Informed Consent for Participation in Research Activities

Project Title: The Neurobiology of Social Decision-Making: Project 1: Social inference and observational learning

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Approval Period: 01/12/2018 - 01/11/2019

Purpose of this Research Study:
The purpose of this study is research. This is not a clinical study and we do not provide medical treatment. This study investigates how we process reward outcomes when we observe other people get those rewards. Such social learning is crucial to human decision-making and social behavior; arguably, we learn most of the values of things in the world through such observational learning rather than through direct experience.

While we will be happy to talk to you more about the scientific findings of our work, we will not be able to give you any clinical feedback. This means we cannot tell you how you compare to other people on any measures.

We cannot show you pictures of your brain. None of our MRI scans are intended to diagnose or treat any disease.
The study will take approximately 2.5 hours (2 hours max in MRI scanner) per day and you may be invited to participate in multiple sessions.

If you have any questions about any part of this informed consent, please ask the researcher. Questions are encouraged.

Background:
This research involves the use of a variety of different methods to measure your behavior, brain activity and physiology. All of the methods we may use are in widespread use within Caltech and in other research labs throughout the world. The goal of the project is to understand how the brain learns about how to make good decisions from observing the actions of others, compared to when learning through direct experience.

Who Can Participate:
We anticipate that this study will enroll 500 male and female participants in the age range of 18-50 years. Only participants who are adults 18-50 years old of any gender or ethnicity who are fluent English speakers are invited to participate.

What Will Be Done:
Subjects who participate in Project 1 will engage in simple cognitive and learning tasks either in the fMRI scanner, or outside on a computer console.

The tasks will involve the following:
(1) Viewing pictures on a computer monitor. These will be pictures of various objects, of money, or of food items. You may be asked to make judgments about these pictures, such as how much you like them, or how much out of a small endowment they would be willing to pay for the

items. You may be asked to choose between different pictures, or perform motor actions in order to obtain particular outcomes. In some cases this will result in losing or winning real money. In other experiments you can obtain food items that you may subsequently consume. Some experiments will be designed to resemble simple arcade games in which participants make movements or press buttons to move objects around the screen and obtain points.

(2) Observation of and interactions with other people. In some experiments, you will be asked to to observe and learn from the actions, choices or behaviors of another person performing on similar tasks. On some occasions you may be in competition with that other person to obtain a particular goal, while on other occasions you will be co-operating with that person in order to pursue that goal (such as winning money or food items). In other experiments you will simply observe the actions and behavior of the other person without any competitive or co-operative interaction.

(3) You may also be asked to consume solid or liquid foods inside or outside of the scanner. You will be monitored while swallowing in the scanner. Sometimes, you will be asked to eat as much of a particular food as possible as you would for a meal, until you are full and do not want any more. On other occasions, we may only ask you to consume smaller quantities of a particular food. In experiments in which we will use food or liquid flavors, before starting the experiment we will check whether you have any known allergies to any of the foods or flavors used. It is important you tell us if you do have any known allergies to any of these foods before beginning the experiment, as testers may be able to use alternative foods or else ask you not to participate in that particular experiment.

(4) Tasting juices. Experimenters may squirt small quantities of juice into you mouth. Some of this juice may taste good, and some may taste bad. You may be asked to push buttons to receive these juice squirts. These juices may include any of the following: Cranberry Juice, Green Tea (Lipton), White Grape Juice, Apple Juice, Melon Juice, Grape Juice, Sunny Delight, Punch (Juicy Juice brand), Gatorade (Yellow), Gatorade (Blue), Gatorade (Red), Grapefruit juice, Tap Water, G2 (Blue), Artificial Saliva, Salty Tea, Coke or Pepsi Cola, Orange Juice, Sugared Water (with glucose), Chocolate Milk, Tomato juice or Tomato soup (cold).

(5) Perishable foods will be stored in a refrigerator at ca. 40 degrees F. The stimuli will be prepared using a food area dedicated for these experiments. Strict food preparation hygiene standards will be observed. The area will be kept clean and all tubing, valves and surfaces coming into contact with the flavor stimuli will be washed thoroughly between uses. For each subject new tubing will be used to guarantee the necessary hygienic standards. All food expiration dates will be honored.

(6) Measures of how the body responds to pictures or the receipt of monetary or food outcomes. This will be done through measuring pupil responses or eye-gaze measured through an eye-tracker, positioned in the fMRI scanner, or else outside. We may also attach devices to measure your pulse, heart-rate or breathing.

We will also obtain measurements of your brain using MRI. MRI is a non-invasive imaging method that uses a strong magnetic field and radio waves to make pictures of your body. No X-rays or ionizing radiation are used in MRI. You will not be given MRI contrast agent or any other drugs in this study.

We will have you lie in a magnetic resonance (MR) scanner on a long, narrow bed while we acquire images of your brain. (If you would like, you can experience what this is like in a fake, non-working scanner before participating in the actual scanning.) The MRI scan will be approximately Up to 2 hours. During this time, you will be exposed to a magnetic field and radiofrequency waves. You will hear repetitive tapping noises and will be required to wear earplugs or earphones to reduce the noise experienced during the scan. You will perform simple learning and decision-making tasks.

Possible Risks and Discomforts:

You have been informed that the possible risks and discomforts of this study are as follows:

Physical discomfort: Subjects will be lying in a narrow scanner for about up to 2 hours. This may feel uncomfortable. Outside of the scanner, subjects will be looking at a computer-screen possibly for up to 2 hours or more. This may be tedious. Subjects can ask to take a break or stop at any time.
Psychological discomfort: Subjects may find it stressful to lie in the MRI scanner. Some people feel claustrophobic in the scanner. In the games and interactions with other people, subjects will be making choices in which they can win or lose real money. However, subjects can never lose any of their own money that they walked in with. Interacting with another person, either that the subjects know or have not met before, may be stressful.
Allergy concerns: Before starting the experiment experimenters will check with subjects whether they have any known allergies to any of the foods or flavors used. It is important subjects tell the experimenters if they do have any known allergies to any of these foods before the experiment begins, as experimenters may be able to use alternative foods or else ask subjects not to participate in that particular experiment.

MRI Scanning Risk: MRI poses life-threatening physical risks if you have objects in or attached to your body that are metal, such as a cardiac pacemaker, metallic clips (i.e., an aneurysm clip in the brain), or metal fragments such as shrapnel, bullets, or small pieces of metal from metal working. Please tell the investigator if you have any metal items in your body. You may also be unable to be in the MRI if you have metal-containing tatoos on your skin, since these can heat up, or if you wear unremovable metal braces.

You will be asked to fill out an additional safety questionnaire and answer questions to one of the MR staff before your MRI session. You will also be required to walk through a metal detector before going into the scanner (like at the airport).

As a general rule, all metallic objects must be removed before entering the magnet room.This includes keys, jewelry, pocketknives, money clips, paper clips, safety pins, hairpins, and barrettes. In addition, objects such as watches, credit cards, and hearing aids could be damaged in the presence of the magnetic field. A locker will be provided for you to secure all your items and valuables.

If you are pregnant, or are trying to get pregnant, the effects of the scan on a fetus are not well studied and you will not be able to participate in any MRI studies.

If all metallic objects have been removed from your body, there are no known significant physical risks with MRI. There is no known limit to the time you can spend inside an MRI scanner.

MRI scanning is painless but you may feel some discomfort during the scan. Some people experience claustrophobia when placed inside the scanner, discomfort from the loud hammering and beeping noises, or mild nerve stimulation or twitching in your extremities (hand, feet). If you feel heating when other monitoring equipment is used inside the scanner, please report this and the scan will be stopped. You may also discontinue the scan at any time, for any reason, by pushing a button while you are in the scanner.

The MRI machine at Caltech may be used by other universities or by industry. It is cleaned between uses.

Incidental Findings:

THE SCANS PERFORMED IN THIS STUDY ARE INTENDED FOR RESEARCH PURPOSES ONLY.

THEY ARE NOT INTENDED, AND MAY NOT BE USED, FOR ANY CLINICAL DIAGNOSIS.

As part of the review of the data, your MRI scans will be reviewed by a licensed physician specialist (radiologist) to ensure the scientific integrity of the data collected.

On occasion, images from a particular subject's scan will be identified by the radiologist as unacceptable for the study. The reasons for an image being identified as unacceptable can vary widely. In some cases, they are technical issues having to do only with the operation of the MRI machine. In other cases, they may be due to abnormalities in your brain. If your images are identified by the radiologist as reflecting potential abnormalities in your brain, otherwise known as an incidental finding, you will be contacted by the radiologist. The radiologist will also be available to confer with your physician if so desired. Please keep in mind that such an incidental finding does not constitute any clinical diagnosis. It is intended only to alert you to the possibility of a medical abnormality that you should follow up with your doctor. Because the images collected in this study do not comprise a clinical scan, copies of these research images cannot be made available to you or your physician.

In order for the radiologist to be able to contact you in the event of an incidental finding, you must agree to provide your contact information, including your name, email, and phone number, as well as your physician's name, and his/her phone number.

Photographic/Video/Audio Recording:
Videotapes or photos may be taken of your face, hand movements and profile as your participate in various tasks. These videos will only be used for research purposes. These videos will be used in two ways: (1) the recordings (or a live feed) may be shown to other research participants to see how one person can learn through observing the behavior of another. (2) the recordings may be analyzed to assess changes in emotional expression, eye gaze, pupil dilation. (3) Stored photos or videos can be deleted on request
* I agree to be videotaped during this study:
Please initial: ___Yes ___No
* I agree for the recording or photographs resulting from this study may be used as described above.
Please initial: ___Yes ___No

Internet Follow-up Testing:
In some cases, we may not have enough time to finish all tasks during your visit to Caltech, or we may wish to have you participate in additional tasks. We may then invite you to complete additional tasks on the internet, if you have a computer at home. This will involve filling out questionnaires over the internet, and rating pictures or videos over the internet. We will explain how this works in detail if you decide to participate in this internet component.

Please initial below if you would like to be contacted for internet-based follow-up testing.

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Collaborative Study/Sharing Research Data:
Data acquired in this study will be shared with other researchers funded by the Conte Center Grant, NIH/Nimh #12163701 at Caltech.

We also ask for your permission to share data acquired from you with other researchers, including magnetic resonance imaging scans and questionnaire responses. The data will be shared with researchers outside of the California Institute of Technology (including but not limited to Huntington Memorial Hospital, Cedars-Sinai Medical Center, University of Toronto, and University of Iowa), and will

be included in data repositories. The data may be used for research that is different from what was described in your previous informed consent(s).
Any data shared with other researchers and repositories will have all of your identifying information removed, including any images of your facial features present in magnetic resonance imaging scans of your head, and will not include your name. Your shared data will be linked to coded identifiers that cannot be traced to your true identity by researchers with whom we share this data. Research data will be uploaded to a data repository accessible to other researchers, or transferred directly using strong encryption to research collaborators.

One repository that your data may be shared with is the National Database for Autism Research (NDAR). NDAR is a collection of data, managed by the National Institutes of Health, that allows researchers to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things more quickly than before.

You may decide now or later that you do not want your de-identified data shared. If so, contact the researchers who conducted the study, and they will not share your information in the future, and make their best efforts to stop the future sharing of your data by other researchers and repositories. However, it may be impossible to take back information that was shared, for example, if it is no longer linked to coded identifiers or if it was published before you changed your mind.

Possible Benefits:
You personally will not benefit directly from participation in this research study in any way. This research may help extend our understanding of others who suffer from psychiatric illnesses such as autism, since our research findings will inform those diseases.

Alternatives:
The alternative is to choose not to participate in this study.

Compensation:
You are entitled to compensation for participating in this experiment. Your compensation will include $20 per hour, with a bonus $100 for every 5 studies completed that are funded by the Conte center project The Neurobiology of Social Decision- Making. (Introductory screening sessions are not eligible for the bonus.) You may additionally win extra money based on your performance on the task. You can quit the experiment at any time. If you quit in the middle of a session, you will still be compensated for the time you participated. Because the payments for financial compensation are arranged via Caltech, it may take about one month before you receive a check.

You will NOT be reimbursed for travel expenses to and from the experiment unless this is specifically arranged ahead of time.

If you receive more than $600 per year for taking part in studies at Caltech, you may be required to pay taxes on that income. This does not include any payments you receive to pay you back for expenses like parking fees or travel. You may receive an Internal Revenue Service (IRS) Form 1099 if you receive more than $600 in one year for taking part in these research studies.

Withdrawal from Study:
Your paticipation is voluntary. If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and discontinue your participation in this study at any time. Your decision will not affect your relationship, if any, with the California Institute of Technology or the Jet Propulsion Laboratory and you will not be penalized or lose any benefits to which you would otherwise be entitled.

To withdraw from the study, you only need to let the experimenter or the principal investigator (John O'Doherty) know. You can do this by calling them on the phone or email. You will not be asked to explain your reasons.

We may also withdraw you from the study without your consent for scientific or technical reasons. We will not be able to give you detailed explanations of the reasons.

Confidentiality of Records:
Any information from this study in which you might be identified will be confidential. By signing this form, however, you allow the study investigators to make your records available to the Caltech Institutional Review Board Office and regulatory or funding agencies as required by law. If information generated by this study is published, you will never be identified by name.

Data collected from this study will be kept in John O'Doherty's laboratory at the California Institute of Technology. We will take reasonable steps to ensure that no unauthorized person will have access to the data generated by this study. Paperwork about this research will be kept in a locked file and digital data will be password protected.

Future Contact:
We may wish to contact you in the future about participating in other research studies.

Please initial here if you authorize the researchers with this study to use your information in order to contact you about participating in other studies in the lab.

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Offer to Answer Questions and Research Injury Notification:
The principal investigators or their research associates have offered to answer any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact the principal investigator at 626-395-5981(John O'Doherty), or the Caltech Institutional Review Board Administrator at (626)395-4699 or at irb@caltech.edu.

Explanation of Treatment and Compensation for Injury:
In the unlikely event of illness or physical injury resulting during participation in this research, the principal investigator and the research study staff will assist you in obtaining appropriate medical treatment by summoning the paramedics by calling Caltech Security (x5000). Should the medical professionals determine a need, you will be transported to the nearest hospital emergency room. In most cases this would be Huntington Hospital located in Pasadena. This study does not provide financial assistance for medical or other related costs. Your insurance carrier will be billed for the cost of such treatment. You, however, do not waive any legal rights by signing this form.

Voluntary Participation with Right of Refusal:
You have been informed that your participation in this research study is voluntary. You are free to withdraw your consent for participation in any part of this study without any penalty.

IRB Review and Impartial Third Party:
This study has been reviewed and approved by the Institutional Review Board (IRB) of the California Institute of Technology. A representative of that board, from the IRB Office, is available to discuss the review process or your rights as a research subject. The telephone number of the IRB office is 626-395-4699 and their email is irb@caltech.edu.

Sponsor of this Research:
NIH/NIMH Caltech Conte Center Renewal

Signature for Consent: The above-named investigator has answered your questions and you agree to be a research subject in this study. You have carefully read the information contained above in the

"Experimental Subject's Bill of Rights" and understand fully your rights as a potential subject in a research experiment involving people as subjects.

Print Subject's Name: _____Date: _____

Subject's Signature: _____ Date: _____

Parent or Guardian's Name: _____ Date: _____

Parent or Guardian's signature: _____Date: _____
(only if subject is younger than 18)

Print Investigator's Name: _____Date: _____

Investigator's Signature: _____Date: _____

Experimental Subject's Bill of Rights:

You have been asked to participate as a subject in a research study. Before you decide whether you want to participate in the study, you have a right to:

a. Be informed of the nature and purpose of the experiment;
b. Be given an explanation of the procedures to be followed in the research experiment, and any drug or device to be utilized;
c. Be given a description of any attendant discomforts and risks reasonably to be expected from your participation in the experiment;
d. Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;
e. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you an their relative risks and benefits;
f. Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications should arise;
g. Be given an opportunity to ask any questions concerning the research experiment or the procedures involved;
h. Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the research experiment without prejudice;
i. Be given a copy of this form and the signed and dated consent form; and
j. Be given the opportunity to decide to consent or not to consent to the research experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on your decision.

I understand my rights as described above:

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Signature of participant