
Date of the Document:	• April 22, 2019

Research Subject
Informed Consent Form

Title of Study:	Neural Mechanisms of Cost and Benefit Integration During Decision-Making, Aim 2: Acute & Lifetime Stress S18-01945
Principal Investigator:	Paul Glimcher, PhD. NYU Langone Health Neuroscience Institute Science Building 435 E 30th Street, 1260 New York, NY 10016 USA
Emergency Contact:	Paul Glimcher, PhD. 212-263-8167

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to investigate how emotion influences how the brain makes decisions about rewards.
You qualify for this study because you are a healthy volunteer.

3. How long will I be in the study? How many other people will be in the study?

Participation in this study will involve a 1 to 3 behavioral sessions that will take approximately 1-2 hours of your time and include the procedures listed below. Should you agree, you may be asked to return for 1-2 additional behavioral sessions on a different day, with at least 1 day between sessions. We will be recruiting approximately 60 participants for this study.

4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedure with the study staff that are part of the study.

In this study you will be asked to do the following:

- Refrain from eating or drinking for 2- 3 hours prior to coming to the lab
- Bid for the chance to win or buy foods or consumer items, or bid to remove certain foods/consumer items from choice menus, in 'auction' trials
- Rate different features of snack foods, consumer items or monetary prizes in 'rating' trials
- Choose between pairs or bundles of foods or consumer items in 'choice' trials
- Choose between pairs of monetary lotteries in 'lottery' trials
- Undergo a mild to moderate stressor while being videotaped [either the cold-pressor task (i.e., submersion of your arm in cold water) or a psychosocial stressor (i.e., giving a presentation in front of the experimenter and two other members of the research team)], or you will complete the respective control condition (submerging your arm in warm water or practicing a presentation by yourself).
- Provide saliva samples by placing a salivette under your tongue for 2 minutes. These samples will allow us to measure cortisol and alpha-amylase, two markers of neuroendocrine activity, and will be identified by a code, not by name. All samples will be destroyed within 2 years of their collection and will not be used to run additional tests before they are destroyed.
- If you are a female participant, you may be asked to fill out a short questionnaire about oral contraceptives use or current menstrual cycle status, due to their notable effects on the stress hormones in which we are interested.
- Complete self-report questionnaires on demographic information, a self-report inventory of stressors you have experienced over your lifetime, emotional processing/mood or current stress level, dieting/eating behaviors, cognitive function and other demographic details.

5. What are the possible risks or discomforts?

There are no known risks associated with subjects' participation in this research. You might experience some eye fatigue or discomfort from working on the computer screen, but it won't be beyond of what you would normally experience when working with a computer in daily life. If you are assigned to the stressor group, the cold water may be uncomfortable, but poses no risks outside of those you may encounter in daily life. You may experience frustration that is often experienced when completing surveys. Some questions may be of a sensitive nature, and you may therefore become upset as a result. However, such risks are not viewed as being in excess of "minimal risk". If, however, you become upset by questions, you may stop at any time or choose not to answer a question.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study. However, this research may contribute to our understanding of human decision-making and how the brain works when we make decisions.

8. What other choices do I have if I do not participate?

You may choose not to participate in this study. Your participation in this study bears no positive or negative effect on your life.

9. Will I be paid for being in this study?

You will be paid $15/hr in cash to take part in this study. In addition, you will receive $10 in cash at the start of the study that you will use to bid for the chance to win or buy foods/consumer items or bid to remove certain foods/consumer items from choice menus, in 'auction' trials. Finally, at the end of the study, you will receive a bonus payment from either a randomly selected auction, choice or lottery trial. If this trial is an auction trial, we will determine whether you won that trial using an auction procedure. If the trial is a choice trial, you will simply receive whichever item you chose on that trial. If the trial is a lottery trial, you will receive the money offered if a randomly drawn poker chip is a winning chip. This amount will range from $5 - $120. Thereafter, you may be asked to stay in the lab for an additional hour and the only food you will be allowed to consume is what you have selected or won in the experiment

10. Will I have to pay for anything?

There will be no cost to you associated with participation in this study. The National Institute of Health (NIH) is providing financial support to conduct this study.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for the NYU School of Medicine or Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by the principal investigator or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Information about study subjects will be kept confidential and will be anonymized with a unique subject identifier. No PHI other than Name, Address and Birthdate will be gathered. That data will be encrypted and stored with the subject identifiers in a separate file or will be kept in paper form under lock and key. These data are independent of all patient data and are not covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor. No PHI will be released.

Certificate of Confidentiality

To help us further protect your confidentiality, a Certificate of Confidentiality from the National Institutes of Health (NIH) covers this research. The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

14. Optional permission for future use

NYULH would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULH or its research partners. Such health information may include biological samples from the study.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULH will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULH or its research partners.

_____
Subject Initials

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date